ORAL ARGUMENT SCHEDULED FOR MAY 4, 2018

NO. 18-5004

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

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs-Appellants,

v.

ALEX M. AZAR II, in his official capacity, *et al.*,

Defendants-Appellees.

On Appeal from the U.S. District Court
for the District of Columbia,

REPLY BRIEF OF PLAINTIFFS-APPELLANTS

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SUMMARY OF ARGUMENT

HHS's opposition brief argues that this Court should not resolve the merits of this case because the Medicare Act precludes judicial review, because Plaintiffs have failed to satisfy a separate jurisdictional requirement of the Social Security Act, and because the Secretary's decision was committed to agency discretion under the Administrative Procedure Act. It is not difficult to understand why HHS is so eager to avoid the merits. In promulgating a rule that reduced by nearly 30% Medicare reimbursements to non-exempted 340B hospitals, which serve a disproportionately large share of underserved patients, HHS fundamentally distorted the congressionally-created system governing reimbursements for separately payable drugs. It did so to advance its questionable policy agenda of reducing reimbursements solely to 340B hospitals. HHS had no authority to reduce these reimbursements by nearly 30% to "better align[]" them with acquisition costs. *See* 82 Fed. Reg. 52,356, 52,498 (Nov. 13, 2017) (final rule).

As we explained in our opening brief (Br. 37-49), the statute allows HHS to use acquisition cost as a basis for these reimbursements only if the agency relies on specific data expressly identified in the statute. Absent that data, HHS must use average sales, which it may "adjust" – a term that this Court has found to have an inherently limited meaning. In this case, HHS admits it lacked the data required to use acquisition cost, and therefore, as the statute required, HHS acted under the

statute's average sales price provision. But, to address its concerns about the size of reimbursements to 340B hospitals, HHS adjusted the average sales price for a subset of 340B hospitals so reimbursements would be reduced by the minimum discount that drug manufacturers are required to offer 340B hospitals.

That was not an "adjustment" to the average sales price, which is a market price specifically defined in the statute. Instead it was an end-run of the statute used by HHS to establish a price that eliminated most of the benefit of the 340B program to the unique class of hospitals for which it was established. In essence, HHS used an "adjustment" as a pretext for eliminating $1.6 billion of reimbursements to 340B hospitals because of policy concerns relating to a different statute and unrelated to the purposes of the rate-setting structure for separately payable drugs for which "adjustments" are permitted.

HHS's attempts to avoid judicial review fare no better than its defense of the challenged price "adjustment." Although arguing for complete statutory preclusion of review, HHS identifies no statutory provision expressly precluding review. While arguing alternatively that individual claims for reimbursement must be submitted to the agency before judicial review of the new reimbursement rule, HHS has confirmed that the agency cannot grant relief from the new rule – a position reflected in its recent summary denial of individual claims submitted by one of the Hospital Plaintiffs. Further confirming the unavailability of

administrative relief, HHS declared in a recent filing in another case that all requests for administrative relief of 340B claims *will be dismissed*. Plaintiffs' entitlement to judicial review and a preliminary injunction is clear, and this Court should reverse and remand with the instruction that an appropriate preliminary injunction be entered, as described more fully below.

ARGUMENT

I. THE MEDICARE ACT DOES NOT PRECLUDE REVIEW OF THE RATE CHANGE AT ISSUE IN THIS CASE.

A. The Medicare Act Does Not Preclude Judicial Review of Administrative Action Taken Under Section 1395*l*(t)(14).

HHS argues that section 1395*l*(t)(12) of title 42 ("Paragraph (12)") prohibits judicial review of agency actions under section 1395*l*(t)(14) of title 42 ("Paragraph (14)"), under which the outpatient reimbursement rule was promulgated. However, the provisions on which HHS relies – Subparagraphs (A) and (E) of Paragraph (12) − reference other parts of the Outpatient Prospective Payment System ("OPPS") for covered outpatient services, *not Paragaph (14)*. HHS nevertheless looks past those provisions' limiting language to invoke a preclusion not expressed in the statutory text.

HHS's construction cannot be reconciled 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 & internal quotations omitted). The presumption can be overcome only by "clear and convincing evidence that

Congress intended to preclude the suit." *Id.* HHS's brief does not attempt to reconcile its implausible statutory analysis with this presumption of reviewability.

i. Subsection (t)(12)(A)

Section 1395*l*(t)(12)(A) of title 42 ("Paragraph (12)(A)") precludes judicial review of:

> The *development of the [OPPS] classification system under paragraph (2)*, including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, *other adjustments*, and methods described in paragraph (2)(F).

(Emphasis added). Isolating the words "development of the [OPPS] classification system," HHS argues that Paragraph (12)(A) precludes review of the outpatient reimbursement rule at issue here because the rule pertains to the OPPS classification system. While the outpatient rule is part of the OPPS system, it is *not* part of the system "develop[ed] . . . under paragraph (2)," the key part of the quoted statutory text that HHS ignores. The new rule for separately payable drugs at issue here was promulgated under Paragraph (14), a separate part of OPPS. Paragraph (14), unlike Paragraph (2), is not referenced in Paragraph (12)(A). HHS's argument fails to give effect to the "under paragraph (2)" limitation in the statute.[1]

[1] HHS does not dispute that it promulgated the new rule pursuant to authority invoked under Paragraph (14), not under Paragraph (2). *See* 82 Fed. Reg. at 52,499.

HHS also argues that Paragraph (12)(A)'s reference to "other adjustments" precludes review of Paragraph (14) adjustments. This reading likewise overlooks the statutory text. Paragraph (12)(A) precludes review of "[t]he development of the [OPPS] classification system *under paragraph (2)*, *including* . . . other adjustments . . . ." (Emphasis added). Paragraph (12)(A) limits preclusion of "other adjustments" to those made under "paragraph (2)" and thus does not reach the Secretary's actions here under Paragraph (14).

In an effort to bring Paragraph (14) within Paragraph (12)(A)'s preclusion restriction, HHS argues that the Paragraph (2) classification system *includes* action under Paragraph (14), under which HHS acted. That argument, however, effectively amends Paragraph (2) to include a reference to Paragraph (14) that does not exist. Moreover, HHS's reading flies in the face of what Congress actually did in 2003, when it added Paragraph (14) to the OPPS statute but did *not* amend either Paragraph (12) or Paragraph (2) to include any reference to Paragraph (14). By contrast, when Congress amended the statute in 1999 to include other new components of the OPPS system (Paragraphs (5) and (6), 42 U.S.C. § 1395*l*(t)(5)-(t)(6)), it amended Paragraph (2) to refer explicitly to actions taken "under paragraph (5)" and "under paragraph (6)," thereby subjecting them to preclusion

under Paragraph (12). 42 U.S.C. § 1395*l*(t)(2)(E).[2] Similarly, in the 2003 law that added Paragraph (14), Congress also added paragraph (13) to section 1395*l*(t), but in the case of paragraph (13), it specifically authorized "an appropriate adjustment under paragraph (2)(E)" with respect to rural hospitals, thereby subjecting them to preclusion under Paragraph (12).[3] In short, Congress made clear that actions taken under these new provisions were "under paragraph (2)" and therefore within Paragraph (12)(A)'s text precluding actions taken "under paragraph (2)." *See also* 42 U.S.C. § 1395*l*(t)(3)(D)(ii) (specifically referring to "the relative payment weight (determined under paragraph (2)(C))"). Actions taken under Paragraph (14), which is referenced nowhere in Paragraph (2) *or* Paragraph (12)(A), are not precluded.

ii. Subsection (t)(12)(E)

HHS also asserts preclusion based on section 1395*l*(t)(12)(E) of title 42 ("Paragraph (12)(E)"), which shields from review:

> 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

[2] Consolidated Appropriations Act, App. F, Sec. 1, § 201(c), 113 Stat. 1501, 1501A-339 (1999).

[3] 42 U.S.C. § 1395*l*(t)(13)(B); Medicare Prescription Drug, Improvement, and Modernization Act, Sec. 1, § 411(b), 117 Stat. 2066, 2274 (2003).

> 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).*

(Emphasis added). HHS isolates Paragraph (12)(E)'s reference to "the portion of the medicare OPD fee schedule amount associated with particular . . . drugs," arguing that this text extends to and includes the Paragraph (14) "adjustments" at issue here. That argument ignores essential limiting language in Paragraph (12)(E), which extends only to "the portion of the medicare OPD fee schedule amount associated with particular drugs . . . *under paragraph (6).*" (Emphasis added). Paragraph (6) has nothing to do with agency action under Paragraph (14), which specifically *excludes* drugs that receive payments under Paragraph (6). *See* Paragraph (14)(B)(ii)(I).

Paragraph (12)(E)'s structure confirms this limitation imposed by paragraph (6). It refers first to a series of actions "under paragraph (5)" and then to a longer series of actions "under paragraph (6)," precluding review of both sets of actions. The longer series preceding "under paragraph (6)" includes the "portion of the medicare OPD fee schedule" phrase that HHS erroneously isolates. Not only does that same phrase appear in Paragraphs (6)(D)(i) and (ii), but the structure of Paragraph (12)(E), tying each series of precluded actions either to Paragraph (5) or Paragraph (6), makes perfect sense because Congress added all of Paragraph

(12)(E) to the OPPS law in 1999, when it added Paragraphs (5) and (6).[4] Congress did not enact Paragraph (14) until 2003 and tellingly did not amend Paragraph (12)(E) to include a reference to Paragraph (14).

iii. Avoidance of Piecemeal Review

HHS repeatedly invokes the concern expressed in *Amgen* that "piecemeal review of individual [OPPS] payment determinations could frustrate the efficient operation of the complex prospective payment system." 357 F.3d at 112. *Amgen* did not express that concern to justify deviating from statutory text, but instead to support adhering to it. Moreover, HHS ignores that *Amgen* defined "piecemeal review" to mean "case-by-case review . . . of the Secretary's individual applications," which in *Amgen* itself related to reimbursement changes for a single drug product. *Id.* at 113.

This case is completely different. It has been brought by three associations representing hundreds of 340B hospitals and by three individual member hospital systems. It challenges the exercise of the Secretary's statutory "adjustment" authority to make a broad-based change to reimbursement rates affecting thousands of drugs, not the agency's factual determinations or process with respect to any particular claim for reimbursement. It is precisely the kind of global legal challenge that *avoids* piecemeal review. As this Court stated in *Amgen*, "the

[4] *See supra* note 2, at § 201(a), (b), and (d), 113 Stat. at 1501A-336 to 339 (adding Paragraphs (5), (6), and (12)(E) to OPPS law).

interference with the administration of the Medicare B program that would result from judicial review pertaining to the overall scope of the Secretary's statutory adjustment authority, as opposed to case-by-case review of the reasonableness or procedural propriety of the Secretary's individual applications," is "sufficiently offset by the likely gains from reducing the risk of systematic misinterpretation in the administration of the Medicare Part B program." *Id.*

B. Plaintiffs' Challenge to HHS's Reimbursement Rate Reduction Is also Judicially Reviewable Because the Secretary Exceeded His Authority Under Paragraph (14)(A)(iii)(II).

Even if Paragraph (12)'s preclusion provisions applied (and, as demonstrated above, they do not), where, as here, a legal challenge to agency action "raises the question of the [agency's] authority to [take particular action]," a court must "merge[] consideration of the legality of the [agency's] action with consideration of [the] court's jurisdiction." *Amgen*, 357 F.3d at 113 (internal quotation & citation omitted). Thus, there is no preclusion if this Court concludes that HHS exceeded its "adjustment" authority in reducing reimbursements for 340B drugs by almost 30%.[5]

[5] *Amgen*, 357 F.3d at 112 ("We construe [the review preclusion provisions] to prevent review *only* of those . . . ['adjustments' that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of . . . ['adjustments' extends no further than the Secretary's authority to make them.") (emphasis added); *id.* at 117 ("[A] more substantial departure from the default amounts would, at some point, violate the Secretary's statutory obligation . . . and cease to be an 'adjustment.'").

Plaintiffs' claim is that HHS exceeded its authority when it promulgated a huge rate reduction by relying on its authority to "adjust" the sales price for separately payable drugs (which the statute defines as average sales price (ASP) plus 6% for overhead). 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("Subclause II"). Here the Secretary did not actually "adjust" the ASP plus 6%. Instead, he developed a new rate based on acquisition costs, even though reliance on acquisition costs is only permitted under a different statutory section, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("Subclause (I)"), that HHS has admitted is inapplicable here because of the lack of specified cost data that Subclause (I) requires. The Secretary designed this adjustment so that it reflected the minimum discount that drug manufacturers must offer hospitals for drugs under the separate 340B statutory program (*see* HHS Br. 3), depriving hospitals (and their patients) of most of the benefit of that program. The result of this approach was an enormous rate reduction, exceeding the most elastic understanding of the Subclause (II) adjustment authority. Consequently, as the new reimbursement rule exceeds HHS's statutory authority, Paragraph (12) preclusion does not foreclose Plaintiffs' claim.

In response, HHS argues the Secretary simply cannot exceed his OPPS "adjustment" authority because that authority is "not subject to any express statutory limitation" and thus is essentially unbounded. Br. 25. But the

Secretary's "adjustment" authority extends only to adjustments "as necessary for the purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The purpose of Paragraph (14) is to establish a rate-setting structure for separately payable drugs based on one of the two methodologies set forth in the statute. HHS admits the Secretary adopted the challenged rate reduction to "better align" reimbursements with 340B hospitals' drug acquisition costs because of his concerns about the growth of the 340B program and the size of discounts 340B hospitals receive.[6] While Plaintiffs vigorously dispute the Secretary's policy justifications for the near-30% reduction in payments for 340B drugs,[7] those policy arguments cannot support an "adjustment" of average sales price that was not intended to accurately adjust the market-based sales price formula required by Subclause (II), but was instead intended to equal the minimum discount of drugs established for certain 340B hospitals under the 340B program, a different statutory regime. Such decisions belong to Congress. *Utility Air Regulatory Grp.*

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[6] 82 Fed. Reg. at 52,498; *see also* HHS Br. 3 ("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.").

[7] As Plaintiffs explained in their opening brief (Br. 12, nn. 8-9), both the Secretary's claims that the 340B program causes overutilization of drugs and higher drug cost are flawed, inaccurate, and in the case of the GAO report relied on by HHS, previously criticized by HHS itself. To the extent HHS suggests that less than half of the covered entities are affected by the near-30% rate reduction, there is no record support for this assertion, and Plaintiffs are aware of no support outside the administrative record.

v. EPA, __ U.S. __, 134 S. Ct. 2427, 2445 (2014) ("An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").[8]

Congress certainly did not intend Subclause (II) sales price "adjustments" to be used to achieve unrelated policy goals, particularly where doing so amounted to end-run the requirements in Subclause (I) for setting reimbursement rates based on actual costs. Indeed, Subclause (I)'s structure reflects Congress's clear concern about how the Secretary might use acquisition costs in setting the reimbursement rates for separately payable drugs, forbidding use of acquisition costs in the absence of data specified in Paragraph (14)(D) − *i.e.*, surveys of hospitals that take into account recommendations of the Comptroller General and that "have a large sample of hospitals that is sufficient to generate statistically significant estimate of the average hospital acquisition cost for each specified covered drug." 42 U.S.C § 1395*l*(t)(14)(D)(iii).

HHS's boundless interpretation of its "adjustment" authority effectively rewrites Congress's chosen structure in two ways, allowing HHS: (1) to use its Subclause (II) "adjustment" authority to end-run the Subclause (I) data requirement; *and* (2) to adopt a rate under Subclause (II) that bears no meaningful

[8] We explain in our opening brief (Br. 45-49) why the rate change at issue here exceeds the Secretary's authority because it undermines the statute enacting the 340B program.

relationship to the ASP plus 6% default rate.[9] By any measure, that approach is beyond the Secretary's statutory authority because it "severe[ly] restructure[s]" Congress's chosen statutory scheme. *Amgen*, 357 F.3d at 117.[10]

HHS argues that because a separate provision of Paragraph (14), 42 U.S.C. § 1395*l*(t)(14)(E), refers to "adjustment[s] . . . to take into account overhead and related expenses," the absence of modifiers to the term "adjust[]" in Subclause (II) means that the Secretary's "adjustment" authority in that Subclause is unlimited. Br. 28-29. That argument ignores the interrelationship between Paragraphs (14)(A) and (14)(E). Paragraph (14)(A)(iii) (42 U.S.C. § 1395*l*(t)(14)(A)(iii)) *requires* the Secretary to set rates "subject to [Paragraph (14)(E)]," which in turn permits the Secretary to "adjust" rates for separately payable drugs "to take into account" recommendations regarding "overhead and related expenses." 42 U.S.C. § 1395*l*(t)(14)(E)(ii). The Secretary's Subclause (II) authority to make

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[9] HHS asserts the ASP plus 6% statutory default rate is merely a "starting point" for the payment rate under Subclause (II). Br. 27. But a "starting point" is meaningless if any departure from it is acceptable. *See Amgen*, 357 F.3d at 117 (noting that "a more substantial departure from the default amounts would, at some point, . . . cease to be an 'adjustment'").

[10] This case contrasts with *Amgen* itself, which involved a rate change for a single drug product made by a single company that quite clearly "[did] not work basic and fundamental changes in the scheme Congress created in the Medicare Act." 357 F.3d at 117 (citation & internal quotations omitted). In that case, this Court "ha[d] no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'" *Id.* That occasion squarely presents itself here, where the Secretary has expanded the scope of his adjustment authority in a manner that affects hundreds of hospitals and millions of patients.

"adjust[ments] as necessary for purposes of this paragraph" must be read in tandem with his authority under Paragraph (14)(A)(iii) to set rates "subject to" adjustments for "overhead and related expenses" permitted under Paragraph (14)(E). Paragraph (14)(A)(iii)'s cross-reference to Paragraph (14)(E) identifies appropriate adjustments under Subclause (II) and renders unnecessary a further description of these adjustments in that section.

Finally, HHS's argument for unlimited "adjustment" authority not only fails to recognize the statutory distinction between setting the reimbursement rate based on acquisition cost versus average sales price, but it also runs counter to this Court's interpretation of "adjust" in *Amgen*. There, this Court interpreted "adjust" by reference to the Supreme Court's interpretation of the analogous word "modify" in *MCI Telecommunications Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 225-228 (1994), concluding that the Secretary's "adjustment" authority was constrained by the "limitations" that "inhere" in that word. *Amgen*, 357 F.3d at 117 (also noting that a "more substantial departure from the default amounts would, at some point . . . cease to be an 'adjustment'"). "Adjust" thus has an inherently limited meaning that circumscribes the Secretary's authority to change statutory default amounts under the OPPS law. As discussed in our opening brief (Br. 38-41), a near-30% reduction of the statutory default rate is not the kind of limited change

that qualifies as an "adjustment" under the ordinary, unambiguous meaning of the term and is thoroughly inconsistent with HHS's past practice.

II. PLAINTIFFS SATISFIED PRESENTMENT REQUIREMENTS, AND EXHAUSTION SHOULD BE WAIVED AS FUTILE.

A. Plaintiffs Presented Their Claim During Rulemaking Proceedings, the Only Forum in Which Relief Could Be Obtained.

HHS does not dispute that Plaintiffs asserted their challenge to the legality of the new reimbursement rate during rulemaking proceedings, that the Secretary rejected that challenge and promulgated the rule, or that no administrative relief from the rule is now available because no agency official has authority to modify a rule promulgated by the Secretary. HHS has also confirmed in a filing in another case (discussed below) that hospitals' efforts to obtain administrative review of the new rate *will be dismissed without consideration*. Nevertheless, HHS clings to the view, also adopted by the district court, that presentment under section 405(g) of the Social Security Act requires challenges to the new rate to await the submission of reimbursement claims by individual hospitals.

Plaintiffs' and others' comments submitted during the rulemaking process satisfied the presentment requirement because HHS provides no other avenue for obtaining relief from the challenged rate reduction. Presentment allows an agency the opportunity to correct its own errors and for a record to be made to facilitate judicial review. *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975). HHS does not

dispute that neither purpose is served by administrative proceedings on individual claims relating to the challenged rate reduction.

As explained in our opening brief (Br. 27-30), HHS's position that a challenge to the Secretary's legal authority cannot proceed except as part of individual hospitals' formal administrative proceedings was rejected by this Court in *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (2010), and by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319, 328-29 (1976), which both treated actions outside the formal administrative claims process as sufficient for presentment.

Two significant developments have occurred since the new reimbursement rule went into effect on January 1, 2018, each showing that Plaintiffs sufficiently presented their claim through their comments during rulemaking proceedings.

First, in a pleading recently filed in separate litigation brought by AHA against HHS to challenge delays in administrative reviews of reimbursement claims, HHS admitted that administrative claims challenging the rate reduction for 340B hospitals "*are not reviewable* 'initial determinations'" because they are merely "'computations of the payment amount for program reimbursement for which CMS ["Center for Medicare & Medicaid Services"] has sole responsibility under Part B.'" HHS's Resp. to Pls.' Notice of Suppl. Authority, *AHA v. Azar*, Case No. 14-cv-851-JEB, ECF No. 79, at 1-2 (D.D.C. Mar. 21, 2018) (emphasis

added) (quoting 42 C.F.R. § 405.926(c)). The Agency explained that "[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." *Id.* at 2. HHS has thus announced it will dismiss *as unreviewable* the same administrative challenges it claims must be filed to meet presentment requirements. This Court can take notice of HHS's filing. *Crumpacker v. Ciraolo-Klepper*, No. 17-5191, 2018 WL 1391544, at *1 (D.C. Cir. Mar. 14, 2018).

Second, since January 1, 2018, all three Hospital Plaintiffs have presented reimbursement claims and have been reimbursed under the new, reduced rate, and each has sought redetermination of that decision (the first step in administratively appealing a reimbursement for this type of drug claim) on the ground that the new rate is illegal. On March 6, 2018, Hospital Plaintiff Henry Ford received denials of its requests for redetermination and it promptly filed a second appeal as provided by the applicable regulations.[11] The other Hospital Plaintiffs expect to receive similar denials within the next 30 days. The denials received by Henry Ford did

[11] Henry Ford's requests for redetermination, HHS's denials of these requests, and Henry Ford's subsequent and pending second appeal are attached as ADD-3 to 14. HHS cannot dispute the authenticity of these documents, which are in its possession, and this Court may take notice of them. *See Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 999 (9th Cir. 2010) (taking judicial notice of information made publicly available by government entities, where "neither party disputes [its] authenticity").

not mention its legal challenge, merely stating as to each claim that "there does not appear to be any error impacting the payment amount" (ADD-5, 7) which, of course, is true given the agency's obligation to apply the new rule. HHS's promise to "dismiss . . . promptly" administrative appeals challenging the new rate and its summary disposition of requests for redetermination of claims paid under that new rate confirm the utter uselessness of requiring individual administrative challenges as a condition of seeking judicial review of the new rule.

The cases HHS cites do not support an inflexible rule requiring formal administrative presentment of individual claims after a rule goes into effect, where there is no benefit to any party, the courts or the public, but only harm and waste of time and money for all concerned. In *Heckler v. Ringer*, 466 U.S. 602, 623, 625-26 (1984), the Supreme Court required presentment to be made in "a concrete claim for reimbursement" because the plaintiff − unlike each Hospital Plaintiff here − might not have sought reimbursement for the medical procedure in question, resulting in the impermissible issuance of advisory opinions by courts, and in any event without benefit of agency consideration. *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000) (noting that the plaintiff in *Ringer* did not sufficiently present a valid claim because he "would likely never" undergo the procedure). Similarly, in *National Kidney Patients Association v. Sullivan*, 958 F.2d 1127, 1131 (1992) (internal quotations omitted), this Court, after

acknowledging the lack of clarity on "the exact meaning of presentment," found that the plaintiffs had not sufficiently presented their claims because those claims − unlike here − had never been submitted to the agency at all.

B. Plaintiffs Have Cured Any Presentment Deficiency by Presenting Specific Claims for Reimbursement to HHS.

Even if HHS were correct that individual hospitals must present specific claims for reimbursement before obtaining judicial review, facts that are undisputed by HHS show that the Hospital Plaintiffs have now presented their claims and that this Court can so determine. While subject matter jurisdiction generally "is determined by the facts existing at the time of filing an original complaint," that rule originated in diversity cases "where heightened concerns about forum-shopping and strategic behavior offer special justifications for it." *U.S. ex rel. Gadbois v. PharMercia Corp.*, 809 F.3d 1, 5 (1st Cir. 2015). "Where, as here, there are no allegations of manipulative abuse of the rule, the time-of-filing rule is inapposite to the federal question context." *Id.* Indeed, where it is undisputed that jurisdiction has been established following the filing of the complaint, "it is not too late, even [on appeal], to supplement the complaint to allege [the needed jurisdictional] fact." *Matthews v. Diaz*, 426 U.S. 67, 75 (1976).

Because all three Hospital Plaintiffs have submitted reimbursement claims, received reduced payments under the new rate, and sought redetermination of the payment amount based on the alleged illegality of the new rate, and one Hospital

Plaintiff, Henry Ford, has already had its redetermination requests denied, presentment has occurred under even a restrictive reading of the relevant standards.

C. Plaintiffs Have Satisfied the Exhaustion Requirement Because Further Pursuit of Their Claims Through Administrative Channels Is Futile.

HHS does not dispute that pursuing Plaintiffs' legal challenge to the near-30% rate reduction through the agency administrative process would be futile. HHS's summary rejection of Henry Ford's redetermination requests and its recent representation in other litigation that such claims involve "non-reviewable determinations" that will be "promptly dismissed" confirm this futility. Under this Circuit's leading case on exhaustion, *Tataranowicz v. Sullivan*, 959 F.2d 268, 273-275 (D.C. Cir. 1992), this showing of futility excuses further pursuit of administrative remedies. *See* Pl. Br. 33-35.

HHS argues that the Supreme Court's *Illinois Council* decision held that even where the agency "lack[s] the power to resolve certain questions," claims against it must nevertheless undergo "an abbreviated administrative process that establishes a path to expedited judicial review." Br. 37. *Illinois Council*, however, did not principally concern the exhaustion/futility issue. To the extent it addressed that issue at all, the Supreme Court noted that "a court can deem [many of the procedural steps set forth in § 405(g)] waived in certain circumstances." *Illinois Council*, 529 U.S. at 24. This authority derives both from the agency's authority to

waive certain procedural steps, *see* 42 U.S.C. § 1395ff(b)(1)(F) (authorizing agencies to establish a process for expedited access to judicial review), and from the courts' independent authority to determine whether waiver of the exhaustion requirement is appropriate. *Tataranowicz*, 959 F.2d at 274.

III. THE SECRETARY'S EXERCISE OF "ADJUSTMENT" AUTHORITY IS NOT COMMITTED TO AGENCY DISCRETION BY LAW.

HHS's argument that the Secretary's exercise of "adjustment" authority is "committed to agency discretion by law" is foreclosed by this Court's decision in *Amgen*. That case holds that "a more substantial departure from the default amounts would, at some point violate the Secretary's statutory obligation and cease to be an 'adjustment,'" 357 F.3d at 117, and would therefore be subject to judicial review. In other words, *Amgen* identifies a "meaningful standard" against which to measure the Secretary's exercise of "adjustment" authority.

Further, regarding the statutory provision at issue here, Paragraph (14)(A)(iii), the Secretary's authority is limited by more than the natural meaning of the term "adjustment." It is found also in the Subclause (II) requirement that the adjustment be consistent with the average sales price of drugs and the Subclause (I) requirement that reimbursement may be based on acquisition cost only if the Secretary has certain rigorous data. These "statutory obligations," to use *Amgen*'s

language, also provide meaningful standards by which to assess the legality of the new rule. 357 F.3d at 117.

HHS's cases are inapposite. *Sierra Club v. Jackson*, 648 F.3d 848 (D.C. Cir. 2011), involved an "agency decision[] not to take enforcement action," and in that unique context courts "begin with the presumption that the agency's action is unreviewable." *Id.* at 855. *Webster v. Doe*, 486 U.S. 592, 595 (1988), involved statutory language authorizing the agency to take action it "*deemed* . . . necessary." (Emphasis added). The Supreme Court indicated the dismissal decision at issue would have been reviewable had the statute omitted the word "deem" and authorized action "simply when [it] *is* necessary" in the interests of the United States. *Id*. at 600 (emphasis in original). The language that *Webster* concluded would permit review is analogous to the adjustment language here. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (authorizing adjustment "as necessary for purposes of this paragraph").

IV. PLAINTIFFS HAVE MET THE TEST FOR A PRELIMINARY INJUNCTION.

A. Plaintiffs Are Likely to Succeed on the Merits.

We demonstrated above that the new reimbursement rule for separately payable drugs exceeds the Secretary's "adjustment" authority. The unprecedented, near-30% deviation is too large to be an "adjustment" within the intent of Congress, which would have expected the word to have its usual, inherently

limited meaning. Moreover, the Secretary has admitted that the "adjustment" was not based on calculations actually related to the Subclause (II) ASP plus 6% statutory default rate, but rather on acquisition cost data insufficient to permit the setting of the reimbursement rate based on acquisition costs under Subclause (I). Adjusting average sales price based on acquisition cost data to reach a rate that more closely aligns with average acquisition cost for certain 340B drugs in order to correct perceived deficiencies in the 340B program exceeds the authority to adjust average sales price as defined in Subclause (II) and also violates Subclause (I).

B. The Balance of Equities and the Public Interest Favor an Injunction.

Plaintiffs in their opening brief (Br. 49-53) and the *amici curiae* (35 state and regional hospital associations) (Amici Br. 18-25) detailed the irreparable harms that the near-30% rate reduction is causing non-exempt 340B hospitals and their patients. HHS makes no effort to dispute this harm, but argues it will suffer its own harm because enjoining the rate reduction would require it to "recalculate payment rates made under other OPPS payment rates in order to preserve budget neutrality," and that the public interest and "balance of equities" therefore favor denial of the requested injunction. Br. 40-41. But that concern is thoroughly overstated. OPPS reimbursement rates are revised annually, and in any given year HHS can set future rates at a level needed to retroactively correct mistakes in past years' rates.

Using next year's rate-setting to retroactively correct mistakes in a prior year's rate is not new. It is what HHS did in 2017 in the analogous context of the Inpatient Prospective Payment System ("IPPS"). There, the agency set future IPPS rates at a level it deemed necessary to address the past financial impact of a 0.2% reduction in reimbursements to hospitals for inpatient services that had been effective during 2014-2016 under HHS's "two-midnight" policy (which required a patient to remain in the hospital for two midnights to qualify as inpatient services). *See* 81 Fed. Reg. 56,762, 56,772 (Aug. 22, 2016) (noting that the agency was "making a temporary one-time prospective increase to the FY 2017 standardized amount . . . of 0.6 percent . . . to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FYs 2014, 2015, and 2016"). Plaintiff AHA, which had filed suit challenging the 0.2% reduction as in excess of the Secretary's authority and which ultimately HHS decided it could not defend, endorsed this solution.

Here, too, CMS can adjust future rates to compensate for the effects of the near-30% reduction during 2018. While the negative effects of that reduction are felt every day by the 340B hospitals subject to it, and there is an imperative to correct HHS's unauthorized reduction as quickly as possible, Plaintiffs recognize that HHS has detailed what it claims are complexities associated with immediate redistribution of funds that have been erroneously paid or withheld under the new

rate, and the disruption this would cause to the OPPS system.[12] Mindful of HHS's assertions but also that this type of complexity has been addressed adequately in the past when a regulation did not pass legal muster, Plaintiffs respectfully request that this Court (1) determine that Plaintiffs have demonstrated entitlement to a preliminary injunction and (2) remand this case to the District Court with instructions to enter an appropriate injunction, which at minimum would order HHS to set OPPS payment rates for calendar year 2019 without the near-30% reduction and also at the level needed to correct the past effects of the reduction. Providing this type of certainty will permit Plaintiffs and their member hospitals to plan for the future without the threat of continued reimbursement cuts into next year that would imperil programs that 340B hospitals provide to their communities. It will also allow sufficient time for HHS to initiate any rulemaking necessary to implement the injunction.[13]

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[12] These complexities were not an issue at the time Plaintiffs filed suit and sought a preliminary injunction, since the near-30% reduction had not yet gone into effect. The requested preliminary injunction, which HHS opposed, would have prevented the harm that HHS now claims pending resolution of this litigation.

[13] HHS disputes that this Court can consider whether to grant a requested injunction, arguing that if it were to hold that there is jurisdiction, it should remand the preliminary injunction issue. Br. 40 n.11. This Court can, however, issue injunctions on appeal when appropriate. *League of Women Voters v. Newby*, 838 F.3d 1, 7 (D.C. Cir. 2016). In this case, Plaintiffs request only that this Court determine that Plaintiffs are *entitled* to an injunction meeting the minimum requirements identified above, and then remand to the district court to enter the

The burden HHS faces in recalculating Medicare benefits – which it can address through reconciliation of future claims payments − pales in comparison to the financial and reputational damage suffered by 340B hospitals as a result of the illegal near-30% rate reduction and the irreparable harm suffered by patients denied essential care because of the rate cuts. *See Children's Hosp. of the King's Daughters, Inc. v. Price*, 258 F. Supp. 3d 672, 691-92 (E.D. Va. 2017) (noting that "[w]ithout an injunction, the Plaintiff's ability to offer lifesaving medical care may be diminished or delayed, the effects of which will fall on a particularly vulnerable set of the general public," that "[t]he harm to the members of the public whose quality of care is diminished . . . cannot be undone," and that "[t]he potential harm caused to the [government] Defendants by the injunction is less severe and more remote than the immediate and lasting harm the Plaintiff will suffer without an injunction"). Moreover, the harms HHS complains of are its own fault – the result of its consistent resistance to Plaintiffs' efforts to obtain expedited judicial review of the rate reduction in order to establish HHS's legal obligations before the rate reduction was to take effect.

Finally, even if the harms to HHS were deemed to be as substantial as the harms to Plaintiffs and their patients, the balance of harms would "result[] roughly

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appropriate injunction. *See Mendoza v. Perez*, 754 F.3d 1002, 1020 (D.C. Cir. 2014)).

in a draw," the propriety of a preliminary injunction would rest on an evaluation of the merits, and Plaintiffs have demonstrated a strong likelihood of success. *See Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

CONCLUSION

The Court should reverse dismissal of the complaint, determine that Plaintiffs have demonstrated entitlement to a preliminary injunction, and remand this case to the District Court with instructions to enter an appropriate injunction, which at minimum would order HHS to set OPPS payment rates for calendar year 2019 without the near-30% reduction and also at the level needed to correct the past effects of the reduction.

Respectfully Submitted,

/s/ Michael R. Smith
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Washington, DC 20036
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Attorneys for Plaintiffs-Appellants

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 6,335 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ Michael R. Smith
Michael R. Smith
Attorney for Plaintiffs-Appellants

CERTIFICATE OF SERVICE

Pursuant to D.C. Circuit Local Rule 25(c), I hereby certify that on April 2, 2018, I caused the foregoing Reply Brief of Plaintiffs-Appellants to be electronically filed with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Michael R. Smith
Michael R. Smith
Attorney for Plaintiffs-Appellants

ADDENDUM

TABLE OF CONTENTS

DOCUMENT DESCRIPTION **PAGE**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ALEX M. AZAR, in his official capacity as Secretary of Health and Human Services, Defendant.	Civil Action No. 14-cv-00851 (JEB)

RESPONSE TO PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiffs' notice of supplemental authority (ECF No. 78) asserts that HHS could reduce the Medicare appeals backlog by agreeing to toll the purported deadline for hospitals to file appeals related to the 340B Drug Discount Program pending the resolution of *American Hospital Association v. Azar*, No. 18-5004 (D.C. Cir.), in which the American Hospital Association and other organizations challenged a recent rulemaking by HHS that adjusts Medicare Outpatient Prospective Payment System (OPPS) payments for 340B hospitals. HHS declined Plaintiffs' request for such tolling, and Plaintiffs now assert that this decision calls into question HHS's commitment to reduce the backlog. This argument is without merit.

As HHS has explained in the 340B litigation, Congress has expressly precluded administrative and judicial review of OPPS adjustments. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (applying 42 U.S.C. § 1395l(t)(12) to preclude review of equitable adjustments made to the OPPS under section 1395l(t)(2)(E)). These adjustments are not reviewable "initial determinations" because they are "computations of the payment amount of program reimbursement for which CMS has sole responsibility under Part B." 42 C.F.R.

§ 405.926(c). If 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. The filings will not add to the backlog of Medicare appeals awaiting a hearing before an administrative law judge at OMHA.

Dated March 21, 2018

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

JOEL McELVAIN
Assistant Director, Federal Programs Branch

/s/ Adam C. Siple
NICHOLAS CARTIER (D.C. Bar # 495850)
ADAM SIPLE (NY Bar # 4387296)
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Counsel for Defendant

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Deputy Associate General
Counsel for Litigation
KIRSTEN FRIEDEL RODDY
Attorneys
United States Department of Health and
Human Services

MEDICARE REDETERMINATION REQUEST FORM — 1ST LEVEL OF APPEAL

1. Beneficiary's name: [redacted]
2. Medicare number: [redacted]
3. Item or service you wish to appeal: J1569
4. Date the service or item was received: 01/03/18
5. Date of the initial determination notice (please include a copy of the notice with this request):
(If you received your initial determination notice more than 120 days ago, include your reason for the late filing.)
01/25/18

5a. Name of the Medicare contractor that made the determination (not required):

5b. Does this appeal involve an overpayment? ☐ Yes ☒ No
(for providers and suppliers only)

6. I do not agree with the determination decision on my claim because:
The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg, 52,356. Numerous comments to the proposed rule (see pp. 52,499-502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $5,451.99.

7. Additional information Medicare should consider:
The new rate violates 42 U.S.C. § 1395l(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.

8. ☐ I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the redetermination.
☒ I do not have evidence to submit.

9. Person appealing: ☐ Beneficiary ☒ Provider/Supplier ☐ Representative

10. Name, address, and telephone number of person appealing: Shannon Weier, 5600 New King Dr Suite 250 Troy, MI 48098, 248-641-4084

11. Signature of person appealing: Shannon Weier

12. Date signed: 2/8/18

PRIVACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare and Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about these disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at http://www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

MEDICARE REDETERMINATION REQUEST FORM — 1ST LEVEL OF APPEAL

1. Beneficiary's name: [redacted]
2. Medicare number: [redacted]
3. Item or service you wish to appeal: J9310
4. Date the service or item was received: 01/03/18
5. Date of the initial determination notice (please include a copy of the notice with this request):
(If you received your initial determination notice more than 120 days ago, include your reason for the late filing.)
01/25/18

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5b. Does this appeal involve an overpayment? ☐ Yes ☒ No
(for providers and suppliers only)

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Troy, MI 48098, 248-641-4084

11. Signature of person appealing: Shannon Weier

12. Date signed: 2/8/18

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

WPS GOVERNMENT HEALTH ADMINISTRATORS

March 06, 2018

Henry Ford Health System
PO BOX 670884
DETROIT, MI 48267

Medicare Number of Beneficiary:
[redacted]
72476076Q

Beneficiary Contact Information

1-800-MEDICARE
or
1-800-633-4227

Provider Contact Information

If you have questions, write or call:

WPS Government Health Administrators - J8
Medicare Appeals PO Box 8604
Madison, WI 53708-8604
(866) 234-7331

Re: Appeal # 1-7298171061
MEDICARE APPEAL DECISION

Dear Henry Ford Health System,

This letter is to inform you of the decision on your Medicare appeal. An appeal is a new and independent review of a claim. On February 13, 2018, we received a redetermination request for outpatient hospital / asc services provided by Henry Ford Health System. WPS Government Health Administrators - J8 was contracted by Medicare to review your appeal.

The redetermination decision is unfavorable because the services in question have already been paid by the Medicare Administrative Contractor (MAC) on January 25, 2018. We have evaluated the information submitted, and there does not appear to be any errors impacting the payment amount, which is the maximum payment amount allowed by Medicare for this service. As a result, we are issuing an unfavorable decision on your request for redetermination for claims referenced in Attachment A.

If you disagree that the claim in question was previously processed for payment, and/or you otherwise disagree with this decision, you may appeal to a Qualified Independent Contractor (QIC). You must file your appeal, in writing, within 180 days of receipt of this letter.

MAXIMUS Federal Services Inc.
Medicare Part A West
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

Sincerely,

Travis Parvin
Redetermination Representative
WPS Government Health Administrators - J8
A Medicare Contractor

cc: [redacted]

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

WPS | GOVERNMENT HEALTH ADMINISTRATORS

March 06, 2018

Henry Ford Health System
PO BOX 670884
DETROIT, MI 48267

Medicare Number of Beneficiary:
[redacted]
725127902

Beneficiary Contact Information

1-800-MEDICARE
or
1-800-633-4227

Provider Contact Information

If you have questions, write or call:

WPS Government Health Administrators - J8
Medicare Appeals PO Box 8604
Madison, WI 53708-8604
(866) 234-7331

Re: Appeal # 1-7298171151
MEDICARE APPEAL DECISION

Dear Henry Ford Health System,

This letter is to inform you of the decision on your Medicare appeal. An appeal is a new and independent review of a claim. On February 13, 2018, we received a redetermination request for outpatient hospital / asc services provided by Henry Ford Health System. WPS Government Health Administrators - J8 was contracted by Medicare to review your appeal.

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Medicare Part A West
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

Sincerely,

Travis Parvin
WPS Government Health Administrators - J8
A Medicare Contractor

cc: [redacted]

MEDICARE RECONSIDERATION REQUEST FORM — 2ND LEVEL OF APPEAL

1. Beneficiary's name: [redacted]
2. Medicare number: [redacted]
3. Item or service you wish to appeal: J1569
4. Date the service or item was received: 01/03/18
5. Date of the redetermination notice (please include a copy of the notice with this request):
   (If you received your redetermination notice more than 180 days ago, include your reason for the late filing.)
   3/6/18

   5a. Name of the Medicare contractor that made the redetermination (not required if copy of notice attached):

   5b. Does this appeal involve an overpayment? ☐ Yes ☒ No
   (for providers and suppliers only)
6. I do not agree with the redetermination decision on my claim because:
   The payment(s) received for 340B drugs reflect a new reimbursement rate of Average Sales Price (ASP) minus 22.5%, as provided by the 2018 OPPS Rule. 82 Fed. Reg. 52,356. Numerous comments to the proposed rule (see pp. 52,499-502) correctly explained that this new rate exceeds the Secretary's authority. The reimbursement rate should reflect the ASP plus 6% 2017 rate, as required by law. The payment(s) should be $5,451.99.
7. Additional information Medicare should consider:
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8. ☐ I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the reconsideration.

   ☒ I do not have evidence to submit.
9. Person appealing: ☐ Beneficiary ☒ Provider/Supplier ☐ Representative
10. Name, address, and telephone number of person appealing: Shannon Weier, 5600 New King Dr Suite 250
    Troy, MI 48098, 248-641-4084
11. Signature of person appealing: Shannon Weier
12. Date signed: 3-27-18

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WPS | GOVERNMENT HEALTH ADMINISTRATORS

March 06, 2018

Henry Ford Health System
PO BOX 670884
DETROIT, MI 48267

Medicare Number of Beneficiary:
[redacted]
724760762

Beneficiary Contact Information

1-800-MEDICARE
or
1-800-633-4227

Provider Contact Information

If you have questions, write or call:

WPS Government Health Administrators - J8
Medicare Appeals PO Box 8604
Madison, WI 53708-8604
(866) 234-7331

Re: Appeal # 1-7298171061
MEDICARE APPEAL DECISION

Dear Henry Ford Health System,

This letter is to inform you of the decision on your Medicare appeal. An appeal is a new and independent review of a claim. On February 13, 2018, we received a redetermination request for outpatient hospital / asc services provided by Henry Ford Health System. WPS Government Health Administrators - J8 was contracted by Medicare to review your appeal.

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MAXIMUS Federal Services Inc.
Medicare Part A West
3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

Sincerely,

Travis Parvin
Redetermination Representative
WPS Government Health Administrators - J8
A Medicare Contractor

cc: [redacted]

MEDICARE RECONSIDERATION REQUEST FORM — 2ND LEVEL OF APPEAL

1. Beneficiary's name: [redacted]
2. Medicare number: [redacted]
3. Item or service you wish to appeal: J9310
4. Date the service or item was received: 01/03/18
5. Date of the redetermination notice (please include a copy of the notice with this request):
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   3/6/18

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CENTERS FOR MEDICARE & MEDICAID SERVICES

WPS | GOVERNMENT HEALTH ADMINISTRATORS

March 06, 2018

Henry Ford Health System
PO BOX 670884
DETROIT, MI 48267

Medicare Number of Beneficiary:
[redacted]
725127902

Beneficiary Contact Information

1-800-MEDICARE
or
1-800-633-4227

Provider Contact Information

If you have questions, write or call:

WPS Government Health Administrators - J8
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(866) 234-7331

Re: Appeal # 1-7298171151
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3750 Monroe Avenue Suite 706
Pittsford, NY 14534-1302

Sincerely,

Travis Parvin
WPS Government Health Administrators - J8
A Medicare Contractor

cc [redacted]