ORAL ARGUMENT SCHEDULED FOR MAY 4, 2018

No. 18-5004

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs-Appellants,

v.

ALEX M. AZAR II, Secretary of Health & Human Services, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs-Appellants are the American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Eastern Maine Healthcare Systems, Henry Ford Health System, and Fletcher Hospital, Inc., d/b/a Park Ridge Health.

Defendants-Appellees are Alex M. Azar II, in his official capacity as Secretary of Health and Human Services, and the United States Department of Health and Human Services. Before the district court, then-Acting Secretary of Health and Human Services Eric D. Hargan was a defendant, but he has been replaced by Secretary Azar pursuant to Fed. R. App. P. 43(c).

Before this Court, the following state and regional hospital associations submitted a brief as amicus curiae in support of plaintiffs-appellants:

Alabama Hospital Association, Arkansas Hospital Association, California Hospital Association, Colorado Hospital Association, Georgia Hospital Association, Illinois Health and Hospital Association, Iowa Hospital Association, Kansas Hospital Association, Louisiana Hospital Association, Maine Hospital Association, Massachusetts Hospital Association, Michigan Health & Hospital Association, Minnesota Hospital Association, Mississippi Hospital Association, Missouri Hospital

Association, New Hampshire Hospital Association, New Jersey Hospital Association, New Mexico Hospital Association, Healthcare Association of New York State, Greater New York Hospital Association, Pandion Healthcare Advocacy, Inc., Suburban Hospital Alliance of New York State, Western New York Healthcare Association, North Carolina Healthcare Association, North Dakota Hospital Association, Ohio Hospital Association, Oregon Association of Hospitals and Health Systems, Hospital and Healthsystem Association of Pennsylvania, South Dakota Association of Healthcare Organizations, Tennessee Hospital Association, Texas Hospital Association, Washington State Hospital Association, Vermont Association of Hospitals and Health Systems, West Virginia Hospital Association, and Wisconsin Hospital Association.

Before the district court, the following additional state and regional hospital associations joined a brief as amicus curiae:

Iroquois Healthcare Association, Rochester Regional Healthcare Association, and Virginia Hospital and Healthcare Association.

B. Rulings Under Review

Appellants seek review of the district court's order and opinion granting the government's motion to dismiss issued December 29, 2017. *See American Hospital Association v. Hargan*, No. 1:17-cv-02447-RC (D.D.C.); JA 527-43.

C. Related Cases

Appellees are not aware of any related cases within the meaning of D.C. Circuit Rule 28.

s/ Laura Myron
LAURA MYRON

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GLOSSARY

APA	Administrative Procedure Act
ASP	Average Sales Price
CMS	Centers for Medicare & Medicaid Services
GAO	Government Accountability Office
HHS	U.S. Department of Health & Human Services
MedPAC	Medicare Payment Advisory Commission
OPD	Outpatient Department
OPPS	Outpatient Prospective Payment System

INTRODUCTION

The plaintiff hospitals and hospital trade associations seek to challenge a final rule that, in relevant part, adjusted for calendar year 2018 the payments made by the Centers for Medicare & Medicaid Services (CMS) under the Outpatient Prospective Payment System (OPPS or Payment System) in Medicare Part B for certain drugs covered by a program known as the 340B Program. *See* 82 Fed. Reg. 52,356 (Nov. 13, 2017) (final rule announcing the OPPS for calendar year 2018). Their claim is barred because Congress expressly precluded judicial and administrative review of adjustments to the Outpatient Prospective Payment System. *See Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004).

The Medicare statute requires that CMS announce each year the components of the Outpatient Prospective Payment System and adjustments to components of that system, and requires that adjustments be budget neutral. *See* 42 U.S.C. § 1395*l*(t)(2), (9). The Medicare statute expressly precludes review of components of the Outpatient Prospective Payment System and adjustments to those components. *See id.* § 1395*l*(t)(12) ("Limitation on review"). As this Court explained in applying this preclusion-of-review provision in *Amgen*, "[p]ayments to hospitals are made on a prospective basis, and given the length of time that review of individual payment determinations could take, review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year." *Amgen*, 357 F.3d at 112 (applying subsection 1395*l*(t)(12) to preclude review of equitable

adjustments made to the OPPS under subsection (t)(2)(E)). As in *Amgen*, the adjustments at issue here "are subject to a budget-neutrality requirement," "such that judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year." *Id.*

Plaintiffs' contention that the adjustment at issue here was "*ultra vires*" in the sense used by *Amgen*, 357 F.3d at 113, does not bear scrutiny. This Court held that "the reference to 'other adjustments' in § (t)(12)(A)" should "be confined to those 'other adjustments' otherwise provided for in the Act." *Id.* The Medicare Act expressly authorized the Secretary to adjust the payment rate at issue here. *See* 42 U.S.C. § 1395w-3a(b) (providing for payments of the average sales price (ASP) of a 340B drug plus six percent); *id.* § 1395*l*(t)(14)(A)(iii)(II) (providing that this rate will be "adjusted by the Secretary as necessary for purposes of this paragraph").

As the Secretary explained in issuing the final rule for the 2018 calendar year, the adjustment at issue here was justified by developments in the market. The 340B Program, which is intended to "stretch scarce Federal resources as far as possible," H.R. Rep. No. 102-384, pt. 2, at 12 (1992), requires drug manufacturers, as a condition of participation in Medicaid, to sell these drugs at or below a ceiling price to covered hospitals. At the outset of the 340B Program, covered hospitals were generally limited to those serving a disproportionate share of Medicaid patients. Over time, however, the program has expanded and now includes approximately 40% of U.S. hospitals. *See*

U.S. Gov't Accountability Office (GAO), GAO-15-442, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, 1 (2015) (GAO Rep. 15-442).

In promulgating the final rule for 2018, CMS concluded that in light of market developments, payments above the average sales price for 340B drugs no longer served the interests of the Medicare program or Medicare patients. In practice, covered hospitals are able to acquire drugs at prices well below even the ceiling prices set under the 340B Program. The agency noted a 2015 report of the Medicare Payment Advisory Commission (MedPAC) which estimated that "on average, hospitals in the 340B Program receive a *minimum discount of 22.5 percent* of the [average sales price] for drugs paid under the [OPPS]." 82 Fed. Reg. at 52,494 (emphasis added) (quotation marks omitted). Providing Medicare payments of six percent over the average sales price produced large profits dependent on a hospital's purchase and use of 340B drugs, reducing the amount of payments available for non-drug items and services in the OPPS system, and resulting in an increase in the usage of these drugs by providers at 340B hospitals. The agency also explained that inflated Medicare payment rates for 340B drugs result in higher drug costs for beneficiaries, who are responsible for a 20% copayment that is tied to the Medicare payment rate, not the actual purchase price. *Id.* at 52,495. The agency noted a report by the U.S. Department for Health & Human Services (HHS) Inspector General which found that, for many drugs, the "difference between the Part B [payment] amount and the 340B ceiling price was so large that, in

at least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug." *Id.* Based on these and several other studies, the agency established a new reimbursement rate of average sales price minus 22.5%, a figure that represented "the lower bound" of the "minimum" average discount, and would ensure that 340B providers will "retain a profit on these drugs[.]" *Id.* at 52,496-97.

The district court did not address the government's threshold contention that this suit is barred by the Medicare statute's preclusion-of-review provision. Instead, the court held that review is barred by plaintiffs' failure to present their claim to the agency as required under 42 U.S.C. § 405(g) and (h). Assuming *arguendo* that review is not barred outright, the district court's determination should be affirmed. Moreover, if this Court reaches the issue, plaintiffs have also failed to meet their burden of showing a likelihood of success on the merits and that the balance of harms and the public interest favor issuance of the injunction they request. As noted, the Outpatient Prospective Payment System is budget neutral. CMS estimated that the reduced payments for 340B drugs would result in an increase of $1.6 billion in payments made for non-drug items and services, and thus, the agency made a corresponding 3.2% payment increase for those services starting January 1, 2018. 82 Fed. Reg. at 52,510. Setting aside the final rule for 2018 would direct payments away from these other services while creating administrative havoc in the OPPS system. *See Amgen*, 357 F.3d at 112 (pointing to "the havoc that piecemeal review of OPPS payments could bring about").

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331. The district court dismissed the complaint for lack of jurisdiction on December 29, 2017. Plaintiffs filed a notice of appeal on January 9, 2018. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

Plaintiffs seek to challenge an adjustment made to a component of the Outpatient Prospective Payment System for calendar year 2018. The questions presented are:

1. Whether this suit is barred by 42 U.S.C. § 1395*l*(t)(12), which precludes judicial and administrative review of payment adjustments under the Outpatient Prospective Payment System.

2. In the alternative, whether the suit is barred because plaintiffs failed to present their claim to the agency or exhaust their administrative remedies as required under 42 U.S.C. § 405(g) and (h).

3. Assuming the Court reaches the issue, whether plaintiffs have failed to demonstrate a likelihood of success on the merits and that the balance of harms and the public interest support issuance of an injunction.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. The 340B Program

The 340B Program, created in 1992, allows healthcare providers known as "covered entities" to purchase "covered outpatient drugs" at discounted prices from drug manufacturers as a condition of their participation in the Medicaid program. *See* Public Health Service Act, § 340B, 42 U.S.C. § 256b. The program initially encompassed only federal healthcare grant recipients and hospitals that met a threshold disproportionate share hospital percentage. In 2010, Congress expanded the program to include a number of other types of providers. *See id.* § 256b(a)(4) (defining "covered entity"); *see also* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 821 (2010).

Section 340B requires participating drug manufacturers to offer drugs to covered entities at or below a "maximum" or "ceiling price," which is calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1)-(2). In practice, covered entities are often able to purchase covered outpatient drugs at well below the already-discounted maximum price set by the government. In addition, the Health Resources and Services Administration, a component of HHS, operates a Prime Vendor Program through which covered entities may contract with a prime vendor to purchase covered drugs at even deeper discounts. For example, at the end of fiscal year 2015, the Prime Vendor Program made "nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average

savings of 10 percent below the [already-discounted] 340B ceiling price." 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017).

In 2016, MedPAC submitted a report to Congress citing data that demonstrate that "discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of [the average sales price], allowing these [340B] providers to generate significant profits when they administer Part B drugs." 82 Fed. Reg. at 52,494. Similarly, a 2015 report by the GAO, titled *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, found that "the amount of the 340B discount ranges from an estimated 20 to 50 percent, compared to what the entity would have otherwise paid to purchase the drug." *Id.*; *see also id.* at 52,495 (citing HHS Office of Inspector General report finding that Medicare payments were "58 percent more than [already-discounted] 340B ceiling prices"). Perhaps unsurprisingly, therefore, the number of hospitals participating in the 340B Program more than tripled between 2005 and 2014. *See id.* at 52,495.

The GAO explained in its 2015 report that "drug spending increases . . . are correlated with participation in the 340B Program" and "on average, beneficiaries at 340B . . . hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals." 82 Fed. Reg. at 52,494 (citing GAO Rep. 15-442, at 20). The GAO further concluded that these "differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status." *Id.*

B. The Medicare Outpatient Prospective Payment System

Medicare is a federal health insurance program for the elderly and disabled, administered by HHS through CMS. *See* 42 U.S.C. § 1395 *et seq.* Part A of Medicare provides insurance coverage for inpatient hospital care, skilled nursing facility services, home health care, and hospice services. *Id.* § 1395c. Part B, at issue here, provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k. A component of Part B is the Outpatient Prospective Payment System (OPPS), which pays hospitals directly to provide outpatient services to beneficiaries. *See id.* § 1395*l*(t) (establishing the OPPS). Under the Outpatient Prospective Payment System, hospitals are paid at prospectively determined rates for services in the upcoming year. *Id.*

The Medicare statute confers broad authority on the Secretary to develop a classification system for covered outpatient services and to make adjustments to the OPPS. *See* 42 U.S.C. § 1395*l*(t). As part of the OPPS, the Secretary "establish[es] groups of covered [outpatient] services . . . [that] are comparable clinically," taking account of "the use of resources," and then sets "relative payment weights" for each covered service and group of such services. *Id.* § 1395*l*(t)(2)(B), (C). The Secretary makes annual updates to the classification system in order to, for example, "take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395*l*(t)(9)(A). Such adjustments must be made in a "budget-neutral" manner such

that "the adjustments for a year may not cause the estimated amount of expenditures . . . for the year to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made." *Id.* § 1395*l*(t)(9)(B).

Congress also shielded the Secretary's development of and adjustments to the OPPS payment system from administrative and judicial review. The statute provides:

> There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of—
>
> (A) the development of the [OPPS] classification system under paragraph (2), including the establishment of groups and relative payment weights for covered [outpatient department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);
>
> * * * *
>
> (C) periodic adjustments made under paragraph [(9)];[1]
>
> * * * * [; and]
>
> (E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or

[1] Although subsection 1395*l*(t)(12)(C) refers to "periodic adjustments made under paragraph (6)," the statutory history makes clear that Congress in fact meant the Secretary's authority to make periodic adjustments under paragraph (9). *Compare* Pub L. No. 105-33, 111 Stat. 330, 448-49 (Aug. 5, 1997), *with* 42 U.S.C. § 1395*l*(t)(9) & (12). In the 1997 statutes at large, the preclusion-of-review provision—which was then in subsection (t)(9)—expressly precluded administrative and judicial review of "periodic adjustments made under paragraph (6)." 111 Stat. at 449. The provision providing for "periodic review and adjustments [to] components of [the] prospective payment system" was then found at subsection (t)(6) and was materially identical to the provision that is now in subsection 1395*l*(t)(9). *Id.* at 448. In 1999, Congress added what are now provisions (t)(5) through (t)(8). *See* Pub. L. No. 106-113, div. B., 113 Stat. 1536, 1501A-336-342 (Nov. 29, 1999). Although it "redesignat[ed]" the other provisions in section 1395*l*(t), Congress neglected to update the number of the provision cross-referenced in what is now (t)(12)(C). *Id.* at 1501A-336, 1501A-342.

> 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 [outpatient department (OPD)] fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

42 U.S.C. § 1395*l*(t)(12)(A), (C), (E).

In 2003, Congress amended the Medicare statute to authorize the Secretary to set payment rates for "specified covered outpatient drug[s]," a category of separately payable drugs that are not bundled with outpatient services, and for which a "separate ambulatory payment classification group" has been established. 42 U.S.C. § 1395*l*(t)(14)(A)-(B). As relevant here, these specified covered outpatient drugs include outpatient drugs purchased by covered entities under the 340B Program. The statutory scheme directs the Secretary to set payment rates for these 340B drugs to be equal to either:

> (I) . . . the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered [outpatient] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or
>
> (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under . . . section 1395w-3a of this title . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

Id. § 1395*l*(t)(14)(A)(iii).[2] The cross-referenced provision, section 1395w-3a, specifies that the payment rate should be the average sales price for the drug plus six percent (ASP + 6%), *id.* § 1395w-3a(b), which is then "adjusted by the Secretary as necessary for purposes of this paragraph," *id.* § 1395*l*(t)(14)(A)(iii)(II).

CMS publishes an annual rule addressing the Outpatient Prospective Payment System. From 2006 to 2012, CMS used what it called a "standard drug payment methodology" to determine OPPS payment rates for separately payable drugs and biologicals included in the 340B Program. *See* 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012). During this period, CMS set the rates for separately payable drugs and biologicals at the average sales price plus a fixed, add-on percentage of four to six percent, intended to reflect "hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses." *Id.* at 68,385. In 2013, CMS set the rate for separately payable drugs at average sales price plus six percent but also noted there was "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs." *Id.* at 68,386.

[2] For 2004 and 2005, the statute provided specific instructions on how to set payment rates for specified covered outpatient drugs. From 2006 onward, the provisions in 42 U.S.C. § 1395*l*(t)(14)(A)(iii) have governed the Secretary's setting of payment rates. Moreover, while not all separately payable drugs are considered "specified covered outpatient drug[s]" under the statute, CMS applies the statutory payment methodologies in subsection 1395*l*(t)(14)(A)(iii) to all separately payable drugs. This decision reflects "a policy choice rather than a statutory requirement." 77 Fed. Reg. at 68,383.

C. The OPPS Rule for Calendar Year 2018

In its proposed rule for calendar year 2018, CMS noted recent studies from the GAO, the Medicare Payment Advisory Commission, and the HHS Inspector General indicating wide discrepancies between the amounts that 340B Program participants were paying for covered outpatient drugs and the rate at which Medicare was reimbursing hospitals for those drugs, and proposed to adjust the drug payment rates to address these discrepancies. *See* 82 Fed. Reg. 33,558, 33,632-33 (July 20, 2017). In its final rule for 2018, adopted November 13, 2017, CMS relied on the Secretary's authority under subsection 1395*l*(t)(14)(A)(iii)(II) to "adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent." 82 Fed. Reg. at 52,362.

In reaching this determination, CMS noted both the rapid and substantial growth of Medicare spending under the 340B Program and the studies detailing that hospitals were able to purchase 340B drugs well below the statutory ceiling price. *See* 82 Fed. Reg. at 52,494-95. For example, in addition to the reports referenced above, *see supra* p.7, CMS noted that a 2015 report of the Medicare Payment Advisory Commission estimated that "on average, hospitals in the 340B Program receive a *minimum discount of 22.5 percent* of the [average sales price] for drugs paid under the [OPPS]." 82 Fed. Reg. at 52,494 (alteration in original) (emphasis added). CMS also explained that higher Medicare payment rates for 340B drugs result in higher drug costs for beneficiaries,

who are responsible for a 20% copayment that is tied to the Medicare payment rate, not the actual purchase price. *Id.* at 52,495. An HHS Inspector General report cited by CMS found that for 35 drugs out of 500 studied, the "difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug." *Id.*

In light of these concerns, CMS announced that the Secretary was exercising his discretion under subsection 1395*l*(t)(14)(A)(iii)(II) "to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent." 82 Fed. Reg. at 52,362. The 22.5% figure was selected, in part, because it represented the "lower bound" of the "minimum" average discount. *Id.* at 52,496. In other words, on average, the *minimum* discount hospitals are getting is 22.5% below the average sales price. *Id.*; *see also id.* at 52,494 ("[D]iscounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of [the average sales price], allowing these [340B] providers to generate significant profits when they administer Part B drugs."). Because in most cases, "the average discount is higher, potentially significantly higher, than . . . 22.5 percent," *id.* at 52,496, the "conservative" figure, *id.* at 52,502, was selected to ensure that 340B providers will "retain a profit on these drugs," *id.* at 52,497. The adjustment was necessary to "better, and more appropriately, reflect the resources and

acquisition costs that [340B] hospitals incur," as well as "allow the Medicare program and Medicare beneficiaries to pay less for drugs . . . that are purchased under the 340B Program," ensuring that beneficiaries "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." *Id.* at 52,495.

CMS estimated that the payment adjustments would reduce Medicare's 340B payments by $1.6 billion for 2018. 82 Fed. Reg. at 52,509. Because the Outpatient Prospective Payment System is required to be budget neutral by statute, these savings are being redistributed within the OPPS system, and CMS directed that payments for non-drug items and services within the OPPS system be adjusted by 3.2 percent beginning January 1, 2018.

CMS exempted from the adjustment rural sole community hospitals, children's hospitals, and prospective-payment-system-exempt cancer hospitals, and the adjustment does not apply to covered entities that are paid under a separate payment scheme outside OPPS, such as critical access hospitals. *See* 82 Fed. Reg. at 52,493-511. As a result, approximately 52% of covered entities in the 340B Program are not affected by the payment adjustment.

Plaintiffs and other entities participated in the notice-and-comment rulemaking process, submitting comments that argued, among other things, that CMS did not have the legal authority to change the 340B payment rates in the manner it proposed and that adopting the new payment rate would hurt covered entities' ability to provide critical outpatient healthcare services. *See* American Hospital Association Comments

at 1-9, Dkt. No. 2-6; Association of American Medical Colleges Comments at 3-6, Dkt. No. 2-7; America's Essential Hospitals Comments, JA 137-40; Eastern Maine Healthcare Systems Comments, JA 167-69; Henry Ford Hospital & Health Network Comments, JA 171-74.

CMS did not alter the rule in response to plaintiffs' comments, but it explained that the adjustment fell within the Secretary's broad authority to "calculate and adjust" payment rates "as necessary for purposes of this paragraph" under subsection 1395*l*(t)(14)(A)(iii)(II). 82 Fed. Reg. at 52,499. CMS rejected the assertion that the Secretary's authority was limited to "minor changes," explaining that there was "no evidence in the statute to support that position." *Id.* at 52,500. The final rule went into effect on January 1, 2018.

D. Prior Proceedings

In November 2017, plaintiffs—three hospital associations and three member hospitals—filed this suit in district court under the Administrative Procedure Act (APA). They alleged that in issuing the OPPS rule setting payment rates for 2018, the Secretary exceeded his authority under subsection 1395*l*(t)(14)(A)(iii) to adjust the payment rate for 340B drugs. Plaintiffs sought a preliminary injunction to block implementation of the 340B provisions pending resolution of this challenge.

The government moved to dismiss, arguing that the Medicare statute precludes judicial or administrative review of components of the Outpatient Prospective Payment System and adjustments to those components. *See* 42 U.S.C. § 1395*l*(t)(12) ("Limitation

on review"). In the alternative, assuming review was available at all, the government argued that plaintiffs failed to meet the claim presentment and exhaustion requirements of 42 U.S.C. § 405(g) and (h).

The district court dismissed the complaint on December 29, 2017. The court did not address whether plaintiffs' claims were barred by the preclusion of review of payment adjustments for components of the Outpatient Prospective Payment System. Instead the court held that it lacked jurisdiction to hear the claims under 42 U.S.C. § 405(g) and (h). *See* JA 528-43. The court explained that because plaintiffs had not "presented any specific claim for reimbursement to the Secretary," they had not satisfied the jurisdictional claim presentment requirement in Section 405(g) of the Social Security Act. JA 537. The court rejected plaintiffs' arguments that detailed comments submitted during the rulemaking process met the presentment requirement. *See* JA 539-42.[3]

SUMMARY OF ARGUMENT

1. This suit is barred by 42 U.S.C. § 1395*l*(t)(12), which precludes both administrative and judicial review of agency decisions concerning the Secretary's administration of the Outpatient Prospective Payment System, including adjustments to payment rates for covered outpatient services such as 340B drugs at issue

[3] In their opening brief, plaintiffs state that the three hospital plaintiffs have since "submitted claims for 340B drug reimbursements, two have been paid under the new rate, and one has sought redetermination of the payment based on the alleged illegality of the new rate." Appellants' Br. 25 n.14.

here. Congress expressly provided that "[t]here shall be no administrative or judicial review . . . of . . . *the development of the* [*OPPS*] *classification system under paragraph (2),* including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, *other adjustments*, and methods described in paragraph (2)(F)" or of "the determination of . . . the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals." 42 U.S.C. § 1395*l*(t)(12)(A), (E) (emphases added). As this Court emphasized in addressing this preclusion-of-review provision's application to analogous adjustments to the OPPS, Congress's intent "to preclude judicial review of the Secretary's adjustments to prospective payment amounts is 'clear and convincing' from the plain text of § (t)(12) alone." *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004).

Review of the adjustment at issue here is barred by the plain text of subsections 1395*l*(t)(12)(A) and (E). Because the setting of drug payment rates under subsection (t)(14) is a component of the ambulatory payment classification system, as well as the broader OPPS, the Secretary's adjustment of those rates for 340B drugs is within the "adjustment" to and "development" of the system such that subsection 1395*l*(t)(12)(A) clearly precludes judicial review of the part of the rule at issue here. In addition, plaintiffs' claim is also barred by subsection (t)(12)(E)'s preclusion of judicial review of "the portion of the medicare [outpatient department] fee schedule amount associated with particular . . . drugs." 42 U.S.C. § 1395*l*(t)(12)(E).

That Congress would preclude judicial review of adjustments to the Outpatient Prospective Payment System, including the Secretary's adjustments to 340B drug payment rates, is "unsurprising." *Amgen,* 357 F.3d at 112. "[P]iecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system." *Id.* That concern applies here with full force. Because adjustments to the OPPS payment rates must be budget neutral, any "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere." *Id.* The estimated savings from the adjustment to the payment rate for 340B drugs have resulted in corresponding increases for other OPPS payment rates. *See* 82 Fed. Reg. at 52,623. If a court were to invalidate the adjustment at issue here, it would affect not only payment rates for 340B drugs, but also payment rates for services across the classification system.

This Court has recognized a limited exception to the preclusion of judicial review for agency action that is *ultra vires*. *See Amgen*, 357 F.3d at 113. Plaintiffs' arguments reflect a disagreement with the Secretary's understanding of the statute, but their assertions do not remotely describe the kind of patent violation of agency authority that would constitute *ultra vires* conduct.

2. Assuming that review were available at all, the district court correctly concluded that the claims here fail because they were not channeled through the agency as required under 42 U.S.C. § 405(g) and (h). The Medicare statute requires that plaintiffs present claims arising under the Medicare statute to the Secretary and exhaust

all administrative remedies before seeking judicial review. *See* 42 U.S.C. § 405(h); *id.* § 1395ii (making provisions of section 405(h) applicable to Medicare). The presentment requirement in Section 405(g) requires a litigant to submit a concrete claim for reimbursement to the Secretary. This provision is jurisdictional and cannot be waived. *See Mathews v. Eldridge*, 424 U.S. 319, 328 (1976).

Plaintiffs here attempted to bring an anticipatory challenge to a rule that had not yet gone into effect. There is no contention, therefore, that they actually presented a claim for payment. The district court thus correctly held that suit was barred by 42 U.S.C. § 405(h). Contrary to their contention, plaintiffs did not satisfy the presentment requirement by "submission of detailed comments challenging the Secretary's authority to adopt the . . . rate reduction during rulemaking proceedings." Appellants' Br. 26. They cannot circumvent the statute's channeling requirements in this manner, and the two cases on which they rely concerned disputes that came before the courts in the context of a discrete claim for benefits. *See Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860, 861 (D.C. Cir. 2010); *Eldridge*, 424 U.S. at 328.

Plaintiffs have also failed to meet the exhaustion requirement of Section 405(g). Plaintiffs contend exhaustion should be excused because no HHS administrative review body would have authority to "alter or deviate from the rate reduction unless and until it is repealed by the agency." Appellants' Br. 34. But the Supreme Court has made clear that the Medicare statute's channeling requirement applies even in cases where "the agency might not provide a hearing for [a] particular contention, or may lack the

power to provide one." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 23 (2000) (emphasis omitted) (*Illinois Council*).

3. Plaintiffs have failed to demonstrate that any of the factors that would entitle them to a preliminary injunction. They have not demonstrated a likelihood of success on the merits. In addition, they emphasize that reducing payments for 340B drugs will reduce the profits of some covered hospitals. But the payment system program is budget neutral, and decreases in payment for these drugs will result in increased payments for other outpatient services, while also reducing the copayments of Medicare beneficiaries for 340B drugs.

STANDARD OF REVIEW

This Court reviews de novo a district court's dismissal for lack of subject matter jurisdiction. *National Air Traffic Controllers Ass'n v. Federal Serv. Impasses Panel*, 606 F.3d 780, 786 (D.C. Cir. 2010).

ARGUMENT

I. The Medicare Act, § 1395*l*(t)(12), Precludes Review Of The Components Of The Outpatient Prospective Services System.

A. The plaintiff hospitals seek to challenge an aspect of the final rule issued in November 2017, which announced Medicare's payment rates under the Outpatient Prospective Payment Schedule for calendar year 2018. Plaintiffs contend that the payment rate for 340B drugs should be increased and, because the program is budget neutral, that various other payment rates should be reduced by a corresponding amount.

The claim is barred by 42 U.S.C. § 1395*l*(t)(12), which provides that "[t]here shall be no administrative or judicial review" of, *inter alia*, "the development of the [OPPS] classification system," including specified adjustments and "other adjustments," *id.* § 1395*l*(t)(12)(A), or the "fee schedule" amounts associated with particular drugs, *id.* § 1395*l*(t)(12)(E). Interpreting this statutory provision, this Court found it "'clear and convincing' from the plain text of § (t)(12) alone" that "Congress intended to preclude judicial review of the Secretary's adjustments to prospective payment amounts." *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004); *see also* H.R. Rep. No. 105-149, at 724 (1997) ("The Secretary would be authorized periodically to review and revise the groups, relative payment weights, and the wage and other adjustments . . . The provision would prohibit administrative or judicial review of the prospective payment system.").

This Court held that "the reference to 'other adjustments' in § (t)(12)(A)" should "be confined to those 'other adjustments' otherwise provided for in the Act." *Amgen*, 357 F.3d at 113. The Medicare Act expressly authorized the Secretary to adjust the payment rate at issue here. *See* 42 U.S.C. § 1395w-3a(b) (providing for payments of the average sales price of a 340B drug plus six percent); *id.* § 1395*l*(t)(14)(A)(iii)(II) (providing that this rate will be "adjusted by the Secretary as necessary for purposes of this paragraph"). When Congress added subsection (t)(14) in 2003, it made clear that it was adding to the Secretary's authority to establish and adjust payment rates for certain covered outpatient drugs within the OPPS system developed pursuant to subsection 1395*l*(t)(2). *See, e.g.*, *id.* § 1395*l*(t)(14)(B)(i) (subsection (t)(14)(A) applies to

certain "covered outpatient drug[s]" "for which a separate . . . classification group . . . has been established" within the OPPS classification system pursuant to the Secretary's (t)(2) authority). Accordingly, the payment rates at issue here are not subject to administrative or judicial review.

This conclusion is reinforced by the provision of subsection (t)(12) that separately bars review of "the portion of the medicare [outpatient department] fee schedule amount associated with particular . . . drugs." 42 U.S.C. § 1395*l*(t)(12)(E). The outpatient department "fee schedule" is a listing of Medicare payment rates for "each covered [outpatient department] service (or group of such services), furnished in a year," including separately payable drugs. 42 U.S.C. § 1395*l*(t)(3)(D). Here, the Secretary necessarily changed the "fee schedule amount associated with particular . . . drugs" when he adjusted the payment rate for 340B drugs pursuant to his authority under subsection 1395*l*(t)(14)(A)(iii)(II). *See* 82 Fed. Reg. at 52,503 (explaining that hospitals can find reduced payment rates for 340B drugs by using the fee schedule in Addendum B to the OPPS rule for calendar year 2018). Thus, based on the plain text of subsections (t)(12)(A) and (E), the Secretary's adjustment of the payment rate for 340B drugs is not subject to administrative or judicial review.

B. Plaintiffs' demand for review of the Secretary's adjustment to the 340B payment rates is manifestly at odds with the purposes of the preclusion-of-review provision. As this Court recognized in *Amgen*, Congress's preclusion of judicial review of adjustments to the OPPS system is "unsurprising, [because] piecemeal review of

individual payment determinations could frustrate the efficient operation of the complex prospective payment system." 357 F.3d at 112. "Payments to hospitals are made on a prospective basis, and given the length of time that review of individual payment determinations could take, review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year." *Id.*

This Court "has noted similar concerns with respect to the prospective payment system the Medicare A program utilizes to reimburse hospitals for the costs of providing inpatient care," *Amgen*, 357 F.3d at 112, even in the absence of a statutory preclusion of judicial review. Thus, in *County of Los Angeles v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999), this Court noted that "retroactive corrections [to certain prospective payment rates] would cause a significant, if not debilitating, disruption to the Secretary's administration of the already-complex Medicare program," *id.* at 1019 (quoting *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1233 (D.C. Cir. 1994)).

These concerns apply with equal force here. Because adjustments to the OPPS payment rates must be budget neutral, any "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere." *Amgen*, 357 F.3d at 112. For example, as part of the OPPS rule for 2018, the Secretary dispersed the estimated savings from the adjustment to the payment rate for 340B drugs across other OPPS payment rates. *See* 82 Fed. Reg. at 52,623. If a court were to invalidate the adjustment at issue here, it would impact not only the payment

rates for 340B drugs, but also the payment rates for services across the OPPS classification system, and would likely require CMS to recalculate payments made under other OPPS payment rates in order to preserve budget neutrality.

The Medicare program currently processes more than 100 million outpatient hospital claims per year. *See, e.g.*, 2016 CMS Statistics, at 42, Table V.6, https://go.usa.gov/xQ3p9 (outpatient hospital claims represent 59.7% of 214.1 million total claims received). As a result, in similar circumstances, this circuit and others "have noted the havoc that piecemeal review of OPPS payments could bring about." *Amgen*, 357 F.3d at 112 (citing *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996); *American Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002)); *see also Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012)). Given the volume and complexity of OPPS payments and the interdependent nature of their calculation, it is unsurprising that Congress took pains to insulate the Secretary's development of and adjustments to the OPPS system from judicial review.

C. The Secretary's adjustment of the 340B payment rates here does not fall within the extremely limited exception to subsection 1395*l*(t)(12)'s preclusion of judicial review for agency action that is *ultra vires*. *Amgen*, 357 F.3d at 113. Review is available only in the limited instances in which the plaintiff has shown a "patent violation of agency authority." *Florida Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 522 (D.C. Cir. 2016); *see also Qwest Corp. v. FCC*, 482 F.3d 471, 476 (D.C. Cir. 2007)

(defining *ultra vires* action as "patently in excess of [the agency's] authority") (alteration in original). No plausible claim of *ultra vires* action can be made here.

The Secretary's statutory authority to "adjust[]" OPPS payment rates "as necessary" under subsection 1395*l*(t)(14)(A)(iii)(II) is unequivocal, and not subject to any express statutory limitation. Plaintiffs' contentions fail to identify *ultra vires* action, and, indeed, fail to identify any error that would permit invalidating the rule even if jurisdiction existed.

Plaintiffs argue (Br. 45-46) that the Secretary's exercise of his adjustment authority in setting the 2018 OPPS payment rate for 340B drugs impermissibly undermines the 340B Program by 1) unfairly targeting certain hospitals, and 2) reducing payments to better align them with acquisition costs. On its face, this contention merely describes a difference with the Secretary's policy choice. *See Florida Health*, 830 F.3d at 522-23 ("We will not permit [plaintiff] to couch this type of reasonableness challenge in terms of the agency's exceeding its statutorily-defined authority." (quotation marks and alteration omitted)). In any event, plaintiffs have no support for their claim that the Secretary would exceed his authority under one statute (the Medicare statute, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)) by purportedly "undermining" the purposes of a different statute (the 340B statute, 42 U.S.C. § 256b).

To the extent plaintiffs are arguing that the Secretary exceeded his statutory authority because he expressly exempted certain providers from the adjustment, that argument was not presented to the district court and is waived. It is "well settled that

issues and legal theories not asserted at the District Court level ordinarily will not be heard on appeal." *Ellipso, Inc. v. Mann*, 480 F.3d 1153, 1157 (D.C. Cir. 2007) (quoting *District of Columbia v. Air Florida, Inc.*, 750 F.2d 1077, 1084 (D.C. Cir. 1984)).

In any event, this argument is also wrong. The rule for 2018 exempted certain providers from the rate reduction because other parts of the Medicare statute treat those types of providers differently. For example, subsection 1395*l*(t)(13) provides that the Secretary can treat rural hospitals differently, and the Secretary relied on this authority to exempt rural sole community hospitals from the 340B payment adjustment. *See* 42 U.S.C. § 1395*l*(t)(13); *see also* 82 Fed. Reg. 52,505-06 (explaining differential treatment of rural sole community hospitals, and setting forth statutory basis). Likewise, children's hospitals and cancer hospitals are treated differently under subsection (t)(7)(D)(ii). *See* 42 U.S.C. § 1395*l*(t)(7)(D)(ii). Plaintiffs point to no statutory provision that would require the Secretary to ignore his authority to treat different types of providers differently merely because they are all 340B providers.

Plaintiffs similarly err in arguing that the Secretary is precluded from considering "acquisition costs" in adjusting the payment rate pursuant to subsection 1395*l*(t)(14)(A)(iii)(II). Plaintiffs point to the fact that subclause (II) cross-references Section 1395w-3a to argue that the statute "requires" the Secretary to set the payment rate only based on average sales price when exercising his authority under subclause (II). Appellants' Br. 42. Plaintiffs contend that the agency can rely on acquisition costs "if and only if it has specific, statutorily defined acquisition cost data" and is thus,

exercising authority to set payment rates under subsection 1395*l*(t)(14)(A)(iii)(I). *Id.* (emphasis omitted). The statute does not support plaintiffs' overly restrictive view of the Secretary's adjustment authority.[4]

Their argument misreads the Secretary's authority under subsection 1395*l*(t)(14)(A)(iii). Under subclause (I) of that provision, if the "average acquisition cost" for 340B drugs is available from the "hospital acquisition cost survey data under subparagraph (D)," then the Secretary must rely on that data. If that data are not available, however, the statute does not impose any limit on the Secretary's consideration of acquisition costs when exercising his authority to set payment rates under subclause (II). Congress set average sales price plus six percent as the starting point for the payment rate under subclause (II), but the statute imposes no limitation on what the Secretary may consider in exercising his authority under subclause (II) to

[4] Plaintiffs claim that "[t]he 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." Appellants' Br. 44. First, the GAO's interpretation of the Secretary's statutory authority is not binding on either the Secretary or on this Court. Moreover, the GAO's statements provide little support for plaintiffs' position. The cited 2015 GAO report simply states, in the context of explaining that 340B hospitals prescribe more drugs and more expensive drugs than their counterparts, that "Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs." GAO Report 15-442, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, 29, https://www.gao.gov/assets/680/670676.pdf. The GAO did not engage in any substantive statutory analysis or address the Secretary's adjustment authority under subsection 1395*l*(t)(14)(A)(iii). *See id.*

make such adjustments "as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).[5] If Congress had intended to enact the statute plaintiffs propose, it would—like plaintiffs—have included the phrase "and only if" in order to circumscribe the Secretary's authority. It did not do so. *See Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there.").

Plaintiffs' reliance on subparagraph (E) of subsection 1395*l*(t)(14) is equally unavailing. That provision authorizes a separate "adjustment of payment . . . to take into account overhead and related expenses, such as pharmacy services and handling costs." 42 U.S.C. § 1395*l*(t)(14)(E)(i); *see also id.* § 1395*l*(t)(14)(E)(ii). This adjustment authority is wholly distinct from, and more limited than, the Secretary's broader authority to adjust 340B drug payment rates under subsection 1395*l*(t)(14)(A)(iii)(II). Plaintiffs' narrow reading of "adjust[ment]" in subclause (II) to match the authority in subparagraph (E) is belied by the fact that Congress specifically included the language "to take into account overhead and related expenses, such as pharmacy services and handling costs" in subparagraph (E), but did not similarly limit the Secretary's adjustment authority in subclause (II) of subparagraph (A). When "Congress includes

[5] The Secretary has previously considered acquisition costs to be relevant in calculating and adjusting the payment rates for drugs paid under the OPPS. *See, e.g.*, 77 Fed. Reg. at 68,385 ("As discussed above, since [calendar year] 2006, we have attempted to establish a drug payment methodology that reflects hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses.").

particular language in one section of a statute but omits it in another—let alone in the very next provision—[a] Court presumes that Congress intended a difference in meaning." *Loughrin v. United States*, 134 S. Ct. 2384, 2390 (2014) (quotation marks and alteration omitted).

At bottom, plaintiffs' argument boils down to the contention that the Secretary's adjustment authority is limited to small changes and cannot justify a "near-30% rate reduction." Appellants' Br. 38. Nothing in the statute's text, structure, or purpose supports that argument.[6]

In *Amgen*, this Court—in considering the Secretary's authority to make adjustments to OPPS payment rates under subsection 1395*l*(t)(2)(E)—explained that "[l]imitations on the Secretary's equitable adjustment authority inhere in the [statutory] text . . . which only authorizes 'adjustments,' not total elimination or severe restructuring of the statutory scheme." 357 F.3d at 117 (citing *MCI Telecomms. Corp. v. American Tel.*

[6] There are numerous dictionaries that define "adjust" without using the word "slight" or any other term that could be construed to impose a quantitative limitation. *See, e.g.*, *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust ("a: to bring to a more satisfactory state… b: to make correspondent or conformable… c: to bring the parts of to a true or more effective relative position …"); *Adjust*, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=adjust ("1.a. To move or change (something) so as to be in a more effective arrangement or desired condition… b. To change so as to be suitable to or conform with something else…"); *Adjust*, Random House Dictionary, http://www.dictionary.com/browse/adjust ("1. to change (something) so that it fits, corresponds, or conforms; adapt; accommodate … 2. to put in good working order; regulate; bring to a proper state or position …"); *Adjust*, Black's Law Dictionary Free (2d ed.), https://thelawdictionary.org/adjust/ ("To bring to proper relations; to settle; to determine and apportion an amount due.").

& Tel. Co., 512 U.S. 218, 225 (1994), for the proposition that "the Federal Communication Commission's authority to 'modify' certain requirements could not reasonably be read to encompass the power to make 'basic and fundamental changes in the scheme' such as eliminating them entirely"). *Amgen* and *MCI Telecomms.* stand for the proposition that the Secretary may not rely upon his adjustment authority to eliminate payments altogether, or "severe[ly] restructur[e] . . . the statutory scheme" in a manner that would "violate the Secretary's statutory obligation to make such payments and cease to be an 'adjustment.'" *Amgen*, 357 F.3d at 117 (alteration omitted).

The adjustment at issue here does not remotely approximate a "total elimination or severe restructuring of the statutory scheme." *Amgen*, 357 F.3d at 117. The Secretary adjusted the payment rate for 340B drugs from average sales price plus six percent to average sales price minus 22.5% in order to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," as well as "allow the Medicare program and Medicare beneficiaries to pay less for drugs . . . that are purchased under the 340B Program," ensuring that beneficiaries "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." 82 Fed. Reg. at 52,495. Although plaintiffs characterize this adjustment as substantial, they overlook that it was intended to address an enormous disparity between Medicare payment rates and 340B drug acquisition costs when the average sales price plus six percent payment rate was employed. *See id.* (citing HHS Inspector General Report finding that the Medicare payments "were 58 percent more than

[already-discounted] 340B ceiling prices"). Subsection 1395*l*(t)(14)(A)(iii) itself specifically identifies "acquisition cost[s]" as a valid reference point for drug payment rates, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), and the Secretary plainly did not exceed his authority in considering acquisition costs in adjusting the payment rate. Nor did the Secretary eliminate the disparity between acquisition costs and Medicare payment rates. As the Secretary explained, 22.5% below the average sales price represented, on average, the amount that most that 340B providers were paying for drugs. *See* 82 Fed. Reg. at 52,496. In the majority of cases, "the average discount is higher, potentially significantly higher, than . . . 22.5 percent." *Id.* The Secretary chose a "conservative" number in order to ensure both that beneficiaries "share in the savings on drugs acquired through the 340B Program" and also that 340B providers would "retain a profit on these drugs." *Id.* at 52,496-97, 52,502.

The Secretary is charged with advancing the interests of Medicare patients with respect to all aspects of the Outpatient Prospective Payment System, not only that part concerned with 340B drugs. Congress did not preclude the Secretary from considering the impact of high rates of profit by covered hospitals and adjusting the payments in a manner that still guarantees covered hospitals a profit but also takes into account the coverage of other outpatient services.

II. The District Court Lacked Jurisdiction To Hear Plaintiffs' Claims Under 42 U.S.C. § 405(g) And (h).

Assuming that the preclusion-of-review provision discussed above does not bar administrative and judicial review of plaintiffs' claims, the district court lacked jurisdiction because plaintiffs failed to satisfy the presentment and exhaustion requirements of 42 U.S.C. § 405(g) and (h).

A. The District Court Lacked Jurisdiction Because Plaintiffs Did Not Satisfy the Presentment Requirement of Section 405(G).

Plaintiffs contend that jurisdiction is proper under 28 U.S.C. § 1331, which provides federal courts with general federal question jurisdiction. The Medicare statute, however, places "strict limits on the jurisdiction of federal courts to decide any claims arising under the Act," JA 535 (quotation marks omitted), specifying that "[n]o action . . . shall be brought under section 1331 or 1346 of Title 28 to recover on any claim a rising under this subchapter." 42 U.S.C. § 405(h); *id.* § 1395ff(b)(1)(A); *id.* § 1395ii (making provisions of section 405(h) applicable to Medicare).[7] Under this channeling provision, all claims arising under the Medicare statute must be presented to the Secretary, and administrative remedies must be exhausted. Judicial review is available only through review of the Secretary's final decision, as provided in Section 405(g), even if the claim is "framed as a challenge under other laws or the Constitution." JA 535.

[7] A claim arises under the Medicare Act where the Act provides both "the standing and the substantive basis" for the claim. *Heckler v. Ringer*, 466 U.S. 602, 615 (1984) (quotation marks and citation omitted). The parties do not dispute that the claims here arise under the Medicare Act.

Section 405(g) includes two requirements—claim presentment and exhaustion—the first of which is "purely jurisdictional" and "cannot be waived by the Secretary." *Eldridge*, 424 U.S. at 328 (quotation marks omitted). Where a claim for benefits has not been presented to the Secretary, "there can be no 'decision' of any type," which "is clearly required by the statute." *Id.* The presentment requirement is thus an "absolute prerequisite" to judicial review. *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1129 (D.C. Cir. 1992).

Notwithstanding this unambiguous requirement, plaintiffs brought suit without "present[ing] any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision." *See* JA 537. Both this Court and the Supreme Court have rejected similar attempts by plaintiffs to enjoin CMS regulations without first filing a claim for benefits. *See, e.g.*, *Heckler v. Ringer*, 466 U.S. 602 (1984) (rejecting plaintiff's attempt to "establish a right to future payments" on potential future claim); *National Kidney Patients Ass'n*, 958 F.2d at 1129-30 (dismissing plaintiffs' attempt to "proceed[] directly to district court, seeking a preliminary injunction barring HHS . . . from implementing the new rate reduction"). Because presentment is a nonwaivable jurisdictional requirement, the district court was correct to dismiss this suit for want of subject matter jurisdiction.

As a general matter, providers have twelve months after the date of service to timely file a claim for payment for 340B drugs. *See* 42 U.S.C. § 1395n(a); 42 C.F.R. § 424.44. Plaintiffs do not assert that they actually presented a claim before filing this

suit, but argue that they satisfied the presentment requirement by the "submission of detailed comments challenging the Secretary's authority to adopt the . . . rate reduction during rulemaking proceedings, and the Secretary's rejection of that challenge in the Final Rule." Appellants' Br. 26.

Plaintiffs cite no case that treated rulemaking comments as a substitute for the presentment of a specific claim for benefits. *See Ringer*, 466 U.S. at 625 (explaining that the scheme "requires the presentation of a concrete claim [for reimbursement] to the Secretary"). Plaintiffs mistakenly rely on *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010), and *Eldridge*, 424 U.S. at 328, for the proposition that presentment can be satisfied by a general letter sent outside the Medicare administrative claims and appeals process. *See* Appellants' Br. 27-32 (arguing that on the same logic their comments should be deemed to satisfy the claim presentment requirement).

As the district court explained, in both cases, the dispute came to the courts in the context of discrete claims on behalf of individuals. *See* JA 540-42. In *Action Alliance*, this Court considered CMS's refusal to waive recovery of overpayments made to approximately 230,000 Medicare Part D participants. *See* 607 F.3d at 861. Plaintiffs "asserted a right to seek waiver under both the Social Security waiver provision (42 U.S.C. § 404(b)) and the Medicare waiver provision (42 U.S.C. § 1395gg(c))."[8] *Action*

[8] The Social Security Act provision was invoked because the "affected beneficiaries had paid their Part D premiums by having them deducted from their Social Security benefits." *Action All.*, 607 F.3d at 861. CMS erroneously ordered the Social

All., 607 F.3d at 862 n.1. This Court explained that it had previously "concluded that the district court lacked jurisdiction to consider plaintiffs' § 404(b) claim because the claim had not been properly presented." *Id.* Following this Court's decision, "[p]laintiffs' counsel sent a separate letter from each of the plaintiffs to the Secretary and the Commissioner asking them to notify the Medicare Participants of their right to request a waiver under 42 U.S.C. § 404(b) and how to exercise that right." *Action All. of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 37-38 (D.D.C. 2009); *see also* JA 540. After receiving a reply, plaintiffs filed their Second Amended Complaint, and the district court found the jurisdictional presentment requirement satisfied. *Action All.,* 607 F. Supp. 2d at 38-39 (citing *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 5 (2000)).

In *Eldridge*, the dispute arose out of the Social Security Administration's termination of an individual's disability benefits. *See* 424 U.S. at 328-29. The Supreme Court found that the presentment requirement had been satisfied because in plaintiff's "letter in response to the tentative determination that his disability had ceased, he specifically presented the claim that his benefits should not be terminated because he was still disabled." *Id.* at 329. Moreover, "[t]his claim was denied by the state agency and its decision was accepted" by the Social Security Administration. *Id.* As the district

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Security Administration to issue refunds for what it thought were wrongly withheld benefits, but later realized that premiums had not been wrongly withheld, and that the refunds had been made in error. *Id.* at 861-62. CMS then sought to recover the refunds. *Id.*

court recognized, in these cases, the "letters concerned specific claims that *had already accrued to individuals* and thus 'were closer to the "concrete claim for reimbursement" that the Supreme Court has held is required for proper presentment.'" JA 542 (quoting *American Orthotic & Prosthetic Ass'n v. Sebelius*, 62 F. Supp. 3d 114, 123 (D.D.C. 2014)).

Plaintiffs' appellate brief states that "all three Hospital Plaintiffs have now submitted claims for 340B drugs, and two of them have received reimbursements based on the new rate." Br. 32. Doing so does not cure the jurisdictional deficiency in the present case. Subject matter jurisdiction "depends upon the state of things at the time of the action brought." *Grupo Dataflux v. Atlas Global Grp.*, 541 U.S. 567, 570 (2004). "[L]ater events may not create jurisdiction where none existed at the time of filing." *See, e.g.*, *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1337 (Fed. Cir. 2008).[9]

B. Plaintiffs Have Not Satisfied the Exhaustion Requirement of Section 405(g).

Because the claim presentment requirement of Section 405(g) is jurisdictional, the district court dismissed this suit without considering the second prerequisite of the

[9] Under certain limited circumstances not present here, the Supreme Court has acknowledged jurisdiction where the plaintiff "satisfied [the missing jurisdictional] condition while the case was pending in the District Court," but a supplemental complaint was not filed. *Mathews v. Diaz*, 426 U.S. 67, 75 (1976). The Court explained that "since the record discloses, both by affidavit and stipulation, that the jurisdictional condition was satisfied" while the case was in district court, "[it would] treat the pleadings as properly supplemented by the Secretary's stipulation that Espinosa had filed an application." *Id.*

Medicare channeling requirements: that plaintiffs exhaust administrative remedies prior to seeking judicial review. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 272 (D.C. Cir. 1992).

Although the exhaustion requirement is not jurisdictional, it "may be excused only under rather limited conditions." *National Kidney Patients Ass'n*, 958 F.2d at 1130. As this Court has explained, Section "405(g)'s requirement of a 'final decision' was '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." *Tataranowicz*, 959 F.2d at 274 (citing *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975)). Thus, although plaintiffs contend that exhaustion should be excused because no HHS administrative review body would have authority to "alter or deviate from the rate reduction unless and until it is repealed by the agency," Appellants' Br. 34, such assertions do not excuse compliance with the exhaustion requirement, *see Illinois Council*, 529 U.S. at 23 (channeling required even where agency lacks authority to consider certain questions, because plaintiffs "remain free . . . after following the special review route that the statutes prescribe, to contest in court the lawfulness of any regulation or statute upon which an agency determination depends."). "The fact that the agency . . . may lack the power to" resolve certain questions "is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Id.*

Congress provided a "special review route," *Illinois Council*, 529 U.S. at 23, in Section 1395ff(b) which sets out an abbreviated administrative review process that establishes a path to expedited judicial review for those cases in which the

administrative appeals tribunal "does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute," 42 U.S.C. § 1395ff(b)(2)(A).[10] Plaintiffs are not entitled to forgo all administrative review and go straight to court merely because they wish to "resolve [a] statutory or constitutional contention that the agency . . . cannot[] decide." *Illinois Council*, 529 U.S. at 23. So long as plaintiffs can channel the "action" through the agency, a court may later consider "any statutory . . . contention that the agency . . . cannot[] decide." *Id.* (citing *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 & n. 20 (1994); *Ringer*, 466 U.S., at 617; *Salfi*, 422 U.S. at 762).

III. Plaintiffs Also Have Failed To Demonstrate That The Balance Of Harms And Public Interest Support A Preliminary Injunction.

Even assuming they could overcome the barriers to review outlined above, plaintiffs have not demonstrated that they are likely to succeed on the merits of their APA claim. Plaintiffs' only arguments here are that the Secretary exceeded his statutory

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

authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) when promulgating the OPPS Rule for 2018. They have pointed to no statutory provision that the Secretary violated in setting the OPPS rule for 2018, nor have they shown that judicial review is permissible in this case.

As explained above, *see supra* pp. 24-31, all of plaintiffs' theories for why the Secretary exceeded his statutory authority are belied by the plain text of the statute. Congress did not quantitatively limit the Secretary's authority to "calculate[] and adjust[]" the payment rates for 340B drugs "as necessary for purposes of th[e] paragraph" nor did it preclude the consideration of acquisition costs in the Secretary's determination of what is "necessary" to accomplish the purposes of the Medicare statute. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). Plaintiffs have no support for their claim that the Secretary would exceed his authority under one statute (the Medicare statute, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)) by purportedly "undermining" the purposes of a different statute (the 340B statute, 42 U.S.C. § 256b). Moreover, plaintiffs cannot overcome the fact that to the extent the statute is ambiguous, the Secretary's interpretation of his authority under subsection 1395*l*(t)(14)(A)(iii) is reasonable and would be entitled to deference under *Chevron, U.S.A., Inc. v. Nat'l Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Finally, even assuming plaintiffs can overcome the barriers to review in subsection 1395l(t)(12) and Section 405(g), the Medicare statute imposes no limit on the Secretary's adjustment authority—that authority is "committed to agency discretion

by law" and thus is exempt from judicial review under the APA. A matter is "committed to agency discretion" where, as here, there is no "meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). The Medicare statute provides that when the Secretary sets the payment rates for 340B drugs pursuant to his authority under subsection 1395l(t)(14)(A)(iii)(II), he may "calculate[] and adjust[]" that rate "as necessary for purposes of th[at] paragraph." Courts routinely hold that where, as here, a statute authorizes an agency to take certain action wherever deemed necessary, it is not subject to judicial review. *See, e.g.*, *Webster v. Doe*, 486 U.S. 592, 601 (1988); *Sierra Club v. Jackson*, 648 F.3d 848, 856 (D.C. Cir. 2011). This is consistent with Congress's intent—made express in subsection 1395l(t)(12)(A)—to confer unreviewable discretion on the Secretary to make adjustments to the OPPS payment rates, including those for 340B drugs.

In addition, plaintiffs have failed to show that the balance of harms or the public interest favors an injunction.[11] As amicus admits, the budget-neutrality measures will "partially offset" the financial implications for a number of covered 340B providers.

[11] If this Court were to conclude that the district court in fact had subject matter jurisdiction to hear plaintiffs' claims, the appropriate course would be to remand the case for that court to consider whether to enter a preliminary injunction. "[I]t is for the district court to determine, in the first instance, whether the plaintiffs' showing on a particular claim warrants preliminary injunctive relief." *Sherley v. Sebelius*, 644 F.3d 388, 398 (D.C. Cir. 2011). In any event, plaintiffs are not entitled to a preliminary injunction for the reasons outlined in this section.

Br. 20-21 (emphasis omitted). Moreover, as explained above, the estimated savings from the adjustment to the payment rate for 340B drugs will result in a corresponding increase in payments dispersed among other OPPS payment rates. *See* 82 Fed. Reg. at 52,623.

As noted above, the Medicare program currently processes more than 100 million outpatient hospital claims per year. *See, e.g.*, 2016 CMS Statistics, at 42, Table V.6, https://go.usa.gov/xQ3p9 (outpatient hospital claims represent 59.7% of 214.1 million total claims received). An order invalidating the adjustment at issue here thus would affect not only payment rates for 340B drugs, but also payment rates for services across the OPPS classification system, and would likely require CMS to recalculate payments made under other OPPS payment rates in order to preserve budget neutrality.

In addition, because an injunction would be only temporary, it would result in significant uncertainty concerning the OPPS payment rates across the board, frustrating providers' ability to budget and plan appropriately. Congress recognized the difficulty and uncertainty that courts, the Secretary, and providers would face with post-hoc review of OPPS payment rates when it enacted subsection 1395*l*(t)(12), and therefore precluded judicial review of the Secretary's calculation of and adjustments to OPPS payment rates. Given the difficult unscrambling the egg that is resetting OPPS rates for 2018, the balance of equities and the public interest both tip heavily in favor of the Secretary. *See Nken v. Holder*, 556 U.S. 418, 435 (2009) (explaining that these two factors "merge when the Government is the opposing party").

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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March 2018

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 10,904 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2013 in Garamond 14-point font, a proportionally spaced typeface.

s/ Laura Myron
LAURA MYRON

CERTIFICATE OF SERVICE

I hereby certify that on March 19, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Laura Myron
LAURA MYRON

ADDENDUM

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42 U.S.C. § 405(g) Judicial Review

Any individual, after any final decision of the Commissioner of Social Security 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 for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. . . .

42 U.S.C. § 405(h) Finality of Commissioner's Decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 1395ii Applications of Certain Provisions of Sub-Chapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

42 U.S.C. § 1395*l*(t) Prospective Payment System for Hospital Outpatient Department Services

(2) System Requirements Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services

classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

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

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not;

. . . .

(9) Periodic Review and Adjustments Components of Prospective Payment System

(A) Periodic Review - The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than

the Department of Health and Human Services) in conducting such review.

(B) Budget Neutrality Adjustment - If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. . . .

(C) Update Factor - If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

. . . .

(12) Limitation on Review - There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of—

(A) the development of the 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);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

. . . .

(14) Drug APC Payment Rates

(A) In general – The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

. . .

(iii) . . . shall be equal, subject to subparagraph (E)

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(*o*) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for the purposes of this paragraph.

(B) Specified Covered Outpatient Drug Defined

(i) **In general** – In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in section 1396r-8(k) of this title) for which a separate ambulatory payment classification group (APC) has been established and that is

(I) a radio pharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) **Exception** – Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

. . .

(E) Adjustment in payment rates for overhead costs

(i) **MedPAC Report on Drug APC Design**- The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) **Adjustment authorized** - The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i)

. . . .