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)

PLAINTIFFS' SUPPLEMENTAL BRIEF

As directed by the Court in its December 23, 2015 order, Plaintiffs the American Hospital Association (AHA), Banner Health, The Mount Sinai Hospital, Einstein Healthcare Network, Wake Forest Baptist Medical Center, Greater New York Hospital Association, Healthcare Association of New York State, New Jersey Hospital Association, and The Hospital & Healthsystem Association of Pennsylvania hereby respectfully submit this supplemental brief to address the following issues raised by the Court:

- With respect to the two-midnights rule and the physician order rule, the status of Plaintiffs' administrative appeals;
- The bases for those appeals, and whether they could be resolved on factual grounds;
- With respect to the physician order rule, what effect the conclusion of rulemaking proceedings has on Defendant's ripeness argument;
- With respect to the "A/B" rebilling deadline, whether Plaintiffs have had a particular claim denied under that deadline;

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

- To the extent that Plaintiffs rely on their letter to the Secretary to satisfy presentment, how this case differs from *Am. Orthotic & Prosthetic Ass'n, Inc. v. Sebelius*, 62 F. Supp. 3d 114 (D.D.C. 2014);

- The parameters of exhaustion waiver in the Medicare context after *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000); and

- Recent changes to the two-midnights and physician order rules and what effect, if any, those changes have on this case.

I. Status of Plaintiffs' Claim Appeals

Since filing their opposition to the Secretary's motion to dismiss, the Plaintiff hospitals have continued to press their legal challenges to the two-midnights rule, the physician order rule, and the one year time limit through the Medicare claim appeal process.[2] The current status of those efforts is as follows:

Two-midnights rule:

On November 4, 2014, Plaintiff Einstein Healthcare Network appealed one of the claims denied on the basis of the two-midnights rule to an administrative law judge. Brunner Decl. ¶ 19. In its request for a hearing, Einstein specifically challenged the legality of the two-midnights rule, arguing that it is arbitrary and capricious, and asked the ALJ to declare the two-midnights rule invalid. *Id.* The only issues presented in the appeal are legal challenges to the three policies at issue here. *Id.* Einstein conceded that the particular inpatient stay at issue in that claim did not meet the two-midnights standard and did not submit additional documentation from the medical record. *See id.* Einstein's request for a hearing has been awaiting scheduling by an ALJ for more than a year, *see id.* ¶ 21, well beyond the statutory 90-day deadline for an ALJ to issue a decision. *See* 42 U.S.C. § 1395ff(d)(1)(A).

[2] The Court asked the Plaintiffs to provide information on "the specific claims that have been appealed and the specific claims that are giving the Plaintiffs standing to challenge the rules." Tr. 9:8-15, Dec. 18, 2015. The Plaintiffs do not rely on the claims submitted by Wake Forest Baptist Medical Center to establish standing with respect to their challenges to any of the three rules at issue and therefore have not included additional information about those claims here.

In Plaintiffs' previous submissions, Einstein also identified another claim that had been denied on the basis of the two-midnights rule and appealed to its Medicare Administrative Contractor (MAC). Morgan Decl. Supp. Pls.' Opp. ¶ 12, ECF No. 9-2. The only issue in that appeal is the legality of the two-midnights rule. Brunner Decl. ¶ 11. Novitas Solutions issued an unfavorable redetermination, which Einstein appealed to the Qualified Independent Contractor (QIC). *Id.* ¶¶ 12-13. The QIC issued an unfavorable reconsideration decision in January 2015 and Einstein did not appeal that decision. *Id.* ¶¶ 14-15.

The Mount Sinai Hospital also has appealed to an ALJ sixteen claims that were denied by its MAC on the basis of the two-midnights rule. Hermann Decl. ¶¶ 15-17. In its requests for an ALJ hearing, the hospital argued that the two-midnights rule is arbitrary and capricious. *See id.* The ALJ has acknowledged Mount Sinai's request for a hearing in fifteen of the sixteen cases, but a hearing date has not yet been scheduled. *Id.* ¶ 17.

In Plaintiffs' previous submissions, Mount Sinai also identified six claims that had been denied on the basis of the two-midnights rule during the first round of Probe & Educate reviews by its MAC. Farber Decl. Supp. Pls.' Opp. ¶ 11, ECF No. 9-4. Mount Sinai requested a redetermination by the MAC on those six claims, arguing that the two-midnights rule is arbitrary and capricious. Hermann Decl. ¶ 9. The MAC issued unfavorable redeterminations in all six cases, and Mount Sinai did not appeal those decisions. *Id.* ¶¶ 10-11.

Banner Health also has appealed to an ALJ claims that were denied by its MAC on the basis of the two-midnights rule. Morgan Decl. ¶¶ 16-17. Of the five claims that Banner had appealed as of July 2014, one was resolved in Banner's favor by its MAC. Two others were appealed to the QIC and then withdrawn by the hospital and rebilled under Part B after the QIC issued unfavorable reconsideration decisions. *Id.* ¶¶ 11-15. Two claims were appealed to an ALJ as of November 12, 2014 and remain pending at that level. *See id.* ¶¶ 16-17. In its requests for an

ALJ hearing, Banner Health argued that the two-midnights rule is arbitrary and capricious and that the QIC erred in its application of the two-midnights standard. *See id.* ¶ 17.

Physician order rule:

Of the five claims that Plaintiff Banner Health's MAC denied for failure to comply with the technical requirements of the physician order rule, Banner Health requested redetermination of one claim by the MAC. In that request for redetermination, Banner Health specifically challenged the legality of the physician order rule, arguing that it is arbitrary and capricious, and asked the MAC to declare the physician order rule invalid. The request for redetermination was considered untimely and was rejected. *Id.* ¶¶ 18, 20. Banner Health elected not to appeal the remaining four physician order rule denials, and instead billed for those services under Medicare Part B and received Part B payment. *Id.* ¶ 19.

In its request for a hearing on one Part A claim denied under the two-midnights rule, Einstein also argued that it should not be required to provide a formal physician order in order to receive Part A payment because the requirement is contrary to the Medicare statute and thus invalid under both the Medicare Act and the APA. Brunner Decl. ¶ 19. Einstein asked the ALJ to declare the physician order rule invalid. *Id.* ¶ 20. The ALJ has not yet issued a decision in that appeal. *Id.* ¶ 21.

One year time limit:

Plaintiff Einstein also asked the ALJ, in the event that he or she denies Part A payment, to permit the hospital to rebill under Part B after the one-year time limit expires. *Id.* ¶ 19. Einstein also requested a declaration that CMS's decision to apply a one-year time limit to situations where hospitals seek to rebill for Part B payment after Part A denials is unlawful and invalid. *Id.* ¶ 20. The original dates of service for the Part A claim occurred in late 2013 and early 2014 and thus the one year time limit to rebill the claim under Part B has long since expired. *See id.* ¶¶ 22, 25. As a

result of the one-year time limit policy, Einstein is no longer permitted to rebill under Part B. *Id.* ¶ 25. In fact, for all of the Part A appeals that remain pending for Einstein, Mount Sinai, and Banner Health, the time to rebill under Part B has expired. Bruner Decl. ¶ 25; Herman Decl. ¶ 21; Morgan Decl. ¶ 27.

II. Plaintiffs Have Satisfied the Presentment Requirement

In order to establish that this Court has jurisdiction over their claims challenging CMS's three unlawful policies under the APA and the Medicare Act, the Medicare statute requires only that Plaintiffs first "present a claim to the agency before raising it in court." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 15 (2000) (discussing statute's "nonwaivable and nonexcusable" presentment requirement). As is evident from the administrative appeals described above, the Plaintiffs clearly have satisfied this requirement several times over with respect to their claims challenging the validity of the two-midnights rule and the physician order rule under the Administrative Procedure Act and the Medicare Act.[3] Plaintiffs Banner Health, Mount Sinai, and Einstein Healthcare Network have presented claims for payment to the Medicare administrative contractors who make "initial [payment] determinations"; the Medicare contractors denied those claims on the basis of the two-midnights rule and the physician order rule; and the Plaintiff hospitals have appealed many of those denials, raising legal challenges to the validity of the two-midnights rule and the physician order rule in their appeals. Brunner Decl. ¶¶ 10-20; Hermann Decl. ¶¶ 12-18; Morgan Decl. ¶¶ 16-20.

[3] Plaintiffs have attached additional exhibits with additional facts establishing this Court's jurisdiction. A court may look beyond the complaint to establish jurisdiction in response to a Rule 12(b)(1) motion to dismiss. *Pinto v. D.C.*, 938 F. Supp. 2d 25, 30 (D.D.C. 2013). If, however, the Court concludes that these facts must be in the pleadings, Plaintiffs respectfully request leave to amend the Complaint. *See* Fed. R. Civ. P 15 ("The court should freely give leave [to amend] when justice so requires.").

That is more than is required to satisfy the presentment requirement. In *Mathews v. Eldridge*, the Supreme Court concluded that the plaintiff had satisfied the presentment requirement by writing a letter in response to a tentative determination by the state agency charged with monitoring his medical condition that his disability had ceased, which ultimately led to the denial of his claim for benefits by the Social Security Administration, even though the plaintiff had not raised his constitutional challenge to the denial of benefits in his letter or availed himself of the right to seek reconsideration of the state agency's initial determination. 424 U.S. 319, 328-330 (1976). As the "nonwaivable jurisdictional element" of presentment was satisfied, the Court went on to consider the "waivable" exhaustion element and concluded that under the circumstances, exhaustion should be waived. *Id.* at 330-331.

The D.C. Circuit and other courts in this district similarly have concluded that the presentment requirement is satisfied by submission of claims for Medicare payment that subsequently are denied by the agency. In *Tataranowicz v. Sullivan*, for example, the D.C. Circuit found that Medicare beneficiary members of a certified class had satisfied the presentment requirement by presenting claims for skilled nursing facility coverage that were denied because of the Secretary's interpretation of the Medicare statute. 959 F.2d 268, 272 (D.C. Cir. 1992). And in *National Association for Home Care & Hospice, Inc. v. Burwell*, "[b]ecause at least one member of NAHC [National Association for Home Care & Hospice] ha[d] submitted a claim for payment to the agency that was rejected due to [the challenged regulation], NAHC ha[d] satisfied the presentment requirement." 77 F. Supp. 3d 103, 109 (D.D.C. 2015).

Plaintiffs also have satisfied the presentment requirement with respect to the one-year time limit by raising their legal challenge to the validity of the rule in an appeal of a denial under Part A and asking an ALJ to permit the hospital to bill under Part B if Part A payment is denied, Brunner

Decl. ¶¶ 19-20, and by raising the same legal challenge in a letter sent by the AHA to the Secretary, Pls.' Opp. Ex. A.

Thus, Plaintiffs need not rely exclusively on the letter sent to the Secretary by the AHA, on behalf of its members including the Plaintiff hospitals, to satisfy the presentment requirement for their legal challenges to any of the three rules challenged in this lawsuit as unlawful under the APA and the Medicare Act. *See* Compl. ¶ 80; Pls.' Opp'n Ex A. To the extent that the Court considers whether the AHA letter may independently satisfy the presentment requirement, its analysis would affect the satisfaction of the presentment requirement with respect only to Plaintiffs' challenge to the validity of the policy applying the one-year time limit to claims rebilled under Part B. And under this circuit's precedent, the letter from the AHA is sufficient. *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 37-39 (D.D.C. 2009) ("*Action Alliance I*") *aff'd sub nom. Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010) ("*Action Alliance II*").

In *Action Alliance II*, the D.C. Circuit observed that although it had previously concluded that the district court lacked jurisdiction to consider one of the claims raised by the plaintiffs because it had not been properly presented to the Commissioner of Social Security, *Action Alliance of Senior Citizens v. Leavitt*, 483 F.3d 852, 856-858 (D.C. Cir. 2007), the plaintiffs "ha[d] since cured the jurisdictional defect," 607 F.3d at 862 n.1, where they had submitted letters on behalf of their members to the Commissioner identifying the legal basis on which they challenged CMS's demand for repayment of amounts erroneously paid to certain Medicare beneficiaries. *See Action Alliance I*, 607 F.Supp.2d at 39-40; *Action Alliance of Senior Citizens v. Johnson*, No. 1:06-cv-1607-HHK, Second Am. Compl. Ex. B, Aug. 27, 2007, ECF No. 37-2. While a footnote in a D.C. Circuit opinion ordinarily may not command much attention or be given much weight, the court's footnote in *Action Alliance II* included a specific finding that the plaintiffs had satisfied

the necessary element to establish the court's *jurisdiction*. Like any other federal court, the D.C. Circuit has an "independent obligation to ensure that [it] do[es] not exceed the scope of [its] jurisdiction, and therefore [it] must raise and decide jurisdictional questions that the parties either overlook or elect not to press." *Henderson ex rel. Henderson v. Shinseki*, 562 U.S. 428, 434 (2011). And the D.C. Circuit reviews issues of jurisdiction *de novo*. *See, e.g., Council for Urological Interests v. Sebelius*, 668 F.3d 704, 707 (D.C. Cir. 2011) (reversing district court's dismissal for lack of subject matter jurisdiction). Had the D.C. Circuit disagreed with the district court's finding that the plaintiffs satisfied the presentment requirement, it would (indeed, *should*) have said so—just as it did in its prior decision in the same case.

The Secretary has suggested that instead of *Action Alliance II*, this Court should look to *American Orthotic & Prosthetic Association, Inc. v. Sebelius*, 62 F. Supp. 3d 114, 123 (D.D.C. 2014) ("*American Orthotic*"). *See* Def's Reply 5. The court in *American Orthotic* gave short shrift to the *Action Alliance II* footnote. Although the court reluctantly considered whether letters sent by the association regarding the challenged agency guidance document could satisfy the presentment requirement under *Action Alliance II*, it did so only after "questioning the precedential value of those opinions," noting that " '[w]hen a potential jurisdictional defect is *neither noted nor discussed in a federal decision*, the decision does not stand for the proposition that no defect existed.' " 62 F. Supp. 3d 114, 123 (D.D.C. 2014) (quoting *Arizona Christian Sch. Tuition Org. v. Winn*, 536 U.S. 125, 144 (2011) (emphasis added)). But *Arizona Christian* supports the opposite inference to the one drawn by the *American Orthotic* court: After all, the D.C. Circuit explicitly stated that the previously identified jurisdictional defect had been cured. 607 F.3d at 862 n.1. Moreover, the court in *American Orthotic* reached its analysis under *Action Alliance II after* it already had concluded that the plaintiffs lacked standing because their claim was not redressable and that in any event the court lacked jurisdiction because the plaintiffs had

failed to exhaust their administrative remedies or demonstrate that exhaustion would be futile. 62 F. Supp. 3d at 123-24.

There is yet another reason that the court's analysis in *American Orthotic* should not be applied to this case—namely, that unlike in that case, there is no other effective way for Plaintiffs here to present their challenge to the one-year time limit to the Secretary. The members of the American Orthotic & Prosthetic Association could challenge an alleged change in the documentation required for Medicare coverage of a prosthesis through the claim appeal process; indeed, they alleged that they won a significant percentage of those administrative appeals. 62 F. Supp. 3d at 124. But Plaintiffs cannot funnel their challenge to the Secretary's system-wide policy applying the one-year time limit to rebilled Part B claims through the administrative appeal process. Medicare regulations provide that claim rejections based on the one-year time limit are not "initial determinations" and thus *cannot be litigated* through the administrative appeals process. 42 C.F.R. § 405.926(n). And although Plaintiff Einstein has asked an administrative law judge, in the event that the ALJ denies Part A payment, to permit the hospital to rebill under Part B after the one-year time limit expires—as already occurred while the appeal was pending before the ALJ—and to declare that CMS's decision to apply a one-year time limit to situations where hospitals seek to rebill for Part B payment after Part A denials is unlawful and invalid, Brunner Decl. ¶ 19, the ALJ is not allowed to award the requested relief. The Secretary has *prohibited* her adjudicators from making payment under Part B to hospitals that are partially successful in their Part A appeals, meaning that they demonstrate that the care that they provided was reasonable and necessary but the adjudicator concludes that the patient should have been treated on an outpatient basis. *See Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Final Rule,* 78 Fed. Reg. 50,496, 50,927-28 (Aug. 19, 2013). Plaintiffs therefore cannot

avail themselves of the administrative process. For that reason, Plaintiffs should be exempt from 42 U.S.C. § 405(g)'s channeling requirement altogether, because applying the requirement would mean "no review at all" of the Secretary's system-wide policy. *See Illinois Council on Long Term Care, Inc.*, 529 U.S. at 19; *Council for Urological Interests*, 668 F.3d at 712. In the alternative, the same rationale counsels in favor of finding that in these circumstances, the Plaintiffs can satisfy the presentment requirement by presenting a detailed letter from the AHA on behalf of its members outlining the specific legal bases for its claims.

For all of these reasons, this Court need not follow the approach taken in *American Orthotic* of examining the contents of the letter presented by the plaintiff association to ascertain whether it is a generalized grievance or whether it is "closer to" a concrete claim for reimbursement, *see* 62 F. Supp. 3d at 123, to find that the letter submitted by the AHA satisfies the presentment requirement. But even if the Court were to consider a similar approach in this case, the AHA submitted a letter that specifically states that the application of the one-year time limit will deprive many of its member hospitals of millions of dollars of Medicare reimbursement to which they are entitled and outlines the specific legal bases on which their challenge is based. Pls.' Opp. Ex. A. The letter also notes that the AHA and several members are prepared to pursue litigation in federal court to challenge those policies. *Id.* The D.C. Circuit has confirmed that that type of letter is enough to satisfy the presentment requirement. *Action Alliance II*, 607 F.3d at 862 n.1. Nothing more is required.[4]

[4] The Secretary also invokes *Three Lower Ctys. Cmty. Health Servs. Inc. v. U.S. Dep't of Health & Human Services* to support the proposition that a letter cannot satisfy the presentment requirement. 517 F. Supp. 2d 431, 434-436 (D.D.C. 2007) *aff'd*, 317 F. App'x 1 (D.C. Cir. 2009). But that court found that the plaintiffs had failed to *exhaust* the available administrative appeals process, not that plaintiffs' submission of a letter to an administrative tribunal failed to satisfy the *presentment* requirement. *See id.* at 435.

III. *Illinois Council* Does Not Foreclose This Court's Waiver of Exhaustion When Administrative Exhaustion Is Futile.

The Supreme Court's interpretation of the administrative channeling requirements for Medicare cases in *Shalala v. Illinois Council on Long Term Care, Inc.* does not prohibit this Court from waiving exhaustion when it would be futile. *See* 529 U.S. at 14-15. Although the Court described 42 U.S.C. § 405(h) as demanding the "channeling" of "virtually all legal attacks through the agency," 529 U.S. at 13, at the same time, the Court reiterated that the only non-waivable, non-excusable component of 42 U.S.C. § 405(g)'s requirement that there be a "final decision" by the Secretary is "that an individual present a claim to the agency before raising it in court." 529 U.S. at 14-15 (citing *Mathews v. Eldridge*, 424 U.S. at 329). The *Illinois Council* Court did not overrule *Eldridge* in this regard; rather, it characterized *Eldridge* as a case in which the Social Security beneficiary "*had followed* the special review procedures set forth in § 405(g), thereby *complying with*, rather than *disregarding*, the strictures of § 405(h)," *Illinois Council*, 529 U.S. at 14-15, and expressly left open the possibility that as long as the presentment requirement is met, a court could deem exhaustion waived in certain circumstances. *See Illinois Council*, 529 U.S. at 24 (citing *Eldridge*, 424 U.S. at 330–331). The Court did not limit the availability of waiver of exhaustion to the circumstances in *Eldridge* (involving a constitutional challenge that was "collateral" to the claim for benefits where a delay in the decision would have caused irreparable harm) and did not directly address whether, or in what circumstances, exhaustion could be waived on the basis of futility in the context of 42 U.S.C. § 405(g). *See id.*

In *Tataranowicz v. Sullivan*, the D.C. Circuit examined what were—at the time—the three main Supreme Court cases involving waiver of exhaustion under 42 U.S.C. § 405(g), including *Eldridge*, *Mathews v. Diaz*, 426 U.S. 67, 76-77 (1976), and *Bowen v. City of New York*, 467 U.S. 467, 483 (1986). 959 F. 2d at 274. The D.C. Circuit concluded that *Mathews v. Diaz*, "a pure

futility case," governed the circumstances before it, where the plaintiffs sought a declaration that the Secretary's interpretation of a provision of the Medicare statute was invalid. The court explained that it was "hard to see how any factual disputes might stand in the way of that relief," and the Secretary "gives no reason to believe that the agency machinery might accede to [the] plaintiffs' claims." *Tataranowicz*, 959 F.2d at 274. That interpretation has never been overruled by the Supreme Court. Notably, in *Illinois Council*, the Court did not address *Diaz* at all. *See* 529 U.S. at 14-25, 23-24. And in the years since *Illinois Council*, other courts in this district have relied on *Tataranowicz* and excused administrative exhaustion in Medicare cases where exhaustion would be futile. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 18, 24 (D.D.C. 2009); *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 112 (D.D.C. 2015).

To be sure, exhaustion may be waived on futility grounds only in "exceptional circumstances," where exhaustion would be "clearly useless," *Hall*, 689 F. Supp. 2d at 23 (citations omitted). But courts have recognized that such circumstances exist when the agency has adopted a policy or practice of general applicability that is contrary to federal law and the plaintiffs' legal challenge did not depend on the facts unique to any particular case. *Id.*; *see also Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d at 112.

Here, there is no doubt that requiring further exhaustion of Plaintiffs' two-midnights, physician order, and one-year time limit claims would be futile. *National Association for Home Care & Hospice, Inc. v. Burwell* is instructive. There, the court noted that the plaintiff association's challenge that the Secretary's regulation exceeded her statutory authority "require[d] the [c]ourt to consider nothing more than the statute, its legislative history, and the regulation," and that "nothing indicate[d] that administrative appeals might result in the agency overturning its regulation," because in responding to commenters in the rulemaking, "HHS flatly stated that 'we do not agree that the narrative requirement goes beyond Congressional intent." *Nat'l Ass'n for*

Home Care & Hospice, Inc., 77 F. Supp. 3d at 112. The Court had no difficulty concluding that the exhaustion requirement should be excused for that claim. *Id.*

So too here. Plaintiffs' challenges to the two-midnights rule, physician order rule, and one-year time limit turn on pure questions of law under the APA and the Medicare Act—namely, whether the Secretary's interpretation of the term "inpatient" is arbitrary and capricious, whether the Secretary's requirement of a physician order for every inpatient admission is contrary to law and arbitrary and capricious, and whether the system-wide policy of applying the one-year time limit to prohibit hospitals from rebilling under Part B after Part A payment has been denied is arbitrary and capricious.[5] Plaintiff Einstein, for example, is not challenging whether a particular inpatient admission is reasonable and necessary, whether a particular physician order meets the technical specifications set by CMS, or whether a particular Part B claim rebilled more than a year after the services were rendered should be paid. *See* Brunner Decl. ¶ 19. Rather, Einstein has conceded, for purposes of its pending Part A appeal, that the documentation in the patient's medical record does not satisfy the two-midnights rule and does not include a formal physician order for an inpatient admission. *See* Brunner Decl. ¶ 19. The one-year time limit for rebilling under Part B has already expired for that inpatient stay. *Id.* ¶ 25. Thus, the only basis on which Einstein could obtain the requested relief—Part A payment and a declaration that the three rules are invalid—would be for the ALJ to rule in Einstein's favor on the legal questions under the APA. Similarly, the only basis on which Mount Sinai could prevail in its pending Part A appeals would be for the ALJ to rule in Mount Sinai's favor on the APA challenge to the two-midnights

[5] The Secretary attempts to cast doubt as to whether Plaintiffs' challenges are "purely legal" because they have not availed themselves of another pathway for administrative exhaustion that is available once an appeal reaches the ALJ—"expedited access to judicial review." *See* 42 C.F.R. § 405.990. But the Secretary misses the point. That process would not lead to a different outcome. An ALJ does not have the authority to disregard CMS's rules. Thus it is equally futile to require the Plaintiffs to pursue expedited access to judicial review.

rule. *See* Hermann Decl. ¶¶ 15-17. There are no factual issues to be resolved in any of these appeals that are unique to the hospital's claims.

But there is no reason to believe that the Plaintiff hospitals will succeed in their pending administrative appeals. CMS has clearly staked out its positions through notice-and-comment rulemaking: adopting the two midnights rule, *see* 78 Fed. Reg. at 50,908, 50,949, 50,965; rejecting 300 commenters opposing the application of the one-year time limit to rebilled Part B claims despite having received only one comment in support of the proposal, *id.* at 50,922-24; and rejecting commenters' objections that the legislative history of the Social Security Amendments of 1967 precludes the adoption of the physician order rule, *id.* at 50,939.[6] The ALJs are not at liberty to reject those rules. The exhaustion requirement accordingly should be waived.

IV. Subsequent Changes to the Two-Midnights Rule and Physician Order Rule Do Not Affect Plaintiffs' Claims.

Since the parties submitted their briefs on the pending motion to dismiss and motion for summary judgment, CMS has completed notice-and-comment rulemaking procedures in which it significantly revised both the two-midnights and physician order rules. *See Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Stays; Final Rule*, 80 Fed. Reg. 70,298, 70,538-49 (Nov. 13, 2015); *Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Final Rule*, 79 Fed. Reg. 66,770, 66,997-99 (Nov. 10, 2014). These changes apply prospectively only, 80 Fed. Reg. at 70,298; 79 Fed. Reg. at 66,770, and thus do not affect Plaintiffs' pending challenges to either rule.

[6] Even though CMS has changed the statutory authority on which it relies to impose the physician order requirement for inpatient stays that occur after January 1, 2015, and the agency has created a new exception to the two-midnights rule for inpatient stays that occur after January 1, 2016, those changes have only prospective effect, and thus do not alter the standards that CMS's adjudicators are bound to apply to the pending appeals. *See infra* at 15-16.

Two-midnights rule: In response to stakeholder concerns that the two-midnights rule overrides the clinical judgment of the physician and does not appropriately reflect individual patient needs, *see* 80 Fed. Reg. at 70,540-41, CMS created a new exception to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not meet the two-midnights standard, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than two-midnights, *id.* at 70,541 (codified at 42 C.F.R. § 412.3(d)(3)).[7] CMS specifically stated that the change "is not a return to the policy prior to the adoption of the 2-midnight rule" and that the "policy continued to employ the 2-midnight rule." *Id.* at 70,542.

The modification to the two-midnights rule has only prospective effect and applies to inpatient stays that occur after January 1, 2016. *Id.* The change thus does not affect Plaintiffs' legal challenge to CMS's arbitrary and capricious interpretation of the meaning of "inpatient" for inpatient stays that occurred between October 1, 2013 and December 31, 2014—or the harm that Plaintiffs suffered as a result. CMS's Medicare contractors denied the Plaintiff hospitals' claims for reimbursement under Part A on the ground that they did not meet the two-midnights rule. Brunner Decl. ¶ 16; Hermann Decl. ¶ 12; Morgan Decl. ¶ 11. The Plaintiff hospitals also have been forced to comply with the two-midnights rule and bill Medicare Part B for short hospital stays, which has resulted in millions of dollars in lost Medicare reimbursement. *See, e.g.*, Compl. ¶ 82; Morgan Decl. ¶ 15. The creation of a new exception for inpatient stays after January 1, 2016 does not alleviate *any* of those harms. Moreover, even under the revised two-midnights rule, CMS continues to rely on the same counter-intuitive definition of what it means to be an "inpatient" in

[7] CMS also made a number of other changes related to its review that are not directly related to the two-midnights rule, including shifting responsibility for conducting medical reviews of inpatient admissions to Medicare contractors called Quality Improvement Organizations, rather than the Recovery Audit Contractors or Medicare Administrative Contractors. 80 Fed. Reg. at 70,545-49. Those changes took effect on October 1, 2015. *Id.* at 70,547.

most cases. The two-midnights rule remains arbitrary and capricious because it defies common sense, just as much now as it did when initially adopted. *See* Pls.' Opp'n 10-17.

Physician order rule: In her motion to dismiss, the Secretary urged this Court to delay considering the merits of Plaintiffs' challenge to her authority under the Medicare Act to adopt the physician order rule, pending the completion of a notice-and-comment rulemaking in which CMS proposed to rely on a different provision of the Medicare Act, the Secretary's general rulemaking authority under section 1871 of the Social Security Act, 42 U.S.C. § 1395hh, to require a signed physician order as a condition for Part A payment for every inpatient admission. *See Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule*, 79 Fed. Reg. 40,916, 41,057–58 (July 14, 2014). Although the Secretary acknowledged that the proposed rule did not state that it would apply retroactively, she hinted at a possibility that a final rule could be given retroactive effect and suggested—incorrectly—that if so, the Court may not need to decide this issue. Def's Reply 16-17. The conclusion of the rulemaking procedures now confirms that the Secretary's ripeness argument was a red herring. The final rule was adopted as proposed and does not apply retroactively. It applies to claims for reimbursement for services furnished only on or after January 1, 2015. *See* 79 Fed. Reg. at 66,999. Thus, the now-final rule does not change the fact that Plaintiffs were forced to comply with an unlawful physician order requirement in order to obtain Medicare Part A payment for inpatient stays that occurred from October 1, 2013 through December 31, 2014 and that the Plaintiffs lost Medicare reimbursement as a result. Morgan Decl. ¶ 21.

CONCLUSION

For all of these reasons, and those stated in their previous submissions, Plaintiffs respectfully request that the Court deny Defendant's motion to dismiss and allow Plaintiffs to

proceed with their challenges to the two-midnights rule, physician order rule, and application of the one-year time limit to rebilled claims under the Administrative Procedure Act and the Medicare Act.

Dated: February 1, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2016, I filed the foregoing document with the Clerk of Court via the CM/ECF system, causing it to be served electronically on Defendant's counsel of record.

/s/ *Catherine E. Stetson*
Catherine E. Stetson