UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, 800 Tenth Street, NW, Suite 400 Washington, DC 20001, *et al.*, *Plaintiffs,* –v– ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, 200 Independence Avenue, SW Washington, DC 20201, *et al.*, *Defendants.*	**Case No. _____**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION

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INTRODUCTION

This action seeks to invalidate a regulation issued by the Defendant Department of Health and Human Services ("HHS") that, for calendar year 2018, reduces by $1.6 billion reimbursements to public and non-profit hospitals that provide vital services to their communities, including to vulnerable, poor, and other underserved populations. Plaintiffs are three non-profit hospitals (Henry Ford Health System ("Henry Ford"), Eastern Maine Healthcare Systems ("EMHS"), and Fletcher Hospital, Inc. d/b/a Park Ridge Health ("Park Ridge") (collectively, the "Hospital Plaintiffs")) and three hospital associations (American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), and America's Essential Hospitals ("AEH") (collectively, the "Association Plaintiffs")) whose members include non-profit hospitals that are impacted by this deep cut, which decreases by nearly 30% Medicare payments to these and other non-profit hospitals for outpatient drugs purchased under section 340B of the Public Health Service Act ("the 340B Program"). Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017) ("2018 OPPS Rule"). The 340B Program was designed to help hospitals and clinics that serve a disproportionate share of persons unable to pay their medical bills to provide critical healthcare programs and services to their communities, including underserved populations in those communities. But the part of the regulation Plaintiffs challenge ("340B Provisions of the OPPS Rule"), which became effective on January 1, 2018, is jeopardizing those very programs and services, including oncology, dialysis, and immediate stroke treatment services, causing irreparable injury to the Hospital Plaintiffs and to members of the Association Plaintiffs. *See id.* at 52,493–511, 52,622–25; Ex. A.

HHS instituted this drastic cut by basing the reimbursement rate on a forbidden metric—acquisition cost—and impermissibly sought to subvert the purposes of the statutory 340B

Program. Under its statutory authority to set the reimbursement rate for "separately payable" drugs, HHS must base the rate on acquisition costs if it has statistically valid data specifically identified in the statute. But if it lacks that data, as the Secretary acknowledges was the case here, the statute provides that HHS must base the reimbursement rate on the average sales price of the drug ("ASP") plus 6% to account for overhead and related costs. Although the statute authorizes the Secretary to "adjust[]" the ASP-plus-6% rate "as necessary for purposes of this paragraph," 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), here HHS attempted to use its adjustment authority to end-run the statutory requirement that acquisition costs be based on statistically valid data. The result of the new methodology was not an "adjustment" of the ASP, but instead was a near-30% cut in reimbursements for 340B hospitals based on improper reliance on acquisition costs. Moreover the Secretary's authority to adjust the ASP for overhead cannot be used to make significant changes that effectively undermine the 340B Program.

This Court previously dismissed a substantively identical challenge because Plaintiffs had not yet presented the Secretary with claims for payment under the 2018 OPPS Rule. *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45 (D.D.C. 2017) ("*AHA I*"), *aff'd sub nom.*, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018) ("*AHA II*"). Plaintiffs have now done so, and this matter is ready for resolution on the merits.

BACKGROUND

I. STATUTORY FRAMEWORK

A. The Outpatient Prospective Payment System

In 1997, to control Medicare expenditures for outpatient services, Congress directed the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS, to develop a hospital Outpatient Prospective Payment System ("OPPS") for Medicare to pay for services offered by hospitals' outpatient departments, for example rehabilitation services. The OPPS is

comprised of many different payment rates for different categories of services, and CMS updates the OPPS payment rates each year.

Beginning in 2004, Congress required CMS to set OPPS payment rates each year for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled as part of an outpatient service. *See* 42 U.S.C. § 1395*l*(t)(14). These drugs include some of the outpatient drugs covered under the 340B Program.

Under the statute, the rate-setting methodology CMS may use in 2006 and subsequent years depends on the information available to it, as follows:

> The amount of payment under this subsection for a specified covered outpatient drug . . .
>
> (iii) in [any year after 2005] shall be equal, subject to subparagraph (E)—
>
> (I) to the average acquisition cost for the drug for that year . . . 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 [42 U.S.C. § 1395w-3a] as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

42 U.S.C. § 1395*l*(t)(14)(A); Ex. B-1.[1] Under Subclause I, CMS *must* set rates based on drugs' actual acquisition costs if, but only if, it possesses the acquisition cost data specifically identified in the statute. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) (requiring the use of "hospital acquisition cost survey data under [§ 1395*l*(t)(14)(D)]"). It is undisputed that CMS does not have and has never had this data. Where, as here, the specified acquisition cost data are not available, Subclause II requires CMS to use a mandatory, statutorily defined default rate based on average sales price ("ASP"). 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). That rate is ASP plus 6%. *Id.* (referring to 42

[1] The statute sets forth different rates for these separately payable outpatient drugs for 2004 and 2005 that are not relevant here. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(i)-(ii).

U.S.C. § 1395w-3a, which sets the payment rate at 106% of "the volume-weighted average of the average sales prices" for drugs and biologics). Subclause II also provides that this ASP-plus-6% default rate may be "calculated and adjusted [by HHS] as necessary for purposes of this paragraph." *Id.* The meaning of this "adjustment" authority and its limits are central in this case.

The scope of the Secretary's authority to "adjust" ASP "as necessary for purposes of this paragraph" is illuminated by the fact that reimbursement rate determinations under Subclause I or Subclause II must be "subject to subparagraph (E)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii). Subparagraph (E) directs the Medicare Payment Advisory Commission ("MedPAC") to report on "adjustment" of payment rates to "take into account overhead and related expenses." 42 U.S.C. § 1395*l*(t)(14)(E)(i).[2] It also authorizes HHS to "adjust" the rates "to take into account" any recommendations made in this report regarding these expenses. 42 U.S.C. § 1395*l*(t)(14)(E)(ii). As provided in subparagraph (E), an "adjustment" to the ASP-plus-6% rate is permissible if it seeks to "take into account overhead and related expenses."

From 2006-2011, CMS applied a reimbursement formula of ASP *plus* a small fixed percentage, generally 4-6%. *See* 77 Fed. Reg. 68,210, 68,383-68,386 (Nov. 15, 2012). CMS's variations from "ASP plus 6%" were generally intended to reflect overhead costs for providing the drugs. *Id.* In 2012, CMS formally adopted the Subclause II default rate of ASP plus 6%, acknowledging the "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost" and expressing concern that deviating from the default rate "may not appropriately account for average acquisition and pharmacy overhead cost . . . ." *Id.* at 68,387.

[2] MedPAC is an independent federal commission comprised of experts in the financing and delivery of healthcare services that advises Congress on issues affecting the administration of the Medicare program. *See* About MedPAC, http://www.medpac.gov/-about-medpac- (last visited Aug. 30, 2018).

From 2012 until its adoption of the near-30% rate reduction at issue in this case, CMS consistently applied the ASP-plus-6% statutory rate.

B. The 340B Program

Congress created the 340B Program in 1992 to provide certain hospitals and federally funded clinics servicing low-income patients (under the statute, "covered entities") with outpatient drug discounts comparable to those available to state Medicaid agencies. Under the 340B Program, manufacturers of prescription drugs, as a condition of having their outpatient drugs covered through Medicaid, are required to offer 340B hospitals and clinics outpatient drugs at or below an applicable, discounted, statutorily-determined ceiling price. In general, drug manufacturers must offer a minimum discount of between 13% and 23.1% depending on the type of drug. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b(a)(1); Ex. B-2. Drugs purchased under the 340B Program include drugs that are reimbursed under the OPPS outpatient drug reimbursement system.

Congress enacted the 340B Program "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* 2018 OPPS Rule, 82 Fed. Reg. at 52,493 & n.18 (acknowledging this legislative intent and quoting House Report). As explained by the Health Resources and Services Administration ("HRSA"), the HHS agency responsible for administering the 340B Program, the Program furthers this legislative purpose by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional resources from "health insurance reimbursements" − including reimbursements under Medicare − that are "maintained or not reduced as much as the 340B discounts or rebates."[3] In

[3] HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act 14 (July 2005) ("2005 HRSA

other words, under the Program, 340B hospitals receive Medicare and other insurance reimbursements that exceed the discounted price paid by these hospitals to drug manufacturers. These increased resources, in turn, enable 340B hospitals to deliver programs and services to serve their communities, including vulnerable populations in those communities.

Since the 340B Program was first implemented, and consistent with the statutory design, 340B hospitals and clinics have retained savings generated by the Program. Recognizing the importance of financial flexibility to the operation of covered entities, Congress did not specify how funds generated through the Program must be used, *see* 42 U.S.C. § 256b, although it anticipated that participation in the Program would enable 340B hospitals and clinics to provide additional healthcare services to communities with vulnerable populations. A 2011 report from the U.S. Government Accountability Office ("GAO") found that this is exactly what happened and that covered entities have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services − for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services.[4]

Recognizing the value of the 340B Program, Congress has increased the categories of "covered entities" over time. Originally, "covered entities" included federally-funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income or uninsured populations. H.R. Rep. No. 102-384(II), at 13; 42 U.S.C.

Manual"), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/-hemophiliatreatmentcenter340bmanual.pdf.

[4] U.S. Gov't Accountability Off., GAO-11-836, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 17–18 (2011), http://www.gao.gov/assets/330/323702.pdf.

§§ 256b(a)(4)(A)–(L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. 42 U.S.C. §§ 256b(a)(4)(M)-(O).

II. PROCEDURAL HISTORY

A. The Proposed and Final Rule

On July 13, 2017, CMS issued its annual Proposed OPPS Rule for Calendar Year 2018. 82 Fed. Reg. 33,558 (July 20, 2017). CMS proposed changing the reimbursement rate for 340B hospitals for outpatient drugs whose reimbursement is not bundled with medical procedures from the longstanding rate of ASP plus 6% to ASP minus 22.5% – a 28.5 percentage point reduction.[5] *Id.* at 33,564. The Proposed Rule retained the ASP-plus-6% rate for separately payable outpatient drugs purchased by non-340B hospitals and certain exempted 340B hospitals.

CMS admitted that the purpose of the reduction was to set a reimbursement rate for separately payable drugs that "better represents the average acquisition cost for these drugs" by 340B hospitals. *Id.* at 33,634. CMS acknowledged, however, that it (and MedPAC) lacked the data required under the statute to permit the use of acquisition cost as the measurement for reimbursement. *E.g., id.* (noting that "the confidentiality of ceiling and subceiling prices limits our ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug"). Absent the required survey data, CMS based its rate change on a MedPAC estimate that, on average, 340B hospitals "receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS]." 82 Fed. Reg. at 33,632. CMS proposed to set the reimbursement rate at ASP minus 22.5%—*i.e.*, the MedPAC aggregate estimate of acquisition cost—and characterized that rate as an "adjustment" of ASP, invoking its authority under

[5] Because the baseline is 106% (ASP plus 6%), the 28.5 percentage point decrease (from "plus 6%" to "minus 22.5%") is a 27% decrease in the payment rate (28.5/106).

Subclause II to "adjust" the ASP-plus-6% rate "as necessary for purposes of this paragraph." 82 Fed. Reg. at 33,634. In other words, although CMS was not allowed under the statute to use average acquisition cost to set the rate, it effectively adopted the MedPAC acquisition cost estimates under the guise of an "adjustment" to the ASP-based default rate by simply expressing estimated acquisition cost as a percentage of ASP.

CMS admitted that its rate reduction was motivated by a policy disagreement with the 340B Program, stating – inaccurately − that the 340B Program was responsible for "unnecessary utilization and potential overutilization of separately payable drugs"[6] (*id.* at 33,633) and that, because of the "inextricable link" between the Medicare payment rate and Medicare beneficiaries' 20% cost-sharing obligation, lowering the rate would "allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program." *Id.* at 33,634.[7]

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[6] CMS relied on a 2015 GAO study, *see* 82 Fed. Reg. at 52,494-52,495, but failed to mention that HHS's response to the study questioned the study's methodology and its characterization of "spending on [340B drugs] as 'more . . . than necessary to treat Medicare Part B beneficiaries.'" HHS pointed out that the GAO study "did not examine any patient differences in terms of outcomes or quality" and did not sufficiently account for the health status of the populations served by 340B hospitals. 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 38 (June 2015) ("2015 GAO Report"), https://www.gao.gov/assets/680/670676.pdf (reproducing HHS response). Indeed, an analysis of the cumulative payment for Part B drugs ranked by percentage of total drug payments shows that 340B and non-340B hospitals utilize the same drugs at the same rates, and that the skyrocketing cost of pharmaceuticals is the main driver of Part B drug expenditure increases. Ex. C at 12–15 (AHA comments); *see also* Ex. E at 10–11 (AEH comments).

[7] Most Medicare beneficiaries have supplemental coverage (including Medicaid for those with the lowest incomes) that reduces or entirely covers their copayments, limiting the potential benefit from any copayment reduction. Also, the OPPS Rule will cause increases in out-of-pocket costs for some beneficiaries for other non-drug OPPS services. Ex. C at 12 (AHA comments); Ex. E at 9–10 (AEH comments); Ex. F at 2 (Henry Ford comments).

CMS proposed this near-30% reduction without consulting the Advisory Panel on Hospital Outpatient Payment, even though the Medicare law requires such consultation with respect to matters relating to payment rates. 42 U.S.C. § 1395*l*(t)(9)(A). Indeed, when that Advisory Panel reviewed the rate change at its annual meeting in August 2017, after the proposed rule had been issued, it advised CMS not to adopt the change, recommending instead that CMS collect additional data "on the potential impact of revising the payment rate," including the "potential impact on 340B hospitals."[8]

Numerous parties − including Plaintiffs − submitted comments opposing the Proposed Rule. Ex. C (AHA comments); Ex. D (AAMC comments); Ex. E (AEH comments); Ex. F (Henry Ford comments); Ex. G (EMHS comments); Ex. H (Adventist/Park Ridge[9] comments). These comments addressed the incorrectness of CMS's policy justifications for the rate reduction[10] and the devastating impact of the reduction on 340B covered entities' ability to provide critical healthcare programs to their communities, including underserved patients.[11] These comments also presented detailed arguments that HHS lacked statutory authority to use a cost-based approach to calculate the reimbursement rate or to so drastically reduce the rate and undercut the 340B Program. *E.g.* Ex. C at 6–7 (AHA comments); Ex. E at 4–7 (AEH comments); Ex. F at 3 (Henry Ford comments).

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[8] CMS, Advisory Panel on Hospital Outpatient Payment: Recommendations 2 (Aug. 21, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2017-08-21-Panel-Recommendations.pdf.

[9] Park Ridge is a member of the Adventist system.

[10] *E.g.*, Ex. E at 10–12 (AEH comments); Ex. F at 2 (Henry Ford comments); Ex. H at 2–3 (Adventist/Park Ridge comments).

[11] *E.g.*, Ex. C at 9–12 (AHA comments); Ex. D at 2–3 (AAMC comments); Ex. E at 8–10 (AEH comments); Ex. F at 1–2 (Henry Ford comments); Ex. G at 1–2 (EMHS comments); Ex. H at 2–3 (Adventist/Park Ridge comments).

On November 1, 2017, CMS adopted the near-30% reduction as part of the Final OPPS Rule, applying it to 340B hospitals other than certain rural 340B hospitals. 82 Fed. Reg. 52,356, 52,493-52,511 (Nov. 13, 2017). In its Final Rule, CMS increased to $1.6 billion its estimate of the reduction's total impact on 340B hospitals. *Id.* at 52,623.

B. *American Hospital Association v. Hargan* and Subsequent HHS Rulemaking

On November 13, 2017, Plaintiffs filed a complaint and a motion for a preliminary injunction seeking to vacate the Rule. *See Am. Hosp. Ass'n v. Hargan*, Civ. Action No. 1:17-cv-2447 (RC) (D.D.C. filed Nov. 13, 2017). Plaintiffs claimed that drastic cuts to 340B Program reimbursement rates in the OPPS Rule exceeded the Secretary's authority to "calculate[] and adjust[]" average sales price under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). *See Am. Hosp. Ass'n v. Hargan*, ECF No. 1 at ¶¶ 44–46.

On December 29, 2017, this Court granted Defendants' motion to dismiss. *See AHA I*, 239 F. Supp. 3d at 47. The Court accepted Defendants' procedural argument that review of Medicare reimbursement disputes must be channeled through 42 U.S.C. § 405(g), and that the Court did not have subject matter jurisdiction under that provision because Plaintiffs "ha[d] not yet presented any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision." *Id.* at 51–52. Plaintiffs appealed, and on July 17, 2018, the D.C. Circuit affirmed this Court's decision. *See AHA II*, 895 F.3d at 828.

On July 25, 2018, CMS issued a proposed OPPS Rule for 2019. *See* 83 Fed. Reg. 37,046 (July 31, 2018). As proposed, the 2019 OPPS Rule would continue the near 30% cut in reimbursements for 340B Hospitals that CMS implemented in the 2018 OPPS Rule. *Id.* at 37,125–26.

C. Plaintiffs' Claims for Payment

After January 1, 2018, once the 340B Provisions of the OPPS rule had become effective, the Hospital Plaintiffs and members of the Association Plaintiffs began presenting claims for reimbursement for 340B Program drugs.

Under the relevant regulatory framework, a hospital must present a claim for reimbursement to a Medicare Administrative Contractor ("MAC"), which makes an initial determination whether to pay all or a portion of the claim. If the MAC denies a claim for payment in whole or in part, the Social Security Act provides a four-level administrative appeal process: First, the provider may present its claim again to the MAC for "redetermination." 42 U.S.C. § 1395ff(a)(3). Second, the provider may seek "reconsideration" from a Qualified Independent Contractor ("QIC"). *Id.* § 1395ff(c). Third, the provider may seek *de novo* review by an administrative law judge in the Office of Medicare Hearings and Appeals. *Id.* § 1395ff(d)(1). If, however, an appeal turns on a question of law or regulation and does not present any material disputes of fact, a provider that has requested review by an administrative law judge may ask the Departmental Appeals Board to certify the appeal for expedited access to judicial review. *Id.* § 1395ff(b)(1)(A), (b)(2) . Fourth, the provider may seek *de novo* review by the Medicare Appeals Council, which is a division of the HHS Departmental Appeals Board. *Id.* § 1395ff(d)(2). If HHS's final decision after this process is unfavorable, a provider may seek judicial review. *Id.* § 1395ff(b)(1)(A).

All three Hospital Plaintiffs presented multiple claims to their respective MACs for reimbursement for 340B Program drugs in early 2018.[12] Each hospital received initial

[12] Henry Ford presented three claims to a MAC: one on January 9, 2018, and two on January 10, 2018. Ex. I at 1; Ex. J at 1; Ex. K at 1. EMHS presented five claims to a MAC: one on January 23, 2018, and four on February 6, 2018. Ex. L at 1; Ex. M. at 1; Ex. N at 1; Ex. O at 1; Ex. P at 1. And Park Ridge presented two claims to a MAC: one on February 5, 2018, and the

determinations on its claims indicating that it would be reimbursed approximately 30% less than what it had received on identical claims in 2017, which was mandated by the OPPS Rule's reduction in reimbursement rates for 340B Program drugs of approximately 30%. Exs. I at 2; J at 2; K at 2; L at 1; M at 1; N at 1; O at 1; P at 1; Q at 1; R at 2.

In response to the reduced reimbursements, each Hospital Plaintiff submitted requests to its respective MAC for redetermination of each claim.[13] Each redetermination request challenged the reimbursement issued as insufficient because "the payment(s) received for 340B drugs reflect a new reimbursement of Average Sales Price (ASP) minus 22.5%" and because the new reimbursement rate

> violates 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), the authority to pay for this drug, because it: (1) is not an 'adjustment' to the statutory default rate (ASP+6%); (2) is based on acquisition cost, when reliable data on acquisition cost is concededly unavailable; and (3) is for the explicit purpose of significantly reducing benefits provided by the statutorily-created 340B program.

See supra note 13. Plaintiffs did not raise any factual disputes with the initial determinations or otherwise suggest that they were incorrect applications of the new OPPS Rule. Rather, Plaintiffs only challenged the validity of that Rule. The Hospital Plaintiffs' respective MACs rejected each of their redetermination requests either on the grounds that the payment already issued was the maximum payment allowed under then-existing Medicare regulations or that the MACs had no authority to review Plaintiffs' challenge. *See* Exs. I at 5–6; J at 5–6; K at 5–6 (MAC WPS Government Health Administrators denying Henry Ford's redetermination requests on March 6,

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other on February 7, 2018. Ex. Q at 1; Ex. R at 1. The Hospital Plaintiffs and members of the Association Plaintiffs have submitted numerous other claims for reimbursement since the OPPS Rule went into effect.

[13] *See* Ex. I at 5; Ex. J at 5; Ex. K at 5; Ex. L at 2; Ex. M at 2; Ex. N at 2; Ex. O at 2; Ex. P at 3; Ex. Q at 4; Ex. R at 4. Henry Ford submitted its redetermination requests on February 8, 2018; Park Ridge on May 11, 2018; and EMHS on March 19, 2018. *See id.*

2018 on the grounds that the amount Henry Ford had already received was "the maximum payment allowed by Medicare" for the service at issue); Exs. L at 3–4; M at 3–4; N at 3–4; O at 3–4; P at 3–4 (MAC National Government Services dismissing EMHS's redetermination requests on May 30 and 31, 2018 on the grounds that "[42 U.S.C. § 1395w-4(i)(1)] prohibits administrative and judicial review of these periodic adjustments. (Reference: 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) and 42 U.S.C. § 1395*l*(t)(12)(A), (C), (E))"); Exs. Q at 5–6; R at 5–6 (MAC First Coast Service Options, Inc. dismissing Park Ridge's redetermination requests on June 1, 2018 on the grounds that "administrative review is not available for this issue").

Each Hospital Plaintiff next submitted requests to a QIC for reconsideration of each claim.[14] In their reconsideration requests, Plaintiffs again challenged the validity of the 340B Provisions of the OPPS Rule and raised no other objections. *See supra* note 14. To date, EMHS and Park Ridge have not received decisions on their reconsideration requests. Henry Ford's reconsideration requests were dismissed by QIC Maximus Federal Services on July 11, 2018 on the grounds that administrative review is not available for 340B Program reimbursement disputes. Ex. I at 18; Ex. J at 19; Ex. K at 18.[15]

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[14] Ex. I at 7; Ex. J at 7; Ex. K at 7; Ex. L at 5; Ex. M at 5; Ex. N at 5; Ex. O at 5; Ex. P at 6; Ex. Q at 8; Ex. R at 8. Henry Ford submitted its reconsideration requests on March 27 and April 10, 2018; EMHS on July 17, 2018; and Park Ridge on July 23, 2018. *See id.*

[15] Maximus initially issued "favorable" reconsideration decisions on each of Henry Ford's three appeals, indicating in letters dated May 22 and June 1, 2018 that Henry Ford had been "underpaid" and would receive additional reimbursement. Ex. S at ¶ 7 (Aff. of Shannon Weier); *see* Ex. I at 11–14; Ex. J at 11–14; Ex. K at 9–13. Henry Ford received the first of these letters on June 6, 2018. Aff. of Shannon Weier at ¶ 7. CMS recouped its original payments on Claims '704 and '004 and reprocessed those claims, but on June 13 at 15, 2018, it reissued reimbursements for exactly the same amounts that it had issued previously on each claim: $10,533.62 on Claim '704 and $3,734.85 on Claim '004. Aff. of Shannon Weier at ¶ 9; *see* Ex. J at 15; Ex. K at 14. CMS never reprocessed the third claim. Aff. of Shannon Weier at ¶ 9. In other words, CMS decided that the Maximus "favorable" decisions were incorrect and reimbursed Henry Ford in accordance with the 2018 OPPS Rule, namely the initial amount authorized by the MAC and no more. Maximus subsequently issued letters to Henry Ford dated

On August 2, 2018, Henry Ford submitted requests to the Office of Medicare Hearings and Appeals for review of each of its three claims by an administrative law judge ("ALJ"). Ex. I at 19–22; Ex. J at 20–23; Ex. K at 19–22. Henry Ford reiterated the same statutory objection to the 340B Provisions of the OPPS Rule that it had raised in its redetermination requests to the MAC and its reconsideration requests to the QIC. *See id.* Henry Ford has not received decisions on any of its ALJ review requests.

On August 10, 2018, Henry Ford submitted a request to the Departmental Appeals Board for expedited access to judicial review pursuant to 42 C.F.R. § 405.990. Ex. T. In accordance with the governing regulation, Henry Ford explained that "there are no material issues of fact in dispute," 42 C.F.R. § 405.990(c)(1), because its administrative appeals raise a purely legal dispute regarding the validity of the 340B Provisions of the OPPS Rule. *See id.* at 4. Henry Ford also explained, consistent with the statute governing expedited access to judicial review, that adjudicators within HHS "do[] not have the authority to decide the question of law or regulation relevant to the matters in controversy," 42 U.S.C. § 1395ff(b)(2)(A), because Henry Ford's appeals challenge a regulation that all HHS adjudicators are bound to follow. *See id.* at 5

June 25 and 29, 2018, indicating that it had reopened each of the three appeals (presumably for the purpose of correcting its decision). *See* Ex. I at 15; Ex. J at 16; Ex. K at 15. On a phone call on July 12, 2018, a Maximus representative informed Henry Ford that CMS had instructed Maximus to reopen and dismiss the three appeals. Aff. of Shannon Weier at ¶ 12. The Maximus representative explained that the reason for this decision was that, in CMS's view, there are no administrative appeal rights for disputes about reimbursement under the 340B Program, and that Maximus had issued letters to that effect the previous day. *Id.* On July 30, 2018 and August 2, 2018, Henry Ford received letters from Maximus dated July 11, 2018 regarding its three appeals. Aff. of Shannon Weier at ¶ 14; *see* Ex. I at 18; Ex. J at 19; Ex. K at 18. Each letter stated that the reopened appeal "has been deleted from our system" and that "MAXIMUS will not be issuing a new reconsideration decision at this time." Ex. I at 18; Ex. J at 19; Ex. K at 18. The letters of July 11, 2018 constitute dismissals of each of Henry Ford's three claims. To date, Henry Ford's reimbursement for its three claims have equaled the amounts that were initially remitted in January 2018. Aff. of Shannon Weier at ¶ 15.

(citing 42 C.F.R. § 405.1063(a)). To date, Henry Ford has not received a decision from the Departmental Appeals Board on its request for expedited access to judicial review.

ARGUMENT

I. THIS COURT HAS SUBJECT MATTER JURISDICTION TO ADJUDICATE PLAINTIFFS' CLAIMS.

This Court has subject matter jurisdiction to review "any final decision of the [Secretary]" arising under the Medicare provisions of the Social Security Act. 42 U.S.C. § 405(g); *see also id.* §§ 405(h), 1395ii.[16] The requirement that there be a "final decision" of the Secretary "consists of two elements, only one of which is purely 'jurisdictional' in the sense that it cannot be 'waived' by the Secretary in a particular case." *Matthews v. Eldridge*, 424 U.S. 319, 328 (1976); *accord AHA II*, 895 F.3d at 825–26. "The nonwaivable element is the requirement that a claim for benefits shall have been presented to the Secretary." *Matthews*, 424 U.S. at 328. "The waivable element is the requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id.* Plaintiffs have presented their claims. The Court should waive the exhaustion element because further administrative process would be entirely futile.

A. Plaintiffs Have Presented Claims for Payment to the Secretary.

All three hospital Plaintiffs have presented the Secretary (through the MACs and QICs) with specific claims for reimbursement for drugs subject to the 340B Program. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 272 (D.C. Cir. 1992) (explaining that, for purposes of the presentment requirement in a Medicare case, the Secretary is "represented by the fiscal intermediaries who make initial payment determinations on his behalf"). As explained above, *see supra* § II.C, Henry Ford (three claims) EMHS (five claims) and Park Ridge (two claims)

[16] Federal question jurisdiction also exists under 28 U.S.C. § 1331 where necessary to preserve an opportunity for judicial review. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 19–20 (2000).

have all submitted claims to a MAC for reimbursement. All three plaintiffs have also submitted claims to the QICs, and Henry Ford has received an adverse decision from a QIC and submitted a request for review by an ALJ.

Each Hospital Plaintiff has also presented its specific legal challenge to the agency in the context of a claim for payment, articulating the statutory challenge that is now before the Court both in redetermination requests to MACs and in reconsideration requests submitted to QICs. *See* Ex. I–K (Henry Ford); Exs. L–P (EMHS); Exs. Q–R (Park Ridge). Thus, plaintiffs have plainly presented their claims for payment to the Secretary. *See Matthews*, 424 U.S. at 329 (stating that claimants in previous case satisfied presentment requirement by "fully present[ing] their claims for benefits to their district Social Security Office and, upon denial, to the Regional Office for reconsideration" (citation omitted)); *Tataranowicz*, 959 F.2d at 272 (holding that plaintiffs had "clearly met the nonwaivable presentment requirement" where they submitted claims for payment and were denied based on the challenged policy); *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell* ("*NAHC*"), 77 F. Supp. 3d 103, 109 (D.D.C. 2015) ("[B]ecause at least one member of [an association plaintiff] has submitted a claim for payment to the agency that was rejected [based on the challenged policy at the initial determination stage], [the association plaintiff] has satisfied the presentment requirement.").

B. Plaintiffs Have Satisfied the Exhaustion Requirement.

The waivable second element of section 405(g)'s "final decision" requirement is that the claimant must have exhausted the administrative remedies set forth in HHS regulations. *Matthews*, 424 U.S. at 328. If a claimant "did not exhaust the full set of internal-review procedures provided by the Secretary," then the agency (or, if the agency refuses, the Court) must determine "whether the denial of [the claim] was a sufficiently 'final' decision . . . to satisfy the statutory exhaustion requirement" such that further regulatory exhaustion procedures should

be excused. *Matthews*, 424 U.S. at 330. In this case, although Plaintiffs have not fully exhausted every administrative remedy set forth in HHS regulations, any further administrative process would be demonstrably futile.

Although it is the Secretary's decision in the first instance whether to waive exhaustion, *see id.*, "the [Supreme] Court has extended the term ['waiver'] to situations where the Secretary staunchly demands that the claim be dismissed for want of exhaustion, but the Court itself has excused non-compliance." *Tataranowicz*, 959 F.2d at 274. Futility of further administrative exhaustion can be a standalone basis for judicial waiver. *Id.*; *NAHC*, 77 F. Supp. 3d at 110. A judicial waiver based on futility is, in essence, "a finding that dispensing with further administrative process is consistent with the purposes of exhaustion." *Tataranowicz*, 959 F.2d at 275. This is so where further administrative process is not likely to yield helpful factual development or insight from agency expertise, the agency gives no reason to believe that it might accede to Plaintiffs' claims, and judicial review would not interfere with the agency's efficient functioning. *NAHC*, 77 F. Supp. 3d at 111; *see also Tataranowicz*, 959 F.2d at 274 (stating that further administrative review is futile where "the Secretary gives no reason to believe that the agency machinery might accede to plaintiffs' claims").

The standard is plainly satisfied in this case. There can be no doubt that further administrative process in this case would be futile, and indeed, the statutory challenge in this case is materially indistinguishable from the Medicare challenges for which further administrative exhaustion was found to be futile by the D.C. Circuit in *Tataranowicz* and by Judge Cooper in *NAHC*. First, just as in those cases, Plaintiffs here raise "a purely legal challenge to the agency's established interpretation of the Medicare Act." *NAHC*, 77 F. Supp. 3d at 112. There are no disputed facts that need to be developed through the administrative process,

as demonstrated by the fact that none of the hospital Plaintiffs has presented any evidence at any stage of the administrative appeals process. Indeed, Plaintiffs agree that the 340B Provisions of the OPPS Rule were applied correctly to their claims; they simply contend that those provisions are invalid. Just as in *Tataranowicz* and *NAHC*, "[t]he Secretary does not contend that [Plaintiffs'] claim will turn on any disputed facts, as it requires the Court to consider nothing more than the statute, its legislative history, and the regulation." *NAHC* 77 F. Supp. 3d at 112; *see also Tataranowicz*, 959 F.2d at 274 ("It is hard to see how any factual disputes might stand in the way of that relief, and the Secretary suggests none."). There is thus no chance that further administrative review would yield helpful factual development. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 24 (D.D.C. 2009) (finding exhaustion futile because "there are no facts unique to any of [Plaintiffs'] claims that would allow the [agency] to reach a particular decision for one Plaintiff and a different decision for another, or that should be put on the record to later assist this Court").

Second, just as in *Tataranowicz* and *NAHC*, "the Secretary gives [or in this case can give] no reason to believe that the agency machinery might accede to plaintiffs' claims" and self-correct the challenged policy. *Tataranowicz*, 959 F.2d at 274; *see also NAHC*, 77 F. Supp. 3d at 112. In *NAHC*, Judge Cooper recognized that an HHS policy was especially unlikely to be overturned by individual agency adjudicators where, as here, it was "promulgated by regulation after notice and comment rulemaking." 77 F. Supp. 3d at 112. Medicare regulations are "binding" on HHS adjudicators, 42 C.F.R. § 405.1063(a), meaning that there is no lawful way that HHS could use the administrative appeals process to set aside the challenged 340B Provisions of the OPPS Rule and grant Plaintiffs' claims. And HHS has explained in another lawsuit that, in light of its position that the challenged reimbursement determinations are not

reviewable, "[i]f AHA member hospitals attempt to challenge non-reviewable determinations by filing administrative appeals with the Office of Medicare Hearings and Appeals (OMHA), then OMHA will flag those filings and dismiss them promptly." Ex. U, *Am. Hosp. Ass'n v. Azar*, Case No. 14-cv-851-JEB, ECF No. 79, at 2 (D.D.C. Mar. 21, 2018). Defendants have made abundantly clear that Plaintiffs' administrative appeals have no chance of success, and Plaintiffs' experience to date with the administrative appeals process only confirms that reality.[17]

Third and finally, judicial review will not interfere with the agency's efficient functioning—in fact, it will do just the opposite. The exact legal issue presented in this lawsuit is likely raised in thousands or tens of thousands of currently pending Medicare appeals.[18] Although these appeals have been universally denied or dismissed, hospitals will continue to file them until a court resolves the legality of the 340B Provisions of the OPPS Rule one way or the other. And the Medicare appeals machinery is already "[b]uried under an ever-growing backlog of over a half-million appeals." *Am. Hosp. Ass'n v. Price*, 867 F.3d 160, 162 (D.C. Cir. 2017). Indeed, at the third level of administrative review where Plaintiff Henry Ford's claims are currently pending, an ALJ takes an average of over three years to process a Medicare appeal.[19] Speedy judicial resolution of the issue will *help* the agency to function more efficiently by

[17] Indeed, notwithstanding the statutory challenge that Plaintiffs have raised in comments and in litigation, Defendants recently issued the proposed 2019 OPPS Rule, which would continue the reduction in reimbursement rate that Plaintiffs are challenging. *See NAHC*, 77 F. Supp. 3d at 112 (concluding that there was no prospect of HHS self-correcting where HHS had expressly rejected arguments akin to the ones raised in the lawsuit in issuing a new version of the challenged regulation).

[18] One of the plaintiffs has been informed that MAC National Government Services has stated that 340B Program appeals now constitute over half of its appeal workload and that it is backlogged as a result. *See* Ex. T at 2 n.2.

[19] HHS, Office of Medicare Hearings and Appeals: Workload Information and Statistics—Average Processing Times by Fiscal Year (Aug. 28, 2018). https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html.

clearing the backlog that has resulted. Further clogging the administrative machinery with appeals that all agency adjudicators are bound to dismiss or deny serves no purpose of any kind.

It would be "wholly formalistic not to regard further appeals as completely futile." *Tataranowicz*, 959 F.2d at 274.

II. PLAINTIFFS' CHALLENGE IS NOT STATUTORILY PRECLUDED UNDER 42 U.S.C. § 1395*L*(t)(12).

We anticipate that Defendants will argue, as they have before, that Plaintiffs' challenge is statutorily precluded under 42 U.S.C. § 1395*l*(t)(12).[20] It is not.

Any preclusion analysis begins with the "strong presumption that Congress intends judicial review of administrative action." *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (citation omitted). That presumption "can only be overcome by [] clear and convincing evidence that Congress intended to preclude the suit." *Id.* (internal quotation marks and citation omitted). The presumption in favor of judicial review applies with full force to review of HHS decisions about Medicare reimbursements. *See Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1065 (D.C. Cir. 2018).

Defendants have previously argued that judicial review of a challenge to its decision to reduce Medicare reimbursements to 340B hospitals is precluded under § 1395*l*(t)(12)(A) and (E), but neither provision applies to agency action under subsection (t)(14), which is the authority HHS relied on in adopting its near 30% reduction in reimbursements. Subsection (t)(12)(A) precludes judicial review under paragraph (2) of subsection (t), but does not bar judicial review of agency action under (t)(14). Similarly, (t)(12)(E) only precludes judicial review of agency action under (t)(5) and (t)(6). It also does not preclude review of agency action under (t)(14). Since neither subparagraph (A) nor (E) of subsection (t)(12) mentioned subsection (t)(14), the

[20] *See Am. Hosp. Ass'n v. Hargan*, ECF No. 18 at 14–21.

plain language of (t)(12)(A) and (E) demonstrates that there is no preclusion. There is certainly no basis for an argument by HHS that there is "clear and convincing evidence" that Congress intended to preclude judicial review of agency decisions under subsection (t)(14).

III. EACH OF THE FOUR PRELIMINARY INJUNCTION FACTORS FAVORS GRANTING PLAINTIFFS' MOTION.[21]

A. Plaintiffs Are Likely to Succeed on the Merits.

The central question in this case is whether the near-30% reduction from the ASP-plus-6% statutory default rate qualifies as an "adjustment" to the statutory average sales price rate under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). In *AHA I* and *AHA II*, the Government took the position that the Secretary's "adjustment" authority gives him carte blanche to depart from the statutory default rate by any amount and for any reason. *See, e.g.*, *Am. Hosp. Ass'n v. Hargan*, ECF No. 18 at 20 (arguing that the Secretary's adjustment authority is "not subject to any express statutory limitation"); *id.* at 21 ("The statute imposes no limitation on the Secretary's 'adjust[ment]' of the payment rate . . . ."). But the Secretary is wrong because (1) the agency used its "adjustment" authority to implement an average acquisition cost methodology that it was not allowed to implement because it lacked the data required under the statute for relying on acquisition cost; (2) such a large reduction is not an "adjustment" to "price" under the statute;

[21] Historically, the D.C. Circuit has used a "sliding scale" to evaluate whether a movant satisfies the four-factor preliminary injunction test, "allow[ing] . . . a strong showing on one factor [to] make up for a weaker showing on another." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (explaining past use of the "sliding scale" approach). In recent years, however, this Circuit has questioned whether the "sliding scale" approach remains available after the Supreme Court's decision in *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 22 (2008). *See Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009) (noting that *Winter* "could be read to create a more demanding burden" than the sliding scale analysis, and to require a clear showing on each of the four preliminary injunction factors). It remains an "open question" in this Circuit whether the "sliding scale" approach is acceptable (*Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014)), but the question need not be answered here because in this case each of the four preliminary factors independently favors granting Plaintiffs' requested relief.

and (3) the reduction improperly targeted and undermined the 340B Program. The 340B Provisions of the OPPS Rule are therefore contrary to law and should be set aside.

1. The Secretary cannot set payment amounts based on acquisition costs using his statutory authority to "adjust" ASP.

Instead of using his authority to make an adjustment to the statutory formula of ASP plus 6%, the Secretary used it to promulgate a regulation requiring reimbursement of 340B drugs based on acquisition cost – specifically, the estimate of average acquisition costs for 340B drugs compiled by MedPAC. 82 Fed. Reg. at 52,496. This violated 42 U.S.C. § 1395*l*(t)(14)(A)(iii), which permits an acquisition cost methodology only if HHS has acquisition cost data that it admits it lacked here.

As discussed above, *see supra* § I.A, under Subclause I of section 1395*l*(t)(14)(A)(iii), the Secretary may rely on acquisition costs in setting payment amounts if he has certain "hospital acquisition cost survey data." The statute specifically requires that the survey data must be based on "a large sample of hospitals that is sufficient to generate *a statistically significant estimate* of the average hospital acquisition cost for *each* specified covered outpatient drug." 42 U.S.C. § 1395*l*(t)(14)(D)(iii) (emphasis added). If survey data meeting these requirements "are not available," then the Secretary "shall" use the sales price methodology in Subclause II, namely the ASP-plus-6% rate, as "adjusted" by the Secretary. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

In the OPPS Rule, the Secretary relied on the Subclause II sales-price methodology as authority for the near-30% reduction in reimbursements for 340B drugs, but actually used an *acquisition cost* methodology that, absent the required data, he was not permitted to use, and that did not identify the acquisition cost of separate outpatient drugs, as required by the statute. CMS admitted this effort when it explained that its objective in reducing payments on 340B purchased drugs was to "better align" those payments "with hospital *acquisition costs*." 82 Fed. Reg. at

52,498 (emphasis added). CMS then proceeded to rely on *estimates* of *aggregate* acquisition costs compiled by MedPAC, rather than use statistically significant acquisition cost data for each drug as required by Subclause I. *See id.* at 52,496. CMS then expressed that aggregated estimate as a percentage of ASP—ASP minus 22.5 percent—but its ultimate choice of reimbursement rate was based on an estimated, average cost of acquiring 340B drugs.[22]

In short, CMS's approach fundamentally restructured the congressionally-established system of reimbursing hospitals for separately payable drugs under the OPPS by effectively bypassing the requirement in Subclause I that it reimburse providers based on acquisition cost only if statistically significant cost data are available for each drug. This approach, if upheld, would give CMS broad discretion to ignore express statutory requirements based on its own determination that doing so would serve disputed and unrelated policy goals. CMS could simply decide on a reimbursement rate based on any metric it wants and then express that rate as a percentage of ASP under the guise of an "adjustment." If Congress had intended to give CMS broad discretion in using acquisition cost data, it would not have enacted the Subclause I data requirement. Rather, it could have simply given CMS flexibility to use whatever data was available to arrive at what it determined was a reasonable estimate of acquisition cost. It quite clearly did no such thing.

The Government Accountability Office has concluded that the Secretary's adjustment authority does not allow HHS to establish reimbursement rates based on acquisition costs under Subclause II. GAO noted in a 2015 report that "Medicare uses a statutorily defined formula to

[22] MedPAC stated that this estimate was based on approximations of other metrics, such as average manufacturer price and best price, that were admittedly unknown to MedPAC. *See* MedPAC, Overview of the 340B Drug Pricing Program, at App. A (May 2015), http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0.

pay hospitals at set rates for drugs, *regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs*." 2015 GAO Report, *supra* note 6, at 29 (emphasis added). The near-30% rate reduction in the OPPS Rule flies in the face of this statutory limitation.

2. The almost 30% reduction was not an "adjustment" of the average sales price.

The Secretary's ASP-adjustment authority is limited by the plain meaning of the word "adjust." Under the statutory provisions on which rate reductions relied, reimbursement for separately payable drugs in any year after 2005 must be equal to "the average price for the drug in the year . . . 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). Defendants' near-30% reduction in payments is not an "adjustment" to ASP because it is too large to be an "adjustment" and because it bears no coherent relationship to Average Sales Price, the thing being "adjusted."

First, the statutory term "adjust" authorizes the Secretary to make changes to make the average sales price or the related overhead and similar costs more accurate. These are inherently minor changes. In *Amgen v. Smith*, the D.C. Circuit held that the Secretary's authority to "make . . . adjustments" to payments to providers under a different part of the OPPS system, 42 U.S.C. § 1395*l*(t)(2)(E), was constrained by the "limitations" that "inhere" in the word "adjustment." *Amgen*, 357 F.3d at 117. The Court found those "inhere[nt]" "limitations" to be similar to those the U.S. Supreme Court placed on the word "modify" in *MCI Telecommunications Corp. v. AT&T*, 512 U.S. 218, 225 (1994). In *MCI*, the Supreme Court held that "'modify' . . . has a connotation of *increment or limitation*," 512 U.S. at 225 (emphasis added), and that "every dictionary we are aware of says that 'to modify' means to *change moderately or in minor*

fashion." *Id.* (emphasis added) (citing dictionary definitions of modify). *See also id.* at 227-28 ("'Modify', in our view, connotes moderate change.").

The court's reading of "adjustment" in *Amgen* − in light of the Supreme Court's reading of "modify" in *MCI* and in connection with the same general statutory scheme at issue in this case − disposes of the Government's argument that its "adjustment" authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) is unlimited. *See also Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears."). Dictionary definitions of "adjust" confirm *Amgen*'s understanding of the limits inherent in the word.[23] The near-30% rate reduction at issue here is a dramatic departure from the ASP-plus-6% statutory rate that cannot possibly be viewed as a "moderate," "minor," or "limited" change. The large size of the reduction also is evidence that tethering the new reimbursement rate to ASP was simply a pretext for setting the rate based on cost, which CMS essentially admits.

CMS's past use of the adjustment authority supports this point. From 2006 until 2011, CMS annually adjusted the ASP-plus-6% rate by one or two percentage points (77 Fed. Reg. at 68,383–86) and from 2012 until 2017 did not adjust that rate at all. This use of the adjustment

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[23] *Adjust*, Oxford Dictionaries, https://en.oxforddictionaries.com/definition/adjust (last visited Aug. 30, 2018) (defining "adjust" to mean "alter or move (something) *slightly* in order to achieve the desired fit, appearance, or result." (emphasis added); *Adjust*, Cambridge Dictionary, https://dictionary.cambridge.org/dictionary/english/adjust (last visited Aug. 30, 2018) ("to change something *slightly*, especially to make it more correct, effective, or suitable") (emphasis added); *Adjust*, Collins English Dictionary (12th ed. 2014) ("to alter *slightly*, esp. to achieve accuracy; regulate") (emphasis added); *Adjust*, Longman Dictionary, https://www.ldoceonline.com/dictionary/adjust (last visited Aug. 30, 2018) ("to gradually become familiar with a new situation;" "to change or move something *slightly* to improve it or make it more suitable for a particular purpose") (emphasis added); *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust (last visited Aug. 30, 2018) (defining "adjust" for English language learners to mean "to change (something) *in a minor way* so that it works better.") (emphasis added).

authority preserved the basic statutory formula, ASP plus 6%, but tweaked the 6% portion of the formula to better estimate overhead and related costs. *Id.* at 68,383. The near-30% reduction for 2018, by contrast, is such a dramatic departure from the statutory sales price rate that it bears no conceptual or numerical relationship to, and is completely untethered from, that rate. As the Court noted in *Amgen* in a separate but analogous OPPS context:

> The statutory requirement that the Secretary "shall" develop certain aspects of the payment system is qualified by the Secretary's authority to "adjust[]" those payment amounts, but *a more substantial departure from the default amounts would, at some point, violate the Secretary's obligation to make such payments and cease to be an "adjustment[]."*

357 F.3d at 117 (emphasis added). The near-30% reduction is not an adjustment of the average sales price (for example, to more accurately reflect that price) or of the additional 6% that is intended to reflect overhead and similar costs. Rather, it is such a "substantial departure" from the ASP-plus-6% "default amount" that it plainly exceeds the Secretary's "adjustment" authority.

Second, an adjustment must bear some coherent relationship to the pre-adjusted number. Its purpose is to alter that number to make it more accurate or appropriate. The adjustment to the average sales price must more accurately reflect that price. The Secretary may not "adjust" the ASP to more closely reflect another way of valuing the drug, such as acquisition costs. Here, the Secretary claimed to "adjust" the ASP when what he actually did, as he admits, is set the reimbursement rate at the average acquisition costs. The Secretary violated the statute because his new rate was not an adjustment of the ASP.

Third, ASP may only be "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). Thus, the italicized language further constrains the Secretary's authority, since only one purpose for adjustments is enumerated in paragraph (t)(14): subparagraph (E) authorizes "[a]djustment in

payment rates *for overhead costs*." *Id.* § 1395*l*(t)(14)(E) (emphasis added). Looking to subparagraph (E) to delineate which "adjustments" are permissible under subparagraph (A) is appropriate not only because subparagraph (A) authorizes adjustments "as necessary *for purposes of this paragraph*," but also because subparagraph (A) explains that the calculation of payment for separately payable drugs is "subject to subparagraph (E)." *Id.* § 1395*l*(t)(14)(A)(iii). And subparagraph (E) demonstrates that "adjustments" are appropriate to better account for outside factors such as "overhead" and "pharmacy services and handling costs" if the ASP-plus-6% formula does not adequately address those costs. Indeed, all past adjustments to the ASP-plus-6% rate were made expressly to account for estimates of overhead, according to HHS at the time. *See* 77 Fed. Reg. at 68,383–86. That type of incremental modification, which is tethered to the ASP-plus-6% rate and is designed to make it more accurately reflect cost factors not captured by ASP alone, is an appropriate "adjustment" given the text and structure of the statute. A dramatic change replacing ASP plus 6% with an estimate of acquisition cost to change the rate by almost 30% is not.

3. The authority to adjust average sales price for purposes of Medicare reimbursement may not be used to target and undermine the 340B Program.

In addition to improperly using its Subclause II average sales price adjustment authority to circumvent the Subclause I prohibition on actual cost reimbursement absent specified data, HHS also abused its adjustment authority by targeting a specific set of hospitals – *i.e.*, non-exempt 340B hospitals, which provide critical care to disproportionately large numbers of persons who cannot afford to pay their medical bills. The methodology in Subclause II (ASP plus 6%) allows HHS to establish a single price that applies to *all* hospitals; it does not allow for a methodology (here, ASP minus 22.5%) to be applied only to a subset of hospitals. Notably, Subclause I expressly allows the Secretary to vary payment amounts by hospital group, but there

is no such authority under Subclause II. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)–(II). Yet HHS in this case expressly adjusted the reimbursement rate to "align[] [Medicare payments] with the resources expended *by hospitals to acquire [340B] drugs*." 82 Fed. Reg. at 52,495 (emphasis added). For non-340B hospitals (and exempted 340B hospitals), HHS has left the ASP-plus-6% statutory default rate undisturbed, regardless of acquisition costs. Nothing in the statute allows for this differential treatment under Subclause II.

The problem of HHS's selective targeting of 340B hospitals is compounded because the reduced rate that is applicable only to these hospitals undermines the basic purposes of the 340B Program. That Program envisioned that eligible hospitals and clinics – *i.e.*, those that served a disproportionately large share of persons who cannot afford to pay medical bills – would receive drug price discounts from pharmaceutical companies. As the Health Resources Services Administration, the HHS agency responsible for the 340B Program, has recognized, the Program's purpose is for insurance reimbursements for those drugs (which necessarily includes reimbursements from Medicare, a government insurance program) to generate additional resources that these hospitals could use to serve their communities, including underserved populations in those communities. 2005 HRSA Manual, *supra* note 3, at 14 (noting that the Program furthers its legislative purpose by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional resources from "health insurance reimbursements" that are "maintained or not reduced as much as the 340B discounts or rebates"). Nothing in the text, structure, or legislative history of the OPPS drug reimbursement provisions, or in HHS's interpretation of those provisions between 2003 and 2017, suggests that Congress intended to give HHS authority through the OPPS system to "align" 340B drug prices with Medicare reimbursements for those drugs, as HHS seeks to do in this case. *Cf. Whitman v. Am.*

Trucking Ass'ns, Inc., 531 U.S. 457, 468 (2001) ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

Thus, CMS's rate reduction amounts to an impermissible attempt by the Secretary "to reconfigure" both Congress's statutory 340B scheme *and* the OPPS drug reimbursement scheme. *Howard v. Pritzker*, 775 F.3d 430, 432 (D.C. Cir. 2015). *See also Can-Am Plumbing, Inc. v. NLRB*, 321 F.3d 145, 154 (D.C. Cir. 2003) (holding that an agency must apply a statute "insofar as possible, in a manner that minimizes the impact of its actions on the policies of . . . [an]other statute") (citation omitted). Indeed, CMS forthrightly acknowledged that its rate reduction was a frontal attack on the congressional purposes behind the 340B Program. *See* 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.").

HHS has justified its efforts to "align" 340B drug prices and reimbursements to 340B hospitals by invoking its policy concerns regarding the effects of the 340B Program on drug utilization and Medicare beneficiaries. Even if those concerns were well-founded, and they are not, "[a]n agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Utility Air Reg. Grp. v. EPA*, 134 S. Ct. 1427, 2445 (2014). *See also Pettibone Corp. v. United States*, 34 F.3d 536, 541 (7th Cir. 1994) (an agency's authority to interpret a statute "must not be confused with a power to rewrite."). The OPPS law says nothing about using HHS's adjustment authority to target perceived problems with the 340B Program or to close a gap between drug prices and reimbursements that is at the heart of that Program, and HHS's use of its authority for these ends is unlawful.

Once again, the GAO has agreed that HHS lacks statutory authority in this regard, considering in its 2015 report whether HHS could "limit[] hospitals' Medicare Part B reimbursement for 340B discounted drugs" and concluding that "CMS and HRSA are unable to take such action[] *because they do not have the statutory authority to do so*." 2015 GAO Report, *supra* note 6, at 30 (emphasis added). *See also* HHS Office of Inspector Gen., Part B Payments for 340B-Purchased Drugs 13 (Nov. 2015) (examining "payment scenarios that show how Medicare . . . could share in 340B discounts" and concluding that this "is not possible under the current design of the 340B Program and Part B payment rules").[24]

Finally, Congress's intent in the OPPS law to leave operation of the 340B Program undisturbed was confirmed by its decision in the Affordable Care Act to significantly expand the number of 340B hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O) (adding certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals to the list of "covered entities"). This endorsement of the 340B Program is inconsistent with the conclusion that Congress intended to allow HHS to dramatically cut the Program back through the kind of dramatic reimbursement rate reduction at issue here.

B. Plaintiffs Will Suffer Irreparable Harm in the Absence of the Requested Preliminary Injunction.

A showing of irreparable harm has two components. First, the claimed harm must be "certain and great, actual and not theoretical, and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm." *League of Women Voters of the U.S. v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016) (citations omitted). Second, the harm must be beyond remediation. *Id.*

Plaintiffs in this case easily satisfy both of these components.

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[24] *Available at* https://oig.hhs.gov/oei/reports/oei-12-14-00030.asp.

The harms alleged by Plaintiffs in this case are certain and imminent. As set forth in the affidavits attached hereto as Exhibits V–X,[25] the 340B Provisions of the OPPS Rule are resulting in dramatic and automatic lost savings for each of the Hospital Plaintiffs (which are each a member of one or more of the Association Plaintiffs). *E.g.* EMHS Aff. ¶ 12 (estimating EMHS's annual net loss from 340B Provisions of the OPPS Rule to be $3.6 million); Henry Ford Aff. ¶ 14 (estimating Henry Ford's annual net loss across its system from 340B Provisions to be $8.5 million); Park Ridge Aff. ¶ 14 (estimating Park Ridge's annual net loss from 340B Provisions to be $3.3 million). *See also* 82 Fed. Reg. at 52,623 (estimating total lost savings to hospitals from payment reduction to be $1.6 billion). The margin between acquisition costs and Medicare reimbursement rates created by the 340B Program has helped the Hospital Plaintiffs (as well as other members of the Association Plaintiffs) provide critical services to their communities, including underserved populations in those communities. *E.g.*, EMHS Aff. ¶ 13; Henry Ford Aff. ¶¶ 15–18; Park Ridge Aff. ¶¶ 15–17. The closing of that margin through the 340B Provisions of the OPPS Rule threatens these critical services. *E.g.* EMHS Aff. ¶¶ 14–19; Henry Ford Aff. ¶¶ 19–20; Park Ridge Aff. ¶¶ 18–19. Thus, the effect of these provisions, if implemented, on Plaintiffs would be certain, immediate, and dramatic.

Nor is there any doubt that the harms caused by the 340B Provisions of the OPPS Rule are beyond remediation. As noted above, the loss of funds caused by the nearly 30% reimbursement reduction would threaten critical programs and services offered by the Hospital Plaintiffs (as well as other members of the Association Plaintiffs). *E.g.* EMHS Aff. ¶¶ 14–19; Henry Ford Aff. ¶¶ 18–20; Park Ridge Aff. ¶¶ 18–19. To take just one example, the 340B

[25] These affidavits are submitted, respectively, by (1) Tony Filer, Chief Financial Officer of Hospital Plaintiff EMHS (Ex. V, "EMHS Aff."); (2) Robin Damschroder, Chief Financial Officer for Hospital Plaintiff Henry Ford (Ex. W, "Henry Ford Aff."); and (3) Wendi Barber, Chief Financial Officer of Hospital Plaintiff Park Ridge (Ex. X, "Park Ridge Aff.").

provisions of the OPPS Rule are threatening Plaintiff Park Ridge's infusion services for the comprehensive treatment of cancer, which disproportionately serve Medicare patients. *See* Park Ridge Aff. ¶ 16. Even if these payment reductions could theoretically be reversed, any temporary suspension of services, and denial of those services to hospitals' patients during that temporary period, would cause harm that would not be remedied by hospitals' ability to offer those services at a later time. *See Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 243 (D.D.C. 2014) (granting preliminary injunction and finding irreparable harm where plaintiff hospitals would be subject to recoupment of Medicaid payments by CMS and noting that "[p]laintiffs . . . are not for-profit entities facing the loss of profit; rather, they are non-profits for whom lost funds would mean reducing hospital services for children . . . ."). Put simply, a hospital denied funds to provide services on Day 1 is not made whole by the restoration of funds enabling it to provide the same services on Day 2. *Cf. id.* at 242–43.

C. The Balance of the Equities Favors an Injunction.

The balance of equities factor requires comparison of the hardship that would befall the movant(s) if the requested injunction were not awarded with the harm that would befall other parties if the injunction were awarded. *Newby*, 838 F.3d at 12.

In this case, the non-moving parties are government agencies and officials that would suffer no direct harms if the requested injunction suspending the rate reduction were granted. In short, the effects of the requested injunction on the Government pale in comparison to the direct and substantial harms – outlined above − that Plaintiffs would suffer absent the injunction. *See Children's Hosp. of the King's Daughters, Inc. v. Price*, 258 F. Supp. 3d 672, 692 (E.D. Va. 2017), *aff'd in relevant part, vacated in part* 895 F.3d 615 (4th Cir. 2018). The balance of equities therefore favors granting Plaintiffs' request.

D. The Preliminary Injunction Is in the Public Interest.

The public interest favors the preliminary injunction for two reasons. First, the effect of the new payment reduction is to deprive 340B hospitals, including the Hospital Plaintiffs and other members of the Association Plaintiffs, of hundreds of millions of dollars currently used for care in those hospitals' communities. Hospitals use savings from the 340B Program to fund uncompensated care that would not otherwise be financially sustainable, often serving the neediest in their communities. *See* EMHS Aff. ¶ 13; Henry Ford Aff. ¶¶ 15–18; Park Ridge Aff. ¶¶ 15–17. It is not only in the interest of hospitals, but also in the interest of these communities, and particularly their vulnerable patients, for these critical services to continue. *See Children's Hosp. of the King's Daughters*, 258 F. Supp. 3d at 692 (concluding that public interest factor favored plaintiff hospital where, "[w]ithout an injunction, the Plaintiff's ability to offer lifesaving medical care may be diminished or delayed, the effects of which will fall upon a particularly vulnerable subset of the general public" and that "[t]he harm to the members of the public whose quality of care is diminished . . . cannot be undone.").

Second, it is in the public interest for government agencies to lawfully implement the statutes they administer. *Newby*, 838 F.3d at 12 ("There is generally no public interest in the perpetuation of unlawful agency action.") (citations omitted)). As demonstrated above, the near-30% reduction is clearly contrary to law, and the public interest lies in remedying that unlawful agency action. *Id.* (noting that "appellants' extremely high likelihood of success on the merits is a strong indicator that a preliminary injunction would serve the public interest.").

IV. THE COURT SHOULD ADVANCE ITS DETERMINATION OF THE MERITS UNDER RULE 65(a)(2) AND ISSUE A PERMANENT INJUNCTION.

Under Federal Rule of Civil Procedure 65(a)(2), "[b]efore or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and

consolidate it with the hearing." Advancing a decision on the merits under Rule 65(a)(2) is appropriate when "[t]here are no material factual disputes," "[t]he questions raised by the parties are matters of law, and they have been fully briefed." *March for Life v. Burwell*, 128 F. Supp. 3d 116, 124 (D.D.C. 2015). In cases where "an expedited decision on the merits [is] appropriate, Rule 65(a)(2) of the Federal Rules of Civil Procedure provides a means of securing one." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).

This is manifestly a case in which "an expedited decision on the merits [is] appropriate." *Id.* Plaintiffs have raised a purely legal challenge to an HHS regulation. Review will be on the administrative record of the regulation at issue, and it is inconceivable that further factual development would be necessary or helpful. The parties have briefed the merits of their dispute twice – once in this Court, and once before the D.C. Circuit – and are now doing so a third time. *See March for Life*, 128 F. Supp. 3d at 124 (advancing merits decision under Rule 65(a)(2) where "[t]he questions raised by the parties are matters of law, and they have been fully briefed"). In the time since this Court held that Plaintiffs were required to present specific claims for payment to HHS, Defendants have continued to forestall judicial review of their OPPS Rule by refusing at every step to cooperate with Plaintiffs in expediting the administrative appeals process. Now that this dispute is back before the Court, there is no reason to delay a decision on the merits any further.

If the Court decides to advance its determination of the merits and to consolidate that determination with Plaintiffs' motion for a preliminary injunction, the Court "do[es] not need to analyze the typical preliminary injunction factors." *March for Life*, 128 F. Supp. 3d at 124; *accord Pharm. Res. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 34 (D.D.C. 2014) ("Because the Court decides that on the merits of the case, the plaintiff is entitled to a permanent injunction, it

need not decide the preliminary injunction."). Plaintiffs hereby incorporate their arguments regarding likelihood of success on the merits, *see supra* § III.A, as arguments on the merits for purposes of Rule 65(a)(2).

CONCLUSION

For the foregoing reasons, this Court should declare the 340B Provisions of the OPPS Rule to be unlawful and issue an order directing Defendants to: strike 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 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. § 1395*l*(t)(14)(A)(iii)(I).

Dated: September 5, 2018

Respectfully submitted,

/s/ William B. Schultz

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