UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	:		
Plaintiffs,	:	Civil Action No.:	18-2084 (RC)
v.	:	Re Document Nos.:	2, 14
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,	:		
Defendants.	:		

ORDER

DENYING DEFENDANTS' MOTION TO DISMISS; GRANTING PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**, the Secretary's Motion to Dismiss (ECF No. 14) is **DENIED**, and Plaintiffs' Motion for a Permanent Injunction (ECF No. 2) is **GRANTED**. It is **HEREBY ORDERED** that:

1. The parties shall provide supplemental briefing on the appropriate remedy, limited to no more than 25 pages per brief, within 30 days of this Order's issuance; and
2. The parties shall respond to those briefs, limited to no more than 15 pages per response, within 14 days after the supplemental briefs are filed.

SO ORDERED.

Dated: December 27, 2018

RUDOLPH CONTRERAS
United States District Judge

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MEMORANDUM OPINION

DENYING DEFENDANTS' MOTION TO DISMISS; GRANTING PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I. INTRODUCTION

This action concerns whether the Department of Health and Human Services ("HHS") acted lawfully when it reduced Medicare payments worth billions of dollars to private institutions, to correct what it views as a fundamental misalignment of Medicare programs. Plaintiffs, a group of hospital associations and non-profit hospitals,[1] contend that HHS exceeded its statutory authority when it cut Medicare reimbursement rates for certain outpatient

[1] The hospital association Plaintiffs ("Association Plaintiffs") are the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), and America's Essential Hospitals ("AEH"). Compl. ¶¶ 4–9. The non-profit hospital Plaintiffs ("Hospital Plaintiffs") are the Henry Ford Health System ("Henry Ford"), Northern Light Health ("Northern Light")—formerly Eastern Maine Healthcare Systems—and Fletcher Hospital, Inc., doing business as Park Ridge Health ("Park Ridge"). Compl. ¶¶ 10–18; Notice of Party Name Change at 1, ECF No. 21 (stating that Eastern Maine Healthcare Systems has changed its name to Northern Light Health).

pharmaceutical drugs by nearly 30%. Defendants, HHS and its Secretary, contend that the rate adjustment was statutorily authorized and necessary to close the gap between the discounted rates at which Plaintiffs obtain the drugs at issue—through Medicare's "340B Program"—and the higher rates at which Plaintiffs were previously reimbursed for those drugs under a different Medicare framework.

Presently before this Court are Plaintiffs' motion for a preliminary or permanent injunction and Defendants' motion to dismiss. Among other relief, Plaintiffs ask the Court to vacate the Secretary's rate reduction, require the Secretary to apply previous reimbursement rates for the remainder of this year, and require the Secretary to pay Plaintiffs the difference between the reimbursements they have received this year under the new rates and the reimbursements they would have received under the previous rates. Defendants contest the Court's ability to hear the case, arguing that Congress has shielded the Secretary's action from judicial review, that the Secretary's boundless discretion precludes review, and that Plaintiffs' failure to exhaust their administrative remedies is fatal. Defendants also argue that the Secretary's action was well within his statutory authority.

For the reasons stated below, the Court concludes that it has jurisdiction to provide relief in this case and that Plaintiffs are entitled to such relief. While in certain circumstances the Secretary could implement the rate reduction at issue here, he did not have statutory authority to do so under the circumstances presented. Moreover, because the parties have fully and vigorously debated the merits of Plaintiffs' claims, which turn on questions of law, not fact, the Court concludes that further merits briefing would be redundant and inefficient. However, while Plaintiffs are entitled to *some* relief, the potentially drastic impact of this Court's decision on Medicare's complex administration gives the Court pause. Accordingly, the Court grants

Plaintiffs' motion for a permanent injunction and orders supplemental briefing on the question of a proper remedy.

II. BACKGROUND AND PROCEDURAL HISTORY

A. Medicare

Medicare is a federal health insurance program for the elderly and disabled, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395–1395*lll*. Medicare Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id*. § 1395c. Medicare Part B provides supplemental coverage for other types of care, including outpatient hospital care. *Id*. §§ 1395j, 1395k. HHS's Outpatient Prospective Payment System ("OPPS"), which directly reimburses hospitals for providing outpatient services and pharmaceutical drugs to Medicare beneficiaries, is a component of Medicare Part B. *See id*. at 1395*l*(t). OPPS requires "payments for outpatient hospital care to be made based on predetermined rates." *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Under this system, HHS—through the Centers for Medicare and Medicaid Services ("CMS")—sets annual OPPS reimbursement rates prospectively, before a given year, rather than retroactively based on covered hospitals' actual costs during that year.[2]

B. The 340B Program

In 1992, Congress established what is now commonly referred to as the "340B Program." Veterans Health Care Act of 1992, Pub L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. The 340B Program allows participating hospitals and other health care providers ("covered entities") to purchase certain "covered outpatient drugs" from manufacturers at or below the drugs'

[2] CMS is a component of HHS and is overseen by the Secretary. *See* HHS Organizational Chart, HHS (Nov. 14, 2018), https://www.hhs.gov/about/agencies/orgchart/index.html.

"maximum" or "ceiling" prices, which are dictated by a statutory formula and are typically significantly discounted from those drugs' average manufacturer prices. *See* 42 U.S.C. § 256b(a)(1)–(2).[3] Put more simply, this Program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011). It is intended to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,493 & 52,493 n.18 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419).[4] Importantly, and as discussed in greater detail below, the 340B Program allows covered entities to purchase certain drugs at steeply discounted rates, and then seek reimbursement for those purchases under Medicare Part B at the rates established by OPPS.

C. Medicare Reimbursement Rates for 340B Drugs

The statutory provision governing OPPS, codified at 42 U.S.C. § 1395*l*(t), imposes the framework by which HHS must set prospective Medicare reimbursement rates. Among other requirements under that provision, HHS must determine how much it will pay for "specified covered outpatient drugs" ("SCODs") provided by hospitals to Medicare beneficiaries. 42 U.S.C. § 1395*l*(t)(14)(A). SCODS are a subset of "separately payable drugs," which are not bundled with other Medicare Part B outpatient services and are therefore reimbursed on a drug-

[3] The manufacturers must offer these discounts as a condition of their participation in the Medicaid program. *Id*. § 256b(a)(3).

[4] While the regulations setting 340B drug reimbursement rates, including the 2018 OPPS Rule, are technically issued by CMS, *see* 82 Fed. Reg. at 52,356, for simplicity's sake the Court will refer to them as HHS regulations.

by-drug basis. *See id*. § 1395*l*(t)(14)(B). And as noted, the 340B Program covers certain separately payable drugs, some of which are SCODs and some of which are not. 82 Fed. Reg. at 52,496; Defs.' Mot. to Dismiss ("Defs.' Mot.") at 5, ECF No. 14.

Congress has authorized two potential methodologies for setting SCOD rates.[5] First, if HHS has certain "hospital acquisition cost survey data," it must set the reimbursement rate for each SCOD according to "the *average acquisition cost* for the drug for that year . . . as determined by the Secretary taking into account" the survey data. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). Second, if the survey data is not available, each SCOD's reimbursement rate must be set equal to "the *average price* for the drug in the year established under . . . section 1395w-3a . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id*. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Section 1395w-3a, in turn, provides that a given drug's default reimbursement rate is the average sales price ("ASP") of the drug plus 6%.[6] *Id*. § 1395w-3a(b)(1)(A)–(B); *see also* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center

[5] While not all separately payable drugs qualify as SCODs, to which the payment methodologies of § 1395*l*(t)(14)(A) apply, "[HHS] applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS." Defs.' Mot. at 6 n.1 (citing 77 Fed. Reg. at 68,383); *see also* 82 Fed. Reg. at 52,509 (stating that the rate reduction will apply to "separately payable Part B drugs . . . that are acquired through the 340B Program"). Thus, the methodology at issue here applies to all 340B drugs, not just SCODS covered by the 340B Program. This "is a policy choice rather than a statutory requirement." Defs.' Mot. at 6 n.1 (quoting 77 Fed. Reg. at 68,383). Because neither party raises the question of whether the Secretary's statutory authority to alter reimbursement rates for SCODs also governs the Secretary's "policy choice" to apply the same rates to non-SCOD, separately payable drugs, the Court will not address that question here.

[6] Both parties seem to agree that § 1395w-3a sets a default payment rate of 106% of a given drug's volume-weighted average sales price, and that this rate is the presumptive reimbursement rate under § 1395*l*(t)(14)(A)(iii)(II). *See* Defs.' Mot. at 6; Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. ("Pls.' Mem.") at 3–4, ECF No. 2-1; 82 Fed. Reg. at 52,501 (acknowledging ASP plus 6% as the "statutory benchmark").

Payment Systems and Quality Reporting Programs ("2012 OPPS Rule"), 77 Fed. Reg. 68,210, 68,387 (Nov. 15, 2012) (codified at 42 C.F.R. pt. 419) (adopting a reimbursement rate of ASP plus 6% for covered drugs in light of the "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost" and the concern that deviating from the default rate "may not appropriately account for average acquisition and pharmacy overhead cost . . . .").

D. The 340B-Medicare Payment Gap

As explained above, hospitals participating in the 340B Program purchase 340B drugs at steeply discounted rates, and when those hospitals prescribe the 340B drugs to Medicare beneficiaries they are reimbursed by HHS at OPPS rates. Before 2018, the relevant OPPS rate for 340B drugs was ASP plus 6%. *See, e.g.*, 77 Fed. Reg. at 68,387. This rate resulted in a significant gap between what hospitals paid for 340B drugs and what they received in Medicare reimbursements for those drugs, because the 340B Program allowed participating hospitals to buy the drugs at a far lower rate than ASP plus 6%. *See* 82 Fed. Reg. at 52,495 (citing an Office of Inspector General report finding that this margin "allowed covered entities to retain approximately $1.3 billion in 2013"). Plaintiffs allege that the revenues derived from this payment gap have "helped [Plaintiffs] provide critical services to their communities, including underserved populations in those communities." Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. ("Pls.' Mem.") at 31 (citing Aff. of Tony Filer ("Northern Light Aff.") ¶ 13, Pls.' Mot. Prelim. & Permanent Inj. ("Pls.' Mot.") Ex. V, ECF No. 2-25; Aff. of Robin Damschroder ("Henry Ford Aff.") ¶¶ 15–18, Pls.' Mot. Ex. W, ECF No. 2-26; Aff. of Wendi Barber ("Park Ridge Aff.") ¶¶ 15–17, Pls.' Mot. Ex. X, ECF No. 2-27), ECF No. 2-1. They further allege that the narrowing of this gap "threatens these critical services" because Plaintiffs may be unable to

fund the services with lower reimbursement amounts. *Id*. (citing Northern Light Aff. ¶¶ 14–19; Henry Ford Aff. ¶¶ 19–20; Park Ridge Aff. ¶¶ 18–19).

E. The 2018 OPPS Rule

In mid-2017, HHS proposed reducing the Medicare reimbursement rates for SCODs and other separately payable drugs acquired through the 340B Program from ASP plus 6% to ASP minus 22.5%. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,634 (Jul. 20, 2017) (codified at 42 C.F.R. pt. 419). HHS provided a detailed explanation of why it believed this rate reduction was necessary. First, HHS noted that several recent studies have confirmed the large "profit" margin created by the difference between the price that hospitals pay to acquire 340B drugs and the price at which Medicare reimburses those drugs. *See id.* at 33,632–33. Second, HHS stated that because of this "profit" margin, HHS was "concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs." *Id*. at 33,633. It cited, as an example of this phenomenon, a 2015 Government Accountability Office Report finding that Medicare Part B drug spending was substantially higher at 340B hospitals than at non-340B hospitals. *Id*. at 33,632–33. The data indicated that "on average, beneficiaries at 340B . . . hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis." *Id*. at 33,633. Third, HHS expressed concern "about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of the Medicare payment rate for these drugs," rather than the lower 340B rate paid by the covered hospitals. *Id.*

Thus, HHS concluded that lowering the Medicare reimbursement rates for 340B Program drugs would "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs[,] while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals to stretch scarce resources while continuing to provide access to care." *Id.* HHS, however, did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug." *Id.* at 33,634. For that reason, HHS estimated 340B hospitals' drug acquisition costs based on those hospitals' average 340B discount. *See id.* Specifically, HHS proposed applying the average 340B discount estimated by the Medicare Payment Advisory Commission ("MedPAC")—22.5% of a covered drug's average sales price—to govern the 340B drug reimbursement rates. *See id.* HHS believed that MedPAC's estimate was appropriate and, in fact, conservative because the "actual average discount experienced by 340B hospitals is likely much higher than 22.5[%]." *Id.*

In addition to explaining its rationale and methodology for reducing the 340B reimbursement rates to ASP minus 22.5%, HHS stated its purported statutory basis for taking that action. Because HHS did not "have hospital acquisition cost data for 340B drugs," 82 Fed. Reg. at 33,634, it could not invoke its express authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) to set rates according to the drugs' average acquisition costs. Instead, HHS invoked its authority under § 1395*l*(t)(14)(A)(iii)(II), "which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug . . . as calculated and adjusted by the Secretary as necessary." 82 Fed. Reg. at 33,634. HHS would thus "adjust the applicable payment rate as necessary" for separately payable drugs acquired under the 340B program, "to ASP minus 22.5[%]." *Id.* HHS stated that the adjustment was necessary

because ASP minus 22.5% "better represents the average acquisition cost for [340B] drugs and biologicals." *Id*.

Plaintiffs strongly opposed the proposed 2018 340B reimbursement rates, and they voiced their opposition in comments to the proposed rule. Plaintiffs argued primarily that HHS did not have the legal authority to change the 340B reimbursement rates in the manner proposed, and that reducing reimbursement rates by nearly 30% would severely impact covered entities' ability to provide critical healthcare programs to their communities, particularly to their underserved patients. *See generally* AHA Comments, Pls.' Mot. Ex. C, ECF No. 2-6; AAMC Comments, Pls.' Mot. Ex. D, ECF No. 2-7; AEH Comments, Pls.' Mot. Ex. E, ECF No. 2-8; Henry Ford Comments, Pls.' Mot. Ex. F, ECF No. 2-9; Northern Light Comments, Pls.' Mot. Ex. G, ECF No. 2-9.

Nevertheless, in November 2017, HHS adopted the proposed 340B reimbursement rate reduction. *See* 82 Fed. Reg. at 52,362. In issuing its final rule, HHS responded to Plaintiffs' arguments about its authority to change Medicare reimbursement rates for 340B drugs. *See id.* at 52,499. HHS argued that the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gave the Secretary broad discretion, including discretion to adjust Medicare payment rates according to whether or not certain drugs were acquired at a significant discount. *Id.* HHS also disagreed with commenters that the authority to "calculate and adjust" drug rates as necessary was limited to "minor changes"; it saw "no evidence in the statute to support that position." *Id.* at 52,500. Accordingly, HHS used its purported authority "to apply a downward adjustment that is necessary to better reflect acquisition costs of [340B] drugs." *Id.* The 340B reimbursement rates

dictated by this rule, and its ASP minus 22.5% methodology, became effective on January 1, 2018. *Id.* at 52,356.

F. Procedural History

In late 2017, Plaintiffs raised an Administrative Procedure Act ("APA") challenge to the 2018 OPPS Rule's 340B provisions. *See generally* Compl., *Am. Hosp. Ass'n v. Hargan ("AHA I")*, No. 17-2447, ECF No. 1 (D.D.C.). However, this Court dismissed the action because Plaintiffs failed "to present any concrete claim for reimbursement to the Secretary for a final decision[,]" which is "a fundamental jurisdictional impediment to judicial review under 42 U.S.C. § 405(g)." *AHA I*, 289 F. Supp. 3d 45, 55 (D.D.C. 2017).[7] Both parties agree that Plaintiffs have now presented reimbursement claims covered by the 2018 OPPS Rule, Defs.' Mot. at 15 n.6; Pls.' Mem. at 11–12, and Plaintiffs have re-filed suit asserting nearly identical challenges to the rule, *see generally* Compl., ECF No. 1.

Plaintiffs allege that the Secretary's reimbursement rate reduction for 340B drugs violates the APA and the Social Security Act because it is "arbitrary and capricious and contrary to law, and in excess of the Secretary's authority under the Medicare provisions of the Social Security Act." Compl. ¶¶ 68–69 (citing 42 U.S.C. §§ 405(g), 1395ii, 1395*l*(t)(14)(A)(iii); 5 U.S.C. § 706(2)). In conjunction with filing their complaint, Plaintiffs have moved for either a preliminary injunction or a permanent injunction under Rule 65 of the Federal Rules of Civil Procedure. Pls.' Mot. at 1, ECF No. 2. Plaintiffs request that this Court direct the Secretary to:

> [S]trike the changes in the payment methodology for 340B drugs from the OPPS Rule and use the methodology used in calendar year 2017 for all future 340B Program payments in 2018; pay the Hospital Plaintiffs and all provider members of the Association Plaintiffs the difference between the payments for 340B drugs that they received under the 2018 OPPS Rule and the payments they would have

[7] This decision was recently affirmed by the D.C. Circuit. *See Am. Hosp. Ass'n v. Azar ("AHA II")*, 895 F.3d 822, 828 (D.C. Cir. 2018).

> received under the 2017 OPPS Rule; and conform the payment methodology that they use for 340B drugs in calendar year 2019 and subsequent years to the requirements of the Social Security Act, and specifically not to use acquisition cost to calculate payment rates unless Defendants have complied with 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).

Pls.' Mem. at 35. The government has opposed Plaintiffs' motion and filed a motion to dismiss the action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). *See generally* Defs.' Mot. The parties' motions are fully briefed and ripe for this Court's consideration.

III. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(1)

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) "presents a threshold challenge to the Court's jurisdiction." *Curran v. Holder*, 626 F. Supp. 2d 30, 32 (D.D.C. 2009) (quoting *Agrocomplect, AD v. Republic of Iraq*, 524 F. Supp. 2d 16, 21 (D.D.C. 2007)). "It is to be presumed that a cause lies outside [the federal courts'] limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (citing *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182–83 (1936); *Turner v. Bank of N.A.*, 4 U.S. 8, 11 (1799)). In determining whether the plaintiff has met this burden, a court must accept "the allegations of the complaint as true," *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1129 (D.C. Cir. 2015), and "construe the complaint 'liberally,' granting the plaintiff 'the benefit of all inferences that can be derived from the facts alleged,'" *Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004) (quoting *Kowal v. MCI Commc'ns. Corp.*, 16 F.3d 1271, 1276 (D.C. Cir.1994)). However, "the [p]laintiff's factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13–14 (D.D.C. 2001)

(internal quotation marks omitted) (citing 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1350).

The Court must confirm its jurisdiction for each type of claim brought before it, including APA challenges. Indeed, while 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) (internal quotation marks omitted) (quoting 5 U.S.C. § 701(a)(1); *Koretoff v. Vilsack*, 614 F.3d 532, 536 (D.C. Cir. 2010)). Similarly, courts lack jurisdiction over claims brought under the Social Security Act until the claimants have exhausted their administrative remedies and received final decisions from the Secretary regarding the issues underlying those claims. 42 U.S.C. § 405(g).

B. Federal Rule of Civil Procedure 12(b)(6)

The Federal Rules of Civil Procedure require that a complaint contain "a short and plain statement of the claim" to give the defendant fair notice of the claim and the grounds upon which it rests. Fed. R. Civ. P. 8(a)(2); *accord Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (per curiam). A motion to dismiss under Rule 12(b)(6) does not test a plaintiff's ultimate likelihood of success on the merits; rather, it tests whether a plaintiff has properly stated a claim. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *abrogated on other grounds by Harlow v. Fitzgerald*, 457 U.S. 800 (1982). A court considering such a motion presumes that the complaint's factual allegations are true and construes them liberally in the plaintiff's favor. *See, e.g., United States v. Philip Morris, Inc.*, 116 F. Supp. 2d 131, 135 (D.D.C. 2000).

To survive a motion to dismiss, a complaint need not contain all elements of a prima facie case. *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 511–14 (2002); *Bryant v. Pepco*, 730 F. Supp. 2d 25, 28–29 (D.D.C. 2010). However, the "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) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This means that a plaintiff's factual allegations "must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 at 555 (citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are therefore insufficient to withstand a motion to dismiss. *Iqbal*, 556 U.S. at 678. A court need not accept a plaintiff's legal conclusions as true, *see id.*, nor must a court presume the veracity of legal conclusions couched as factual allegations, *see Twombly*, 550 U.S. at 555.

C. Administrative Procedure Act

The APA governs the conduct of federal administrative agencies. *See* 5 U.S.C. §§ 101–913. It permits a court to "compel agency action unlawfully withheld or unreasonably delayed," *id*. § 706(1), and to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id*. § 706(2)(A). It provides for judicial review of a "final agency action for which there is no other adequate remedy in a court[,]" *id*. § 704, except when "statutes preclude judicial review" or the "agency action is committed to agency discretion by law[,]" *id*. § 701(a).

IV. ANALYSIS

By and large, the Secretary's arguments for dismissal concern whether this Court has jurisdiction to hear Plaintiffs' allegations. First, the Secretary argues that Plaintiffs' failure to

exhaust their administrative remedies forecloses judicial review. Second, the Secretary argues that certain Medicare provisions preclude the Court's review. Third, the Secretary argues that the decision to reduce 340B drug reimbursement rates was "committed to agency discretion by law," and therefore outside the scope of APA review. Fourth, the Secretary argues that he had clear statutory authority to "adjust" 340B drug reimbursement rates. The Court addresses each argument in turn and concludes that the potential jurisdictional obstacles are not fatal here, and that the Secretary's action exceeded his authority to "adjust" rates. Accordingly, Plaintiffs are entitled to relief, to be determined after the Court considers the parties' supplemental briefing.

A. Plaintiffs Need Not Exhaust Their Administrative Remedies

The Secretary argues that the Court lacks jurisdiction because Plaintiffs failed to exhaust their administrative remedies prior to filing suit. In evaluating this argument, the Court must consider the mechanism by which Plaintiffs have brought this suit. Plaintiffs assert their claims under a specific Social Security Act provision, 42 U.S.C. § 405(g),[8] which is the proper provision by which to raise an APA challenge to a Medicare-related agency action. 42 U.S.C. §§ 405(h), [9] 1395ii; *Heckler v. Ringer*, 466 U.S. 602, 615 (1984); *Am. Hosp. Ass'n v. Azar ("AHA*

[8] This provision states, in relevant part, that:

> Any individual, after any *final decision* of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States . . . .

42 U.S.C. § 405(g) (emphasis added).

[9] This provision states that:

> The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency *except as herein provided*. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346

II"), 895 F.3d 822, 825 (D.C. Cir. 2018). And as noted, judicial review of a claim brought under § 405(g) is foreclosed until the claimants have exhausted their administrative remedies and received a final decision from the Secretary. 42 U.S.C. § 405(g); *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976); *AHA II*, 895 F.3d at 826. Although the concept of "exhaustion" exists under typical administrative law principles, the Supreme Court has explained that § 405(h)'s channeling mechanism imposes an even more exacting exhaustion requirement. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000) ("[T]he bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'. . . ."). Indeed, § 405(h) "demands the 'channeling' of virtually all legal attacks through the agency." *Id*. at 13.

Section 405(g)'s review channeling mechanism contains two elements. First, the provision contains a jurisdictional, non-waivable "requirement that a claim for benefits shall have been presented to the Secretary." *Eldridge*, 424 U.S. at 328. Second, the provision contains a non-jurisdictional "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id*. This requirement may be waived by the agency or a court. [10] *See*

> [federal defendant jurisdiction] of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h) (emphasis added). The Supreme Court has interpreted § 405(h) to require that Medicare claims be pursued through the special review system laid out in § 405(g), rather than through other judicial mechanisms that may otherwise be available. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8–15 (2000). 42 U.S.C. § 1395ii expressly applies § 405(h) to claims arising under the Medicare provisions of the Social Security Act, and the D.C. Circuit has reasoned that "expressly incorporating the judicial-review bar in § 405(h) also effectively incorporates the exception 'herein provided' in § 405(g)." *Am. Hosp. Ass'n v. Azar ("AHA II")*, 895 F.3d 822, 825 (D.C. Cir. 2018) (citing *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1103 (11th Cir. 1998)).

[10] In arguing that Plaintiffs must fully exhaust their administrative remedies, the Secretary notes that the Social Security Act provides an "abbreviated review process" by which a claimant may request expedited judicial review. Defs.' Mot. at 27 (citing 42 U.S.C. § 1395ff(b)(2)(A); 42 C.F.R. § 405.990). However, the Secretary does not explain why that

id. at 330. Together, these requirements serve the practical purpose of "assur[ing] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Ill. Council*, 529 U.S. at 13. Because, as noted, both parties agree that Plaintiffs have satisfied § 405(g)'s presentment requirement, the Court must consider whether Plaintiffs may be excused from exhausting their administrative remedies.

"A court may waive the exhaustion requirements of § 405(g) when: (1) the issue raised is entirely collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; [or] (3) exhaustion would be futile." *Triad at Jeffersonville I, LLC v. Leavitt*, 563 F. Supp. 2d 1, 16 (D.D.C. 2008) (citing *Bowen v. City of New York*, 476 U.S. 467, 483–85 (1986)); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). In such situations, a "district court may, in its discretion, excuse exhaustion if 'the litigant's interests in immediate judicial review outweigh the government's interests in the efficiency or administrative autonomy that the exhaustion doctrine is designed to further.'" *Avocados Plus Inc. v. Veneman*, 370 F.3d 1243, 1247 (D.C. Cir. 2004) (quoting *McCarthy v. Madigan*, 503 U.S. 140, 146 (1992)).

Here, Plaintiffs rely solely on what they claim is the futility of exhausting their administrative remedies. "Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with [the] other factors . . . ." *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015); *see also Tataranowicz*, 959 F.2d at 274 (waiving the plaintiffs' §405(g) exhaustion requirement as futile, without recourse to other factors). That said, the ordinary standard for futility in administrative law cases is inapplicable

provision would prevent a court from waiving 42 U.S.C. § 405(g)'s exhaustion requirement when appropriate, nor does the Secretary cite case law establishing that principle.

in Medicare cases. *See Weinberger v. Salfi*, 422 U.S. 749, 766 (1975) (stating that § 405(g) is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility"). Instead, the Court must consider whether judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record. *Tataranowicz*, 959 F.2d at 275 (citing *Salfi*, 422 U.S. at 765).

Applying these principles, the futility of requiring Plaintiffs to exhaust their administrative remedies in this case is readily apparent. The Secretary does not argue that proceeding with Plaintiffs' lawsuit would somehow "interfere with the agency's efficient functioning."[11] Nor does the Secretary contend that this dispute must be resolved based on facts that would be more fully developed through the administrative process. Indeed, as the Secretary recognizes, Plaintiffs' claim "raises pure legal questions regarding the scope of the Secretary's statutory authority . . . ." Defs.' Mot. at 28 n.10. Finally, there is no reason to believe that the agency might overturn the regulation, should Plaintiffs be given additional opportunities to raise their arguments through the administrative process. In the notice and comment proceedings, HHS specifically considered and rejected the arguments that Plaintiffs now raise here. *See* 82 Fed. Reg. at 52,499–502 (asserting that the Secretary could reduce SCOD reimbursement rates pursuant to the Secretary's authority to "adjust" reimbursement rates under 42 U.S.C § 1395*l*(t)(14)(A)(iii)(II), and rejecting Plaintiffs' claims to the contrary). Moreover, HHS's

[11] In fact, Plaintiffs assert, and the Secretary does not contest, that clarity regarding the 340B reimbursement rates will *improve* the agency's efficiency by resolving a large portion of the agency's administrative appeal workload raising the same issues addressed by this opinion. *See* Pls.' Mem. Ex. T at 2 n.2.

proposed 2019 OPPS Rule continues to reimburse 340B drugs at ASP minus 22.5%, indicating HHS's commitment to its position here. Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("Proposed 2019 OPPS Rule"), 83 Fed. Reg. 37,046, 37,122 (July 31, 2018) (to be codified at 42 C.F.R. pt. 419).

In fact, as Plaintiffs point out and the Secretary does not dispute, because the 2018 OPPS Rule is final, it appears that no administrative review body would even have authority to alter or deviate from its requirements, due to the Rule's binding nature on HHS. Indeed, HHS regulations provide that "[a]ll laws *and regulations* pertaining to the Medicare and Medicaid programs . . . are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council." 42 C.F.R. § 405.1063(a) (emphasis added); *see also* HHS Expedited Access to Judicial Review Ruling at 6, ECF No. 19-1 (stating that "neither the ALJ nor the [Medicare Appeals] Council has the authority to find the 2018 OPPS Rule invalid").

When faced with similar circumstances, the Supreme Court and other courts in this jurisdiction have waived the Social Security Act's exhaustion requirement.[12] *See Mathews v. Diaz*, 426 U.S. 67, 76–77 (1976) (treating, for jurisdictional purposes, the Secretary's "stipulat[ion] that no facts were in dispute, that the case was ripe for disposition by summary judgment, and that the only issue before the District Court was the constitutionality of the statute . . . as tantamount to a decision denying the application and as a waiver of the exhaustion requirements" because the "constitutional question [was] beyond the Secretary's competence");

[12] Because the Court concludes that Plaintiffs' exhaustion of their administrative remedies here would be futile, it need not consider Plaintiffs' argument that they *have* exhausted their administrative remedies with respect to certain claims for reimbursement. *See* Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 11–12, ECF No. 16.

Tataranowicz, 959 F.2d at 274 (excusing exhaustion requirement on futility grounds where "the Secretary g[ave] no reason to believe that the agency machinery might accede to plaintiffs' claims"); *Nat'l Ass'n for Home Care & Hospice*, 77 F. Supp. 3d at 112 (excusing exhaustion requirement on futility grounds because plaintiff's "statutory claim—that the Secretary exceeded her authority under the [Affordable Care Act] in promulgating [a rule]—[was] a purely legal challenge to the agency's established interpretation of the Medicare Act"); *Hall v. Sebelius*, 689 F. Supp. 2d 10, 23–24 (D.D.C. 2009) (stating that "exhaustion may be excused where 'an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law'" (quoting *DL v. District of Columbia*, 450 F. Supp. 2d 11, 17 (D.D.C. 2006)). The Court does the same here. Because Plaintiffs have presented claims for reimbursement to the Secretary under the 2018 OPPS Rule, and because Plaintiffs' exhaustion of their administrative remedies would be futile, the Court waives Plaintiffs' exhaustion requirement and exercises its subject matter jurisdiction under 42 U.S.C. § 405(g).

B. This Court Is Not Precluded From Evaluating Plaintiffs' *Ultra Vires* Claim

The Secretary also argues that the Court is precluded by certain Medicare provisions from hearing Plaintiffs' suit. Again, the precise mechanism by which Plaintiffs have brought this suit is key to the Court's analysis. Although, as discussed above, this Court has jurisdiction under § 405(g) to hear Plaintiffs' action, Plaintiffs ultimately seek relief not under § 405(g), but under the APA. *See* Compl. ¶¶ 68–69. And under the APA, litigants may seek review of agency action, "except to the extent that [a] statute[] preclude[s] judicial review." 5 U.S.C. § 701(a)(1).

"There is a 'strong presumption that Congress intends judicial review of administrative action.'" *Amgen*, 357 F.3d at 111 (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). This presumption weighs "particularly strong[ly]" in favor of "judicial review

of agency action taken in excess of delegated authority," as alleged here. *Id*. at 111–12 (citing *Leedom v. Kyne*, 358 U.S. 184, 190 (1958); *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1173 (D.C. Cir. 2003)). To overcome the presumption, there must be "'clear and convincing evidence' of a contrary legislative intent." *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967) (quoting *Rusk v. Cort*, 369 U.S. 367, 380 (1962)), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 107 (1977). This analysis requires that the Court 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).

The Secretary contends that three Medicare provisions preclude this Court's review of Plaintiffs' suit: 42 U.S.C. § 1395*l*(t)(12)(A), (t)(12)(C), and (t)(12)(E). Defs.' Mot. at 17. Subsection (t)(12)(A) states:

> There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of . . . the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, *other adjustments*, and methods described in paragraph (2)(F).

42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). Subsection (t)(12)(C) states that "[t]here shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of . . . *periodic adjustments* made under paragraph [9]."[13] *Id*. § 1395*l*(t)(12)(C) (emphasis added). And subsection (t)(12)(E) states:

[13] Both parties agree that because of a scrivener's error, subsection (t)(12)(C) explicitly refers to "periodic adjustments made under paragraph [(t)](6)" but should refer to subsection (t)(9). *See* Defs.' Mot. at 6 n.2; Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 7 n.6, ECF No. 16. Subsection (t)(9) requires that "[t]he Secretary . . . review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph [(t)](2)." *Id*. § 1395(t)(9)(A).

> There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of . . . the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), *the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals*, and the application of any pro rata reduction under paragraph (6).

Id. § 1395*l*(t)(12)(E) (emphasis added).

It is uncontested that none of these subsections explicitly preclude judicial review of rate adjustments made under subsection (t)(14). *See* Pls.' Opp'n Defs.' Mot. ("Pls.' Opp'n") at 3, ECF No. 16. And Plaintiffs argue that without this explicit reference, there is no "clear and convincing evidence" that subsection (t)(12) is intended to preclude judicial review of the subsection (t)(14) rate adjustment at issue here. *Id*. a 3–4. The Secretary, on the other hand, argues that the separately payable drugs addressed by subsection (t)(14) fall within the OPPS payment "classification system" established under subsection (t)(2). Defs.' Mot. at 19. Therefore, according to the Secretary, adjustments to those drugs' reimbursement rates are "adjustments" described in subsection (t)(2), made to the agency's "fee schedule amount associated with particular . . . drugs," review of which are precluded by subsections (t)(12)(A) and (t)(12)(E). *Id*. at 19–21; Reply Supp. Defs.' Mot. ("Defs.' Reply") at 4–5, ECF No. 20. The Secretary further argues that in finalizing the 2018 OPPS Rule, the Secretary explicitly invoked his subsection (t)(9) authority to periodically revise relative payment rates, review of which is precluded by subsection (t)(12)(C). Defs.' Mot. at 20 (citing 82 Fed. Reg. at 52,356); Defs.' Reply at 7–8.

The parties' preclusion arguments notwithstanding, because Plaintiffs claim that the Secretary acted in excess of his statutory authority—that he acted *ultra vires*—the Court need not resolve the parties' conflicting interpretations of subsection (t)(12). "[T]he case law in this

circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Lutherans*, 321 F.3d at 1173 (citing *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996)). Thus, "the APA's stricture barring judicial review 'to the extent that statutes preclude judicial review,' 'does not repeal the review of *ultra vires* actions' . . . ." *Id.* (quoting 5 U.S.C. § 701(a)(1); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988)). Put simply, if the Secretary's 340B drug reimbursement rate reduction was an "adjustment" under subsection (t)(14), review of that adjustment is arguably precluded by subsection (t)(12). But if the Secretary's action was not an "adjustment," the Court may review it. *See Amgen*, 357 F.3d at 112 (section 1395*l*(t)(12)(A) prevents "review only of those 'other adjustments' that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of 'other adjustments' extends no further than the Secretary's statutory authority to make them.").

Accordingly, to determine whether Plaintiffs raise an *ultra vires* claim falling outside the scope of subsection (t)(12)'s preclusion provisions, the Court must consider that claim's merits. *See id*. at 113 ("[T]he determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review."); *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20–21 (D.D.C. 2014) ("[I]f Apligraf qualifies as a SCOD, this Court may hear the case under the *ultra vires* doctrine of review," but "if Apligraf does not qualify as a SCOD, 42 U.S.C. § 1395*l* (t)(12)(A) precludes this Court's review."); *cf. COMSAT Corp. v. FCC*, 114 F.3d 223, 226–27 (D.C. Cir. 1997) (in determining whether a statutory provision precluded judicial review of an agency action, noting that such a determination "merges consideration of the legality of the [agency]'s action with consideration of th[e] court's

jurisdiction in cases in which the challenge to the [agency]'s action raises the question of the [agency]'s authority to enact a particular amendment. Where, as here, we find that the [agency] has acted outside the scope of its statutory mandate, we also find that we have jurisdiction to review the [agency]'s action."). Because the Court concludes, as explained below, that the Secretary exceeded his authority under the Medicare provisions of the Social Security Act, the Court also necessarily concludes that subsection (t)(12) does not preclude judicial review of Plaintiffs' claims.

C. HHS's 340B Reimbursement Rate Reduction Was *Ultra Vires*

Having waded through the potential impediments to its jurisdiction, the Court may consider Plaintiffs' core allegation; that the Secretary acted *ultra vires* in "adjusting" the 340B drug reimbursement rates from ASP plus 6% to ASP minus 22.5%. "To challenge agency action on the ground that it is *ultra vires*, [a plaintiff] must show a 'patent violation of agency authority.'" *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016) (quoting *Indep. Cosmetic Mfrs. & Distribs., Inc. v. U.S. Dep't of Health, Educ. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978)). "A violation is 'patent' if it is '[o]bvious' or 'apparent.'" *Id.* (quoting Black's Law Dictionary (10th ed. 2014)). "Such ultra vires review is 'quite narrow.'" *H. Lee Moffitt Cancer Center & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11 (D.D.C. 2018) (quoting *Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 307 (D.C. Cir. 2014)).

Plaintiffs' *ultra vires* argument here turns on the scope of the Secretary's discretion under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) to alter the statutory benchmark drug reimbursement rates. As noted, under that provision, a given drug's reimbursement rate "shall be equal . . . [to] 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*. (emphasis added). And the parties agree that § 1395w-3a sets a default payment rate of ASP plus 6%, which HHS implemented for several years preceding the 2018 OPPS Rule. Defs.' Mot. at 6; Pls.' Mem. at 3–4; 77 Fed. Reg. at 68,387.

Thus, the principle dispute among the parties is whether the Secretary acted within his authority to "calculate[] and adjust[]" the statutory benchmark rate of ASP plus 6% when he reduced that rate to ASP minus 22.5% based on his estimation of 340B hospitals' drug acquisition costs, rather than the drugs' average sales prices. 82 Fed. Reg. at 52,496. The Secretary argues that the authority to "adjust" reimbursement rates is essentially a plenary power to change rates according to any methodology, so long as the rates are expressed as a function of average drug prices. *See* Defs.' Mot. at 34. This argument relies on the premise that the statute's text does not impose any limits on the Secretary's authority to adjust rates. *See id*. at 31. This is plainly wrong.

In fact, the statute's plain text *does* limit the Secretary's "adjust[ment]" authority. The D.C. Circuit held as much under nearly identical circumstances in *Amgen*. In that case, the Circuit considered the Secretary's authority to adjust reimbursement rates under a different, but related, Medicare provision: 42 U.S.C. § 1395*l*(t)(2)(E). *Amgen*, 357 F.3d at 107. Like subsection (t)(14)(A)(iii)(II), subsection (t)(2)(E) authorizes the Secretary to make "adjustments" to certain hospital reimbursement rates "to ensure equitable payments" under the OPPS scheme. 42 U.S.C. § 1395*l*(t)(2)(E).[14] In addressing the *Amgen* plaintiff's claim that the Secretary

[14] This subsection states:

> the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph [(t)](5) and transitional pass-through payments under paragraph [(t)](6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals[.]

exceeded his adjustment authority under subsection (t)(2)(E), the Circuit observed that "[l]imitations on the Secretary's equitable adjustment authority *inhere in the text* of § (t)(2)(E)." *Amgen*, 357 F.3d at 117 (emphasis added). Indeed, because the statute "only authorizes 'adjustments,'" it could not be read to permit "total elimination or severe restructuring of the statutory scheme." *Id*. Though the relatively insignificant rate reduction at issue in *Amgen* was not *ultra vires*, the Circuit concluded that because "the term 'adjustments'" did not "encompass the power to make 'basic and fundamental changes in the [statutory] scheme' . . . a more substantial departure from the default amounts would, at some point . . . cease to be an 'adjustment[].'" *Id*. (quoting *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994)).

Amgen's logic applies equally here. First, "identical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007). Thus, because Congress did not intend for the term "adjust" to confer unbridled authority in the context of subsection (t)(2)(E), there is good reason to believe that Congress did not intend to confer such authority in the context of subsection (t)(14)(A)(iii)(II). But more fundamentally, the structure of subsection (t)(14)(A)(iii)(II) necessitates this conclusion. That provision commands that SCOD reimbursement rates "shall" be set "equal" to a rate specified in certain other statutory provisions; here, each drug's average sales price plus 6%. 42 U.S.C. § 1395*l* (t)(14)(A)(iii)(II). This clear directive is qualified only by the Secretary's authority to "adjust" those rates. *Id*. Notably, the Medicare subsection at issue in *Amgen* followed this very same structure by articulating a clear requirement and then qualifying that requirement with the modest authority to adjust rates. Thus, like in *Amgen*, the language and structure of subsection (t)(14)(A)(iii)(II) make clear that the Secretary may not

make "basic and fundamental changes" under the purported auspices of making mere "adjustments" to the rates statutorily imposed by that subsection.[15] *See Amgen*, 357 F.3d at 117; *cf. Railway Labor Execs.' Ass'n. v. Nat. Mediation Bd.*, 29 F.3d 655, 669 (D.C. Cir. 1994) (en banc) ("[I]t goes without saying that the bald assertion of power by [an] agency cannot legitimize it.").

Amgen also answers another critical question: whether an abuse of the Secretary's adjustment authority might form the basis of an *ultra vires* action. That is to say, whether a court could find, under some set of circumstances, that the Secretary has "patent[ly]" violated his authority to "adjust" payment rates. *Fla. Health Scis. Ctr.*, 830 F.3d at 522. *Amgen* suggests that such a finding is possible. The D.C. Circuit explained that, although the Secretary's equitable adjustment authority permitted "the adjustment of OPPS payments otherwise set by the Medicare Act," it did not "give the Secretary the absurdly broad power to make drastic adjustments, such as the elimination of the entire pass-through program, and term it an 'equitable adjustment,' thereby undermining the mandatory nature of the pass-through payment system *while evading judicial review*." *Amgen, Inc.*, 357 F.3d at 117 (emphasis added). Rather, if the Secretary makes "basic and fundamental changes in the scheme . . . the Secretary would, in that event, exceed his statutory authority [to make adjustments] under § (t)(2)(E) [and] *the preclusion on judicial*

[15] In addition to arguing that § 1395*l*(t)(14)(A)(iii)(II)'s plain text imposes no limitation on the Secretary's adjustment authority, the Secretary argues that had Congress wished to limit that authority, it would have done so explicitly, as it did in the same subsection with respect to 2004 and 2005 payment rates. Defs.' Mot. at 31 (citing 42 U.S.C. § 1395*l*(t)(14)(A)(i)–(ii)). This argument is essentially an all or nothing proposition; Congress either imposes rigid instructions or it grants unbridled authority. As discussed, the Court believes that Congress acted with more nuance here. In granting the Secretary authority to "adjust" the statutory benchmark rate, Congress provided leeway for the Secretary to alter and even reduce that benchmark, but not leeway to toss it aside entirely.

review in § (t)(12)(A) would not apply." *Id.* (emphasis added). In other words, judicial review would be permitted because the Secretary's purported "adjustment" would be, in fact, an *ultra vires* act (i.e. a patent violation of his authority).

The question for the Court, then, is whether the change at issue here—reducing the default 340B drug reimbursement rate of ASP plus 6% to ASP minus 22.5%—is so substantial as to be a patent violation of the Secretary's § (t)(14)(A)(iii)(II) adjustment authority. Although similar arguments have been raised in this jurisdiction, no court has held that the Secretary acted outside of his authority to make "adjustments" to any Medicare reimbursement rates. For example, in *Amgen*, the D.C. Circuit had "no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments'" because the rate adjustment at issue there involved "only the payment amount for a single drug, [which] does not work 'basic and fundamental changes in the scheme' Congress created in the Medicare Act . . . ." *Amgen, Inc.*, 357 F.3d at 117 (quoting *MCI*, 512 U.S. at 225). Likewise, in other cases, courts have found that payment reductions of 0.2% and 2.9% were not significant enough to warrant a finding that the Secretary exceeded his adjustment authority. *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 260 (D.D.C. 2015) (citing *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 700 (D.C. Cir. 2014)).

But the circumstances here are quite different than those previously presented in this jurisdiction. The Secretary's rate adjustment at issue here does not affect a single drug or even a handful of drugs, but rather potentially thousands of pharmaceutical products found in the 340B Program. *See* 82 Fed. Reg. at 52,494 (discussing the number of 340B "covered products" available to 340B covered entities). Moreover, the changes that the Secretary imposed are not modest. Indeed, by changing the formula from the statutory default of ASP plus 6% to ASP

minus 22.5%, the Secretary is imposing a nearly 30% reduction from the formula that Congress expressly set as the standard. When viewed together, the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining SCOD reimbursement rates, thereby exceeding the Secretary's authority to "adjust[]" SCOD rates under § (t)(14)(A)(iii)(II).

In attempting to justify this drastic departure from the statutorily mandated rates, the Secretary argues that because § (t)(14)(A)(iii) "itself identifies 'acquisition cost[s]' as a valid reference point for drug payments," the Secretary must necessarily have been within his authority to adjust 340B reimbursement rates to achieve that goal. *Id*. at 29, 33. It is true that § (t)(14)(A)(iii) authorizes the Secretary to set reimbursement rates at levels consistent with hospitals' acquisition costs for those drugs. 42 U.S.C. 1395*l* § (t)(14)(A)(iii)(I). But that authorization is found in subsection *(I)*, which requires the Secretary to consider certain hospital acquisition cost survey data. *Id*.

Here, the Secretary eschewed the use of subsection (I) because the required acquisition cost data was not available. 82 Fed. Reg. at 52,496. And the statutory scheme is clear that if the Secretary does not have that data, he must calculate reimbursement rates by reference to the drugs' *average sales prices*. 42 U.S.C. § (t)(14)(A)(iii)(II). While the Secretary is permitted to make "adjust[ments]" to those rates for whatever reasons he deems "necessary," adjustments are all he can make.[16] *Id*. He cannot fundamentally rework the statutory scheme—by applying a

[16] The Secretary argues that subsection (II) cannot mandate a reimbursement rate "based strictly on ASP" because that interpretation would render the Secretary's adjustment authority meaningless. Defs.' Mot. at 29. The Court's holding is not so rigid; it agrees that the Secretary has *some* authority to deviate from the statutory benchmark of ASP plus 6%. The Court merely holds that if an adjustment is sufficiently large and entirely de-coupled from the methodology imposed by subsection (II), it may exceed the Secretary's statutory authority and cease to be an "adjustment."

different methodology than the provision requires—to achieve under subsection (II) what he could not do under subsection (I) for lack of adequate data.[17] Indeed, the Secretary's admission that he sought to mimic the result of subsection (I)—by setting rates designed to approximate *acquisition costs*—under the authority of subsection (II)—which dictates that rates approximate *average sales prices*—only further supports the notion that the Secretary's purported adjustments were, in fact, fundamental changes in the statutory scheme.[18] *See* 82 Fed. Reg. at 52,500 (stating that the Secretary is "using [his] authority [under § (t)(14)(A)(iii)(II)] to apply a downward adjustment that is necessary to better reflect acquisition costs of those drugs"). Congress could very well have chosen to treat Medicare reimbursements for 340B drugs differently than reimbursements for other separately payable drugs, but it did not do so. To the extent the Secretary disagrees on policy grounds with Congress's decision, *see, e.g.*, 82 Fed. Reg. at 52,495 ("While we recognize the intent of the 340B program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs."), the Secretary may either collect the data necessary to set payment rates based on acquisition costs, or he may raise his disagreement with Congress, but he may not end-run Congress's clear mandate.

[17] Because the Court concludes that the Secretary's rate reduction is unsupported by the statute's unambiguous text, the Court need not address whether the Secretary's statutory interpretation is entitled to deference under *Chevron, U.S.A., Inc. v, NRDC*, 467 U.S. 837, 842–43 (1984). *See* Defs.' Mot. at 28.

[18] The Secretary urges the Court to take into account the rate reduction's "context," and consider that it will allow Medicare beneficiaries to "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." Defs.' Mot. at 32 (quoting 82 Fed. Reg. at 52,495). The Court does not dispute the Secretary's policy reasons for seeking to reduce 340B reimbursement rates. But a noble goal does not excuse the Secretary's *ultra vires* action taken in pursuit of that goal.

For these reasons, the Court concludes that the Secretary acted *ultra vires*.[19] This conclusion carries two implications. First, the Court's conclusion means that 42 U.S.C. § 1395*l*(t)(12), which ordinarily proscribes judicial review of the Secretary's OPPS reimbursement rate determinations, presents no barrier in this case.[20] Therefore, the Secretary's Federal Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction must fail. Second, the Court's conclusion means that Plaintiffs have adequately alleged a claim for relief under the APA, thereby defeating the Secretary's Federal Rule 12(b)(6) motion to dismiss.

D. Disposition

Having resolved that this Court has jurisdiction over this matter and that, on the merits, the Secretary's action was *ultra vires*, the Court must now consider the proper way forward.

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[19] Accordingly, the Court declines to address Plaintiffs' alternative arguments that (1) the Secretary's adjustment authority is limited to the consideration of hospitals' overhead costs, Pls.' Mem. at 26–27; (2) the Secretary's action was *ultra vires* because it improperly treats certain providers differently than others, *id*. at 27–28; and (3) the Secretary's action was *ultra vires* because it undermines the purpose of the 340B program, *id*. at 28–30.

[20] The Secretary also argues that, even if §1395*l*(t)(12) does not preclude judicial review, any payment adjustment under § 1395(t)(14)(A)(iii)(II) is committed to agency discretion by law, and is therefore unreviewable by this Court. Defs.' Mot. at 25–26; *see also* 5 U.S.C. § 701(a)(2) (stating that an agency action may not be challenged under the APA if it "is committed to agency discretion by law"). Again, the provision at issue requires the Secretary to set SCOD payment rates 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). In raising his "agency discretion by law" argument, the Secretary focuses on the part of the statute that reads "as necessary for the purposes of this paragraph." Defs.' Mot. at 25–26. According to him, this language leaves the court without any "meaningful standard against which to judge the agency's exercise of discretion." *Id*. at 25 (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)). But this argument can only carry force to the extent that one understands the Secretary's 340B rate reduction to be an "adjustment." That is, a court may not inquire into the "necessity" of an "adjustment" made by the Secretary, but that does not prevent the Court from inquiring into whether the Secretary's actions were, in fact, an "adjustment" or something more. Because, as described above, the Secretary's actions did not constitute an "adjustment" for purposes of the statute, the Secretary's argument presents no barrier to this Court's review. *See Amgen*, 357 F.3d at 117 (interpreting the statutory scheme to impose limitations on the Secretary's authority to "adjust" reimbursement rates).

Plaintiffs urge the Court to "[a]dvanc[e] a decision on the merits" under Federal Rule of Civil Procedure 65(a)(2). Pls.' Mem. at 34. Rule 65(a)(2) states that "[b]efore or after beginning [a] hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing." Fed. R. Civ. P. 65(a)(2); *accord Teva Pharm. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 181 n.1 (D.D.C. 2005) ("This type of consolidation is a procedural tool designed to conserve the resources of the Court and the parties by avoiding duplicative efforts." (citing *NOW v. Operation Rescue*, 747 F. Supp. 760, 768 (D.D.C. 1990))), *vacated on other grounds by* 441 F.3d 1 (D.C. Cir. 2006). In determining whether a decision on the merits is appropriate, a court must consider whether, at this stage, "the record is sufficient for a determination on the merits under the summary judgment standard, or, where reliance on the record is unnecessary, under the motion to dismiss standard." *March for Life v. Burwell*, 128 F. Supp. 3d 116, 124 (D.D.C. 2015). Both parties contend that the record is sufficient for a determination on the merits here, and the Court agrees.

The Secretary has had every opportunity and incentive to argue the merits of Plaintiffs' claim, and he was aware that the Court may enter judgment on the merits at this stage. Indeed, the Secretary urged this Court to decide this case on the merits, asserting that "[b]ecause Plaintiffs' APA claims raise pure legal questions regarding the scope of the Secretary's statutory authority, the Court may reach the merits of those claims on a Rule 12(b)(6) motion."[21] Defs.'

[21] Even if the parties had not been on notice of the Court's inclination to render a decision on the merits, summary judgment would likely still be appropriate under Federal Rule of Civil Procedure 56. *See* Fed. R. Civ. P. 56(f)(3) (stating that a court may "consider summary judgment on its own after identifying for the parties material facts that may not be genuinely in dispute."). It is generally understood that "'[a] district court may grant summary judgment without notice if' . . . the losing party has had a full and fair opportunity to present arguments and . . . the parties have no genuine dispute as to a material fact." *Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1332 (Fed. Cir. 2010) (quoting *United States v. Grayson*, 879 F.2d 620, 625 (9th Cir. 1989)); *accord Colbert v. Potter*, 471 F.3d 158, 168 (D.C.

Mot. at 28 n.10. This, of course, is true. Plaintiffs' Complaint "actually presents no [disputed] factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action." *Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); *see also* Defs.' Mot. at 28 n.10 ("[I]t is unnecessary for the Court to consider the administrative record in evaluating Plaintiffs' claim, since the claims present pure questions of statutory interpretation."); Defs.' Reply at 3 n.2 ("Defendant's motion . . . does not depend upon the contents of any documents other than the final rule challenged by plaintiffs and other judicially noticeable materials."). Thus, "the sufficiency of the complaint is the question on the merits, and there is no real distinction in this context between the question presented on a 12(b)(6) motion and a motion for summary judgment." *Marshall Cty.*, 988 F.2d at 1226; *see also March for Life*, 128 F. Supp. 3d at 124 ("Where a plaintiff's complaint properly states a claim, summary judgment is the appropriate method by which to resolve the merits of a dispute regarding federal agency action 'because the . . . regulation's validity is a question of law.'" (quoting *Lederman v. United States*, 89 F. Supp. 2d 29, 33 (D.D.C. 2000), *on recons. in part*, 131 F. Supp. 2d 46 (D.D.C. 2001))).

Consequently, in their briefing, both parties argued at length about the Secretary's authority to implement the Medicare rate reduction at issue. Moreover, the Secretary did not oppose, or even address, Plaintiffs' request that the Court render a judgment on the merits. And the Secretary gave no reason to believe that he might present different or additional legal

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Cir. 2006) (stating that summary judgment, even if entered erroneously, constitutes harmless error "[w]hen a nonmoving party could not have produced any 'evidence sufficient to create a substantial question of fact material to the governing issues of the case'" (quoting *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003)). In this case, the Secretary vigorously argued the merits of Plaintiffs' claim and conceded that there can be no genuine dispute of any material fact, as the case involves a pure question of law.

arguments at some later stage in the litigation.[22] As discussed above, having considered the parties' arguments, the Court concludes that the Secretary exceeded his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) in setting the 340B drug reimbursement rates in the 2018 OPPS Rule. Because the Secretary had every opportunity and every reason to present his merits arguments, because he did present those arguments, and because there is no reason to believe that a more developed record in the future could lead to any other outcome than the one reached today, the Court will enter judgment in favor of Plaintiffs.[23]

E. Remedies

The typical remedy for an agency rule promulgated contrary to law is to vacate the rule. *See Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 614 (D.C. Cir. 2017) (citing *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002)); *St. Lawrence Seaway Pilots Ass'n, Inc. v. U.S. Coast Guard*, 85 F. Supp. 3d 197, 208 (D.D.C. 2015). As noted, Plaintiffs seek that relief and its logical consequences, including that the Court require HHS to

[22] This Court held oral argument in *AHA I*, which involved the same parties, the same procedural posture, and substantially similar claims raised by Plaintiffs against the Secretary. *See AHA I*, 289 F. Supp. 3d at 50; Min. Entry, Dec. 21, 2017, *AHA I*, No. 17-2447 (noting that the Court heard oral argument on that date); Pls.' Mem. at 2 (conceding that *AHA I* concerned a "substantively identical challenge"); Defs.' Mot. at 15 (same). During that argument the Court asked the Secretary's counsel whether there was any reason why the Court should not enter judgment at this stage in the proceedings, and counsel could identify none apart from his general desire for a "second bite at the apple." The Court sees no reason to grant the Secretary a "second bite" when there is no evidence that the second bite would be any different than the first. The Court also declines to hear oral argument on the parties' motions at this stage because it believes that oral argument would "be of no meaningful assistance in rendering a final decision[,]" in light of the *AHA I* oral argument and the clear, thorough briefing in *AHA I* and this case. *Owen-Williams v. BB&T Inv. Servs., Inc.*, 797 F. Supp. 2d 118, 126 (D.D.C. 2011); *see also* LCvR 7(f) (stating that the decision to conduct an oral argument "shall be within the discretion of the Court").

[23] Because the Court has consolidated Plaintiffs' preliminary injunction motion with a decision on the merits, the Court "need not decide the preliminary injunction." *Pharm. Research & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 34 (D.D.C. 2014).

apply the 2017 OPPS drug reimbursement methodology—ASP plus 6%—to 340B drug payments made for the remainder of 2018,[24] and pay the Hospital Plaintiffs, and all 340B Program participants who are members of the Association Plaintiffs, the difference between the 340B drug payments that they have received under the 2018 OPPS Rule and the higher payments that they would have received under the 2017 OPPS Rule.[25] Pls.' Mot. at 1–2. In other words, Plaintiffs seek retroactive Medicare Part B payments and a reallocation of those payments going forward. Plaintiffs' complaint also seeks declaratory relief. Compl. at 23. In determining whether to provide these remedies, the Court must consider "'the seriousness of the . . . deficiencies' of the [agency's] action" and "the disruptive consequences of vacatur." *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 197 (D.C. Cir. 2009) (first alteration in original) (quoting *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1048–49 (D.C. Cir. 2002)).

Here, vacatur and the other relief sought by Plaintiffs are likely to be highly disruptive. An important component of the Medicare Part B scheme is its budget neutrality requirement. *See* 42 U.S.C. § 1395*l*(t)(9)(B) (stating that OPPS payment "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"). And the Secretary claims that this requirement applies to the 340B drug

[24] Considering the timing of the Court's Order, this first remedy is likely to have little impact compared to the second remedy.

[25] Plaintiffs also ask this Court to enjoin the Secretary and HHS from incorporating the payment methodology challenged here into the HHS rule setting 2019 340B drug reimbursement rates. *See* Pls.' Mem. at 35; Compl. at 24. However, Plaintiffs' complaint does not explicitly challenge the 2019 rule, and Plaintiffs have once again failed to show that they have presented the Secretary with a concrete claim for reimbursement under the 2019 rule, as required by 42 U.S.C. § 405(g). *See Eldridge*, 424 U.S. at 328. This Court is thus foreclosed from reviewing the 2019 rule, and it declines to impose injunctive relief concerning that rule. *AHA II*, 895 F.3d at 828.

reimbursements at issue here. Defs.' Mot. at 5, 14; *see also* 82 Fed. Reg. at 52,623 ("[W]e are implementing this payment reduction in a budget neutral manner within the OPPS").

Under the budget neutrality requirement, reducing 2018 340B reimbursement rates allowed the Secretary to increase reimbursements for other drugs and services covered under Medicare Part B; increasing 340B reimbursement rates would likewise require the Secretary to reduce reimbursements elsewhere in the program. For instance, in finalizing the 2018 OPPS Rule, the Secretary stated that "the reduced payments for separately payable drugs purchased through the 340B Program w[ould] increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount." 82 Fed. Reg. at 52,623. The Secretary could thus "increase OPPS payment rates for non-drug items and services by approximately 3.2[%]." *Id*. The retroactive OPPS payments that Plaintiffs seek here would presumably require similar offsets elsewhere; a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018.

The D.C. Circuit and other circuits have recognized the "havoc that piecemeal review of OPPS payments could bring about" in light of the budget neutrality requirement. *Amgen*, 357 F.3d at 112 (citing *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002) (noting the "disruptive" impact of requiring Medicare Part B payment adjustments); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386–87 (9th Cir. 1996)); *see also Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012) ("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." (citation omitted)). In the interest of

avoiding that havoc, and because neither party thoroughly addressed the question of remedies in their briefs,[26] the Court will order supplemental briefing on this issue.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**, the Secretary's Motion to Dismiss (ECF No. 14) is **DENIED**, and Plaintiffs' Motion for a Permanent Injunction (ECF No. 2) is **GRANTED**, insofar as Plaintiffs are entitled to equitable relief. Fashioning that relief, however, requires supplemental briefing from the parties addressing the relief's proper scope and implementation. Consequently, it is **HEREBY ORDERED** that:

1. The parties shall provide supplemental briefing on the appropriate remedy, limited to no more than 25 pages per brief, within 30 days of this Memorandum Opinion's issuance; and
2. The parties shall respond to those briefs, limited to no more than 15 pages per response, within 14 days after the supplemental briefs are filed.

An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: December 27, 2018

RUDOLPH CONTRERAS
United States District Judge

[26] The Secretary argues that the potential disruption caused by judicial intervention motivated Congress to preclude judicial review of OPPS payment adjustments. Defs.' Mot. at 40–41. The Secretary does not, however, address how that disruption may be mitigated in the event of a decision for Plaintiffs. And Plaintiffs make the conclusory argument that the disruption would be offset by gains resulting from the lawful implementation of Medicare Part B. Pls.' Opp'n at 10–11. While a noble sentiment, this does not bring the Court any closer to understanding how to provide Plaintiffs with relief without wreaking havoc on the system.