IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, et al., Plaintiffs, v. SYLVIA M. BURWELL, in her official capacity as Secretary of Health and Human Services,[1] Defendant.	Civil Action No. 14-609 (APM)

DEFENDANT'S RESPONSE TO PLAINTIFFS' SUPPLEMENTAL BRIEF

Defendant respectfully responds to Plaintiffs' supplemental brief, as directed by the Court in its minute order of December 23, 2015.

I. Plaintiffs' successful pursuit of administrative remedies demonstrates that exhaustion is not futile, and that their claims may be resolved on grounds other than those they ask the Court to decide.

Plaintiffs' description of the status of their administrative appeals illustrates three key points. First, contrary to Plaintiffs' central contention that exhaustion would be futile, at least some of Plaintiffs' claims have apparently been paid on appeal. 2d Morgan Decl. (Banner) ¶ 11 (Medicare contractor "issued a favorable redetermination decision on the fifth two-midnights denial"); see Hermann Decl. (Mt. Sinai) ¶¶ 13-14 (although hospital "appealed eighteen" two-midnights denials, Medicare contractor "issued unfavorable decisions" for only "sixteen of the claims" appealed). These claims are not only moot, but show that the administrative process is hardly the pointless exercise that Plaintiffs suggest.

[1] Pursuant to Fed. R. Civ. P. 25(d), Sylvia M. Burwell is substituted for her predecessor as Secretary of Health and Human Services.

Second, Plaintiffs' appeals may be, and some have been, decided on factual grounds, without reaching what Plaintiffs characterize as the "purely legal" questions they ask the Court to decide. For example, Banner prevailed on a two-midnights appeal because the particular medical procedure at issue was properly considered "inpatient only" and was therefore payable under Part A regardless of the expected duration of the hospital stay. 2d Morgan Decl. ¶ 11; see Def.'s Mot. to Dism. 3 (explaining "inpatient only" billing). Banner may find similar success in its other appeals, where in addition to arguing that the two-midnights rule is arbitrary and capricious, it has "also submitted additional documentation from the patients' medical records to establish that the two-midnights rule was satisfied" in any event. 2d Morgan Decl. ¶ 17. Likewise, Mount Sinai "further argue[s]" that its medical records satisfy "the inpatient admissions criteria that existed before the two-midnights rule," Hermann Decl. ¶ 9—criteria that, like the two-midnights rule, do not depend solely on the length of a hospital stay, but instead turn on a number of factors including the reasonableness of the physician's judgment under the circumstances. Def.'s Mot. to Dism. 4-5.

The same is true for Einstein, despite its contortions to suggest otherwise. Einstein now argues that, in its only pending appeal, it "did not submit additional information from the medical record" to the ALJ but instead "conceded that the . . . claim did not meet the two-midnights standard," so the appeal presents "only . . . legal challenges to the three policies at issue here." Pls.' Supp. Br. 2.[2] But that is a remarkable about-face. Earlier in the administrative process, Einstein submitted "the beneficiary's medical record and other supporting documentation" to the Medicare contractor, Carr Decl. ¶ 14, and argued to the QIC "that . . . [the Medicare contractor]

[2] In contrast to Plaintiffs' brief, Einstein's declaration states that its appeal raises yet a fourth issue—"Whether the hospital is entitled to Part A reimbursement for . . . reasonable and medically necessary items and services," Brunner Decl. ¶ 19—seemingly preserving the claim that inpatient treatment was reasonable and necessary under the circumstances notwithstanding the two-midnights benchmark.

had failed to apply the two-midnights standard correctly based on the evidence in the medical record," Brunner Decl. ¶ 16. That factual issue is still properly before the ALJ, and Plaintiffs cannot concede it away to circumvent the administrative process. See 42 C.F.R. § 405.1032(a) ("The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor."); see also id. § 405.1042(a)(2) (the ALJ "record will include . . . the documents used in making the decision under review"); id. § 405.1000(d), (g) (the "ALJ conducts a de novo review" and "may . . . issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding").

Indeed, there is yet another ground on which the ALJ might resolve Einstein's remaining appeal without reaching the issues that Plaintiffs ask the Court to decide. In rejecting Einstein's appeal, the "QIC stated that 'although the expectation of a stay greater than 2 midnights was a reasonable one, the actual time in the hospital fell short of the expectation.'" Brunner Decl. ¶ 18. But that reasoning is arguably at odds with Medicare guidance on the two-midnights rule, which explains that, "if it was reasonable for the physician to expect the beneficiary to require a stay lasting 2 midnights, and that expectation is documented in the medical record, inpatient admission is generally appropriate," regardless of whether the physician's expectation was actually met. 78 Fed. Reg. at 50,950. This, too, is a fact-intensive question that will turn on the documentation in the medical record, and is therefore best left to the administrative process in the first instance.

Third, despite their apparent success in appealing at least some claims, Plaintiffs have withdrawn their appeals of other claims, even while contending that all of their claims present the same, "purely legal" issues. Plaintiffs have rebilled some of these claims under Part B—perhaps in recognition that their Part A claims were improper—each of which has been paid and is therefore moot. 2d Morgan Decl. (Banner) ¶ 15 (two two-midnights appeals withdrawn, rebilled

under Part B, and paid); id. ¶ 19 (four physician order denials rebilled under Part B and paid). Other claims have simply been abandoned without explanation. Brunner Decl. (Einstein) ¶¶ 14-15 (the "QIC issued an unfavorable decision" but the hospital "did not request an [ALJ] hearing"); Hermann Decl. (Mt. Sinai) ¶¶ 10-11 (Medicare contractor "issued unfavorable decisions . . . for the six claims" but the hospital "did not appeal" to the QIC).

As these background points illustrate, no Plaintiff hospital has properly exhausted its administrative remedies for any of the three challenges that Plaintiffs seek to raise in this case:

A/B rebilling deadline. Plaintiffs have yet to identify any Medicare claim, in the nearly two years since the complaint was filed, for which they have received an unfavorable determination from a Recovery Audit Contractor—which of course was the very premise of their challenge to the one-year statutory deadline for rebilling Part A claims under Part B. Compl. ¶¶ 5, 51, 104-05; Def.'s Mot. to Dism. 29-30. What is more, Plaintiffs still fail to identify any rebilled claim to which that deadline has been "appli[ed]" to deny payment, Compl. ¶¶ 102-09, let alone any claim denial that has been appealed and exhausted. Indeed, every claim that Plaintiffs report having rebilled under Part B was apparently deemed timely and paid. 2d Morgan Decl. (Banner) ¶¶ 15, 19.

Physician order rule. Nor have Plaintiffs properly appealed and exhausted any claim denied on the basis of the physician order rule. While Banner states that it had five claims denied on that basis, only one was ever appealed. 2d Morgan Decl. ¶ 18. That appeal was rejected as untimely, id. ¶ 20—a conclusion that Plaintiffs do not contest—and the remaining four were rebilled under Part B and paid, id. ¶ 19, and are therefore moot. Although Einstein notes that, for one of its claims, a Medicare contractor requested a physician order, that request was made after the complaint was filed and is therefore irrelevant to the analysis. See Grupo Dataflux v. Atlas Global Group, 541 U.S. 567, 570 (2004) ("It has long been the case that the 'jurisdiction of the

court depends upon the state of things at the time of the action brought.'") (citation omitted). In any event, Einstein's declarations indicate that the claim was denied and any appeals were actually decided on the basis of the two-midnights rule, not the physician order rule. See Carr Decl. ¶¶ 15, 17; Brunner Decl. ¶ 18.

Two-midnights rule. Although Plaintiffs have several appeals of claims denied on the basis of the two-midnights rule pending at the ALJ level, only two were filed before the complaint, and neither has been exhausted:

- Einstein points to two such appeals, but both were filed after the complaint and are thus irrelevant. Carr Decl. ¶¶ 12, 16; see Dataflux, 541 U.S. at 570. The first appeal (its "Claim No. 1") was ultimately denied by a QIC but not appealed to an ALJ, and has thus been abandoned. Brunner Decl. ¶¶ 14-15. The second appeal (its "Claim No. 2") is pending at the ALJ level. Id. ¶¶ 18, 19, 21.

- Mount Sinai identifies two batches of two-midnights appeals. The first batch consists of six claims, each of which was appealed after the complaint was filed and is thus irrelevant. See Dataflux, 541 U.S. at 570. Regardless, each was denied by a Medicare contractor but not appealed to a QIC, and has thus been abandoned. Hermann Decl. ¶¶ 10-11. The second batch, consisting of eighteen claims, was identified for the first time in Plaintiffs' supplemental brief; these claims were initially denied in fall 2014 and appealed in 2015—well after briefing on Defendant's motion to dismiss concluded—and are also irrelevant. Id. ¶¶ 12-13; see Dataflux, 541 U.S. at 570. Of these eighteen, two were apparently paid, and the remaining sixteen are pending at the ALJ level. Id. ¶¶ 12-13, 17.

- Banner points to five two-midnights appeals. Morgan Decl. ¶ 11-14. One was paid on appeal, and is therefore moot. 2d Morgan Decl. ¶ 11. Two others were withdrawn by Plaintiffs, rebilled under Part B, and paid, and are also moot. Id. ¶ 15. The remaining two are pending at the ALJ level. Id. ¶ 16.[3]

While Plaintiffs repeat their previous suggestion that administrative delays at the ALJ level warrant a waiver of exhaustion, see Pls.' Supp. Br. 2, they offer no response to Defendant's showing that the Supreme Court has repeatedly and squarely held to the contrary. See Def.'s

[3] Plaintiffs acknowledge that the fourth Plaintiff hospital, Wake Forest Baptist Medical Center, has neither alleged nor shown by declaration that it has appealed any claim denied on the basis of any the rules challenged here. Pls.' Supp. Br. 2 n.2; see Def.'s Reply at 4 n.2 (noting this deficiency). Wake Forest therefore lacks standing and should be dismissed from the case.

Reply at 12-13; Heckler v. Ringer, 466 U.S. 602, 627 (1984) ("Congress must have felt that cases of individual hardship resulting from delays in the administrative process had to be balanced against the potential for overly casual or premature judicial intervention . . . ."); Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 11 (2000) (the benefits of exhaustion "come[] at a price, namely, individual, delay-related hardship"). Moreover, Plaintiffs ignore that the Medicare statute itself provides a remedy for such delays: If an ALJ fails to act within 90 days, a provider may "escalate" its appeal to the Departmental Appeals Board, 42 U.S.C. § 1395ff(d)(3)(A), and from there to district court if the Departmental Appeals Board fails to act within 90 days, id. § 1395ff(d)(3)(B). Plaintiffs have not pursued that route for any of their claims.[4] And Medicare regulations provide yet another option: Once an appeal reaches the ALJ level, a provider may seek "expedited access to judicial review" of a "question of law" where "there are no material issues of fact in dispute" and the "Medicare Appeals Council does not have the authority to decide the question." 42 C.F.R. § 405.990; cf. Three Lower Counties Cmty. Health Servs. v. HHS, 517 F. Supp. 2d 431, 435 (D.D.C. 2007), aff'd, 317 F. App'x 1 (D.C. Cir. 2009). Plaintiffs have not pursued that option either.

[4] These delays, caused by a backlog of appeals and insufficient appropriations to manage them, are the subject of separate litigation, brought by the lead Plaintiff here, seeking mandamus relief that would direct the Secretary to process the appeals more quickly. The D.C. Circuit recently stated that these circumstances "likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time—say, the close of the next full appropriations cycle"—but left that decision to the district court in the first instance. Am. Hosp. Ass'n v. Burwell, No. 15-5015, — F.3d —, 2016 WL 491658, at *10 (D.C. Cir. Feb. 9, 2016). The court did not, however, suggest that exhaustion should simply be excused—a solution that would do nothing more than push a massive backlog from one forum (the agency) to another (district court). Indeed, while Plaintiffs do not seek mandamus relief here, the D.C. Circuit emphasized that its "precedent forecloses" any mandamus claims that would have "the effect of allowing the plaintiffs to jump the line, functionally solving their delay problem at the expense of other similarly situated applicants." Id. at *8.

II. Neither Plaintiffs' unexhausted appeals nor their general letter to the Secretary satisfy the presentment requirement.

By its terms, 42 U.S.C. § 405(g) limits federal jurisdiction over claims arising under the Medicare statute to those challenging a "'final decision of the Secretary made after a hearing.'" Mathews v. Eldridge, 424 U.S. 319, 327-28 (1976) (quoting 42 U.S.C. § 405(g)). This provision—which "demands the 'channeling' of virtually all legal attacks through the agency," Illinois Council, 529 U.S. at 11—consists of two components. The first is the "nonwaivable . . . requirement that a claim for benefits shall have been presented to the Secretary." Eldridge, 424 U.S. at 327-28. This "presentment" requirement is not a mere technicality, but is "'central to the requisite grant of jurisdiction.'" Id. (citation omitted). Its purpose, of course, is to give the Secretary an opportunity to consider and make a decision on a claim before suit is filed. For "[a]bsent such a claim, there can be no 'decision' of any type. And some decision by the Secretary is clearly required by the statute." Id.

Plaintiffs argue that they have satisfied the presentment requirement either by submitting appeals to Medicare contractors just three days before filing suit, or by sending a letter to the Secretary just four days earlier. Neither argument is correct. While Plaintiffs suggest that it is "evident from the[ir] administrative appeals" that they have satisfied presentment "several times over," Pls.' Supp. Br. 5, in fact only two of their pending appeals were submitted before the complaint was filed. Compl. ¶ 85 (five pre-complaint appeals); 2d Morgan Decl. (Banner) ¶¶ 11-15 (one paid on appeal; two withdrawn, rebilled under Part B, and paid; two pending); see Illinois Council, 529 U.S. at 15 (claim must be presented "before raising it in court") (emphasis added). Each challenged only the two-midnights rule, and each was submitted just three days before the complaint—hardly enough time for the Secretary to reach any decision, let alone a final one. The cases cited by Plaintiffs are not to the contrary. As previously explained in Defendants' reply

brief, in each of those cases—unlike here—the agency was given and utilized the opportunity to make a decision, albeit not a "final decision," before suit was filed. See Def.'s Reply at 4 & n.3 (discussing cases).[5]

Plaintiffs' reliance on their letter to the Secretary fares no better. To satisfy the presentment requirement, a plaintiff must "give[] the Secretary an opportunity to rule on a concrete claim for reimbursement." Heckler v. Ringer, 466 U.S. 602, 622 (1984) (emphasis added); see also id. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary."). Thus, a letter raising "generalized complaints" untethered to such a "concrete claim," like Plaintiffs' letter here, will not suffice. Am. Orthotic & Prosthetic Ass'n v. Sebelius, 62 F. Supp. 3d 114, 123 (2014). Plaintiffs' attempts to distinguish American Orthotic are unpersuasive.

Plaintiffs principally argue that American Orthotic conflicts with a footnote in Action Alliance of Senior Citizens v. Sebelius, 607 F.3d 860 (D.C. Cir. 2010). Pls.' Supp. Br. 7-8. But American Orthotic considered and rejected the same argument, and properly so. 62 F. Supp. 3d at 123. In Action Alliance, the D.C. Circuit initially held that presentment was not satisfied; to remedy that defect, the associations representing the plaintiffs then "sent a separate letter from each of the plaintiffs" to the Secretary and to the Commissioner of Social Security, and in fact "received a response." Action Alliance of Senior Citizens v. Johnson, 607 F. Supp. 2d 33, 37-38 (D.D.C. 2009). On remand, the government argued that presentment remained unsatisfied because

[5] To the extent that Plaintiffs rely on their initial claims for payment to Medicare contractors, rather than their administrative appeals, to satisfy presentment, they provide no evidence of the content of those submissions, least of all that they asked the Medicare contractors to decide the so-called "purely legal" questions they now ask the Court to decide in the absence of a final decision of the Secretary. Cf. Haro v. Sebelius, 747 F.3d 1099, 1112-13 (9th Cir. 2014) (claim that the "Secretary lacks authority to demand up-front reimbursement" of Medicare secondary payments not properly presented where "at the administrative level" plaintiffs challenged only certain "reimbursement calculations").

the letters "were from the associations rather than [the plaintiffs]" themselves, but raised no objection to the specificity of the letters. Id. The district court rejected that argument, id. at 39-40, but dismissed the case on other grounds. On appeal, the government did not press the presentment issue, see Appellee's Brief, 2009 WL 6043968, at *4, *10-11, so although the D.C. Circuit ultimately noted that the plaintiffs had "cured the jurisdictional defect," 607 F.3d at 862 n.1, it did not explain how. Did the panel independently review the plaintiffs' letters and find them sufficiently specific, without saying so? Was it enough that the agency had, in fact, responded to the letters? Or was the panel simply satisfied that the government had abandoned the only objection it had raised below? The opinion offers no indication. As Judge Lamberth explained in American Orthotic, that is "likely because the precise question presented here—whether generalized grievance letters rather than discrete claims are sufficient to satisfy presentment—was not raised by the parties in Action Alliance," rendering the footnote's precedential effect questionable. 62 F. Supp. 3d at 123. That conclusion was surely correct. "Judicial decisions do not stand as binding 'precedent' for points that were not raised, not argued, and hence not analyzed." Legal Servs. Corp. v. Velazquez, 531 U.S. 533, 557 (2001) (Scalia, J., dissenting) (citations omitted).

Regardless, even if the Action Alliance footnote were binding, American Orthotic does not conflict with it. As Judge Lamberth also explained, Action Alliance "is easily distinguishable" because, there, the plaintiffs "presented HHS with factually detailed letters regarding discrete claims on behalf of individuals" that were "closer to the 'concrete claim for reimbursement' that the Supreme Court has held is required for proper presentment." 62 F. Supp. 3d at 123. Here, Plaintiffs make no serious effort to distinguish their letter from the "generalized grievance" letter found insufficient in American Orthotic. While they argue that the letter "specifically" states that the American Hospital Association and "several" of its 5,000 member hospitals are prepared to

file suit, Pls.' Supp. Br. 10, they do not dispute that the letter names no particular hospital and cites no particular claim that has been denied. See Pls.' Opp'n to Def.'s Mot. to Dism. Ex. 1. Such a letter is plainly insufficient to meet Ringer's requirement to present a "concrete claim." 466 U.S. at 622.

Plaintiffs also suggest that their challenge to the one-year statutory deadline for rebilling denied Part A claims under Part B should be "exempt from 42 U.S.C. § 405(g)'s channeling requirement altogether" because, otherwise, there would be "no review at all" of their claims. Pls.' Supp. Br. 9-10 (citing, inter alia, Illinois Council, 529 U.S. at 19). But that is merely a repackaging of their argument that the Court should permit them to amend their complaint to invoke the general question statute, 28 U.S.C. § 1331, as an alternative basis for jurisdiction, even though their claims clearly "arise under" the Medicare statute, see Pls.' Opp'n to Def.'s Mot. to Dism. 44-45—an argument that Defendant has already thoroughly refuted, see Def.'s Reply at 24-25. As Judge Kollar-Kotelly concluded in rejecting precisely the same challenge, brought by the same lead Plaintiff here, "[t]o allow Plaintiffs to access the courts through § 1331 because they cloaked their Medicare Act challenge in the garb of a challenge to a general policy would subvert the channeling function of § 405(h) in the first instance." Am. Hosp. Ass'n v. Burwell, 68 F. Supp. 3d 54, 64 (D.D.C. 2014). This Court should likewise decline Plaintiffs' invitation.

III. No exception to the Medicare exhaustion requirement that survives Illinois Council applies here.

The second element of § 405(g)'s jurisdictional limitation is the exhaustion requirement, which may be waived by the Secretary—or, "in certain special cases," by the Court, Ringer, 466 U.S. at 622. But this latter category of "certain special cases" has long been narrow indeed, and in Illinois Council, the Supreme Court narrowed it further. Plaintiffs' claims fall outside its bounds.

As the Supreme Court explained in Weinberger v. Salfi, 422 U.S. 749, 766 (1975), the exhaustion requirement in § 405(g) is "something more than simply a codification of the judicially developed doctrine of exhaustion, and [it] may not be dispensed with merely by a judicial conclusion of futility." 422 U.S. at 766 (emphasis added). Thus, except where "the Secretary [herself] does not raise any challenge to . . . exhaustion," Salfi, 422 U.S. at 767, or she "waive[s]" exhaustion by (among other things) explicitly "stipulat[ing] that no facts [a]re in dispute," Mathews v. Diaz, 426 U.S. 67, 76 (1976), the Supreme Court has not excused exhaustion under § 405(g) unless a plaintiff raises a constitutional challenge that is "entirely collateral" in nature and delayed review would cause irreparable harm, Eldridge, 424 U.S. at 331; see also Bowen v. City of New York, 476 U.S. 466, 483 (1986). Indeed, as the Supreme Court confirmed in Ringer, this "exception to exhaustion is inapplicable" where plaintiffs "do not raise a claim that is wholly 'collateral'" and have "no colorable claim" of irreparable harm. 466 U.S. at 618.

Here, of course, Plaintiffs raise no claim—constitutional or otherwise—that could be considered "entirely collateral" to their underlying claims for Medicare payment. Nor do they allege irreparable harm. Rather, they urge the Court to deem exhaustion "futile" based solely on Plaintiffs' characterization of their claims as "purely legal" rather than fact-dependent. But even if that argument were not contradicted by Plaintiffs' own declarations, supra at 2-3—not to mention their partially successful pursuit of administrative remedies, supra at 1—it would run aground on Illinois Council, which "foreclose[d] distinctions based upon . . . the 'general legal' versus the 'fact-specific' nature of the challenge" in determining whether channeling is required. 529 U.S. at 13-14.

In Illinois Council, the Court rejected a nursing home association's attempt to challenge Medicare regulations under the general federal question statute, holding that the channeling requirement of § 405(g)-(h) applies not only to "claims for monetary benefits" but also to

"challenges . . . [to] a policy, regulation, or statute that might later bar recovery" of such benefits. 529 U.S. at 10. In doing so, the Court pointedly refused to create exceptions to this channeling requirement based on several potential distinctions, including "the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge," and "the 'declaratory' versus 'injunctive' nature of the relief sought." Id. at 13-14. It explained: "There is no reason to distinguish among them in terms of the language or in terms of the purposes" of the statute, which seek to "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying 'ripeness' and 'exhaustion' exceptions case by case." Id. To be sure, Illinois Council did not eliminate the exhaustion exception described in Eldridge; indeed, it noted that exhaustion may still be excused where delayed review of a collateral claim would cause irreparable harm. Id. at 24. But Plaintiffs do not claim to meet that exception, and Illinois Council rejects the "general legal" distinction they suggest.

Tataranowicz v. Sullivan, 959 F.2d 268 (D.C. Cir. 1002), is not to the contrary. There, the D.C. Circuit went a step beyond the Supreme Court's decision in Diaz—where the Secretary had affirmatively "stipulated that no facts were in dispute . . . and that the only issue before the [court] was the constitutionality of the statute," 426 U.S. at 76—and excused exhaustion because the court found it "hard to see how any factual disputes might stand in the way of . . . relief, and the Secretary suggests none." 959 F.2d at 274. But here, the Secretary has shown—and Plaintiffs' own submissions confirm—that Plaintiffs' appeals may be (and some have been) decided on factual grounds, without reaching what Plaintiffs characterize as the "purely legal" questions they ask the Court to decide. See supra at 2. Regardless, Plaintiffs' boundless reading of Tataranowicz to excuse the exhaustion of any claim they describe as "purely legal" cannot be reconciled with Illinois Council, which rejects such a distinction and confirms that Congress intended to channel

even policy challenges to regulations through the administrative review process. Indeed, after Illinois Council, the D.C. Circuit has rejected the argument that a so-called "'facial' challenge need not follow the administrative appeals procedures for Medicare reimbursement claims," explaining that Illinois Council requires that "[p]arties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge." Three Lower Counties Cmty. Health Servs. v. HHS, 317 F. App'x 1, 2 (D.C. Cir. 2009) (citing Illinois Council, 529 U.S. at 5).

In the end, however, the Court need not definitively resolve the parameters of any exhaustion exceptions that survive Illinois Council to require exhaustion here, for at least three reasons. First, Plaintiffs have not demonstrated that exhaustion would be futile—that is, "clearly useless," UDC Chairs, 56 F.3d at 1475—and their partial success in pursuing administrative remedies shows otherwise. See supra at 1-5; Def.'s Reply at 6-8. "Proving futility requires demonstration that defeat is certain, which the plaintiff[s] cannot demonstrate if [their] members are succeeding in appeals before the agency." American Orthotic, 62 F. Supp. 3d at 124; see also UDC Chairs, 56 F.3d at 1475 ("The mere 'probability of administrative denial of the relief requested does not excuse failure to pursue' administrative remedies; rather '[plaintiffs] must show that it is certain that their claim will be denied.'") (emphasis added; citations omitted).

Second, even if exhaustion were futile, this case does not present the sort of "purely legal" questions as to which § 405(g)'s "final decision" requirement could be waived for futility alone. For example, contrary to Plaintiffs' repeated characterizations, the two-midnights rule is not a redefinition of the term "inpatient," but merely a benchmark for evaluating whether, in a given case, it is "reasonable and necessary" to provide treatment on an inpatient basis. 42 U.S.C. § 1395y(a)(1)(A). As Plaintiffs recognize, that decision is inherently "fact-sensitive and a matter of judgment," Compl. ¶ 3, and their own arguments during the administrative process show that

the determination turns on the particular facts in a patient's medical record, supra at 2-3; see Def.'s Reply at 8-12, 15-16.

Third, even if exhaustion could be excused for futility alone, that step would be unwarranted here. Plaintiffs are not vulnerable beneficiaries muddling their way through an unfamiliar system, but sophisticated hospitals and industry associations that are well acquainted with the administrative process. Of the five claims they actually appealed (yet did not exhaust) before filing the complaint, one was paid on appeal, two were rebilled and paid under Part B, and only two remain. 2d Morgan Decl. ¶¶ 11, 15, 16. That alone shows that the administrative process is working. The Court should allow it to continue.

IV. Subsequent changes to the two-midnights rule and physician order rule do not affect Plaintiffs' claims.

Two-midnights rule. The two-midnights rule sets forth a "benchmark" that hospital stays spanning two midnights are generally appropriate for inpatient admission, but not a "per se rule" that shorter stays are never reimbursable under Part A. 78 Fed. Reg. at 50,908, 50,945; see Def.'s Mot. to Dism. 4-5. Rather, shorter stays remain reimbursable under Part A under certain circumstances—for example, if they are for "inpatient only" services, id. at 50,944; if the physician's expectation that a patient would need a longer stay was reasonable though ultimately incorrect, id. at 50,950; when the patient's condition improves unexpectedly, allowing earlier discharge, id. at 50,946, and in other "rare and unusual" circumstances, id.

In November 2015, the Secretary amended the two-midnights rule to provide even "greater flexibility in determining when an admission that does not meet the two-midnight benchmark should nonetheless be payable" under Part A. 80 Fed. Reg. 70,298, 70,542 (Nov.13, 2015). This change expands the "rare and unusual" circumstances exception to permit payment under Part A where a stay is not expected to cross two midnights but the medical record supports the admitting

physician's determination that inpatient treatment is nevertheless appropriate. Id. at 70,541. Because this change took effect on January 1, 2016, it does not affect this case. Id. 70,542. But, as noted above, even before this change, stays shorter than two midnights could be reimbursed under Part A depending on the circumstances; indeed, in a given case, the reasonableness of an inpatient admission could turn on a variety of factors, including the particular "procedures being performed and the beneficiary's condition and comorbidities." 78 Fed. Reg. at 50,947; 80 Fed. Reg. at 70,539; see also 42 C.F.R. 412.3(d) ("The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event.").

Physician order rule. The physician order rule was initially promulgated under the authority of the physician certification requirement in 42 U.S.C. § 1395f(a)(3), and thus served the dual purposes of formally initiating an inpatient admission, 42 C.F.R. § 412.3(a), and certifying that, in the judgment of the treating physician, inpatient treatment was medically necessary, id. § 412.3(c) (2014); 78 Fed. Reg. 50,496, 50,938 (Aug. 19, 2013); see Def.'s Mot. to Dism. 24-26. In November 2014, the Secretary amended the physician order rule in two ways. First, she revised the statutory authority for the rule, relying on her general rulemaking authority under 42 U.S.C. § 1395hh rather than the physician certification requirement in 42 U.S.C. § 1395f(a)(3). 79 Fed. Reg. 66,770, 66,997-98 (Nov. 10, 2014). Second, as a result, she eliminated the requirement that the admission order be a part of the physician certification, a change that permits non-physician practitioners to sign the admission order so long as they have admitting privileges under state law (and meet certain other requirements). Id. (deleting the former 42 C.F.R. § 412.3(c)).

These changes took effect on January 1, 2015, and do not affect this case. Given that Plaintiffs themselves asked the Secretary to make any proposed changes to the physician order rule retroactive so that they could benefit from them, see Def.'s Reply 17 & Ex. A, Defendant's

ripeness argument was hardly the "red herring" that Plaintiffs suggest, Pls.' Supp. Br. 16. Nevertheless, because those changes are prospective only, Defendant no longer presses her ripeness argument here. In any event, because no Plaintiff has identified any claim or appeal denied on the basis of the physician order rule, see supra at 4-5, the Court need not resolve whether the rule is consistent with 42 U.S.C. § 1395f(a)(3), particularly since the Secretary no longer relies on that statutory authority.

CONCLUSION

For the foregoing reasons, in addition to those set forth in Defendant's motion to dismiss and reply, the Court should dismiss this case in its entirety.

Dated: February 29, 2016

Respectfully submitted,

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