UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, *et al.*, *Defendants.*	**Case No. 18-cv-2084 (RC)**

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

On the merits, this is a straightforward case of statutory construction. Subclause (I) of Subsection (t)(14)(A)(iii) of the Medicare Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), directs the Secretary to use acquisition costs to calculate the reimbursement rate for separately payable drugs *if* data are available that meet the rigorous statistical standards of the statute. *See* Pls.' Mem., ECF No. 2-1, at 22–24. Acquisition cost data meeting this standard are not, and have never been, available. *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 824 (D.C. Cir. 2018). Thus the Secretary's only authority to set the reimbursement rates for separately payable drugs is under Subclause (II) of Paragraph (14)(A)(iii), which requires that the rate be set at average sales price (ASP) plus 6%. This rate may be adjusted, but, as the Secretary acknowledges, the reduction at issue here was imposed to better align the reimbursement with acquisition costs; it was not a refinement or adjustment to average sales price. *See* Defs.' Mem., ECF No. 15, at 37. Moreover, under *Amgen Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004), CMS's near-30% cut in reimbursements is not an "adjustment" within the meaning of the statute. In any event, Paragraph (14)(E) of Subsection 1395*l*(t) demonstrates that the only permissible adjustments are to the 6% portion of allowable reimbursements which covers overhead and related expenses, such as pharmacy services and handling costs, which is the only circumstance for which CMS has previously used its Subclause (II) adjustment authority. Finally, CMS may not use the adjustment authority to undermine the 340B Program, which it essentially acknowledges was its intent here.

On preclusion, this Circuit requires "clear and convincing evidence that Congress intended to preclude the suit." *Amgen*, 357 F.3d at 111. Although Paragraph (12) of the OPPS statute expressly precludes review of numerous specific decisions under enumerated paragraphs of the statute, no provision of Paragraph (12) references Paragraph (14), which is the authority

invoked by CMS for the action challenged here. In the absence of any provision that expressly precludes judicial review, HHS has offered strained arguments that preclusion is required by three separate provisions of Paragraph (12), one of which it did not identify until oral argument in the D.C. Circuit. Even if its statutory arguments had some validity, and they do not, HHS has plainly not satisfied the D.C. Circuit's "clear and convincing evidence" standard. In any event, even if review of agency action under Paragraph (14) were precluded, the Court would still need to determine whether CMS acted outside its authority under that Paragraph (14). *Amgen*, 357 F.3d at 112–13. CMS's lack of authority for the action that it took means both that judicial review is not precluded and that Defendants lose on the merits.

HHS continues to raise arguments that Plaintiffs must fully exhaust all administrative review procedures and that the challenged decisions are committed to agency discretion, but those arguments fare no better. HHS concedes that Plaintiffs have now presented claims for payment to the Secretary, and it does not dispute that any further review would be futile. Moreover, the boundaries of HHS's statutory authority dictate that the challenged decision is not committed to agency discretion.

This is the third occasion on which the parties have fully briefed all the issues in this case. There are no factual disputes to be resolved and HHS has had more than an ample opportunity to brief the legal issues in this case. The Court should reach the merits and enter final judgment in favor of Plaintiffs.

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 Paragraph (12) of section 1395*l*(t) of title 42 prohibits judicial review of agency actions under Paragraph (14) of section 1395*l*(t)(14) of title 42, under which the outpatient reimbursement rule at issue here was promulgated. However, the provisions on which HHS relies – Subparagraphs (A), (C) and (E) of Paragraph (12) − reference other parts of the Outpatient Prospective Payment System ("OPPS") for covered outpatient services, *not Paragraph (14)*. HHS's own regulation implementing Paragraph (12) references the same other provisions of the OPPS system, and likewise makes no reference to Paragraph (14). *See* 42 C.F.R. § 419.60 ("Limitations on Administrative and Judicial Review"). To explain the lack of any reference to Paragraph (14), HHS has argued that the Secretary's authority under Paragraph (14) is "mushed together" with other authorities that *are* precluded from review under Paragraph (12). Oral Argument at 41:00–41:20, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018) (No. 18-5004), https://www.cadc.uscourts.gov/recordings/recordings2018.nsf/651CFD131E722 35285258283005D50B4/$file/18-5004.mp3.

HHS's construction cannot be reconciled with the "strong presumption that Congress intends judicial review of administrative action." *Amgen*, 357 F.3d at 111 (citation omitted). The presumption can be overcome only by "clear and convincing evidence that Congress intended to preclude the suit." *Id.* As the D.C. Circuit has held, Congress must speak plainly to preclude judicial review, and in Paragraph (12) Congress was careful to preclude review of agency action under certain specific paragraphs but not others. HHS's brief does not attempt to

reconcile its strained statutory analysis – reading in a reference to Paragraph (14) where none exists – with the strong presumption of reviewability.

1. Subsection (t)(12)(A)

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

> [T]he *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).

(Emphasis added). When Congress directed CMS to switch the payment of outpatient department services from a system based on reasonable costs to a system where the payments were established prospectively based on historical data, it instructed CMS in Paragraph (2) to develop a classification system for covered services, specifying, for example, that the Secretary "may establish groups of covered OPD services" (Subparagraph (B)), "shall . . . establish relative payment weights" (Subparagraph (C)), "shall determine a wage adjustment factor" (Subparagraph (D)), and "shall establish . . . other adjustments as determined to be necessary to ensure equitable payments" (Subparagraph (E)). This system was developed and announced in the Federal Register in 2000. HHS Office of Inspector General, *Medicare Program; Prospective Payment System for Hospital Outpatient Services*, 65 Fed. Reg. 18,434 (Apr. 7, 2000).

Relying on the words "development of the classification system under paragraph (2)," 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. This is incorrect. While the outpatient rule is part of the OPPS system and the ambulatory payment classification (APC) system, it is *not* part of the system "develop[ed] . . . under paragraph (2)." 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]

HHS also argues that Paragraph (12)(A)'s reference to "other adjustments" precludes review of the 340B Provisions of the OPPS Rule because "the Secretary's *adjustment* of [payment rates for 2018 under paragraph (14)] was part of his 'development of' the APC system." Defs.' Mem. at 18 (emphasis in original). This reading likewise overlooks the statutory text. Paragraph (12)(A) precludes review of "the 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). *See* note 1, *supra*.[2]

HHS's argument effectively amends Paragraph (2) to include a reference to Paragraph (14) that does not exist. Moreover, this 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)–(6)), it amended Paragraphs (2) and (12) to refer explicitly to

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[1] HHS does not dispute that, when it promulgated the new rule, it invoked its authority under Paragraph (14), not under Paragraph (2). *See* 82 Fed. Reg. at 52,499 (relying on "authority *under section 1833(t)(14)(A)(iii)(II)* to 'calculate and adjust' drug payments" (emphasis added)); *id.* at 52,500 (same).

[2] The "other adjustments" authorized under "paragraph (2)" and precluded from review under Paragraph (12)(A) are "other adjustments as determined [by HHS] to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." 42 U.S.C. § 1395*l*(t)(2)(E). HHS did not invoke its equitable adjustment authority under Paragraph (2)(E) in the 340B Provisions of the OPPS Rule. *See* 82 Fed. Reg. at 52,506–07.

actions taken "under paragraph (5)" and "under paragraph (6)." 42 U.S.C. § 1395*l*(t)(2)(E), (12)(E).[3] Similarly, when Congress amended the statute in 2003 to add the text codified at section § 1395*l*(t)(13) of title 42, it specifically authorized "an appropriate adjustment under paragraph (2)(E)" with respect to rural hospitals, thereby subjecting them to preclusion under Paragraph (12).[4] 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) (referring to "relative payment weight (determined *under paragraph (2)(C)*)" (emphasis added)). Actions taken under Paragraph (14), which is referenced nowhere in Paragraph (2) *or* Paragraph (12)(A), are not precluded from review.[5] HHS has certainly not satisfied the clear and convincing evidence standard.

HHS's reliance on this Court's decision in *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14 (D.D.C. 2014), is also misplaced. In *Organogenesis*, the issue was whether a product (Apligraf) was "properly considered a regular OPD service under § (t)(2)" or whether it "should properly be considered a [drug] under . . . (t)(14)." *Id.* at 20. The Court ruled that, because Apligraf was appropriately classified as a surgical procedure rather than as a drug, HHS had had properly classified it under Paragraph (2), which meant that preclusion applied under Paragraph (12)(A). The clear implication of the decision was that if the product has been reimbursed under

[3] Consol. Appropriations Act, App'x F, Sec. 1, § 201(c), 113 Stat. 1501, 1501A-339 (1999).

[4] Medicare Prescription Drug, Improvement, & Modernization Act, Sec. 1, § 411(b), 117 Stat. 2066, 2274 (2003).

[5] Although HHS argues that *Amgen* recognized Paragraph (12)'s preclusion of review of Paragraph (14) adjustments, *see* Defs.' Mem. at 18–19, in fact *Amgen* concerned the reviewability of adjustments under Paragraph (2)(E), which are expressly referenced in Paragraph (12).

Paragraph (14), as is indisputably the case here, the preclusion provision in Paragraph (12)(A) would not apply.

2. Subsection (t)(12)(C)

HHS also invokes Subsection (t)(12)(C) of the Medicare Act, which precludes review of "periodic adjustments made under paragraph [9]." 42 U.S.C. § 1395*l*(t)(12)(C).[6] HHS did not invoke Subsection (t)(12)(C) when this case was previously before this Court or in its brief on appeal; it first argued that preclusion is required under Paragraph (12)(C) during oral argument in the D.C. Circuit. Oral Argument at 34:20–36:00, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018) (No. 18-5004), https://www.cadc.uscourts.gov/recordings/recordings2018.nsf/651CFD131E72235285258283005D50B4/$file/18-5004.mp3.

Adjustments under Paragraph (9) are separate and apart from agency action under Paragraph (14) such as the payment reduction at issue in this case. As previously explained, CMS established the classification system under the authority granted in Paragraph (2). After the system was established, in Paragraph (9), Congress directed HHS to "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." 42 U.S.C. § 1395*l*(t)(9)(A). In other words after CMS used its authority under Paragraph (2)(B)–(E) to establish groups, relative payment weights, wage and other adjustments, Paragraph (9) requires it to update those factors at least annually.

[6] As HHS points out, as a result of a scrivener's error, Subsection (t)(12)(C) refers to "periodic adjustments made under paragraph (6)" but should refer to Paragraph (9). *See* Defs.' Mem. at 6 n.2.

Setting payment amounts under Paragraph (14) is not the same as, or an example of, making periodic adjustments under Paragraph (9). In particular, "adjustments" under Paragraph (14) are not among the "other adjustments" referenced in Paragraph (9); the "other adjustments" in Paragraph (9) are the same as the "other adjustments" in Paragraph (2) – *i.e.*, equitable adjustments – which the HHS did not claim to be invoking when it made the payment reduction at issue here. *See supra* note 2.

Paragraph (12)(C) only applies to agency action under Paragraph (9), and it does not constitute clear and convincing evidence of congressional intent to preclude review of action under Paragraph (14).

3. Subsection (t)(12)(E)

HHS also asserts preclusion based on Subsection (t)(12)(E) of the Medicare Act, but that preclusion provision only applies to certain "determination[s]" made "under paragraph (5)" or "under paragraph (6)," and not to actions taken under paragraph (14) like the payment reduction at issue in this case. 42 U.S.C. § 1395*l*(t)(12)(E). Paragraph (12)(E) precludes review of:

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

Id. (emphasis added). This provision is plainly inapplicable to the agency action at issue in this case.

HHS isolates Paragraph (12)(E)'s reference to "the portion of the medicare OPD fee schedule amount associated with particular . . . drugs," and argues that this phrase extends to and includes the Paragraph (14) "adjustments" at issue here. Defs.' Mem. at 20–24. In an attempt to circumvent the obvious textual limitation on the scope of (t)(12)(E) to "determination[s]" made

"under paragraph (5)" or "under paragraph (6)," HHS argues that "the 'under paragraph (6) language in § (t)(12)(E) only modifies the phrase immediately preceding it – *i.e.*, 'the application of any pro rata reduction'" – *not* the phrase regarding the Medicare OPD fee schedule that Defendants believe applies here. *Id.* at 24.

The structure of (t)(12)(E) makes plain that *all* of the listed types of determinations are made "under paragraph (5)" or "under paragraph (6)"—not just the types that immediately precede those phrases. Each of the types of determinations listed in the first part of (t)(12)(E) refers to a specific provision of Paragraph (5), and each of the types of determinations listed in the second part of (t)(12)(E), which follow the word "or," refers to a specific provision of Paragraph (6). *Compare* 42 U.S.C. § 1395*l*(t)(12)(E), *with id.* § 1395*l*(t)(5), (6). Critically, this includes the language that Defendants focus on in (t)(12)(E) regarding "the determination of . . . the portion of the medicare OPD fee schedule amount associated with particular . . . drugs." *See* Defs.' Mem. at 20–24. That phrase is obviously a reference to action under Paragraph (6) that must be based on "the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug." 42 U.S.C. § 1395*l*(t)(6)(D)(i). Agency action under Paragraph (6) has nothing to do with agency action under Paragraph (14), which in fact specifically *excludes* drugs that receive payments under Paragraph (6). *See id.* § 1395*l*(t)(14)(B)(ii)(I).

HHS suggests that its reading is required by "the 'last antecedent rule' of statutory construction." Defs.' Mem. at 24. But HHS's argument takes the "last antecedent rule" much too far, and paragraph (12)(E) is a prime example of the precept that "structural or contextual evidence may rebut the last antecedent inference." *Lockhart v. United States*, 136 S. Ct. 958, 965 (2016) (citation omitted).

Reading Paragraph (12)(E) to refer exclusively to types of agency action under paragraphs (5) and (6) makes perfect sense because Congress added all of Paragraph (12)(E) to the OPPS law in 1999 at the same time that it added Paragraphs (5) and (6).[7] Congress did not enact Paragraph (14) until 2003 and, tellingly, did not amend Paragraph (12)(E) to include a reference to Paragraph (14). There is no evidence that Congress intended for Paragraph (12)(E) to preclude review of agency action under Paragraph (14), let alone the requisite clear and convincing evidence.

B. Even if Preclusion Applies to Section 1395*l*(t)(14), Agency Action that Exceeds the Secretary's Authority Under that Provision is Reviewable.

HHS floats a grab bag of preclusion arguments, and its approach amounts to throwing spaghetti at a wall, hoping something will stick. But even if one of Paragraph (12)'s preclusion provisions applied to agency action under Paragraph (14), those provisions do not bar review of agency action under the OPPS system "for which [statutory] authority is lacking." *Amgen*, 357 F.3d at 113. Accordingly, "the determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review." *Id.*; *accord Organogenesis*, 41 F. Supp. 3d at 20–21; *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, No. 16-cv-2237 (TJK), 2018 WL 3459916, at *6–7 (D.D.C. July 18, 2018), *appeal filed*, No. 18-5277, 2018 WL 3459916 (D.C. Cir. Sept. 19, 2018). Denying preclusion under such circumstances does not implicate concerns about piecemeal review because facial challenges to an agency's statutory authority "are infrequent and typically raise issues—unrelated to the facts

[7] *See supra* note 3, at § 201(a), (b), and (d), 113 Stat. at 1501A-336 to 339 (adding Paragraphs (5), (6), and (12)(E) to OPPS law).

of the particular cases—that need only be resolved by the courts once." *H. Lee Moffitt*, 2018 WL 3459916, at *6 (citation omitted); *see also Amgen*, 357 F.3d at 113 ("[T]he 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, would be sufficiently offset by the likely gains from reducing the risk of systematic misinterpretation in the administration of the Medicare B program."). Thus, there is no preclusion if HHS exceeded its "adjustment" authority in reducing reimbursements for 340B drugs by almost 30%. As explained below, HHS did exceed its authority. *See infra* § IV.

II. PLAINTIFFS EMHS AND PARK RIDGE HAVE SATISFIED THE EXHAUSTION REQUIREMENT, AND IN ANY EVENT, EXHAUSTION SHOULD BE WAIVED AS FUTILE.

HHS concedes, as it must, that all Plaintiffs have satisfied the jurisdictional presentment requirement by submitting claims for payment to the Secretary for drugs covered by the 340B Program. Defs.' Mem. at 15 n.6. But HHS contends that, in light of the waivable exhaustion requirement, Plaintiffs cannot bring their claims to the Court until they have completed every stage of administrative review set forth in HHS regulations. *See id.* at 26–27.

As an initial matter, after Plaintiffs filed their Motion for a Preliminary and Permanent Injunction but before Defendants filed their Motion to Dismiss, Plaintiffs Eastern Maine Healthcare Systems ("EMHS") and Park Ridge Health ("Park Ridge") *did* obtain decisions that HHS regulations treat as final. A Qualified Independent Contractor ("QIC") issued letters in three of EMHS's appeals and in one of Park Ridge's appeals stating as follows:

> [B]ecause administrative review is not available for this issue, there is not sufficient cause to reverse the [Medicare Administrative C]ontractor's dismissal. Therefore, the contractor's original dismissal stands. In accordance with 42 CFR Section 405.974(b)(3), **a QIC's reconsideration of a contractor's dismissal of a**

> **redetermination request is final and not subject to any further review. You have no further appeal rights on this case.**

Suppl. Ex. L at 6; Suppl. Ex. N at 6; Suppl. Ex. P at 7; Suppl. Ex. R at 9 (emphasis added). The regulation cited in the letters provides that "[a] QIC's review of a contractor's dismissal of a redetermination request is binding and not subject to further review." 42 C.F.R. § 405.974(b)(3). Plaintiffs EMHS and Park Ridge have fully exhausted the review procedures set forth in HHS regulations and have obtained decisions that those regulations treat as final.[8]

As for the other Plaintiffs (and for EMHS's and Park Ridge's other pending appeals), any further administrative review would be manifestly futile, as Plaintiffs demonstrated in their Motion for a Preliminary and Permanent Injunction. *See* Pls.' Mem. at 16–20. Perhaps the most striking evidence is that HHS itself has stated in another lawsuit that, in light of its position that administrative and judicial review of OPPS adjustments is statutorily precluded, any administrative appeals that reach the Administrative Law Judge stage *will be dismissed as unreviewable.* Ex. U to Pls.' Mem., ECF No. 2-24 ("If AHA member hospitals attempt to challenge non-reviewable [340B] determinations by filing administrative appeals with the Office of Medicare Hearings and Appeals (OMHA), then OMHA *will flag those filings and dismiss them promptly*." (emphasis added)). HHS was similarly blunt in a letter that it submitted to the D.C. Circuit in the prior iteration of the instant lawsuit: "providers cannot challenge the reimbursement rate for [340B] drugs within the current Medicare administrative appeals process." Ex. Y. HHS does not suggest there is any chance it will change its position during the administrative review process. Nor does it suggest that the administrative review process might

[8] Out of an abundance of caution, EMHS has submitted requests for administrative law judge review of the three QIC decisions it has received. *See* Suppl. Ex. L at 8–13; Suppl. Ex. N at 8–13; Suppl. Ex. P at 9–14. Park Ridge will do likewise shortly. EMHS has not received any responses to its requests.

yield a helpful factual record; in fact, HHS flatly acknowledges that the Court need not even "consider the administrative record in evaluating Plaintiffs' claim[s], since the claims present pure questions of statutory interpretation." Defs.' Mem. at 28 n.10. In other words, HHS does not dispute the premise that further administrative review would be entirely futile.

HHS argues instead that "Plaintiffs' contention that administrative review would be futile does not excuse compliance with the exhaustion requirement." *Id.* at 26 (citation omitted). HHS displays considerable audacity in insisting on exhaustion of administrative procedures that HHS believes Plaintiffs "cannot" pursue. Ex. Y. In any event, HHS's argument is squarely foreclosed by binding precedent and is based on a misreading of the authorities that HHS cites. The D.C. Circuit has squarely held that futility of further administrative review is a valid basis for judicial waiver of the exhaustion requirement. *Tataranowicz v. Sullivan*, 959 F.2d 268, 273–75 (D.C. Cir. 1992); *see also Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell* ("*NAHC*"), 77 F. Supp. 3d 103, 110–12 (D.D.C. 2015). Although it cites *Tataranowicz*, HHS makes no attempt to distinguish it (or *NAHC*).

Instead, HHS relies on a misreading of the Supreme Court's decision in *Weinberger v. Salfi*, 422 U.S. 749 (1975), in suggesting that that case supports an argument that futility does not excuse compliance with the exhaustion requirement. *See* Defs.' Mem. at 26. *Salfi* did hold that, where there had been no exhaustion *or presentment*, § 405(g)'s "final decision" requirement cannot be discarded on grounds of futility. *Id.* at 764. But for the plaintiffs in *Salfi* who had presented their claims, as HHS concedes Plaintiffs have here, the Court allowed judicial review to proceed because further administrative review would be futile. *See id.* at 764–67. And although the agency in *Salfi* did not contest exhaustion, *id.* at 767, the Supreme Court and the D.C. Circuit have repeatedly affirmed that courts can determine that exhaustion should be

waived even in cases where the agency disagrees. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 24 (2000); *Matthews v. Eldridge*, 424 U.S. 319, 330–31 (1976); *Tataranowicz*, 959 F.2d at 274.

Finally, 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 review process that establishes a path to expedited judicial review." Defs.' Mem. at 26–27. But the Court in *Illinois Council* stated, citing *Eldridge*, that "a court can deem [many of the procedural steps set forth in § 405(g)] waived in certain circumstances." 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) (authorizing agencies to establish a process for expedited access to judicial review) and from the court's independent authority to determine whether waiver of the exhaustion requirement is appropriate. *Eldridge*, 424 U.S. at 330–32 ("denial of Eldridge's request for benefits constitutes a final decision for purposes of § 405(g) jurisdiction" even where Eldridge "did not exhaust the full set of internal-review procedures provided by the Secretary"); *Tataranowicz*, 959 F.2d at 274.

All three Hospital Plaintiffs have proceeded through multiple stages of administrative review to no avail, and any further review would be demonstrably futile. That is grounds for the Court to determine that the Secretary has reached a "final decision" for purposes of § 405(g) and to waive any requirement of further exhaustion.

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 the D.C. Circuit'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 to make such payments and cease to be an 'adjustment'" and would therefore be subject to judicial review. 357 F.3d at 117. In other words, *Amgen* holds there *is* 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 not only by the meaning of the term "adjustment," but also by 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 340B Provisions of the OPPS Rule. 357 F.3d at 117.

HHS's cases are inapposite. *Sierra Club v. Jackson* 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." 648 F.3d 848, 855 (D.C. Cir. 2011). *Webster v. Doe*, 486 U.S. 592 (1988), and *Wendland v. Gutierrez*, 580 F. Supp. 2d 151 (D.D.C. 2008) both involved statutory language authorizing an agency to take action it "*deem[ed]* necessary." *Doe*, 486 U.S. at 600; 580 F. Supp. 2d at 153 (emphasis added). Indeed, in *Doe*, the Supreme Court indicated that the agency 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. 486 U.S. at 600 (emphasis in original). The language that *Doe* 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"). That language provides meaningful constraints on agency action that a court can enforce. *See Amgen*, 357 F.3d at 117.

IV. ON THE MERITS, THE SECRETARY EXCEEDED HIS "ADJUSTMENT" AUTHORITY UNDER SECTION 1395*l*(t)(14).

We have previously demonstrated that the Secretary exceeded his authority to adjust the statutory rate for separately payable drugs for three reasons: (1) the Secretary cannot use his statutory adjustment authority to set payment amounts based on acquisition costs; (2) the almost 30 percent reduction was not an "adjustment" of the average sales price; and (3) the adjustment authority may not be used for the purpose of undermining the 340B Program. Pls.' Mem. at 21–30. HHS's response on each point is unpersuasive.[9]

A. The Secretary Cannot Use His "Adjustment" Authority Under Subclause (II) to Use Acquisition Costs in a Manner that Would Be Forbidden Under Subclause (I).

As we explained in our opening brief, Congress limited the acquisition-cost methodology for calculating reimbursements for separately payable drugs to circumstances in which the Secretary has "survey data" drawn from "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), (D)(iii). Undaunted by the fact that he "does not have acquisition cost survey data," *Am. Hosp. Ass'n*, 895 F.3d at 824, the Secretary calculated the payment amount based on an estimate of average acquisition cost anyway, framing his calculation as an "adjustment" of Average Sales Price under Subclause (II), claiming he could avoid the limitations of Subclause (I). *See* 82 Fed. Reg. at 52,498. If the Secretary had set the exact same payment rate based on the exact same information and cited Subclause (I) as authority for his action, he would obviously have been violating Subclause (I)'s data requirement. If Congress had intended for Subclause (II) sales price "adjustments" to

[9] Because HHS's interpretation of its authority is clearly foreclosed by the OPPS statute, deference under *Chevron U.S.A. Inc v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), has no application.

enable the Secretary to set reimbursement rates based on acquisition costs, as he has done here, it would not have enacted Subclause (I), imposing rigorous data requirements on HHS.

HHS's arguments to the contrary are unpersuasive. HHS claims that "the Secretary's adjustment authority would be rendered meaningless" if "the ultimate 'payment' must be based strictly on ASP" and that there must be some content to the Secretary's authority to "adjust" ASP so as to adhere to "one of the most basic interpretive canons, that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." Defs.' Mem. at 29. But the Secretary's adjustment authority would not be "rendered meaningless" under Plaintiffs' reading: the Secretary may "adjust" ASP in a manner that bears a coherent relationship to ASP plus 6 percent, and that attempts to refine the national average sales price so it is more accurate, or better approximates pharmacy services and handling costs. *See* Pls.' Mem. at 26–27. The Secretary has made this type of adjustment in the past. *See id.* at 25–26.

Indeed it is *HHS's* reading that would render an entire provision of the statute superfluous. If the Secretary were correct that he may "adjust" ASP under Subclause (II) by whatever percentage is necessary to approximate acquisition cost, without the data required under Subclause (I), then Subclause (I) is superfluous in its entirety. HHS could simply use its "adjustment" authority under Subclause (II) to set the payment rate based on acquisition cost, whether it had statistically significant survey data or not. That is not how Congress writes statutes; if the Secretary does not have the requisite data for considering acquisition costs pursuant to Subclause (I), he may not do so anyway pursuant to Subclause (II) under the guise of "adjusting" ASP.

B. The Payment Reduction in the OPPS Rule Was Not an "Adjustment" of ASP.

We explained in our opening brief that the Secretary's near-30% reduction in payment rate was not an "adjustment" of ASP because (1) it was too large to be an "adjustment" and (2) it bore no coherent relationship to ASP, the thing supposedly being "adjusted." Pls.' Mem. at 24–27.

None of HHS's responses holds water. First, HHS argues that "[t]he statute does not impose any restriction on the Secretary's discretionary 'adjustment' of OPPS drug payment rates . . . , including any restriction on the *amount* of that adjustment." Defs.' Mem. at 30 (emphasis in original); *see also id.* at 1 (claiming that the Secretary's adjustment authority is a "broad and unequivocal grant of discretion"). But that argument ignores the "[l]imitations . . . [that] inhere in the text" of a statutory provision that "only authorizes 'adjustments,' not a total elimination or severe restructuring of the statutory scheme." *Amgen*, 357 F.3d at 117.

HHS breezily dismisses this limitation, arguing that the challenged payment reduction "does not remotely approximate a 'total elimination or severe restructuring of the statutory scheme.'" Defs.' Mem. at 32 (quoting *Amgen*, 357 F.3d at 117). But the statute commands that the payment rate "shall be equal . . . [to] the average price of the drug in the year [ASP] . . . , as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). A reduction of nearly 30% that is explicitly designed to approximate a measure of drug value *other than ASP* constitutes a "total elimination" of the requirement to set the payment rate based on ASP. Furthermore, 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 relationship to

the ASP plus 6% default rate. By any measure, that approach "severe[ly] restructure[s]" Congress's chosen statutory scheme. *Amgen*, 357 F.3d at 117.[10]

Second, HHS argues that the adjustments referenced in Paragraph (14)(E) for "overhead and related expenses, such as pharmacy services and handling costs," 42 U.S.C. § 1395*l*(t)(14)(E)(i), are "wholly distinct from the Secretary's broader authority to adjust OPPS drug payment rates 'as necessary'" under Subclause (II). Defs.' Mem. at 35. HHS contends that while Paragraph (14)(E) expressly authorizes only a limited set of adjustments, Subclause (II) "include[s] no similar qualifying language." *Id.* This argument ignores the fact that, under Subclause (II), the Secretary may only adjust ASP "as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The only type of adjustments referenced in Paragraph (14) are the ones in Subparagraph (E), and the Secretary has no competing explanation for which adjustments are "necessary for purposes of this paragraph." The Secretary's view that "[t]he statute does not impose *any* restriction on the Secretary's discretionary 'adjustment' of OPPS drug payment rates under [Subclause (II)]," Defs.' Mem. at 30, reads this limiting language out of the statute.

Finally, HHS attempts to rebut Plaintiffs' argument that the payment reduction was "inadequately connected to the ASP" by contending that "the Secretary continues to 'calculate' ASP" in the same manner that it did before the 2018 OPPS Rule. Defs.' Mem. at 34. That response is plainly insufficient; the statute requires that the payment be equal to ASP, "as calculated *and adjusted* by the Secretary as necessary for purposes of this paragraph."

[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 omitted). Here, in contrast, the Secretary has expanded the scope of his adjustment authority in a manner that affects hundreds of hospitals and millions of patients.

§ 1395*l*(t)(14)(A)(iii)(II). ASP is the thing being "adjusted," not just the thing being "calculated," and so any adjustment must coherently relate to ASP. Defendants' dictionary definitions agree. *See* Defs.' Mem. at 33 n.12 (citing dictionaries that define "adjust" to mean, for example, "a: to bring to a more satisfactory state . . . b: to make correspondent or comfortable . . . c: to bring the parts of to a true or more effective relative position" (alterations by Defendants)). The default ASP-plus-6% statutory rate is meaningless as a baseline 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'").

C. The Secretary May Not Use His "Adjustment" Authority to Target 340B Hospitals and to Undermine the 340B Program.

HHS argues that it is permitted to treat different hospital groups differently when setting payment rates for separately payable drugs under Subclause (II) "because other parts of the Medicare statute treat those types of providers differently." Defs.' Mem. at 36. As examples, HHS points to provisions that authorize special treatment for rural hospitals, children's hospitals, and cancer hospitals. *See id.* (citing 42 U.S.C. § 1395*l*(t)(7)(D)(ii), (t)(13)). If anything, the fact that *other* parts of the Medicare statute authorize differential treatment for *other* groups of hospitals undercuts HHS's argument that the Secretary may specifically target 340B hospitals, for which Subclause (II) does not authorize differential treatment. Indeed, as Plaintiffs pointed out in their opening brief, Pls.' Mem. at 27–28, Subclause (I) expressly authorizes the Secretary to "vary" payments "by hospital group," and Subclause (II) has no similar authority. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), (II); *see also id.* § 1395*l*(t)(2)(E) (authorizing the Secretary to "establish . . . other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals"). ASP is a nationwide measure of drug

value, *see* 42 U.S.C. § 1395w-3a, and, unlike other provisions of the OPPS statute, Subclause (II) contains no authority for the Secretary to adjust ASP differently for different hospital groups.

HHS also protests that the 340B Provisions of the OPPS Rule were not designed to undermine the purposes of the 340B Program. HHS contends that is so, first, because the 340B Program implements drug discounts, and the 2018 OPPS Rule affects only the amount that hospitals are reimbursed—not the discounts they receive when acquiring drugs. Defs.' Mem. at 36–37. HHS argues that any difference between the discounted drug prices and the amount reimbursed "is an ancillary benefit to providers of a misalignment between acquisition costs and reimbursements, rather than a purpose of the 340B Program." *Id.* at 37 n.13. This argument completely ignores Congress's stated purpose in enacting the 340B Program. Much as HHS may disagree with the 340B Program on policy grounds, the core purpose of that Program is to enable hospitals serving underserved populations "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). In 2010, Congress reaffirmed that purpose by expanding the Program to additional groups of hospitals. *See* Pls.' Mem. at 30 (discussing 42 U.S.C. § 256b(a)(4)(M)–(O)). HHS cannot seriously deny that it is undermining the purpose of the Program by drastically reducing the difference between reimbursements and discounted prices.[11]

[11] Many of HHS's policy objections to the 340B Program rest on inaccurate factual statements. For example, HHS asserted that reducing reimbursements for 340B Drugs would result in lower patient copays. Ex. A, 82 Fed. Reg. at 52,495–96, 52,498. But as several commenters pointed out, most Medicare beneficiaries do not cover their own copays and would not benefit from this reduction. *See, e.g.*, Ex. C at 12 (AHA Comment); Ex. E at 10 (AEH Comment). Commenters also pointed out that HHS's drastic reimbursement cuts in the 340B Provisions of the 2018 OPPS Rule would likely *raise* copays for the majority of Medicare beneficiaries because of corresponding budget-neutrality adjustments. *See* Ex. C at 12 (AHA Comment); Ex. E at 9–10 (AEH Comment). And more fundamentally, HHS may not target and undermine a congressionally mandated program based on its own policy disagreements with that program.

Second, HHS argues that the 340B Provisions of the OPPS Rule were not intended to undermine the purposes of the 340B Program because they sought only to make Medicare reimbursements "more aligned" with providers' acquisition costs, not to "*eliminate*" the difference between the two. Defs.' Mem. at 37 (emphasis in original). That is, at best, a purely semantic distinction, and in any event, when an agency has specifically attempted to undermine a program enacted by Congress, it is no answer that the agency did not *entirely* eliminate the program's benefits, but only *mostly* so.

V. THE COURT SHOULD GRANT PLAINTIFFS FINAL JUDGMENT UNDER RULE 65(a)(2).

Plaintiffs have previously demonstrated that they meet each of the four preliminary injunction factors. *See* Pls.' Mem. at 21–33. Plaintiffs reaffirm the arguments in their Motion regarding each factor. Notably, Defendants have conceded the "irreparable harm" factor by failing to address it. *See* Defs.' Mem. at 39–41 (addressing likelihood of success on the merits, balance of equities, and public interest, but not irreparable harm); *see also Texas v. United States*, 798 F.3d 1108, 1115 (D.C. Cir. 2015) (noting that, under D.D.C. Local Rule 7(b), the district court may "deem[] as conceded any of a movant's arguments to which the opposing party fails to respond").

As Plaintiffs noted in their Motion for a Preliminary and Permanent Injunction, if the Court consolidates the merits with the hearing on the preliminary injunction, it need not consider the four preliminary injunction factors. Pls.' Mem. at 34–35 (citing, *e.g*, *March for Life v. Burwell*, 128 F. Supp. 3d 116, 124 (D.D.C. 2015)). While Plaintiffs have satisfied the

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See Utility Air Reg. Grp. v. EPA, 134 S. Ct. 1427, 2445 (2014) ("An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").

requirements for a preliminary injunction, the Court should reach the merits and issue a final judgment in favor of Plaintiffs.

CONCLUSION

The parties have fully briefed all of the issues in this case three times. As Defendants acknowledge, "this suit is a near carbon copy of [the] suit Plaintiffs filed last year in this Court." Defs.' Mem. at 15. HHS has had more than an ample opportunity to brief the legal issues in this case, and there are no factual issues to be resolved. Plaintiffs respectfully ask that the Court deny Defendants' Motion to Dismiss, advance its determination of the merits under Rule 65(a)(2), enter judgment for the Plaintiffs, and award the relief requested in the Complaint.

Dated: September 26, 2018

Respectfully submitted,

/s/ William B. Schultz

William B. Schultz (DC Bar No. 218990)
Ezra B. Marcus (DC Bar No. 252685)
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1800 M Street, NW, Suite 1000
Washington, DC 20036
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Fax: 202-822-8136
wschultz@zuckerman.com
emarcus@zuckerman.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on September 26, 2018, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ William B. Schultz
William B. Schultz

Supplemented Exhibit L

PAYMENT DATE: 02/06/18 EASTERN MAINE MEDICAL CENTER RUN DATE: 02/06/18
MEDICARE-ACUTE

ELECTRONIC MEDIA REMITTANCE ADVICE SINGLE OUTPATIENT SERVICE LINE DETAIL REPORT

EASTERN MAINE MEDICAL CENTER
43 WHITING HILL RD
BREWER ME 044121005
1790789147

FISCAL PERIOD
ENDING 180930 14011

BILL TYPE 131

NAME [redacted] PCN 000228327128 SERVICE FROM 20180117 THRU 20180117
POL# [redacted] ICN 005440790 PAT STAT CLAIM STAT 1 CLAIM # 603
MRN 00941300 CRN 21802300601207MEA

CHARGES:		PPS DATA:		PAYMENT DATA:	
REPORTED	19319.70	DRG NUMBER		REIMB RATE	0.31
NCOVD	.00	DRG AMOUNT	.00	PRIMARY PAY	.00
DENIED	.00	DRG/OPER	.00	PROF COMP	.00
		DRG/CAPITAL	.00	ESRD AMT	.00
DAYS:		OUTLIER ( )	.00	HCPCS AMT	6156.41
		NON LAB CHRG	.00	OTH ADJ AMT	.00
COST REPT	0	NEG REIMB	.00	CONT ADJ AMT	13025.29
COVD/UTIL	0	TOTAL DEDUCT	.00	INTEREST	.00
NON COVERED	0	COINSURANCE	1231.28	PAT REFUND	.00
LTR	0	MSP LIAB MET	.00	NET REIMB AMT	4826.63
		CO-PAY AMT	.00		

REMARK CDS: MA01 M20

GROUP AND STD CDS:	CO 16	CO 45	CO 253	PR 2		
ADJ AMT:	138.00	13025.29	98.50	1231.28	.00	.00

CHECK/EFT NUMBER: EFT1032886

CROSS-OVER PAYER NAME:

COMMENT 1:

COMMENT 2:

COV EXPR DATE: CLM RCVD DATE: 01/23/2018

REV	DATE	HCPCS/HIPPS	MODS	UNIT/VISIT	CHGS	ALLOWED	GC	RSN	AMT	RMK CD	APC
0331	01/17/18	96401	PO	0	138.00	.00	CO 16		138.00	M20	
HEALTHCARE POLICY ID		L33394									
		A52855									
0636	01/17/18	J3357	JGPO	45	19181.70	4826.63	CO 45		13025.29		09261
							CO 253		98.50		
							PR 2		1231.28		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID 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: J3357

4. Date the service or item was received: 01/17/2018

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.)
2/06/18

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 $7045.3.

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: Peggy Stavitz, VP Enterprise Revenue Cycle
43 Whiting Hill Rd, Brewer, ME 04412. (207) 973-4642

11. Signature of person appealing: Peggy Stavitz

12. Date signed: 3/19/18

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

Form CMS-20027 (12/10)

May 31, 2018

EASTERN MAINE MEDICAL CENTER
43 WHITING HILL RD
BREWER, ME 04412-1005

Medicare Number of Beneficiary:
[redacted]

Beneficiary Contact Information

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

Provider Contact Information

If you have questions, write or call:

National Government Services, Inc.
Medicare Appeals Department
P.O. Box 7111
Indianapolis, IN 46207-7111
(888) 855-4356

Re: Appeal # 1-7428674601
Medicare Beneficiary: [redacted]

Dear Eastern Maine Medical Center,

This letter is in response to your redetermination request that was received in our office on April 03, 2018. The redetermination was requested for the following dates of service.

Claims List

Record #	Claim #	Dates of Service
Claim #1	21802300601207MEA	01/17/2018 - 01/17/2018

Your redetermination request has been dismissed because it did not form a valid request for redetermination. In order to process a redetermination request, we need the following items to be addressed:

Your request has been dismissed because under the Outpatient Prospective Payment System (OPPS), CMS annually sets payment rates for covered outpatient services, including covered outpatient drugs. Section 1848(i)(1) of the Act prohibits administrative and judicial review of these periodic adjustments. (Reference: 42 U.S.C. § 1395l(t)(14)(A)(iii)(II) and 42 U.S.C. § 1395l(t)(12)(A), (C), (E)). You may file your request again if it has been 120 days or less since the date of receipt of the initial determination notice. When you file your request, please make sure you have addressed all of the above listed items and send your request to our office at the address noted above.

If you disagree with this dismissal, you have two options:

1. You may request that we vacate our dismissal. We will vacate our dismissal if you demonstrate that you have good and sufficient cause for failing to address all of the items listed above in your request. Your request to vacate this dismissal **must be received at the address above within six months of the date of receipt of this letter.**

2. If you think we have incorrectly dismissed your request (that is, you believe you did address all of the above listed items in your request), you may request a reconsideration of this dismissal by a Qualified Independent Contractor (QIC). **Your request must be received by the QIC at the address below within 60 days of receipt of this letter.** In your request, please explain why you believe the dismissal was incorrect. Please note that the QIC will not consider any evidence for establishing coverage of the claims being appealed. Their examination will be limited to whether or not the dismissal was appropriate. Please send your request to:

   C2C Solutions Inc.
   Medicare Part A East
   P.O. Box 45305
   Jacksonville, FL 32232-5305

Sincerely,

Carol Smith
National Government Services, Inc.
A Medicare Contractor

cc: [redacted]

Appeal # 1-7428674601

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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: J3357
4. Date the service or item was received: 01/17/2018
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.)
May 31, 2018

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

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. The payment(s) should be $7045.30

7. Additional information Medicare should consider:
The new rate violates 42 U.S.C. §13951(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 reconsideration.
☒ I do not have evidence to submit.

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

10. Name, address, and telephone number of person appealing: Jason Cunningham, Sys Dir Rev Integrity, EMHS
140 Academy St. Prasanna Building, Presque Isle, ME 04769 Phone (207) 768-4278

11. Signature of person appealing: Jason Cunningham

12. Date signed: 07/17/2018

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

Form CMS-20033 (12/10)

Medicare Appeal Number:
1-7714878674

WPCM2500 - 002557 - 001 OF 001

Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc.
Medicare Part A
East QIC Contractor
P.O. Box 45307
Jacksonville, FL
32232-5307

Telephone number:
904-224-7446

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

September 07, 2018

EASTERN MAINE MEDICAL CENTER
140 ACADEMY ST
PRASANNA BLDG
PRESQUE ISLE, ME 04769

RE:
Beneficiary: [redacted]
Med ID#: [redacted]
Appellant: Eastern Maine Medical Center

Dear J. Cunningham:

This letter is to inform you that your request for a QIC (Qualified Independent Contractor) reconsideration of your redetermination dismissal is UNFAVORABLE. Your redetermination request was dismissed by National Government Services Inc. because the party that requested a redetermination does not have a right to a redetermination since administrative review is not available for this issue. In accordance with 42 Code of Federal Regulations (CFR) Section 405.952, because administrative review is not available for this issue, there is not sufficient cause to reverse the contractor's dismissal. Therefore, the contractor's original dismissal stands.

In accordance with 42 CFR Section 405.974 (b)(3), a QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review. You have no further appeal rights on this case.

If you have questions:
Beneficiaries: contact 1-800-MEDICARE (1-800-633-4227)
Providers: contact the Medicare Administrative Contractor
Sincerely,

Christine Smith

CHRISTINE SMITH,
cc: [redacted]

Medicare Appeal Number:

1-7714878674

Appeal Details

Appellant	Eastern Maine Medical Center
AC	National Government Services Inc.(14111)

Redetermination Number	Beneficiary Name/ HIC#	Date of Service
1-7428674601	[redacted]	01/17/18

THIS IS NOT A BILL – Keep this letter or a copy for your records.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

REQUEST FOR ADMINISTRATIVE LAW JUDGE (ALJ) HEARING OR REVIEW OF DISMISSAL

Section 1: Which Medicare Part are you appealing (if known)? (*Check one*)

☐ Part A ☒ Part B ☐ Part C (*Medicare Advantage*) or Medicare Cost Plan ☐ Part D (*Prescription Drug Plan*)

Section 2: Which party are you, or which party are you representing? (*Check one*)

☐ The Medicare beneficiary or enrollee, or a successor (such as an estate), who received or requested the items or services being appealed, or is appealing a Medicare Secondary Payer issue.

☒ The provider or supplier that furnished the items or services to the Medicare beneficiary or enrollee, a Medicaid State agency, or an applicable plan appealing a Medicare Secondary Payer issue.

☐ Other. *Please explain*:

Section 3: What is your (the appealing party's) information? (*Representative information in next section*)

Name (*First, Middle Initial, Last*)		Firm or Organization (*if applicable*)	
Jason T Cunningham		Eastern Maine Healthcare Systems	
Address where appeals correspondence should be sent	City	State	ZIP Code
140 Academy Street, Parsanna Building	Presque Isle	Maine	04769
Telephone Number	Fax Number	E-Mail	
(207) 768-4278	(207) 768-4364	jcunningham2@emhs.org	

Section 4: What is the representative's information? (*Skip if you do not have a representative*)

Name		Firm or Organization (*if applicable*)	
Mailing Address	City	State	ZIP Code
Telephone Number	Fax Number	E-Mail	

Did you file an appointment of representation (form CMS-1696) or other documents authorizing your representation at a prior level of appeal?

☒ No. *Please file the document(s) with this request.*
☐ Yes

Section 5: What is being appealed? *Submit a separate request for each Reconsideration or Dismissal that you wish to appeal. If the appeal involves multiple beneficiaries or enrollees, use the multiple claim attachment (OMHA-100A).*

Name of entity that issued the Reconsideration or Dismissal (*or attach a copy of the Reconsideration or Dismissal*)		Reconsideration (Medicare Appeal or Case) Number (*or attach a copy of the Reconsideration or Dismissal*)	
C2C Innovative Solutions, Inc Part A East QIC Contractor		1-7714878674	
Beneficiary or Enrollee Name		Health Insurance Claim Number	
[redacted]		[redacted]	
Beneficiary or Enrollee Mailing Address	City	State	ZIP Code
[redacted]	[redacted]	[redacted]	[redacted]
What item(s) or service(s) are you appealing? (*N/A if appealing a Dismissal*)		Date(s) of service being appealed (*if applicable*)	
Drug Payment		01/17/2018	
Supplier or Provider Name (*N/A for Part D appeals*)		Supplier or Provider Telephone Number (*N/A for Part D appeals*)	
Eastern Maine Medical Center		(207) 973-5000	
Supplier or Provider Mailing Address (*N/A for Part D appeals*)	City	State	ZIP Code
43 Whiting Hill Road	Bangor	ME	04412

Section 6: For appeals of prescription drugs ONLY (*Skip for all other appeals*)

Part D Prescription Drug Plan Name	What drug(s) are you appealing?

Are you requesting an expedited hearing?
(*An expedited hearing is only available if your appeal is not solely related to payment (for example, you do not have the drug) and applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function*)

☒ No. ☐ Yes. *On a separate sheet, please explain or have your prescriber explain why applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function.*

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed? (*Attach a continuation sheet if necessary*)

See attached continuation sheet.

Section 8: Are you submitting evidence with this request, or do you plan to submit evidence?

☒ I am not planning to submit evidence at this time. (*Skip to Section 9, below*)

☐ I am submitting evidence with this request.

☐ I plan to submit evidence. Indicate what you plan to submit and when you plan to submit it:

Was the evidence already submitted for the matter that you are appealing?

☐ No. *Part A and Part B appeals only. If you are a provider or supplier, or a provider or supplier that is representing a beneficiary, you must include a statement explaining why the evidence is being submitted for the first time and was not submitted previously.*

☐ Yes.

Section 9: Is there other information about your appeal that we should know?

Are you aggregating claims to meet the amount in controversy requirement? (*If yes, attach your aggregation request. See 42 C.F.R. § 405.1006(e) and (f), and 423.1970(c) for request requirements.*)	☒ No	☐ Yes
Are you waiving the oral hearing before an ALJ and requesting a decision based on the record? (*If yes, attach a completed form OMHA-104 or other explanation. N/A if requesting review of a dismissal.*)	☐ No	☒ Yes
Does the request involve claims that were part of a statistical sample? (*If yes, please explain the status of any appeals for claims in the sample that are not included in this request.*)	☒ No	☐ Yes

Section 10: Certification of copies sent to other parties (*Part A and Part B appeals only*)

If another party to the claim or issue that you are appealing was sent a copy of the Reconsideration or Dismissal, you must send a copy of your request for an ALJ hearing or review of dismissal to that party.

Indicate the party (or their representative) to whom and address where you are sending a copy of the request, and when the copy will be sent *(attach a continuation sheet if there are multiple parties)*.

Name of Recipient		
Mailing Address		
City	State	ZIP Code
Date of Mailing		

☒ Check here if no other parties were sent a copy of the Reconsideration or Dismissal.

Section 11: Filing instructions

Your appealed claim must meet the current amount in controversy requirement to file an appeal. See the Reconsideration or Dismissal or visit www.hhs.gov/omha for information on the current amount in controversy. Send this request form to the entity in the appeal instructions that came with your reconsideration (for example, requests for hearing following a Part C reconsideration are generally sent to the entity that conducted the reconsideration). If instructed to send to OMHA, use the addresses below.

Beneficiaries and enrollees, send your request to:	**For expedited Part D appeals, send your request to:**	**All other appellants, send your request to:**
OMHA Centralized Docketing Attn: Beneficiary Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing Attn: Expedited Part D Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316

We must receive this request within 60 calendar days after you received the Reconsideration or Dismissal that you are appealing. We will assume that you received the Reconsideration or Dismissal 5 calendar days after the date of the Reconsideration or Dismissal, unless you provide evidence to the contrary. *If you are filing this request late, attach a completed form OMHA-103 or other explanation for the late filing.*

PRIVACY ACT STATEMENT

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). 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 Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed?

(continuation sheet) 1-7714878674

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 $7,045.30.

The new rate violates 42 U.S.C. § 1359*l*(t)(14)(A)(iii)(II), the authority to pay for the 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

WAIVER OF RIGHT TO AN ADMINISTRATIVE LAW JUDGE (ALJ) HEARING

Instructions: If you are an appellant or other party to a hearing before an Administrative Law Judge (ALJ) with the Office of Medicare Hearings and Appeals (OMHA), you may waive your right to the oral hearing and request that a decision be made based on the record. When you waive your right to a hearing, either an ALJ or an attorney adjudicator may decide your appeal.

If you are the appellant and want your appeal to be decided without a hearing, complete this form and include it with your request for an ALJ hearing (form OMHA-100) or, if you have already filed your request for an ALJ hearing, send this form to the assigned OMHA adjudicator (visit www.hhs.gov/omha and use the appeal status lookup tool to find your assigned adjudicator). Any other party that wants the appeal to be decided without a hearing may complete this form and send it to the assigned OMHA adjudicator. If an adjudicator has not yet been assigned, send this form to OMHA Central Operations, Attention: Waiver Mail Stop (visit www.hhs.gov/omha or call the number at the bottom of this form for the full mailing address).

If all of the parties to the appealed matter who would be sent a notice of hearing do not also waive the ALJ hearing (for example, a provider or supplier that was held financially responsible for the denied items or services), or the assigned ALJ or attorney adjudicator believes a hearing is necessary to decide the appeal, a hearing may be held by an ALJ, and the ALJ will issue the decision or other dispositive order in the appeal.

Section 1: What is the OMHA appeal number or the reconsideration (Medicare appeal or case) number?

OMHA Appeal Number *(if known)*	Reconsideration Number *(if OMHA appeal number not known)*
	1-7714878674

Section 2: What is the information for the party waiving the hearing? *(Representative information in next section)*

Name *(First, Middle initial, Last)*	Firm or Organization *(if applicable)*	Telephone Number
Jason T Cunningham	Eastern Maine Healthcare Systems	207-768-4278

Section 3: What is the representative's information? *(Skip if you do not have a representative)*

Name	Firm or Organization *(if applicable)*	Telephone Number

Section 4: Explain why you wish to waive your right to an ALJ hearing and have the appeal decided based on the record:

There are no factual disputes in this appeal, which challenges provisions of the 2018 hospital OPPS rule regarding payments under the 340B Program. Furthermore, an ALJ would not have authority to invalidate these provisions of the regulation, and thus could not issue a favorable decision in this appeal. 42 C.F.R. § 405.1063(a)

Section 5: Acknowledge the following by signing and dating this form:

I understand that I may have a right to a hearing before an ALJ. I understand that having an ALJ hearing would provide me with the opportunity to present oral testimony and to present and/or question witnesses. I understand that this opportunity to be seen and heard could be helpful to the ALJ in making a decision.

I understand that my waiver of an ALJ hearing does not affect the right of other parties to an ALJ hearing.

I understand that even if all parties waive their right to an ALJ hearing, if the ALJ determines that a hearing is necessary to obtain testimony from a non-party, the ALJ may still hold a hearing to obtain that testimony. If a hearing is held, the ALJ will offer the parties the opportunity to appear at the hearing (which may be in person, by telephone or by video-teleconference), but may hold the hearing even if none of the parties decide to appear. I understand that if a hearing is held and I do not attend the hearing, I still have the right to submit written evidence.

I understand that my waiver may be denied if it is determined that my attendance is necessary to decide the appeal.

If I change my mind and decide that I would like a hearing before an ALJ, I understand I must submit a withdrawal of this waiver (see form OMHA-114) before a notice of decision or other dispositive order is issued by an ALJ or attorney adjudicator. If I withdraw my waiver of hearing, I understand that any applicable time frame to decide the appeal may be extended in order to schedule and hold the hearing. I also understand that if a hearing has already been conducted, the ALJ may decide not to conduct another one.

Party or Representative Signature	Date
Jason T. Cunningham	9/21/18

Privacy Act Statement

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). 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 Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Medicare Appeal Number:
1-7714878674

Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc.
Medicare Part A
East QIC Contractor
P.O. Box 45307
Jacksonville, FL
32232-5307

Telephone number:
904-224-7446

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

September 07, 2018

EASTERN MAINE MEDICAL CENTER
140 ACADEMY ST
PRASANNA BLDG
PRESQUE ISLE, ME 04769

RE:
Beneficiary: [redacted]
Med ID#: [redacted]
Appellant: Eastern Maine Medical Center

Dear J. Cunningham:

This letter is to inform you that your request for a QIC (Qualified Independent Contractor) reconsideration of your redetermination dismissal is UNFAVORABLE. Your redetermination request was dismissed by National Government Services Inc. because the party that requested a redetermination does not have a right to a redetermination since administrative review is not available for this issue. In accordance with 42 Code of Federal Regulations (CFR) Section 405.952, because administrative review is not available for this issue, there is not sufficient cause to reverse the contractor's dismissal. Therefore, the contractor's original dismissal stands.

In accordance with 42 CFR Section 405.974 (b)(3), a QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review. You have no further appeal rights on this case.

If you have questions:
Beneficiaries: contact 1-800-MEDICARE (1-800-633-4227)
Providers: contact the Medicare Administrative Contractor
Sincerely,

Christine Smith

CHRISTINE SMITH,
cc: [redacted]

Medicare Appeal Number:

1-7714878674

Appeal Details

Appellant	Eastern Maine Medical Center
AC	National Government Services Inc.(14111)

Redetermination Number	Beneficiary Name/ HIC#	Date of Service
1-7428674601	[redacted]	01/17/18

THIS IS NOT A BILL – Keep this letter or a copy for your records.

Supplemented Exhibit N

PAYMENT DATE: 02/20/18 EASTERN MAINE MEDICAL CENTER RUN DATE: 02/20/18
MEDICARE-ACUTE

ELECTRONIC MEDIA REMITTANCE ADVICE SINGLE OUTPATIENT SERVICE LINE DETAIL REPORT

EASTERN MAINE MEDICAL CENTER
43 WHITING HILL RD
BREWER ME 044121005
1790789147

FISCAL PERIOD
ENDING 180930 14011

BILL TYPE 131

NAME [redacted] PCN 182907808014 SERVICE FROM 20180115 THRU 20180115
POL# [redacted] ICN 005531503 PAT STAT CLAIM STAT 19 CLAIM # 713
MRN 01229884 CRN 21803700743607MEA

CHARGES:		PPS DATA:		PAYMENT DATA:	
REPORTED	21883.96	DRG NUMBER		REIMB RATE	0.31
NCOVD	.00	DRG AMOUNT	.00	PRIMARY PAY	.00
DENIED	.00	DRG/OPER	.00	PROF COMP	.00
		DRG/CAPITAL	.00	ESRD AMT	.00
DAYS:		OUTLIER ( )	.00	HCPCS AMT	5865.66
		NON LAB CHRG	.00	OTH ADJ AMT	.00
COST REPT	0	NEG REIMB	.00	CONT ADJ AMT	15543.40
COVD/UTIL	0	TOTAL DEDUCT	.00	INTEREST	.00
NON COVERED	0	COINSURANCE	1268.12	PAT REFUND	.00
LTR	0	MSP LIAB MET	.00	NET REIMB AMT	4970.99
		CO-PAY AMT	.00		

REMARK CDS: MA01 MA18

GROUP AND STD CDS:	OA STS19	CO 45	CO 253	PR 2	CO 97	
ADJ AMT:	.00	15423.40	101.45	1268.12	120.00	.00

CHECK/EFT NUMBER: EFT1036432

CROSS-OVER PAYER NAME: BCBS OF MASSACHUSETTS INC.

COMMENT 1:

COMMENT 2:

COV EXPR DATE: CLM RCVD DATE: 02/06/2018

REV	DATE	HCPCS/HIPPS	MODS	UNIT/VISIT	CHGS	ALLOWED	GC	RSN	AMT	RMK CD	APC
0280	01/15/18	G0463	25PO	1	267.00	90.17	CO	45	151.99		05012
							CO	253	1.84		
							PR	2	23.00		
0300	01/15/18	36415	PO	1	7.00	.00	CO	97	7.00		
0300	01/15/18	80053	PO	1	63.00	.00	CO	97	63.00		
0300	01/15/18	85025	PO	1	50.00	.00	CO	97	50.00		
0335	01/15/18	96413	PO	1	536.00	235.99	CO	45	234.98		05694
							CO	253	4.82		
							PR	2	60.21		
0335	01/15/18	96417	PO	1	279.00	46.16	CO	45	220.13		05692
							CO	253	.94		
							PR	2	11.77		
0636	01/15/18	J9306	JGPO	420	11025.00	2752.45	CO	45	7514.22		01471
							CO	253	56.17		
							PR	2	702.16		
0636	01/15/18	J9355	JGPO	32	9656.96	1846.22	CO	45	7302.08		01613
							CO	253	37.68		
							PR	2	470.98		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID 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: J9306 and J9355

4. Date the service or item was received: 01/15/2018

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.)
2/20/18

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. The payment(s) should be $4017.69 (J9306) and $2694.88 (J9355).

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: Peggy Stavitz, VP Enterprise Revenue Cycle
43 Whiting Hill Rd, Brewer, ME 04412. (207) 973-4642

11. Signature of person appealing: Peggy Stavitz

12. Date signed: 3/19/18

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

Form CMS-20027 (12/10)

May 30, 2018

Eastern Maine Medical Center
43 WHITING HILL RD
BREWER, ME 04412

Medicare Number of Beneficiary:
[redacted]

Beneficiary Contact Information

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

Provider Contact Information

If you have questions, write or call:

National Government Services, Inc.
Medicare Appeals Department, P.O. Box 7111
Indianapolis, IN 46207-7111
(888) 855-4356

Re: Appeal # 1-7427073361
Medicare Beneficiary: [redacted]
21803700743607MEA
01/15/2018

Dear Eastern Maine Medical Center,

This letter is in response to your redetermination request that was received in our office on April 03, 2018. The redetermination was requested for the following dates of service.

Claims List

Record #	Claim #	Dates of Service
Claim #1	21803700743607MEA	01/15/2018 - 01/15/2018

Your redetermination request has been dismissed because it did not form a valid request for redetermination. In order to process a redetermination request, we need the following items to be addressed:

Your request has been dismissed because under the Outpatient Prospective Payment System(OPPS), CMS annually sets payment rates for covered outpatient services, including covered outpatient drugs. Section 1848(i)(1) of the Act prohibits administrative and judicial review of these periodic adjustments. (Reference: 42 U.S.C. § 1395l (t) (14) (A) (iii) (II) and 42 U.S.C. §1395l (t) (12)(A), (C), (E)). You may file your request again if it has been 120 days or less since the date of receipt of the initial determination notice. When you file your request, please make sure you have addressed all of the above listed items and send your request to our office at the address noted above.

If you disagree with this dismissal, you have two options:

1. You may request that we vacate our dismissal. We will vacate our dismissal if you demonstrate that you have good and sufficient cause for failing to address all of the items listed above in your request. Your request to vacate this dismissal **must be received at the address above within six months of the date of receipt of this letter**.

2. If you think we have incorrectly dismissed your request (that is, you believe you did address all of the above listed items in your request), you may request a reconsideration of this dismissal by a Qualified Independent Contractor (QIC). **Your request must be received by the QIC at the address below within 60 days of receipt of this letter**. In your request, please explain why you believe the dismissal was incorrect. Please note that the QIC will not consider any evidence for establishing coverage of the claims being appealed. Their examination will be limited to whether or not the dismissal was appropriate. Please send your request to:

   C2C Solutions Inc.
   Medicare Part A East
   P.O. Box 45305
   Jacksonville, FL 32232-5305

Sincerely,

Gabrielle Logalbo
National Government Services, Inc.
A Medicare Contractor

cc: [redacted]

Appeal # 1-7427073361

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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: J9306 and J9355
4. Date the service or item was received: 01/15/2018
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.)
May 30, 2018

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

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. The payment(s) should be $4017.69 (J9306) and $2694.88(J9355).

7. Additional information Medicare should consider:
The new rate violates 42 U.S.C. §13951(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 reconsideration.
☒ I do not have evidence to submit.

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

10. Name, address, and telephone number of person appealing: Jason Cunningham, Sys Dir Rev Integrity, EMHS
140 Academy St. Prasanna Building, Presque Isle, ME 04769 Phone (207) 768-4278

11. Signature of person appealing: Jason Cunningham

12. Date signed: 07/17/2018

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

Form CMS-20033 (12/10)

Medicare Appeal Number:
1-7714878756

WPCM2490 - 000081 - 001 OF 002

September 06, 2018

EASTERN MAINE MEDICAL CENTER
140 ACADEMY ST
PRASANNA BLDG
PRESQUE ISLE, ME 04769

RE:
Beneficiary: [redacted]
Med ID#: [redacted]
Appellant: Eastern Maine Medical Center

Dear J. Cunningham:

This letter is to inform you that your request for a QIC (Qualified Independent Contractor) reconsideration of your redetermination dismissal is UNFAVORABLE. Your redetermination request was dismissed by National Government Services Inc. because the party that requested a redetermination does not have a right to a redetermination since administrative review is not available for this issue. In accordance with 42 Code of Federal Regulations (CFR) Section 405.952, because administrative review is not available for this issue, there is not sufficient cause to reverse the contractor's dismissal. Therefore, the contractor's original dismissal stands.

In accordance with 42 CFR Section 405.974 (b)(3), a QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review. You have no further appeal rights on this case.

If you have questions:
Beneficiaries: contact 1-800-MEDICARE (1-800-633-4227)
Providers: contact the Medicare Administrative Contractor

Sincerely,

Christine Smith

CHRISTINE SMITH,
cc: [redacted]

Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc.
Medicare Part A
East QIC Contractor
P.O. Box 45307
Jacksonville, FL
32232-5307

Telephone number:
904-224-7446

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

Medicare Appeal Number:

1-7714878756

Appeal Details

Appellant	Eastern Maine Medical Center
AC	National Government Services Inc.(14111)

Redetermination Number	Beneficiary Name/ HIC#	Date of Service
1-7427073361	[redacted]	01/15/18
		01/15/18

THIS IS NOT A BILL – Keep this letter or a copy for your records.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

REQUEST FOR ADMINISTRATIVE LAW JUDGE (ALJ) HEARING OR REVIEW OF DISMISSAL

Section 1: Which Medicare Part are you appealing (if known)? (*Check one*)

☐ Part A ☒ Part B ☐ Part C (*Medicare Advantage*) or Medicare Cost Plan ☐ Part D (*Prescription Drug Plan*)

Section 2: Which party are you, or which party are you representing? (*Check one*)

☐ The Medicare beneficiary or enrollee, or a successor (such as an estate), who received or requested the items or services being appealed, or is appealing a Medicare Secondary Payer issue.

☒ The provider or supplier that furnished the items or services to the Medicare beneficiary or enrollee, a Medicaid State agency, or an applicable plan appealing a Medicare Secondary Payer issue.

☐ Other. *Please explain*:

Section 3: What is your (the appealing party's) information? (*Representative information in next section*)

Name (*First, Middle Initial, Last*)		Firm or Organization (*if applicable*)	
Jason T Cunningham		Eastern Maine Healthcare Systems	
Address where appeals correspondence should be sent	City	State	ZIP Code
140 Academy Street, Parsanna Building	Presque Isle	Maine	04769
Telephone Number	Fax Number	E-Mail	
(207) 768-4278	(207) 768-4364	jcunningham2@emhs.org	

Section 4: What is the representative's information? (*Skip if you do not have a representative*)

Name		Firm or Organization (*if applicable*)	
		Zuckerman Spaeder LLP	
Mailing Address	City	State	ZIP Code
Telephone Number	Fax Number	E-Mail	

Did you file an appointment of representation (form CMS-1696) or other documents authorizing your representation at a prior level of appeal?

☒ No. *Please file the document(s) with this request.*
☐ Yes

Section 5: What is being appealed? *Submit a separate request for each Reconsideration or Dismissal that you wish to appeal. If the appeal involves multiple beneficiaries or enrollees, use the multiple claim attachment (OMHA-100A).*

Name of entity that issued the Reconsideration or Dismissal (*or attach a copy of the Reconsideration or Dismissal*)		Reconsideration (Medicare Appeal or Case) Number (*or attach a copy of the Reconsideration or Dismissal*)	
C2C Innovative Solutions, Inc Part A East QIC Contractor		1-7714878756	
Beneficiary or Enrollee Name		Health Insurance Claim Number	
[redacted]		[redacted]	
Beneficiary or Enrollee Mailing Address	City	State	ZIP Code
[redacted]	[redacted]	[redacted]	[redacted]
What item(s) or service(s) are you appealing? (*N/A if appealing a Dismissal*)		Date(s) of service being appealed (*if applicable*)	
Drug Payment		01/15/2018	
Supplier or Provider Name (*N/A for Part D appeals*)		Supplier or Provider Telephone Number (*N/A for Part D appeals*)	
Eastern Maine Medical Center		(207) 973-5000	
Supplier or Provider Mailing Address (*N/A for Part D appeals*)	City	State	ZIP Code
43 Whiting Hill Road	Bangor	ME	04412

Section 6: For appeals of prescription drugs ONLY (*Skip for all other appeals*)

Part D Prescription Drug Plan Name	What drug(s) are you appealing?

Are you requesting an expedited hearing?
(*An expedited hearing is only available if your appeal is not solely related to payment (for example, you do not have the drug) and applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function*)

☒ No. ☐ Yes. *On a separate sheet, please explain or have your prescriber explain why applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function.*

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed? (*Attach a continuation sheet if necessary*)

See attached continuation sheet.

Section 8: Are you submitting evidence with this request, or do you plan to submit evidence?

☒ I am not planning to submit evidence at this time. (*Skip to Section 9, below*)

☐ I am submitting evidence with this request.

☐ I plan to submit evidence. Indicate what you plan to submit and when you plan to submit it:

Was the evidence already submitted for the matter that you are appealing?	☐ No. *Part A and Part B appeals only. If you are a provider or supplier, or a provider or supplier that is representing a beneficiary, you must include a statement explaining why the evidence is being submitted for the first time and was not submitted previously.* ☐ Yes.

Section 9: Is there other information about your appeal that we should know?

Are you aggregating claims to meet the amount in controversy requirement? (*If yes, attach your aggregation request. See 42 C.F.R. § 405.1006(e) and (f), and 423.1970(c) for request requirements.*)	☒ No	☐ Yes
Are you waiving the oral hearing before an ALJ and requesting a decision based on the record? (*If yes, attach a completed form OMHA-104 or other explanation. N/A if requesting review of a dismissal.*)	☐ No	☒ Yes
Does the request involve claims that were part of a statistical sample? (*If yes, please explain the status of any appeals for claims in the sample that are not included in this request.*)	☒ No	☐ Yes

Section 10: Certification of copies sent to other parties (*Part A and Part B appeals only*)

If another party to the claim or issue that you are appealing was sent a copy of the Reconsideration or Dismissal, you must send a copy of your request for an ALJ hearing or review of dismissal to that party.

Indicate the party (or their representative) to whom and address where you are sending a copy of the request, and when the copy will be sent *(attach a continuation sheet if there are multiple parties)*.

Name of Recipient		
Mailing Address		
City	State	ZIP Code
Date of Mailing		

☒ Check here if no other parties were sent a copy of the Reconsideration or Dismissal.

Section 11: Filing instructions

Your appealed claim must meet the current amount in controversy requirement to file an appeal. See the Reconsideration or Dismissal or visit www.hhs.gov/omha for information on the current amount in controversy. Send this request form to the entity in the appeal instructions that came with your reconsideration (for example, requests for hearing following a Part C reconsideration are generally sent to the entity that conducted the reconsideration). If instructed to send to OMHA, use the addresses below.

Beneficiaries and enrollees, send your request to:	**For expedited Part D appeals, send your request to:**	**All other appellants, send your request to:**
OMHA Centralized Docketing Attn: Beneficiary Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing Attn: Expedited Part D Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316

We must receive this request within 60 calendar days after you received the Reconsideration or Dismissal that you are appealing. We will assume that you received the Reconsideration or Dismissal 5 calendar days after the date of the Reconsideration or Dismissal, unless you provide evidence to the contrary. *If you are filing this request late, attach a completed form OMHA-103 or other explanation for the late filing.*

PRIVACY ACT STATEMENT

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). 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 Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed?

(continuation sheet) 1-7714878756

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 (J9306) $4,017.69 and (J9355) $2,694.88.

The new rate violates 42 U.S.C. § 1359*l*(t)(14)(A)(iii)(II), the authority to pay for the 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

WAIVER OF RIGHT TO AN ADMINISTRATIVE LAW JUDGE (ALJ) HEARING

Instructions: If you are an appellant or other party to a hearing before an Administrative Law Judge (ALJ) with the Office of Medicare Hearings and Appeals (OMHA), you may waive your right to the oral hearing and request that a decision be made based on the record. When you waive your right to a hearing, either an ALJ or an attorney adjudicator may decide your appeal.

If you are the appellant and want your appeal to be decided without a hearing, complete this form and include it with your request for an ALJ hearing (form OMHA-100) or, if you have already filed your request for an ALJ hearing, send this form to the assigned OMHA adjudicator (visit www.hhs.gov/omha and use the appeal status lookup tool to find your assigned adjudicator). Any other party that wants the appeal to be decided without a hearing may complete this form and send it to the assigned OMHA adjudicator. If an adjudicator has not yet been assigned, send this form to OMHA Central Operations, Attention: Waiver Mail Stop (visit www.hhs.gov/omha or call the number at the bottom of this form for the full mailing address).

If all of the parties to the appealed matter who would be sent a notice of hearing do not also waive the ALJ hearing (for example, a provider or supplier that was held financially responsible for the denied items or services), or the assigned ALJ or attorney adjudicator believes a hearing is necessary to decide the appeal, a hearing may be held by an ALJ, and the ALJ will issue the decision or other dispositive order in the appeal.

Section 1: What is the OMHA appeal number or the reconsideration (Medicare appeal or case) number?

OMHA Appeal Number *(if known)*	Reconsideration Number *(if OMHA appeal number not known)*
	1-7714878756

Section 2: What is the information for the party waiving the hearing? *(Representative information in next section)*

Name *(First, Middle initial, Last)*	Firm or Organization *(if applicable)*	Telephone Number
Jason T Cunningham	Eastern Maine Healthcare Systems	207-768-4278

Section 3: What is the representative's information? *(Skip if you do not have a representative)*

Name	Firm or Organization *(if applicable)*	Telephone Number

Section 4: Explain why you wish to waive your right to an ALJ hearing and have the appeal decided based on the record:

There are no factual disputes in this appeal, which challenges provisions of the 2018 hospital OPPS rule regarding payments under the 340B Program. Furthermore, an ALJ would not have authority to invalidate these provisions of the regulation, and thus could not issue a favorable decision in this appeal. 42 C.F.R. § 405.1063(a)

Section 5: Acknowledge the following by signing and dating this form:

I understand that I may have a right to a hearing before an ALJ. I understand that having an ALJ hearing would provide me with the opportunity to present oral testimony and to present and/or question witnesses. I understand that this opportunity to be seen and heard could be helpful to the ALJ in making a decision.

I understand that my waiver of an ALJ hearing does not affect the right of other parties to an ALJ hearing.

I understand that even if all parties waive their right to an ALJ hearing, if the ALJ determines that a hearing is necessary to obtain testimony from a non-party, the ALJ may still hold a hearing to obtain that testimony. If a hearing is held, the ALJ will offer the parties the opportunity to appear at the hearing (which may be in person, by telephone or by video-teleconference), but may hold the hearing even if none of the parties decide to appear. I understand that if a hearing is held and I do not attend the hearing, I still have the right to submit written evidence.

I understand that my waiver may be denied if it is determined that my attendance is necessary to decide the appeal.

If I change my mind and decide that I would like a hearing before an ALJ, I understand I must submit a withdrawal of this waiver (see form OMHA-114) before a notice of decision or other dispositive order is issued by an ALJ or attorney adjudicator. If I withdraw my waiver of hearing, I understand that any applicable time frame to decide the appeal may be extended in order to schedule and hold the hearing. I also understand that if a hearing has already been conducted, the ALJ may decide not to conduct another one.

Party or Representative Signature	Date
Jason T Cunningham	9/21/18

Privacy Act Statement

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). 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 Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Medicare Appeal Number:
1-7714878756

September 06, 2018

EASTERN MAINE MEDICAL CENTER
140 ACADEMY ST
PRASANNA BLDG
PRESQUE ISLE, ME 04769

RE:
Beneficiary: [redacted]
Med ID#: [redacted]
Appellant: Eastern Maine Medical Center

Dear J. Cunningham:

This letter is to inform you that your request for a QIC (Qualified Independent Contractor) reconsideration of your redetermination dismissal is UNFAVORABLE. Your redetermination request was dismissed by National Government Services Inc. because the party that requested a redetermination does not have a right to a redetermination since administrative review is not available for this issue. In accordance with 42 Code of Federal Regulations (CFR) Section 405.952, because administrative review is not available for this issue, there is not sufficient cause to reverse the contractor's dismissal. Therefore, the contractor's original dismissal stands.

In accordance with 42 CFR Section 405.974 (b)(3), a QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review. You have no further appeal rights on this case.

If you have questions:
Beneficiaries: contact 1-800-MEDICARE (1-800-633-4227)
Providers: contact the Medicare Administrative Contractor

Sincerely,

Christine Smith

CHRISTINE SMITH,
cc: [redacted]

Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc.
Medicare Part A
East QIC Contractor
P.O. Box 45307
Jacksonville, FL
32232-5307

Telephone number:
904-224-7446

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

Medicare Appeal Number:

1-7714878756

Appeal Details

Appellant	Eastern Maine Medical Center
AC	National Government Services Inc.(14111)

Redetermination Number	Beneficiary Name/ HIC#	Date of Service
1-7427073361	[redacted]	01/15/18
		01/15/18

THIS IS NOT A BILL – Keep this letter or a copy for your records.

Supplemented Exhibit P

PAYMENT DATE: 02/21/18 EASTERN MAINE MEDICAL CENTER RUN DATE: 02/21/18
MEDICARE-ACUTE

ELECTRONIC MEDIA REMITTANCE ADVICE SINGLE OUTPATIENT SERVICE LINE DETAIL REPORT

EASTERN MAINE MEDICAL CENTER
43 WHITING HILL RD
BREWER ME 044121005
1790789147

FISCAL PERIOD
ENDING 180930 14011

BILL TYPE 131

NAME [redacted] PCN 162273758019 SERVICE FROM 20180103 THRU 20180131
POL# [redacted] ICN 005551960 PAT STAT CLAIM STAT 19 CLAIM # 558
MRN 00138744 CRN 21803700775907MEA

CHARGES:		PPS DATA:		PAYMENT DATA:	
REPORTED	30478.70	DRG NUMBER		REIMB RATE	0.31
NCOVD	.00	DRG AMOUNT	.00	PRIMARY PAY	.00
DENIED	.00	DRG/OPER	.00	PROF COMP	.00
		DRG/CAPITAL	.00	ESRD AMT	.00
DAYS:		OUTLIER ( )	.00	HCPCS AMT	3932.45
		NON LAB CHRG	.00	OTH ADJ AMT	.00
COST REPT	0	NEG REIMB	.00	CONT ADJ AMT	23615.80
COVD/UTIL	0	TOTAL DEDUCT	.00	INTEREST	.00
NON COVERED	0	COINSURANCE	1372.60	PAT REFUND	.00
LTR	0	MSP LIAB MET	.00	NET REIMB AMT	5380.51
		CO-PAY AMT	.00		

REMARK CDS: MA01 MA18

GROUP AND STD CDS:	OA STS19	CO 45	CO 253	PR 2	CO 97	
ADJ AMT:	.00	20282.32	109.79	1372.60	3333.48	.00

CHECK/EFT NUMBER: EFT1036555

CROSS-OVER PAYER NAME: MAINECARE

COMMENT 1:

COMMENT 2:

COV EXPR DATE: CLM RCVD DATE: 02/06/2018

REV	DATE	HCPCS/HIPPS	MODS	UNIT/VISIT	CHGS	ALLOWED	GC	RSN	AMT	RMK CD	APC
0260	01/03/18	96367	PO	2	508.00	92.32	CO	45	390.25		05692
							CO	253	1.88		
							PR	2	23.55		
0260	01/17/18	96367	PO	2	508.00	92.32	CO	45	390.25		05692
							CO	253	1.88		
							PR	2	23.55		
0260	01/31/18	96367	PO	2	508.00	92.32	CO	45	390.25		05692
							CO	253	1.88		
							PR	2	23.55		
0280	01/03/18	G0463	25PO	1	267.00	90.17	CO	45	151.99		05012
							CO	253	1.84		
							PR	2	23.00		
0280	01/31/18	G0463	25PO	1	267.00	90.17	CO	45	151.99		05012
							CO	253	1.84		
							PR	2	23.00		
0300	01/17/18	36415	PO	1	11.00	.00	CO	97	11.00		
0300	01/03/18	80053	PO	1	63.00	.00	CO	97	63.00		
0300	01/17/18	80053	PO	1	63.00	.00	CO	97	63.00		
0300	01/31/18	80053	PO	1	63.00	.00	CO	97	63.00		
0300	01/03/18	81003		1	32.00	.00	CO	97	32.00		
0300	01/17/18	81003		1	32.00	.00	CO	97	32.00		
0300	01/31/18	81003		1	32.00	.00	CO	97	32.00		
0300	01/31/18	82378		1	166.00	.00	CO	97	166.00		
0300	01/03/18	82570		1	50.00	.00	CO	97	50.00		
0300	01/17/18	82570		1	50.00	.00	CO	97	50.00		
0300	01/03/18	84156		1	55.00	.00	CO	97	55.00		
0300	01/17/18	84156		1	55.00	.00	CO	97	55.00		
0300	01/03/18	85025	PO	1	50.00	.00	CO	97	50.00		
0300	01/17/18	85025	PO	1	50.00	.00	CO	97	50.00		
0300	01/31/18	85025	PO	1	50.00	.00	CO	97	50.00		
0335	01/31/18	96409	PO	1	351.00	151.55	CO	45	157.70		05693
							CO	253	3.09		
							PR	2	38.66		
0335	01/03/18	96411	PO	1	288.00	46.16	CO	45	229.13		05692
							CO	253	.94		
							PR	2	11.77		
0335	01/17/18	96411	PO	1	288.00	46.16	CO	45	229.13		05692
							CO	253	.94		
							PR	2	11.77		
0335	01/03/18	96413	PO	1	536.00	235.99	CO	45	234.98		05694
							CO	253	4.82		
							PR	2	60.21		
0335	01/17/18	96413	PO	1	536.00	235.99	CO	45	234.98		05694
							CO	253	4.82		

						PR 2	60.21	
0335	01/03/18	96416	PO	1	885.00	235.99	CO 45	583.98	05694
							CO 253	4.82	
							PR 2	60.21	
0335	01/17/18	96416	PO	1	885.00	235.99	CO 45	583.98	05694
							CO 253	4.82	
							PR 2	60.21	
0335	01/31/18	96416	PO	1	885.00	235.99	CO 45	583.98	05694
							CO 253	4.82	
							PR 2	60.21	
0361	01/17/18	36593	PO	1	354.00	235.99	CO 45	52.98	05694
							CO 253	4.82	
							PR 2	60.21	
0636	01/03/18	J0640	PO	7	128.59	.00	CO 97	128.59	
0636	01/17/18	J0640	PO	7	128.59	.00	CO 97	128.59	
0636	01/31/18	J0640	PO	7	128.59	.00	CO 97	128.59	
0636	01/03/18	J2469	JGPO	10	1312.00	116.37	CO 45	1163.57	09210
							CO 253	2.37	
							PR 2	29.69	
0636	01/17/18	J2469	JGPO	10	1312.00	116.37	CO 45	1163.57	09210
							CO 253	2.37	
							PR 2	29.69	
0636	01/31/18	J2469	JGPO	10	1312.00	116.37	CO 45	1163.57	09210
							CO 253	2.37	
							PR 2	29.69	
0636	01/17/18	J2997	JGPO	2	524.82	97.39	CO 45	400.60	07048
							CO 253	1.99	
							PR 2	24.84	
0636	01/03/18	J9035	JGPO	30	7675.20	1318.28	CO 45	5993.73	09214
							CO 253	26.90	
							PR 2	336.29	
0636	01/17/18	J9035	JGPO	30	7675.20	1318.28	CO 45	5993.73	09214
							CO 253	26.90	
							PR 2	336.29	
0636	01/03/18	J9190	PO	9	708.57	.00	CO 97	708.57	
0636	01/17/18	J9190	PO	9	708.57	.00	CO 97	708.57	
0636	01/31/18	J9190	PO	9	708.57	.00	CO 97	708.57	
0940	01/05/18	G0463	PO	1	134.00	90.17	CO 45	18.99	05012
							CO 253	1.84	
							PR 2	23.00	
0940	01/19/18	G0463	PO	1	134.00	90.17	CO 45	18.99	05012
							CO 253	1.84	
							PR 2	23.00	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID 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: J2469, J2997, J9035

4. Date the service or item was received: 1/03/18 & 1/17/18 & 1/31/18, 1/17/18, 1/03/18 & 1/17/18

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.)
2/21/18

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 payments received for 340B drugs reflect a new reimbursement rate of 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. The payments should be $509.59 (J2469), $142.16 (J2997) & $3848.48 (J9035).

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: Peggy Stavitz, VP Enterprise Revenue Cycle
43 Whiting Hill Rd, Brewer, ME 04412. (207) 973-4642

11. Signature of person appealing: Peggy Stavitz

12. Date signed: 3/19/18

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

Form CMS-20027 (12/10)

June 1, 2018

Eastern Maine Medical Center
43 WHITING HILL RD
BREWER, ME 04412-1005

Medicare Number of Beneficiary: [redacted]

Beneficiary Contact Information

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

Provider Contact Information

If you have questions, write or call:

National Government Services, Inc.
Medicare Appeals Department, P.O. Box 7111
Indianapolis, IN 46207-7111
(888) 855-4356

Re: Appeal # 1-7427059841
Medicare Beneficiary: [redacted]

Dear Eastern Maine Medical Center,

This letter is in response to your redetermination request that was received in our office on April 03, 2018. The redetermination was requested for the following dates of service.

Claims List

Record #	Claim #	Dates of Service
Claim #1	21803700775907MEA	01/03/2018 - 01/31/2018

Your redetermination request has been dismissed because it did not form a valid request for redetermination. In order to process a redetermination request, we need the following items to be addressed:

Your request has been dismissed because under the Outpatient Prospective Payment System (OPPS), CMS annually sets payment rates for covered outpatient services, including covered outpatient drugs. Section 1848(i)(1) of the Act prohibits administrative and judicial review of these periodic adjustments. (Reference: 42 U.S.C. § 1395l(t)(14)(A)(iii)(II) and 42 U.S.C. § 1395l(t)(12)(A), (C), (E)). You may file your request again if it has been 120 days or less since the date of receipt of the initial determination notice. When you file your request, please make sure you have addressed all of the above listed items and send your request to our office at the address noted above.

If you disagree with this dismissal, you have two options:

1. You may request that we vacate our dismissal. We will vacate our dismissal if you demonstrate that you have good and sufficient cause for failing to address all of the items listed above in your request. Your request to vacate this dismissal **must be received at the address above within six months of the date of receipt of this letter.**

2. If you think we have incorrectly dismissed your request (that is, you believe you did address all of the above listed items in your request), you may request a reconsideration of this dismissal by a Qualified Independent Contractor (QIC). **Your request must be received by the QIC at the address below within 60 days of receipt of this letter.** In your request, please explain why you believe the dismissal was incorrect. Please note that the QIC will not consider any evidence for establishing coverage of the claims being appealed. Their examination will be limited to whether or not the dismissal was appropriate. Please send your request to:

   C2C Solutions Inc.
   Medicare Part A East
   P.O. Box 45305
   Jacksonville, FL 32232-5305

Sincerely,

Debora Welch
National Government Services, Inc.
A Medicare Contractor

cc: [redacted]

Appeal # 1-7427059841

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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: J2469, J2997, J9305
4. Date the service or item was received: 1/3/18 & 1/17/18 & 1/31/18, 1/17/18, 1/03/18 & 1/17/18
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.)
June 01, 2018

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

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. The payment(s) should be $509.59 (J2469), $142.16 (J2997) & $3848.48 (J9035)

7. Additional information Medicare should consider:
The new rate violates 42 U.S.C. §13951(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 reconsideration.
☒ I do not have evidence to submit.

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

10. Name, address, and telephone number of person appealing: Jason Cunningham, Sys Dir Rev Integrity, EMHS
140 Academy St. Prasanna Building, Presque Isle, ME 04769 Phone (207) 768-4278

11. Signature of person appealing: Jason Cunningham

12. Date signed: 07/17/2018

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

Form CMS-20033 (12/10)

Medicare Appeal Number:
1-7714878788

WFCM2490 - 000083 - 001 OF 001

September 06, 2018

EASTERN MAINE MEDICAL CENTER
140 ACADEMY ST
PRASANNA BLDG
PRESQUE ISLE, ME 04769

RE:
Beneficiary: [redacted]
Med ID#: [redacted]
Appellant: Eastern Maine Medical Center

Dear J. Cunningham:

This letter is to inform you that your request for a QIC (Qualified Independent Contractor) reconsideration of your redetermination dismissal is UNFAVORABLE. Your redetermination request was dismissed by National Government Services Inc. because the party that requested a redetermination does not have a right to a redetermination since administrative review is not available for this issue. In accordance with 42 Code of Federal Regulations (CFR) Section 405.952, because administrative review is not available for this issue, there is not sufficient cause to reverse the contractor's dismissal. Therefore, the contractor's original dismissal stands.

In accordance with 42 CFR Section 405.974 (b)(3), a QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review. You have no further appeal rights on this case.

If you have questions:
Beneficiaries: contact 1-800-MEDICARE (1-800-633-4227)
Providers: contact the Medicare Administrative Contractor

Sincerely,

Christine Smith

CHRISTINE SMITH,
cc: [redacted]

Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc.
Medicare Part A
East QIC Contractor
P.O. Box 45307
Jacksonville, FL
32232-5307

Telephone number:
904-224-7446

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

Medicare Appeal Number:

1-7714878788

Appeal Details

Appellant	Eastern Maine Medical Center
AC	National Government Services Inc.(14111)

Redetermination Number	Beneficiary Name/ HIC#	Date of Service
1-7427059841	[redacted]	01/03/18
		01/03/18
		01/17/18
		01/17/18
		01/17/18
		01/31/18

THIS IS NOT A BILL – Keep this letter or a copy for your records.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

REQUEST FOR ADMINISTRATIVE LAW JUDGE (ALJ) HEARING OR REVIEW OF DISMISSAL

Section 1: Which Medicare Part are you appealing (if known)? (*Check one*)

☐ Part A ☒ Part B ☐ Part C (*Medicare Advantage*) or Medicare Cost Plan ☐ Part D (*Prescription Drug Plan*)

Section 2: Which party are you, or which party are you representing? (*Check one*)

☐ The Medicare beneficiary or enrollee, or a successor (such as an estate), who received or requested the items or services being appealed, or is appealing a Medicare Secondary Payer issue.

☒ The provider or supplier that furnished the items or services to the Medicare beneficiary or enrollee, a Medicaid State agency, or an applicable plan appealing a Medicare Secondary Payer issue.

☐ Other. *Please explain*:

Section 3: What is your (the appealing party's) information? (*Representative information in next section*)

Name (*First, Middle Initial, Last*)		Firm or Organization (*if applicable*)	
Jason T Cunningham		Eastern Maine Healthcare Systems	
Address where appeals correspondence should be sent	City	State	ZIP Code
140 Academy Street, Parsanna Building	Presque Isle	Maine	04769
Telephone Number	Fax Number	E-Mail	
(207) 768-4278	(207) 768-4364	jcunningham2@emhs.org	

Section 4: What is the representative's information? (*Skip if you do not have a representative*)

Name		Firm or Organization (*if applicable*)	
Mailing Address	City	State	ZIP Code
Telephone Number	Fax Number	E-Mail	

Did you file an appointment of representation (form CMS-1696) or other documents authorizing your representation at a prior level of appeal?

☒ No. *Please file the document(s) with this request.*
☐ Yes

Section 5: What is being appealed? *Submit a separate request for each Reconsideration or Dismissal that you wish to appeal. If the appeal involves multiple beneficiaries or enrollees, use the multiple claim attachment (OMHA-100A).*

Name of entity that issued the Reconsideration or Dismissal (*or attach a copy of the Reconsideration or Dismissal*)		Reconsideration (Medicare Appeal or Case) Number (*or attach a copy of the Reconsideration or Dismissal*)	
C2C Innovative Solutions, Inc Part A East QIC Contractor		1-7714878788	
Beneficiary or Enrollee Name		Health Insurance Claim Number	
[redacted]		[redacted]	
Beneficiary or Enrollee Mailing Address	City	State	ZIP Code
[redacted]	[redacted]	[redacted]	[redacted]
What item(s) or service(s) are you appealing? (*N/A if appealing a Dismissal*)		Date(s) of service being appealed (*if applicable*)	
Drug Payment		01/03/2018, 01/17/2018, 01/31/2018	
Supplier or Provider Name (*N/A for Part D appeals*)		Supplier or Provider Telephone Number (*N/A for Part D appeals*)	
Eastern Maine Medical Center		(207) 973-5000	
Supplier or Provider Mailing Address (*N/A for Part D appeals*)	City	State	ZIP Code
43 Whiting Hill Road	Bangor	ME	04412

Section 6: For appeals of prescription drugs ONLY (*Skip for all other appeals*)

Part D Prescription Drug Plan Name	What drug(s) are you appealing?

Are you requesting an expedited hearing?
(*An expedited hearing is only available if your appeal is not solely related to payment (for example, you do not have the drug) and applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function*)

☒ No. ☐ Yes. *On a separate sheet, please explain or have your prescriber explain why applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function.*

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed? (*Attach a continuation sheet if necessary*)

See attached continuation sheet.

Section 8: Are you submitting evidence with this request, or do you plan to submit evidence?

☒ I am not planning to submit evidence at this time. (*Skip to Section 9, below*)

☐ I am submitting evidence with this request.

☐ I plan to submit evidence. Indicate what you plan to submit and when you plan to submit it:

Was the evidence already submitted for the matter that you are appealing?

☐ No. *Part A and Part B appeals only. If you are a provider or supplier, or a provider or supplier that is representing a beneficiary, you must include a statement explaining why the evidence is being submitted for the first time and was not submitted previously.*

☐ Yes.

Section 9: Is there other information about your appeal that we should know?

Are you aggregating claims to meet the amount in controversy requirement? (*If yes, attach your aggregation request. See 42 C.F.R. § 405.1006(e) and (f), and 423.1970(c) for request requirements.*)	☒ No	☐ Yes
Are you waiving the oral hearing before an ALJ and requesting a decision based on the record? (*If yes, attach a completed form OMHA-104 or other explanation. N/A if requesting review of a dismissal.*)	☐ No	☒ Yes
Does the request involve claims that were part of a statistical sample? (*If yes, please explain the status of any appeals for claims in the sample that are not included in this request.*)	☒ No	☐ Yes

Section 10: Certification of copies sent to other parties (*Part A and Part B appeals only*)

If another party to the claim or issue that you are appealing was sent a copy of the Reconsideration or Dismissal, you must send a copy of your request for an ALJ hearing or review of dismissal to that party.

Indicate the party (or their representative) to whom and address where you are sending a copy of the request, and when the copy will be sent *(attach a continuation sheet if there are multiple parties)*.

Name of Recipient		
Mailing Address		
City	State	ZIP Code
Date of Mailing		

☒ Check here if no other parties were sent a copy of the Reconsideration or Dismissal.

Section 11: Filing instructions

Your appealed claim must meet the current amount in controversy requirement to file an appeal. See the Reconsideration or Dismissal or visit www.hhs.gov/omha for information on the current amount in controversy. Send this request form to the entity in the appeal instructions that came with your reconsideration (for example, requests for hearing following a Part C reconsideration are generally sent to the entity that conducted the reconsideration). If instructed to send to OMHA, use the addresses below.

Beneficiaries and enrollees, send your request to:	**For expedited Part D appeals, send your request to:**	**All other appellants, send your request to:**
OMHA Centralized Docketing Attn: Beneficiary Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing Attn: Expedited Part D Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316

We must receive this request within 60 calendar days after you received the Reconsideration or Dismissal that you are appealing. We will assume that you received the Reconsideration or Dismissal 5 calendar days after the date of the Reconsideration or Dismissal, unless you provide evidence to the contrary. *If you are filing this request late, attach a completed form OMHA-103 or other explanation for the late filing.*

PRIVACY ACT STATEMENT

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). 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 Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed?

(continuation sheet) 1-7714878788

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 (J2469) $509.59 and (J2997) $142.16 and (J9035) $3,848.48.

The new rate violates 42 U.S.C. § 1359*l*(t)(14)(A)(iii)(II), the authority to pay for the 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

WAIVER OF RIGHT TO AN ADMINISTRATIVE LAW JUDGE (ALJ) HEARING

Instructions: If you are an appellant or other party to a hearing before an Administrative Law Judge (ALJ) with the Office of Medicare Hearings and Appeals (OMHA), you may waive your right to the oral hearing and request that a decision be made based on the record. When you waive your right to a hearing, either an ALJ or an attorney adjudicator may decide your appeal.

If you are the appellant and want your appeal to be decided without a hearing, complete this form and include it with your request for an ALJ hearing (form OMHA-100) or, if you have already filed your request for an ALJ hearing, send this form to the assigned OMHA adjudicator (visit www.hhs.gov/omha and use the appeal status lookup tool to find your assigned adjudicator). Any other party that wants the appeal to be decided without a hearing may complete this form and send it to the assigned OMHA adjudicator. If an adjudicator has not yet been assigned, send this form to OMHA Central Operations, Attention: Waiver Mail Stop (visit www.hhs.gov/omha or call the number at the bottom of this form for the full mailing address).

If all of the parties to the appealed matter who would be sent a notice of hearing do not also waive the ALJ hearing (for example, a provider or supplier that was held financially responsible for the denied items or services), or the assigned ALJ or attorney adjudicator believes a hearing is necessary to decide the appeal, a hearing may be held by an ALJ, and the ALJ will issue the decision or other dispositive order in the appeal.

Section 1: What is the OMHA appeal number or the reconsideration (Medicare appeal or case) number?

OMHA Appeal Number *(if known)*	Reconsideration Number *(if OMHA appeal number not known)*
	1-7714878788

Section 2: What is the information for the party waiving the hearing? *(Representative information in next section)*

Name *(First, Middle initial, Last)*	Firm or Organization *(if applicable)*	Telephone Number
Jason T Cunningham	Eastern Maine Healthcare Systems	207-768-4278

Section 3: What is the representative's information? *(Skip if you do not have a representative)*

Name	Firm or Organization *(if applicable)*	Telephone Number

Section 4: Explain why you wish to waive your right to an ALJ hearing and have the appeal decided based on the record:

There are no factual disputes in this appeal, which challenges provisions of the 2018 hospital OPPS rule regarding payments under the 340B Program. Furthermore, an ALJ would not have authority to invalidate these provisions of the regulation, and thus could not issue a favorable decision in this appeal. 42 C.F.R. § 405.1063(a).

Section 5: Acknowledge the following by signing and dating this form:

I understand that I may have a right to a hearing before an ALJ. I understand that having an ALJ hearing would provide me with the opportunity to present oral testimony and to present and/or question witnesses. I understand that this opportunity to be seen and heard could be helpful to the ALJ in making a decision.

I understand that my waiver of an ALJ hearing does not affect the right of other parties to an ALJ hearing.

I understand that even if all parties waive their right to an ALJ hearing, if the ALJ determines that a hearing is necessary to obtain testimony from a non-party, the ALJ may still hold a hearing to obtain that testimony. If a hearing is held, the ALJ will offer the parties the opportunity to appear at the hearing (which may be in person, by telephone or by video-teleconference), but may hold the hearing even if none of the parties decide to appear. I understand that if a hearing is held and I do not attend the hearing, I still have the right to submit written evidence.

I understand that my waiver may be denied if it is determined that my attendance is necessary to decide the appeal.

If I change my mind and decide that I would like a hearing before an ALJ, I understand I must submit a withdrawal of this waiver (see form OMHA-114) before a notice of decision or other dispositive order is issued by an ALJ or attorney adjudicator. If I withdraw my waiver of hearing, I understand that any applicable time frame to decide the appeal may be extended in order to schedule and hold the hearing. I also understand that if a hearing has already been conducted, the ALJ may decide not to conduct another one.

Party or Representative Signature	Date
Jason T Cunningham	9/21/18

Privacy Act Statement

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). 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 Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Medicare Appeal Number:
1-7714878788

September 06, 2018

EASTERN MAINE MEDICAL CENTER
140 ACADEMY ST
PRASANNA BLDG
PRESQUE ISLE, ME 04769

RE:
Beneficiary: [redacted]
Med ID#: [redacted]
Appellant: Eastern Maine Medical Center

Dear J. Cunningham:

This letter is to inform you that your request for a QIC (Qualified Independent Contractor) reconsideration of your redetermination dismissal is UNFAVORABLE. Your redetermination request was dismissed by National Government Services Inc. because the party that requested a redetermination does not have a right to a redetermination since administrative review is not available for this issue. In accordance with 42 Code of Federal Regulations (CFR) Section 405.952, because administrative review is not available for this issue, there is not sufficient cause to reverse the contractor's dismissal. Therefore, the contractor's original dismissal stands.

In accordance with 42 CFR Section 405.974 (b)(3), a QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review. You have no further appeal rights on this case.

If you have questions:
Beneficiaries: contact 1-800-MEDICARE (1-800-633-4227)
Providers: contact the Medicare Administrative Contractor

Sincerely,

Christine Smith

CHRISTINE SMITH,
cc: [redacted]

Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc.
Medicare Part A
East QIC Contractor
P.O. Box 45307
Jacksonville, FL
32232-5307

Telephone number:
904-224-7446

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

Medicare Appeal Number:

1-7714878788

Appeal Details

Appellant	Eastern Maine Medical Center
AC	National Government Services Inc.(14111)

Redetermination Number	Beneficiary Name/ HIC#	Date of Service
1-7427059841	[redacted]	01/03/18
		01/03/18
		01/17/18
		01/17/18
		01/17/18
		01/31/18

THIS IS NOT A BILL – Keep this letter or a copy for your records.

Supplemented Exhibit R

ARK RIDGE HEALTH
.00 HOSPITAL DRIVE
ENDERSONVIL NC 287925272
286875281

PARK RIDGE HEALTH
PO BOX 601558
CHARLOTTE NC 28260

[redacted] | OF BILL 0131

5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM	THROUGH	7
56-0543246	011018	011018	

PATIENT NAME: [redacted]

9 PATIENT ADDRESS: [redacted] c NC d [redacted] e

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18	19	20	21	22	23	24	25	26	27	28	29 ACDT STATE	30
[redacted]				3	1		01	28												RECEIVABLES SOLD

31 CODE	OCCURRENCE DATE	32 CODE	OCCURRENCE DATE	33 CODE	OCCURRENCE DATE	34 CODE	OCCURRENCE DATE	35 CODE	OCCURRENCE SPAN FROM	THROUGH	36 CODE	OCCURRENCE SPAN FROM	THROUGH	37
1	011917	A1	051348	B1	051348									

[redacted]

	39 CODE	VALUE CODES AMOUNT	40 CODE	VALUE CODES AMOUNT	41 CODE	VALUE CODES AMOUNT
a						
b						
c						
d						

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
335	CHEMOTHERP-IV	96413PO	011018	1	753.83		
636	N408290306424ML5	J1642PO	011018	50	1479		
636	N400264180032ML100	J7030PO	011018	1	2675		
636	N400264151032ML100	J7070PO	011018	1	2450		
636	N400003377211ML4	J9299POJG	011018	40	6361.71		
636	N400003377412ML20	J9299POJG	011018	200	20890.74		
001	PAGE 1 OF 1	CREATION DATE	020718	TOTALS	28072.32		

PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI 1427075027
EDICARE		Y	Y			57 OTHER PRV ID
UTUAL OF OMAHA SUPP		Y	Y			

INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
[redacted]	18	[redacted]		
[redacted]	18	[redacted]		

TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
		RETIRED RETIRED

Z5112	C3490	Z79899	Z7984						68

ADMIT DX | 70 PATIENT REASON DX: Z5112 | 71 PPS CODE | 72 ECI | 73

PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75

OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE

REMARKS M000

81CC	
a	B3282NR1301X
b	
c	
d	

76 ATTENDING	NPI 1063452506	QUAL	
LAST PASCHAL		FIRST BARTON	
77 OPERATING	NPI	QUAL	
LAST		FIRST	
78 OTHER	NPI	QUAL	
LAST		FIRST	
79 OTHER	NPI	QUAL	
LAST		FIRST	

Florida Medicare Remittance Advice

ETCHER HOSPITAL INC.
BOX 601558
ARLOTTE NC 282601156
I: 1427075027
ECK/EFT: EFT2111686

FPE: 12/31/2018
PAID: 02/22/2018
CLM#: 1155
TOB: 131

FIRST COAST SERVICE OPTIONS, I
532 RIVERSIDE AVENUE
JACKSONVILLE FL 32202
FTN: 560543246

RANSFER TO (COB): MUTUAL OF OMAHA INSURANCE COMP ID CODE: 000030091

ATIENT: [redacted] PCN: 106510743
HIC: [redacted] SVC FROM: 01/10/18 MRN: [redacted]
T STAT: CLAIM STAT: 19 THRU: 01/10/18 ICN: 21803900902607FLA

ARGES:
28072.32=REPORTED
0.00=NCVD/DENIED
0.00=CLAIM ADJS
28072.32=COVERED
YS/VISITS:
0=COST REPT
0=COVD/UTIL
0=NON-COVERED
0=COVD VISITS
0=NCOV VISITS

PAYMENT DATA: =DRG 0.250=REIM RATE
0.00=DRG AMOUNT 0.00=MSP PRIM PAYER
0.00=DRG/OPER/CA 0.00=PROF COMPONENT
0.00=LINE ADJ AM 0.00=ESRD AMOUNT
0.00=OUTLIER 4700.40=PROC CD AMOUNT
0.00=CAP OUTLIER 3903.17=ALLOW/REIM
0.00=CASH DEDUCT 79.65=SEQUESTRATN
0.00=BLOOD DEDUC 0.00=INTEREST
995.71=COINSURANCE 23093.79=CONTRACT ADJ
0.00=PAT REFUND 0.25=PER DIEM AMT
0.00=ACO PIONEER 3903.17=NET REIM AMT

MARK CODES: MA01 MA18

V	DATE	HCPCS	APC/HIPPS	MODS	QTY	CHARGES	ALLOW/REIM	GC	RSN	AMOUNT	REMARK CODES
35	01/10	96413	05694	PO	1	753.83	218.05	CO	45	475.70	
								CO	253	4.45	
								PR	2	55.63	
36	01/10	J1642		PO	50	14.79	0.00	CO	97	14.79	
36	01/10	J7030		PO	1	26.75	0.00	CO	97	26.75	
36	01/10	J7070		PO	1	24.50	0.00	CO	97	24.50	
36	01/10	J9299	09453	PO JG	200	20890.74	3070.93	CO	45	16973.74	
								CO	253	62.67	
								PR	2	783.40	
36	01/10	J9299	09453	PO JG	40	6361.71	614.19	CO	45	5578.31	
								CO	253	12.53	
								PR	2	156.68	

OSSARY

Coinsurance Amount

3 Sequestration - reduction in federal payment

Charge exceeds fee schedule/maximum allowable or contracted/legislated fee arrangement. Usage: This adjustment amount cannot equal the total service or claim charge amount; and must not duplicate provider adjustment amounts (payments and contractual reductions) that have resulted from prior payer(s) adjudication. (Use only with Group Codes PR or CO depending upon liability)

Florida Medicare Remittance Advice

ETCHER HOSPITAL INC.
BOX 601558
ARLOTTE NC 282601156
I: 1427075027
ECK/EFT: EFT2111686

FPE: 12/31/2018
PAID: 02/22/2018
CLM#: 1155
TOB: 131

FIRST COAST SERVICE OPTIONS, I
532 RIVERSIDE AVENUE
JACKSONVILLE FL 32202
FTN: 560543246

RANSFER TO (COB): MUTUAL OF OMAHA INSURANCE COMP ID CODE: 000030091

ATIENT: [redacted] PCN: 106510743
HIC: [redacted] SVC FROM: 01/10/18 MRN: [redacted]
T STAT: CLAIM STAT: 19 THRU: 01/10/18 ICN: 21803900902607FLA

.. CONTINUED FROM PREVIOUS PAGE ...

OSSARY

The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

01 Alert:+ If you do not agree with what we approved for these services, you may appeal our decision. To make sure that we are fair to you, we require another individual that did not process your initial claim to conduct the appeal. However, in order to be eligible for an appeal, you must write to us within 120 days of the date you received this notice, unless you have a good reason for being late.

18 Alert:+ The claim information is also being forwarded to the patient's supplemental insurer. Send any questions regarding supplemental benefits to them.

Medicare National Standard Intermediary Remittance Advice

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID 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: J9299
4. Date the service or item was received: 01/10/2018
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.)
02/22/2018

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 $5,342.66.

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: Mary Wilson, PO BOX 601558, Charlotte, NC 28260-1558 828-687-5281 ext. 6407

11. Signature of person appealing: Mary Wilson

12. Date signed: 5/11/2018

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

Form CMS-20027 (12/10)

Invoice 2

0269376712

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

FIRST COAST
SERVICE OPTIONS, INC.
WHEN EXPERIENCE COUNTS & QUALITY MATTERS

FLETCHER HOSPITAL INC
PO BOX 601558
CHARLOTTE NC 28260-1558

June 01, 2018

Medicare Number of Beneficiary: [redacted]

Beneficiary Contact Information

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

Provider Contact Information

If you have questions, write or call:

First Coast Service Options, Inc.
P.O. Box 45053
Jacksonville, FL 32232-5053
(888) 664-4112

Re: Appeal # 1-7538767541
Medicare Beneficiary: [redacted]

Dear Fletcher Hospital Inc.,

This letter is in response to your redetermination request that was received in our office on May 21, 2018. The redetermination was requested for the following dates of service.

Claims List

Record #	Claim #	Dates of Service
Claim #1	21803900902607FLA	01/10/2018 - 01/10/2018

Your redetermination request has been dismissed because it did not form a valid request for redetermination. In order to process a redetermination request, we need the following items to be addressed:

Required Information:

- The beneficiary's name
- The Medicare health insurance claim number of the beneficiary
- The specific services or items for which the redetermination is being requested and the specific dates of service
- The name and signature of the person filing the redetermination request

Invalid Request:

- Not a proper party, no Appointment of Representative (AOR), or AOR is not valid

Appeal # 1-7538767541

000038 0002 0003 000
696655-O03-0

Back Image

- No initial determination on the claims appealed
- Beneficiary is deceased with no remaining party or appointed representative with financial interest

Your request has been dismissed because administrative review is not available for this issue. You may file your request again if it has been 120 days or less since the date of receipt of the initial determination notice. When you file your request, please make sure you have addressed all of the above listed items and send your request to our office at the address noted above.

If you disagree with this dismissal, you have two options:

1. You may request that we vacate our dismissal. We will vacate our dismissal if you demonstrate that you have good and sufficient cause for failing to address all of the items listed above in your request. Your request to vacate this dismissal **must be received at the address above within six months of the date of receipt of this letter**.

2. If you think we have incorrectly dismissed your request (that is, you believe you did address all of the above listed items in your request), you may request a reconsideration of this dismissal by a Qualified Independent Contractor (QIC). **Your request must be received by the QIC at the address below within 60 days of receipt of this letter**. In your request, please explain why you believe the dismissal was incorrect. Please note that the QIC will not consider any evidence for establishing coverage of the claims being appealed. Their examination will be limited to whether or not the dismissal was appropriate. Please send your request to:

   C2C Solutions Inc.
   Medicare Part A East
   P.O. Box 45305
   Jacksonville, FL 32232-5305

Sincerely,

Tonja Wilson
First Coast Service Options, Inc.
A Medicare Contractor

cc: [redacted]

Appeal # 1-7538767541

Invoice 3

Appeal #: 1-7538767541

Reconsideration Request Form

Directions: If you wish to appeal this decision, please fill out the required information below and mail this form to the address shown below. At a minimum, you must complete/include information for items 1, 2a, 6, 7, 11, & 12, but to help us serve you better, please include a copy of the redetermination notice with your request.

C2C Solutions Inc.
Medicare Part A East
P.O. Box 45305
Jacksonville, FL 32232-5305

1. Name of Beneficiary: _____
2a. Medicare Number: _____
2b. Claim Number (ICN / DCN, if available): _____
3. Provider Name: _____
4. Person Appealing: ☐Beneficiary ☐Provider of Service ☐Representative
5. Address of the Person Appealing: _____
_____
5a. Telephone Number of the Person Appealing: _____
5b. Email Address of the Person Appealing: _____
6. Item or service you wish to appeal: _____
7. Date of the service: From _____ To _____
8. Does this appeal involve an overpayment? ☐Yes ☐No
Please include a copy of the demand letter with your request.
9. Why do you disagree? Or what are your reasons for your appeal? (Attach additional pages, if necessary.) _____
_____
10. You may also include any supporting material to assist your appeal. Examples of supporting materials include:
☐ Medical Records ☐ Office Records/Progress Notes
☐ Copy of the Claim ☐Treatment Plan ☐ Certificate of Medical Necessity
o11. Name of Person Appealing: _____
12. Signature of Person Appealing: _____ Date: _____
Contractor Number: 09101

Appeal # 1-7538767541

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696655-O03-0

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

0269376712

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: J9299
4. Date the service or item was received: 01/10/2018
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.)
   02/22/2018

   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 $5,342.66.
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 reconsideration.
   ☒ I do not have evidence to submit.
9. Person appealing: ☐ Beneficiary ☒ Provider/Supplier ☐ Representative
10. Name, address, and telephone number of person appealing: Mary Wilson, PO BOX 601558, Charlotte, NC 28260-1558 828-687-5281 ext. 6407
11. Signature of person appealing: Mary Wilson
12. Date signed: 07/23/2018

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

Form CMS-20033 (12/10)

Medicare Appeal Number:
1-7732811978

091818

September 10, 2018

FLETCHER HOSPITAL INC
PO BOX 601558
CHARLOTTE, NC 28260

RE:
Beneficiary: [redacted]
Med ID#: [redacted]
Appellant: Fletcher Hospital Inc

Dear M. Wilson:

This letter is to inform you that your request for a QIC (Qualified Independent Contractor) reconsideration of your redetermination dismissal is UNFAVORABLE. Your redetermination request was dismissed by First Coast Service Options because the party that requested a redetermination does not have a right to a redetermination since administrative review is not available for this issue. In accordance with 42 Code of Federal Regulations (CFR) Section 405.952, because administrative review is not available for this issue, there is not sufficient cause to reverse the contractor's dismissal. Therefore, the contractor's original dismissal stands.

In accordance with 42 CFR Section 405.974 (b)(3), a QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review. You have no further appeal rights on this case.

If you have questions:
Beneficiaries: contact 1-800-MEDICARE (1-800-633-4227)
Providers: contact the Medicare Administrative Contractor

Sincerely,

Christine Smith

CHRISTINE SMITH,
cc: [redacted]

Contact Information

If you have questions, write or call:

C2C Innovative Solutions, Inc.
Medicare Part A
East QIC Contractor
P.O. Box 45307
Jacksonville, FL
32232-5307

Telephone number:
904-224-7446

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

Exhibit Y

U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave. NW, Rm. 7222
Washington, DC 20530

Tel: (202) 514-4819

June 18, 2018

VIA CM/ECF

Mark Langer, Clerk of Court
U.S. Court of Appeals for the District of Columbia Circuit
333 Constitution Ave., NW
Washington, DC 20001

RE: *American Hospital Ass'n v. Alex M. Azar II*, No. 18-5004 (D.C. Cir.) (argued May 4, 2018 before Circuit Judges Srinivasan, Millett, and Katsas)

Dear Mr. Langer:

I write in response to plaintiffs' June 14, 2018 letter advising this Court of two recent notices issued by the Medicare Administrative Contractors (MACs).

As explained in the government's brief, the Medicare Act, 42 U.S.C. § 1395*l*(t)(12), precludes both administrative and judicial review of the payment rates under the Outpatient Prospective Payment System for 340B-acquired drugs at issue in this case, *see Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004).

Consistent with this statutory provision, providers cannot challenge the reimbursement rate for such drugs within the current Medicare administrative appeals process.

Sincerely,

/s/ Laura Myron

Laura Myron
Counsel for Respondents

cc: All counsel (via CM/ECF)