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 (RBW)

DEFENDANT'S MOTION TO DISMISS

Defendant Sylvia M. Burwell, in her official capacity as Secretary of Health and Human Services, hereby moves to dismiss this action in its entirety for lack of jurisdiction. See Fed. R. Civ. P. 12(b)(1). The grounds for this motion are set forth in the accompanying memorandum.

Dated: July 16, 2014

Respectfully submitted,

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

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MEMORANDUM IN SUPPORT OF
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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Statutes and Regulations

Other Authorities

INTRODUCTION

Plaintiffs, a collection of hospitals and industry associations, claim that three separate Medicare rules or regulations have caused them to lose Medicare reimbursement to which they believe they are entitled. Curiously, however, they identify no actual Medicare claim that has been denied on the basis of two of those rules. As for the third, while Plaintiffs do identify a handful of allegedly denied claims, they admit that their appeals of those determinations are still pending at the administrative level.

The thread tying Plaintiffs' claims together, however loosely, is that they deal with the circumstances under which Medicare reimburses hospitals for services provided to inpatients (under Medicare Part A) versus services provided to outpatients (under Medicare Part B). In Count I, Plaintiffs challenge the "two-midnights" rule, which changes the "benchmark" for inpatient admission decisions from a 24-hour period to a single calendar day, measured from midnight to midnight. It creates a presumption — but not a per se rule — that inpatient treatment, and thus reimbursement under Part A, is generally appropriate for hospital stays expected to cross at least two midnights. But only one Plaintiff hospital alleges that it has had any Medicare claims denied on the basis of this rule, and even then, it admits that its appeals of those determinations are still pending at the administrative level. Indeed, it lodged those appeals just three days before filing this lawsuit. Compl. ¶ 85. Exhaustion of administrative remedies is a prerequisite to judicial review of claims arising under the Medicare statute, and Plaintiffs' failure to exhaust deprives the Court of jurisdiction over Count I.

In Counts III–V, Plaintiffs challenge the "physician order" rule, which makes explicit that, as a condition of payment under Part A, a patient's record must contain an order admitting the patient to the hospital. But no Plaintiff alleges that it has had any Medicare claims denied on

the basis of this rule, let alone that it has appealed any such denials through the administrative process. Indeed, Plaintiffs concede that preexisting regulations setting forth the Conditions of Participation in the Medicare program "have long required [that] each inpatient's record include a physician order admitting the patient as an inpatient," Compl. ¶ 58, and Plaintiffs do not allege that they did not already comply with those regulations, or that the new rule required them to change their behavior. Moreover, the Secretary recently published a Notice of Proposed Rulemaking proposing to amend both the content of the rule and its cited statutory basis, and the results of the pending rulemaking may afford Plaintiffs relief (if they have been harmed at all) and moot the legal issue they ask the Court to decide. Thus, whether for want of standing, failure to exhaust, or unripeness, the Court lacks jurisdiction over Counts III–V.

In Count II, Plaintiffs complain about the possibility of having Part A claims denied by Recovery Audit Contractors ("RAC") because it was not "reasonable and necessary" to admit the patient to the hospital for inpatient treatment. When faced with such determinations, or on their own accord, providers may rebill denied Part A claims under Part B, provided that the one-year time limit to do so, set forth in the Medicare statute itself, has not expired. Plaintiffs challenge the "application" of that time limit, but no Plaintiff identifies any Medicare claim that has been denied by a RAC. Nor does any Plaintiff allege that any attempt to rebill a Part A claim under Part B has been denied on the basis of the one-year time limit. Further, no Plaintiff alleges that it has appealed any RAC denials, let alone that it has exhausted the administrative process. Finally, although Plaintiffs argue that the Secretary has the discretion to reopen denied Part A claims, or to extend the deadline for untimely Part B claims, Plaintiffs identify no claims for which they have requested either form of relief, and even if they had, the Court would lack

jurisdiction to review those discretionary claims processing decisions. For any or all of these reasons, the Court lacks jurisdiction over Count II.

Thus, whether for want of standing, failure to exhaust, or unripeness, the Court should dismiss this case in its entirety for lack of jurisdiction.

BACKGROUND

A. The Medicare Program

The Medicare program, established by Title XVIII of the Social Security Act, is a federally subsidized system of health insurance for the aged and disabled. The program is divided into four parts, two of which are at issue here: Part A, which generally covers inpatient hospital services, and Part B, which generally covers outpatient services.

Some services are considered "inpatient only" and are reimbursable only under Part A, such as certain major surgeries. See 42 C.F.R. § 419.22(n). Other services are considered "outpatient only" and are reimbursable only under Part B, such as certain minor surgeries. See Medicare Benefit Policy Manual ("MBPM"), Ch. 1, § 10.[2] But many services may be reimbursed under either Part A or Part B depending on the circumstances. However, because these services can often be provided more economically — yet just as safely and effectively — on an outpatient basis, the Medicare statute precludes them from being reimbursed under Part A unless it is "reasonable and necessary" to admit the patient to the hospital for inpatient treatment. 42 U.S.C. § 1395y(a)(1)(A).[3]

[2] Chapter 1 of the Medicare Benefit Policy Manual is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf.

[3] Part B reimbursement can be less desirable to hospitals because it can pay at a lower rate for analogous inpatient services and because, under Part B, patients are responsible for a 20 percent copayment, 42 U.S.C. § 1395cc(a)(2)(A).

B. The "Two-Midnights" Rule

Medicare guidance has long recognized that the appropriateness of inpatient treatment does not depend "solely on the length of time the patient actually spends in the hospital." MBPM, Ch. 1, § 10. Rather, the decision whether to admit a patient is a "complex medical judgment" that depends on a number of factors, including "the patient's medical history and current medical needs, the types of facilities available to inpatients and outpatients, the hospital's by-laws and admissions policies" and the "predictability of something adverse happening to the patient." Id. At the same time, to encourage consistency and clarity, beginning in 2003, Medicare guidance suggested that physicians should use a 24-hour period as a "benchmark" for admission decisions, and thus "should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis." Id.

But that benchmark did not resolve all issues. For example, in 2012, a Medicare study found that, for hospital stays lasting one day or less, the rate of improper payments under Part A exceeded 36 percent — in most cases, because inpatient admission was not "reasonable and necessary" (for example, following a minor procedure or diagnostic test). The rate of improper Part A payments dropped dramatically, to 13 percent, for inpatient stays lasting two days or more. Payment Policies Related to Patient Status, 78 Fed. Reg. 50,495, 50,943 (Aug. 19, 2013).

In 2013, the Secretary promulgated a regulation changing the inpatient admission "benchmark" from a 24-hour period to a single calendar day, measured from midnight to midnight. That regulation, often referred to as the "two-midnights" rule, provides that:

> Surgical procedures, diagnostic tests, and other treatments are generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights.

42 C.F.R. § 412.3(e)(1). Conversely:

> [W]hen . . . the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed.

Id. Thus, the regulation creates a "presumption" that a hospital "stay surpassing 2 midnights . . . was appropriately provided as an inpatient service." 78 Fed. Reg. at 50,908.

The regulation does not, however, create a "per se rule" that shorter hospital stays are never reimbursable under Part A. Id. at 50,945. On the contrary, as before, the mere "length of time the beneficiary actually spends in the hospital" is not alone determinative. 78 Fed. Reg. at 50,907. For example, "inpatient only" services remain reimbursable only under Part A, regardless of the length of the hospital stay. Id. at 50,944. And although other services provided during shorter stays are "generally inappropriate" for reimbursement under Part A, 42 C.F.R. § 412.3(e)(1), reimbursement is still possible depending on the circumstances — for example, when the physician's expectation that the patient would need a longer hospital stay was reasonable though ultimately incorrect, 78 Fed. Reg. at 50,950, when the patient's condition improves, allowing earlier discharge, id. at 50,946, and in other "rare and unusual" circumstances, id.

C. The "Physician Order" Rule

The regulations setting forth the Conditions of Participation in the Medicare program "have long required [that] each inpatient's record include a physician order admitting the patient as an inpatient," as Plaintiffs allege. Compl. ¶ 58.[4] In 2013, the Secretary promulgated a

[4] See, e.g., 42 C.F.R. § 482.24(c) (requiring patient's medical record to "contain information to justify admission and continued hospitalization," including the "admitting diagnosis" and "all practitioners' orders"); 42 C.F.R. § 482.12(c)(2) (patients must be "admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital").

regulation making explicit that "such written physician orders are a condition of Part A payment." Id. The regulation, referred to as the "physician order" rule, provides in relevant part:

> For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital . . . if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and [42 C.F.R.] §§ 482.24(c) [and] 482.12(c) . . . . This physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.

42 C.F.R. § 412.3(a). Plaintiff describes this regulation as "redundant" of preexisting regulatory requirements. Compl. ¶ 58.

Medicare guidance states that the physician order "must specify the admitting practitioner's recommendation to admit 'to inpatient,' 'as an inpatient,' 'for inpatient services,' or similar language specifying his or her recommendation for inpatient care." 78 Fed. Reg. at 50,942. However, even where "the order to admit is missing or defective (that is, illegible or incomplete)," Medicare contractors have "discretion to determine" that the requirement is "constructively satisfie[d]" if "the intent, decision, and recommendation of the physician . . . to admit the beneficiary can clearly be derived from the medical record." Id.

D. Medicare Billing and Claims Processing

Medicare Part A allows an entitled beneficiary "to have payment made on his behalf" for "inpatient hospital services." 42 U.S.C. § 1395d. This entitlement is "subject to the provisions of [Part A]," id., which make the first condition of entitlement to payment the submission of a claim for payment to the Secretary, id. § 1395f(a)(1). Further, the statute requires that such a claim be filed in "such form" and "such manner . . . as the Secretary may by regulation prescribe," and that it be filed within "1 calendar year after the date of service." Id.

Similarly, Medicare Part B allows an enrolled beneficiary "to have payment made . . . on his behalf" for "medical and other health services," including outpatient services. 42 U.S.C.

§ 1395k(a)(1). Like the Part A benefit, this Part B benefit is "subject to the provisions of [Part B]," id., which also make the first condition of entitlement to payment the submission of a claim for payment to the Secretary. 42 U.S.C. § 1395n(a)(1). In addition, the statute also requires that a Part B claim be filed in "such form" and "such manner . . . as the Secretary may be regulation prescribe," and that it be filed within "1 calendar year after the date of service." Id.; see also 42 U.S.C. § 1395u(b)(3)(B).

Pursuant to her statutory authority to implement the Medicare statute, 42 U.S.C. § 1395hh(a)(1), the Secretary has promulgated regulations governing the form and manner in which Part A and Part B claims must be filed. See 42 C.F.R. § 424.30 ("This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments."). As relevant here, those regulations reiterate the statutory one-year filing requirement, but set forth limited exceptions thereto. See 42 C.F.R. § 424.44(b) ("Exceptions to time limits."). For example, "[t]he time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline . . . was caused by error or misrepresentation of an . . . agent of HHS." Id.

The Secretary has also promulgated detailed regulations governing the way she processes claims for Medicare payment. See 42 U.S.C. § 1395hh(a)(1); 42 C.F.R. § 405.900 et seq. As directed by Congress, the Secretary relies on third-party contractors, known as Medicare Administrative Contractors, to take the first cut at processing the billion-plus claims filed each year. See 42 U.S.C. §§ 1395h, 1395kk(a), 1395u (authorizing delegation to contractors); 42 C.F.R. §§ 421.200, 405.904(a)(2).

The first step that a Medicare contractor takes "[a]fter a claim is filed . . . in the manner and form described in [42 C.F.R. § 424 et seq.]" is to "[d]etermine if the items and services

furnished are covered" by Medicare. 42 C.F.R. § 405.920(a). If they are, the contractor "determine[s] any amounts payable and make[s] payment accordingly." Id. § 405.920(b). In either case, the contractor then "[n]otif[ies] the parties" of its decision. Id. § 405.920(c). This is where things get complicated.

Contractors are the first decision makers on claims for Medicare payment, but they are not necessarily the last. Often, either the beneficiary or the provider will be displeased with the contractor's decision. When that happens, what comes next depends on what the contractor decided and when.

1. Properly filed claims, initial payment determinations, appeal to the Medicare Appeals Council, and judicial review

If the contractor accepts a claim but determines that the services rendered were not covered by Medicare, or pays the provider less than the provider believes it is owed, the provider (or any other party) may appeal the contractor's "initial determination" through four levels of administrative review. It may first request, within 120 days, a "redetermination" by the contractor itself, 42 U.S.C. § 1395ff(b)(1)(A); then "reconsideration" by a Qualified Independent Contractor ("QIC"), id. § 1395ff(c); followed by a hearing before an Administrative Law Judge ("ALJ"), id. § 1395ff(d)(1); and, finally, de novo review before the Medicare Appeals Council ("MAC"), a division of the Departmental Appeals Board, id. § 1395ff(d)(2); 42 C.F.R. § 405.1100. The MAC's decision is the "final decision" of the Secretary, and is appealable to district court in accordance with 42 U.S.C. § 405(g). 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1130. If the provider opts not to appeal within 120 days of receiving an initial determination, then the initial determination becomes "binding." 42 C.F.R. § 405.928.

2. Untimely or otherwise defective claims

If, on the other hand, the contractor rejects a claim because it was not properly filed in the first place — for example, because it was untimely — that decision is not considered an "initial determination." See 42 C.F.R. § 405.926(n) ("Actions that are not initial determinations and are not appealable under this subpart include . . . [d]eterminations that a provider or supplier failed to submit a claim timely[.]"). As such, it may not be appealed at all. Id.

3. Reopening an un-appealed or otherwise binding payment determination

Finally, if any party to a payment determination, including the contractor, comes to suspect that a payment decision was in error after the time for appeal has run (and therefore the decision has become binding), it can under limited circumstances seek "reopening" to revise the determination. 42 U.S.C. § 1395ff(b)(1)(G) ("The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations."); 42 C.F.R. § 405.980(a)(1) ("Reopening is "a remedial action taken to change a binding determination or decision that resulted in either an overpayment or underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record."). If a determination is reopened, any resulting revised payment determination is subject to the same appeal procedures as the initial version (as to matters actually revised in the new determination). See 42 C.F.R. § 405.984. A decision not to grant reopening, however, is not an "initial determination," and, like a decision to reject a claim as untimely, may not be appealed at all. See 42 C.F.R. § 405.926(*l*) ("Actions that are not initial determinations and are not appealable under this subpart include . . . [a] contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen[.]").

E. Post-Payment Review by Recovery Audit Contractors

As mentioned above, more than one billion Medicare claims are filed every year, by more than 1.5 million different medical providers, on behalf of 100 million beneficiaries.[5] That is more than 4.8 million Medicare claims every day. Id. Nearly all must be processed and paid within 30 days. See 42 U.S.C. §§ 1395h(c)(2), 1395u(c)(2). In processing these claims, the "Secretary faces an administrative task of staggering proportions," and "[p]erfection in processing millions of such claims annually is impossible." Bowen v. Yuckert, 482 U.S. 137, 157 (1987) (O'Connor, J., concurring). Indeed, as of 2008, "improper payments for Medicare constitute[d] a high percentage, more than ten percent, of all payment errors in federal programs," Palomar, 693 F.3d at 1156 (citation omitted), and cost the federal government, by some estimates, more than $68 billion dollars a year, see Ironworkers Local Union 68 v. AstraZeneca Pharm., 634 F.3d 1352, 1368 (11th Cir. 2011).

Concerned that the growing annual cost of the Medicare program was due in part to overpayments to providers hidden among these billion-plus payment determinations, and after a successful demonstration project, Congress directed the Secretary to use Recovery Audit Contractors ("RACs") to conduct post-payment review of suspect Medicare claims, to recoup (for the Medicare trust fund) any overpayments they found, and to pay (to the hospitals) any underpayments they found. Palomar, 693 F.3d at 1157 (citing 42 U.S.C. § 1395ddd(h)(1), (3)). Congress's intent in so doing was to enable the Secretary to "promote the integrity of the Medicare program." 42 U.S.C. § 1395ddd(a). Under the regulations applicable by default to

[5] See Palomar Med. Ctr. v. Sebelius, 693 F.3d 1151, 1156 (9th Cir. 2012) (citation omitted); Preventing and Recovering Medicare Payment Errors: Hearing Before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and Internet of the Senate Committee on Homeland Security and Government Affairs, 111th Cong. (July 15, 2010) (statement of Deborah Taylor, Chief Financial Officer and Director, CMS Office of Financial Management), available at http://www.hhs.gov/asl/testify/2010/07/t20100715a.html.

reopening, any provider who disagreed with a RAC determination could, within 120 days, appeal that determination administratively, and ultimately seek judicial review. See supra Part D.1 at 8.

The RACs discovered that many hospitals had inappropriately admitted patients and billed for their treatment as inpatients under Part A, and in such cases sought recoupment of the improper payments. A number of hospitals that received unfavorable RAC determinations filed timely administrative appeals, arguing that, even if their Part A claim were in error, they should have been reimbursed as if they had (correctly) refused the patient admission, treated him (or her) as an outpatient, and billed the treatment as a less-expensive Part B claim. See Am. Hosp. Ass'n v. Burwell, No. 12-1770 (D.D.C.), 2d Am. Compl. ¶ 51 & n.1 [ECF No. 26] (citing 16 such cases). This forgiving position was contrary to Medicare guidance issued by the Centers for Medicare & Medicaid Services ("CMS"), the component within the Department of Health and Human Services responsible for administering the Medicare program. See, e.g., Part B Inpatient Billing in Hospitals, 78 Fed. Reg. 16,632, 16,633-34 (Mar. 18, 2013) ("[U]nder Medicare's longstanding policy," where a Part A claim is denied because inpatient treatment was not reasonable and necessary, a provider could rebill under Part B "for only a limited list of ancillary medical and other health services."). Nevertheless, the Medicare Appeals Council, which, as discussed above, is the last resort in the administrative process before judicial review, agreed with hospitals in a number of such appeals. Id. at 16,635.

The Secretary determined that the tension between CMS's guidance governing payment of claims generally and the MAC's rulings on particular appeals "created numerous operational difficulties." Id. After "considering the most efficient way to effectuate the Medicare Appeals Council and ALJ decisions . . . and further assessing [the] Part B inpatient policy," the Secretary issued a Notice of Proposed Rulemaking to change her policy going forward to allow for more

generous rebilling under Part B of improper Part A claims, "provided the statutorily required timeframe for submitting claims is not expired." Part B Inpatient Billing in Hospitals, 78 Fed. Reg. 16,632, 16,635-36, 39-40 (Mar. 18, 2013). The Secretary addressed the latter condition at length in the proposed rule, id. at 16,639-40, specifically proposing to provide that a hospital's mistaken belief that a claim had been appropriately billed under Part A would not support an exception to the one-year statutory limitation period for rebilling the claim under Part B. See id. at 16,640. The Secretary's reasoning for that proposed approach was that "it is the responsibility of providers to correctly submit claims to Medicare by coding services appropriately." Id.[6]

In the final rule, the Secretary again addressed this issue, and ultimately declined to create an exception to the one-year statutory limitation period for filing Part B claims. She explained that the existing exceptions to this requirement were created to address situations where Medicare providers, "through no fault of their own, would be disadvantaged by strict application of the 1-calendar year timely filing requirement." 78 Fed. Reg. at 50,923. By contrast, "it is the responsibility of providers to correctly submit claims to Medicare by coding services appropriately" and "determining whether the submission of a Part A or Part B claim is appropriate within the applicable timeframe." Id. at 50,922-23. Hospitals thus "have the ability to avoid being disadvantaged by the 1-calendar year time limit to file claims and by any subsequent RAC audit if they bill correctly" in the first instance. Id. at 50,923. Moreover,

[6] Because rulemaking takes time and there were appeals (and potential appeals) from unfavorable Part A payment determinations in the administrative pipeline, on the day she initiated the rulemaking, the Secretary issued Ruling 1455-R, an "interim measure" that applied only until a final rule was issued. Id. at 16,635. In that Ruling, the Secretary "acquiesce[d]" in the MAC's approach by providing that hospitals with pending appeals, or for which the time to appeal had not yet run, could submit Part B claims for payment as to services originally billed (inappropriately) as Part A claims. Id. The Ruling, by its own terms, did "not apply to Part A hospital inpatient claim denials for which the timeframe to appeal expired prior to the effective date of the Ruling." CMS Ruling 1455-R, 78 Fed. Reg. 16,634, 16,616 (Mar. 18, 2013).

hospitals remain free to "self-audit" to "correct this type of Part A billing error," and may rebill under Part B "as long as that Part B claim is filed within 1-calendar year after the date of service." Id. at 50,926.

F. This Action

Plaintiffs' complaint contains five counts. Count I alleges that the two-midnights rule is arbitrary and capricious because it redefines the term "inpatient" in a manner at odds with its ordinary meaning. Compl. ¶¶ 97-101. Count II alleges that the "application" of the one-year time limit for rebilling denied Part A claims under Part B is arbitrary and capricious. Id. ¶¶ 102-09. Counts III and IV allege that the physician order rule is contrary to the text of the Medicare Act, and thus invalid. Id. ¶¶ 110-17. Count V alleges that the physician order rule is arbitrary and capricious because the Secretary failed to articulate a sufficiently sound reason for it. Id. ¶¶ 118-22.

As relief, Plaintiffs ask the Court to invalidate the two-midnights rule, the physician order rule, and the one-year time limit for rebilling denied Part A claims under Part B. Id. ¶¶ A-F (prayer for relief). They further ask the Court to "order that the Plaintiff hospitals be reimbursed for the reasonable and necessary care they provided in the appeals at issue." Id. ¶ G (emphasis added).

Plaintiffs are four hospitals (or hospital networks) and five industry associations. Only two of them set forth allegations identifying any Medicare claims or "appeals at issue." Id. First, Mount Sinai Hospital submitted a single Part A claim that, it alleges, does not meet the "technical requirements" of the two-midnights rule or the physician order rule, but still merits payment. Id. ¶ 86. It does not allege that the claim has been denied, even at the first level of review. See id. Second, Banner Health alleges that a Medicare contractor denied seven Part A

claims from one of its hospitals for noncompliance with the two-midnights rule. Id. ¶ 84. Three days before filing this lawsuit, it appealed five of those denials, "argu[ing] that the [two-midnights] rule is arbitrary and capricious and therefore invalid." Id. ¶ 85. It does not allege that any of those appeals has been finally resolved against it.

No Plaintiff alleges that it has had any claim denied on the basis of the physician order rule. Nor does any Plaintiff allege that it has received an unfavorable RAC determination on any claim, or that any attempt to rebill a Part A claim under Part B has been denied on the basis of the one-year statutory filing deadline.

LEGAL STANDARDS

"'Federal courts are courts of limited jurisdiction' and can adjudicate only those cases entrusted to them by the Constitution or an Act of Congress." Kim v. United States, 840 F. Supp. 2d 180, 184 (D.D.C. 2012) (quoting Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994)). In evaluating whether to dismiss a case for lack of subject matter jurisdiction under Rule 12(b)(1), "[t]he district court should begin with the presumption that it does not have subject matter jurisdiction." Id. (citing Kokkonen, 511 U.S. at 377). Plaintiffs bear the burden of showing that the Court has subject matter jurisdiction, Georgiadies v. Martin-Trigona, 729 F.2d 831, 833 n.4 (D.C. Cir. 1984) ("It is the burden of the party claiming subject matter jurisdiction to demonstrate that it exists."), which includes the "burden of showing the issue in this case is ripe." Toca Producers v. FERC, 411 F.3d 262, 267 (D.C. Cir. 2005).

Even where it is grounded in prudential rather than constitutional considerations, ripeness is a "threshold question" that may be addressed by the Court before addressing subject matter jurisdiction. See Toca Producers, 411 F.3d at 265 n.* (D.C. Cir. 2005) ("Because the ripeness requirement, even in its prudential aspect . . . calls for a threshold inquiry that does not involve

an adjudication on the merits, it . . . may be resolved without first addressing whether the [plaintiffs] have Article III standing."). As such, the Court may address the bases offered by the Government for dismissal under Rule 12(b)(1) in any order.

ARGUMENT

I. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE TWO-MIDNIGHTS RULE BECAUSE PLAINTIFFS HAVE NOT EXHAUSTED THEIR ADMINISTRATIVE REMEDIES

Plaintiffs' principal challenge in this case is to the two-midnights rule. See Compl. ¶¶ 97-101 (Count I). They ask the Court to invalidate that regulation, id. ¶¶ A, F, and to "order that the Plaintiff hospitals be reimbursed for the reasonable and necessary care they provided in the appeals at issue," id. ¶ G. Yet only one Plaintiff hospital identifies any Medicare claims that have been denied on the basis of that regulation and, even then, it admits that its appeals of those determinations are still pending at the administrative level. Id. ¶¶ 84-85. Thus, the Court should dismiss Count I for lack of jurisdiction because Plaintiffs have not yet exhausted their administrative remedies.

In their complaint, Plaintiffs identify a single source of jurisdiction over their claims: "42 U.S.C. § 1395ff(b)(1)(A), which provides for 'judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.'" Compl. ¶ 20. Section 405(g), in turn, requires claimants to exhaust their administrative remedies, by obtaining a final decision from the Secretary, before filing suit in federal court: "Any individual, after any final decision of the [Secretary] made after a hearing to which the was a party . . . may obtain a review

of such decision by a civil action." Id. (quoting 42 U.S.C. § 405(g)) (emphasis added; alteration in original).[7]

One thing that is absolutely clear about the reviewability in federal court of claims "arising under" the Medicare statute within the meaning of 42 U.S.C. § 405(g)-(h), such as Plaintiffs' claims here, is that claimants must timely appeal initial denials and fully exhaust any administrative process that exists for prosecuting such claims before there can be judicial review. The Supreme Court has repeatedly so held. See Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 13 (2000) (section 405(h) "demands the 'channeling' of virtually all legal attacks through the agency"); Heckler v. Ringer, 466 U.S. 602, 627 (1984) ("In the best of all worlds, immediate judicial access for all of these parties might be desirable. But Congress, in § 405(g) and § 405(h), struck a different balance, refusing declaratory relief and requiring that administrative remedies be exhausted before judicial review of the Secretary's decisions takes place.").[8]

[7] Plaintiffs properly do not assert that the Court has jurisdiction under the general federal question statute, 28 U.S.C. § 1331, because 42 U.S.C. § 405(h) precludes such jurisdiction over claims arising under the Medicare statute: "No action against the United States, the [Secretary] or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28, United States Code, to recover on any claim arising under this title."

[8] Although Plaintiffs assert that this action "arises under" the Administrative Procedure Act, in addition to the Medicare Act, Compl. ¶ 19, they do not assert that the APA provides an independent source of jurisdiction, and it does not. Your Home Visiting Nurse Services, Inc. v. Shalala, 525 U.S. 449, 457 (1999) (citations omitted) ("[W]e have long held that [5 U.S.C. § 706] is not an independent grant of subject matter jurisdiction."). Rather, "[§] 405(h) . . . makes § 405(g) the exclusive avenue for judicial review of administrative decisions" under the Medicare Act. National Kidney Patients Ass'n v. Sullivan, 958 F.2d 1127, 1130 (D.C. Cir. 1992); see Heckler v. Ringer, 466 U.S. 602, 622 (1984) (assertion that claim "arising under" the Medicare Act also "arises under" the APA does not circumvent § 405(g)-(h)). Likewise, "[d]eclaratory relief is not an independent cause of action," and Plaintiffs' invocation of the Declaratory Judgment Act, Compl. ¶ 21, "does not provide an independent source of federal jurisdiction." Yancey v. District of Columbia, — F. Supp. 2d —, No. 10-1953, 2013 WL

Here, Plaintiffs have not exhausted their administrative remedies. Only two Plaintiffs even set forth allegations identifying any Medicare claims or "appeals at issue." Compl. ¶ G. First, Mount Sinai Hospital submitted a single Part A claim that, it alleges, does not meet the "technical requirements" of the two-midnights rule, but still merits payment. Id. ¶ 86. But it does not allege that the claim has been denied, even at the first level of review, let alone that it has appealed any such denial through the administrative process. See id. Second, Banner Health alleges that a Medicare contractor denied seven Part A claims from one of its hospitals for noncompliance with the two-midnights rule, id. ¶ 84, and that it appealed five of those denials, "argu[ing] that the [two-midnights] rule is arbitrary and capricious and therefore invalid," id. ¶ 85. But it filed suit just three days after those appeals were lodged, and does not allege that any of them has been resolved unfavorably, let alone that it has received a "final decision" from the Secretary entitling it to judicial review in federal court. See id.

If any other Plaintiff hospitals (or member hospitals of the Plaintiff associations) have had claims denied on the basis of the two-midnights rule, they do not say so in the complaint. Nor do they allege that they have appealed any such denials. Certainly, Plaintiffs cannot exhaust their administrative remedies as to such claims by declining to appeal; quite the opposite. See Spanish Int'l Broad. Co. v. FCC, 385 F.2d 615, 628 (D.C. Cir. 1967) ("exhaustion of administrative remedies means utilization of the earliest available corrective step"). Only by pursuing an appeal all the way to the MAC can a claimant obtain a "final decision of the [Secretary] . . . made after a hearing" that is reviewable in federal court under 42 U.S.C. § 405(g). 42 C.F.R. §§ 405.1100, 405.1130, 405.1136.

5931543, at *6 n.6 (D.D.C. Nov. 6, 2013) (citing Ali v. Rumsfeld, 649 F.3d 762, 778 (D.C. Cir. 2011)).

The exhaustion requirement makes particular sense here. Any unfavorable initial determinations that Plaintiffs appeal may not stand upon further review, and Plaintiffs could well obtain the relief they seek through the administrative process, mooting the need for judicial involvement. The central question in any such appeal — whether admission to the hospital for inpatient treatment is "reasonable and necessary" in a given case — may be heavily fact dependent, turning on the patient's "medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk (probability) of an adverse event." 78 Fed. Reg. at 50,949-50. And while the two-midnights rule sets forth a "presumption" that a hospital "stay surpassing 2 midnights . . . was appropriately provided as an inpatient service," id. at 50,908, it does not create a "per se rule" that shorter hospital stays are never reimbursable under Part A, id. at 50,945. On the contrary, shorter stays may still be reimbursed under Part A, depending on the circumstances — for example, when the physician's expectation that the patient would need a longer hospital stay was reasonable though ultimately incorrect, id. at 50,950, when the patient's condition improves, allowing earlier discharge, id. at 50,946, and in other "rare and unusual" circumstances, id. Thus, Banner Health's pending administrative appeals may result in payment of their initially denied claims.

Moreover, because the final agency actions that Plaintiffs purport to challenge have not actually happened, there is not yet an administrative record of those actions for the Court to review. Plaintiffs note that, in the appeals they did lodge, they specifically "argued that the [two-midnights] rule is arbitrary and capricious and therefore invalid." Compl. ¶ 85. Yet they filed this action just three days later, before building a record and obtaining the Secretary's final decision on that question. The existence of an administrative record is particularly important in APA actions because "[t]he focal point for judicial review" in such cases is "the administrative

record already in existence, not some new record made initially in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142 (1973). In cases such as this, the district court "sits as an appellate tribunal, not as a court authorized to determine in a trial-type proceeding" the lawfulness of the agency's action. Marshall County Health Care Auth. v. Shalala, 988 F.2d 1221, 1225 (D.C. Cir. 1993). To assess Plaintiffs' claim that the two-midnights rule is arbitrary and capricious, the Court must evaluate the reasoning and legal basis for any such decision. Without an administrative record, the Court cannot do so. But an administrative record cannot be compiled until the agency has actually taken action, which means that Plaintiffs must exhaust their administrative remedies. See Toilet Goods Ass'n v. Gardner, 387 U.S. 158, 166 (1967) (requiring plaintiff to exhaust the administrative process before seeking judicial review so that "more light may be thrown on the Commissioner's statutory and practical justifications for the regulations").

Because Plaintiffs have failed to exhaust their administrative remedies, the Court should dismiss their challenge to the two-midnights rule for lack of jurisdiction.

II. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE PHYSICIAN ORDER RULE

In Counts III–V, Plaintiffs challenge the physician order rule. See Compl. ¶¶ 110-22. They ask the Court to invalidate that regulation, id. ¶¶ C-F, and to "order that the Plaintiff hospitals be reimbursed for the reasonable and necessary care they provided in the appeals at issue," id. ¶ G. Yet no Plaintiff identifies any Medicare claim that has been denied on the basis of that regulation, let alone that it has appealed any such denial through the administrative process. Moreover, the Secretary recently published a Notice of Proposed Rulemaking proposing to amend both the content of the rule and its statutory basis, and the results of the pending rulemaking may afford Plaintiffs relief (if they have been harmed at all) and moot the

legal issue they ask the Court to decide. Thus, the Court should dismiss Counts III–V for lack of jurisdiction for any of three independent reasons: lack of standing, failure to exhaust administrative remedies, or lack of ripeness.

A. Plaintiffs Lack Standing to Challenge the Physician Order Rule

To establish Article III standing, a plaintiff must meet the familiar requirements of: (1) an injury in fact; (2) causation; and (3) redressability. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992). As the parties invoking the Court's jurisdiction, Plaintiffs bear the burden "clearly to allege facts demonstrating" each of these three elements. Warth v. Seldin, 422 U.S. 490, 518 (1975). The necessary facts "must affirmatively appear in the record" and "cannot be inferred argumentatively from averments in the pleadings." FW/PBS, Inc. v. Dallas, 493 U.S. 215, 231 (1990). Here, Plaintiffs fail to establish that the physician order rule has caused any Plaintiff a concrete harm, or that setting it aside would redress any alleged injury.

To begin, no Plaintiff identifies any Medicare claim that has been denied on the basis of the physician order rule. That may be because the regulation imposes no new legal obligation on them. According to the complaint, the new rule makes explicit that "physician orders are a condition of Part A payment." Compl. ¶ 58. But, as Plaintiffs acknowledge, the preexisting regulations setting forth the Conditions of Participation in the Medicare program "have long required [that] each inpatient's record include a physician order admitting the patient as an inpatient." Id. It is well established that providers, including the Plaintiff hospitals, must meet all such Conditions of Participation in order to participate in the Medicare program. Nat'l Ass'n of Psychiatric Health Sys. v. Shalala, 120 F. Supp. 2d 33, 35 (2000). If they fail to do so, "the Secretary may terminate or refuse to renew the hospital's provider agreement for participation in the Medicare program." Id. (citing 42 U.S.C. § 1395cc(b)(2)(B); 42 C.F.R. §§ 488.456,

489.53(a)(3)). Thus, Plaintiffs were already obligated to meet this requirement, regardless of the new regulation.

It is notable, then, that the Plaintiff hospitals neither allege that they do not already comply with this requirement, nor that they have had to change their behavior to come into compliance. Most likely, they have had to do nothing. Indeed, in promulgating the final rule, the Secretary noted that "some commenters representing hospitals did not object to this requirement because it is already standard practice." 78 Fed. Reg. at 50,942. The Plaintiff hospitals do not allege otherwise.[9]

By the same token, even if the Court were to invalidate the physician order rule, as Plaintiffs request, it would not redress any alleged injury. The Plaintiff hospitals would remain under a legal obligation to satisfy the Conditions of Participation, which, they agree, already "require[that] each inpatient's record include a physician order admitting the patient as an inpatient." Compl. ¶ 58. Thus, with or without the new regulation, the need for a physician order would remain. Its invalidation would therefore redress no concrete injury. See Lujan, 504 U.S. at 560-61.

[9] Mount Sinai Hospital does allege that it has spent time "updating its medical records system . . . to allow a physician to countersign his or her own verbal order for admission." Compl. ¶ 90. But it does not allege that its prior procedures did not satisfy the Conditions of Participation. Nothing in the new regulation requires providers to use verbal orders, rather than orders in any other form; indeed, "no specific procedures or forms are required" and the "provider may adopt any method that permits verification." 78 Fed. Reg. at 50940. And the Conditions of Participation already required that "[a]ll orders, including verbal orders, must be . . . authenticated promptly by the ordering practitioner." 42 C.F.R. § 482.12(c)(2); see also CMS, Hospital Inpatient Admission Order and Certification, at 5 (Jan. 30, 2014) (noting that "authenticated" means "countersigned"), available at http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf.

B. Plaintiffs Have Failed to Exhaust Their Administrative Remedies

In any event, Plaintiffs have not exhausted their administrative remedies with respect to the physician order rule. Only one Plaintiff sets forth allegations identifying any Medicare claim potentially implicating this regulation. Mount Sinai Hospital allegedly submitted a single Part A claim that, it contends, does not meet the "technical requirements" of the physician order rule, but still merits payment. Compl. ¶ 86. But it does not allege that its claim has been denied on the basis of that regulation, let alone that it has appealed any such denial through the administrative process and received a final decision of the Secretary with which it is dissatisfied.

That alone is fatal to Plaintiffs' challenge to the physician order rule. As explained above in the context of the two-midnights rule, 42 U.S.C. § 405(g) requires claimants to timely appeal initial denials and fully exhaust the administrative process before there can be judicial review. And only by pursuing an appeal all the way to the MAC can a claimant obtain a "final decision of the [Secretary] . . . made after a hearing" that is reviewable in federal court under § 405(g). 42 C.F.R. §§ 405.1100, § 405.1130; § 405.1136; see supra Part I at 15-17.

The exhaustion requirement makes good sense here. Like the two-midnights rule, the physician order rule is not a "per se" bar to reimbursement under Part A. To be sure, as Plaintiffs note, Medicare guidance states that the required order "must specify the admitting practitioner's recommendation to admit 'to inpatient,' 'as an inpatient,' 'for inpatient services,' or similar language specifying his or her recommendation for inpatient care." 78 Fed. Reg. at 50,942; see Compl. ¶ 59. However, even where "the order to admit is missing or defective (that is, illegible or incomplete)," Medicare contractors have "discretion to determine" that the requirement is "constructively satisfie[d]" if "the intent, decision, and recommendation of the physician . . . to admit the beneficiary can clearly be derived from the medical record." 78 Fed.

Reg. at 50,942. Thus, in a given case, application of the rule may be fact dependent, and technical noncompliance with the rule — such as Mount Sinai Hospital alleges here — may be excused where the physician's intent is clear. See id. Accordingly, any unfavorable initial determinations that Plaintiffs appeal may not stand upon further review, and Plaintiffs could well obtain the relief they seek through the administrative process, mooting the need for judicial involvement.

Moreover, as with the two-midnights rule, because the final agency actions that Plaintiffs purport to challenge have not actually happened, there is not yet an administrative record of those actions for the Court to review. See supra at 18-19. To assess Plaintiffs' challenge to the physician order rule, the Court must evaluate the reasoning and legal basis for any such decision. Without an administrative record, the Court cannot do so. But an administrative record cannot be compiled until the agency has actually taken action, which means that Plaintiffs must exhaust their administrative remedies. See Toilet Goods, 387 U.S. at 166 (requiring plaintiff to exhaust the administrative process before seeking judicial review so that "more light may be thrown on the Commissioner's statutory and practical justifications for the regulations").

C. Plaintiffs' Challenge to the Physician Order Rule Is Not Ripe

The Secretary recently published a Notice of Proposed Rulemaking proposing to amend both the content of the physician order rule and its cited statutory basis. Physician Certification of Inpatient Hospital Services, 79 Fed. Reg. 40,916, 41,056-58 (July 14, 2014). Because the outcome of the pending rulemaking may afford Plaintiffs relief (if they have been harmed at all) and moot the legal issue they ask the Court to decide, their challenge will be unripe at least until that rulemaking has been completed.

"The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." Nat'l Park Hospitality Ass'n v. Dep't of the Interior, 538 U.S. 803, 808 (2003) (quotation omitted). It "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies." Id. It also "protect[s] the agencies from judicial interference until an administrative decision has been formalized." Id. at 808-09.

In assessing ripeness, courts evaluate both "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967), overruled on other grounds by Califano v. Sanders, 430 U.S. 99, 105 (1977). Here, the former factor counsels strongly in favor of the conclusion that judicial review is premature, and the latter factor does nothing to undermine that conclusion.

1. Plaintiffs' challenge is unfit for judicial resolution because proposed amendments to the rule may provide Plaintiffs relief and moot the legal issue they ask the Court to decide

The Secretary promulgated the current rule under the authority of 42 U.S.C. § 1395f(a)(3), which permits reimbursement under Part A "only if . . . with respect to inpatient hospital services . . . which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis." 42 U.S.C. § 1395f(a)(3); see 78 Fed. Reg. at 50,938-40. Accordingly, in its current form, the physician order requirement serves at least two related purposes: (1) it formally initiates an inpatient admission, 42 C.F.R. § 412.3(a), and (2) it certifies that, in the judgment of the admitting physician, inpatient treatment is medically necessary, id. § 412.3(c); see also id. § 424.13(a).

In promulgating the current rule, the Secretary explained that some commenters had argued that the statutory phrase "over a period of time" indicates that a physician certification is

required only for longer hospital stays, not short-term ones. 78 Fed. Reg. at 50,938. That is the same argument that Plaintiffs make in Counts III and IV of the complaint. Compl. ¶ 67 (Congress "limit[ed] the certification requirement by adding the 'over a period of time' qualifier"); id. ¶ 71 (the statutory "language 'over a period of time' was designed to limit the physician order requirement to extended stays"); id. ¶¶ 112 (the physician order "requirement is contrary to the language, intent, and history of 42 U.S.C. § 1395f(a)(3)"). The Secretary disagreed, however, explaining that the phrase was ambiguous, that Congress had expressly delegated the authority to elucidate its meaning by regulation,[10] and that her interpretation, though not the only possible one, was a permissible one. 78 Fed. Reg. at 50,939 (citing Chevron USA, Inc. v. Nat. Res. Def. Council, 467 U.S. 837 (1984)).

In the proposed rule, the Secretary is considering a different approach. Although she continues to believe that the current rule reflects a permissible interpretation of 42 U.S.C. § 1395f(a)(3), she has proposed changing the cited statutory basis for the requirement. Rather than relying on 42 U.S.C. § 1395f(a)(3), the Secretary now "propos[es] to require such orders as a condition of payment based upon [her] general rulemaking authority." 79 Fed. Reg. at 41,057 (citing 42 U.S.C. § 1395hh, which authorizes the "Secretary [to] prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [the Medicare Act]").

In addition, because the proposed rule would no longer rely on the physician certification requirements of 42 U.S.C. § 1395f(a)(3), it would no longer serve the second purpose discussed above — to certify that inpatient treatment is medically necessary. Accordingly, the Secretary

[10] See 42 U.S.C. § 1395f(a)(3) ("such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations").

has also proposed deleting the portion of the current rule now codified at 42 C.F.R. § 412.3(c) ("The physician order also constitutes a required component of physician certification of hospital inpatient services under subpart B of [42 C.F.R.] Part 424."). 79 Fed. Reg. at 41,057.

These proposed changes have two practical consequences for Plaintiffs' challenge to the physician order rule. First, if the proposed rule takes effect, the central legal question that Plaintiffs have put before the Court — whether the physician order rule is consistent with 42 U.S.C. § 1395f(a)(3) — will be moot, because the rule will no longer rely on that authority. In short, if the Court does not decide that question now, it may never need to. See, e.g., Am. Petroleum Inst. v. EPA, 683 F.3d 382, 387 (D.C. Cir. 2012) ("In light of the . . . proposed rule, . . . '[i]f we do not decide [the issue] now, we may never need to.'") (citation omitted); Utility Air Regulatory Group v. EPA, 320 F.3d 272, 279 (D.C. Cir. 2003) ("It would be a waste of judicial resources for us to reach the merits . . . while the rulemaking is pending.").

Second, if the proposed rule takes effect, it would no longer be tied to the physician certification requirements of 42 U.S.C. § 1395f(a)(3), and thus 42 C.F.R. § 412.3(c) would be deleted. As a result, the required admission order would no longer need to be signed by a physician, but could instead be signed by a non-physician practitioner, so long as he (or she) has admitting privileges at the hospital under state law (and meets certain other requirements). See 42 C.F.R. § 412.3(b). Although, as explained above, Plaintiffs have not demonstrated that they are harmed by rule in its current form — including the requirement that the order by signed by a physician — they appear to complain about the "specific requirements regarding the practitioner who must sign . . . the order." Compl. ¶ 59. Thus, adoption of the proposed rule would appear to provide a measure of relief from this requirement, if Plaintiffs were ever harmed by it.

In similar circumstances, courts have repeatedly held that claims challenging a policy subject to change in an ongoing rulemaking are unripe. See, e.g., Am. Petroleum Inst., 683 F.3d at 387-89 (challenge to regulation unripe where agency had initiated a rulemaking that could significantly amend the regulation); AT&T Corp. v. FCC, 369 F.3d 554, 563 (D.C. Cir. 2004) (claim unripe where issues raised by plaintiff were "still under consideration in ongoing rulemaking proceedings"); Lake Pilots Ass'n v. U.S. Coast Guard, 257 F. Supp. 2d 148, 161-62 (D.D.C. 2003) (holding challenge to rule was not ripe where agency undertook a new rulemaking to address issue raised by plaintiff in the lawsuit).

So too here. Declining jurisdiction over this dispute until the Secretary's proposed position has been shaped by notice and comment rulemaking and finalized would benefit both the Court and the agency, providing a powerful reason to postpone review. It would provide time for Plaintiffs to "convince the agency to alter a tentative position" and provide the agency "an opportunity to correct its own mistakes and to apply its expertise," potentially eliminating the need for (and costs of) judicial review. Pub. Citizen Health Research Group v. Comm'r, FDA, 740 F.2d 21, 30-31 (D.C. Cir. 1984) (citation and internal quotation mark omitted). Even if Plaintiffs fail to persuade the agency, permitting the rulemaking process to reach its end could at least solidify or simplify the factual context and narrow the legal issues at play, allowing for more intelligent resolution of any remaining claims and avoiding inefficient and unnecessary "piecemeal review." Id. at 30 (internal quotation marks omitted).[11]

[11] Be that as it may, even once the rulemaking is completed, the Court's jurisdiction will still depend on the existence of a ripe, properly exhausted "final decision of the [Secretary] . . . made after a hearing." 42 U.S.C. § 405(g).

2. Deferring review would impose no hardship on Plaintiffs

In weighing Abbott's second prong, courts "consider 'not whether the[parties] have suffered any 'direct hardship,' but rather whether postponing judicial review would impose an undue burden on them or would benefit the court.'" Village of Bensenville v. FAA, 376 F.3d 1114, 1119-20 (D.C. Cir. 2004) (quoting Harris v. FAA, 353 F.3d 1006, 1012 (D.C. Cir. 2004)). Here, given that preexisting regulations "have long required [that] each inpatient's record include a physician order admitting the patient as an inpatient," Compl. ¶ 58, Plaintiffs have not demonstrated any harm from the physician order rule, let alone that deferring judicial review would impose an "undue burden" on them.

Unlike the plaintiffs in Abbott Laboratories, the Plaintiff hospitals are not being compelled to make immediate and significant changes in their day-to-day operations. See Abbott Labs., 387 U.S. at 153; Devia v. NRC, 492 F.3d 421, 427 (D.C. Cir. 2007) (claim of hardship "insubstantial" when party "not required to engage in, or to refrain from, any conduct"); Sprint Corp. v. FCC, 331 F.3d 952, 958 (D.C. Cir. 2003) (no hardship where agency action leaves plaintiff "free to conduct its business as it sees fit" and there are no "adverse effects of a strictly legal kind") (quoting Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 733 (1998)). Rather, Plaintiffs are merely seeking relief from a regulation that, by their own telling, is merely "redundant" of preexisting regulatory requirements. Compl. ¶ 58. Moreover, even if Plaintiffs had identified any Medicare claims denied on the basis of the physician order rule — and they have not — the possibility of further delay in receiving payment of a disputed claim is not the sort of hardship that can alone compel immediate judicial review of an otherwise unripe challenge. See, e.g., City of Houston v. HUD, 24 F.3d 1421, 1432 (D.C. Cir. 1994) ("temporary loss of the use of some" grant funds was not "the type of hardship which warrants immediate

consideration"); Tenn. Gas Pipeline Co. v. FERC, 736 F.2d 747, 751 (D.C. Cir. 1984) (concluding plaintiff's "planning insecurity" was not sufficient to show hardship).

Thus, whether for lack of standing, failure to exhaust administrative remedies, or lack of ripeness, the Court should dismiss Plaintiffs' challenge to the physician order rule for lack of jurisdiction.

III. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CHALLENGE TO THE ONE-YEAR FILING DEADLINE FOR REBILLING DENIED PART A CLAIMS UNDER PART B

In Count II, Plaintiffs complain about the possibility of receiving unfavorable RAC determinations on Part A claims because it was not "reasonable and necessary" to provide treatment on an inpatient basis. Compl. ¶¶ 5, 51, 104-05. As explained above, providers have the right to appeal any such determinations administratively, and ultimately to district court. See supra at 10-11. In addition, when faced with such determinations, or on their own accord, providers may rebill denied Part A claims under Part B, provided that the one-year time limit to do so, set forth in the Medicare statute itself, has not expired. See supra at 12-13.

Plaintiffs allege that the "application" of the one-year time limit for rebilling denied Part A claims under Part B is arbitrary and capricious. Id. ¶¶ 102-09. They ask the Court to set aside that time limit, id. ¶¶ B, F, and to "order that the Plaintiff hospitals be reimbursed for the reasonable and necessary care they provided in the appeals at issue," id. ¶ G. Yet no Plaintiff identifies any Medicare claim that has been denied by a RAC. Nor does any Plaintiff allege that any attempt to rebill a Part A claim under Part B has been denied on the basis of the one-year time limit. Further, no Plaintiff alleges that it has appealed any RAC denials, let alone that it has exhausted the administrative process. Finally, although Plaintiffs argue that the Secretary has the discretion to reopen denied Part A claims, id. ¶ 107, or to extend the deadline for untimely Part B claims, id. ¶ 108, Plaintiffs identify no claims for which they have requested either form of relief,

and even if they had, the Court would lack jurisdiction to review those discretionary claims processing decisions. For any or all of these reasons, the Court lacks jurisdiction over Plaintiffs' challenge to the "application" of the one-year time limit for rebilling denied Part A claims under Part B.

A. Plaintiffs Lack Standing to Challenge the One-Year Time Limit

Plaintiffs fail to establish that the one-year time limit has caused any Plaintiff a concrete harm, or that setting it aside would redress any alleged injury. As an initial matter, the entire premise of this claim — that Plaintiffs have been unable to rebill Part A claims denied by a RAC — is unsupported by the allegations in the complaint. No Plaintiff alleges that it has received an unfavorable determination from a RAC. (The one Plaintiff to identify any denied claims, Banner Health, alleges that those claims were denied by a "Medicare contractor," Compl. ¶ 84, a term that is generally understood to refer to the Medicare Administrative Contractor that takes the first cut at processing claims, see supra at 7-8, not to a RAC performing post-payment review, see supra at 10-11.)

What is more, no Plaintiff alleges that any attempt to rebill a Part A claim under Part B has been denied on the basis of the one-year time limit. Thus, although Plaintiffs allege that the "application" of the one-year time limit is arbitrary and capricious, Compl. ¶¶ 102-09, they identify no claim to which the time limit has in fact been "applied." Indeed, the only denied claims identified in the complaint were for patients "discharged after October 1, 2013," Compl. ¶¶ 84-85, suggesting that the one-year statutory time limit to rebill those claims has not yet expired. Thus, no Plaintiff establishes that it has been injured by the "application" of that deadline. See Lujan, 504 U.S. at 560-61.

B. Plaintiffs Have Failed to Exhaust Their Administrative Remedies

In any event, Plaintiffs have not exhausted their administrative remedies with respect to any unfavorable RAC determination. As explained earlier, under the regulations applicable by default to reopening, a provider who disagrees with a RAC determination may appeal that determination administratively, and ultimately to district court. See supra at 10-11. Only by pursuing an appeal all the way to the MAC can a claimant obtain a "final decision of the [Secretary] . . . made after a hearing" that is reviewable in federal court under § 405(g). 42 C.F.R. §§ 405.1100, § 405.1130; § 405.1136; see supra Part I at 15-17. No Plaintiff alleges that it exhausted this administrative process with respect to any unfavorable RAC decision.

Just as with the two-midnights rule and physician order rule, requiring exhaustion makes good sense here. While RACs may correct many kinds of billing errors, Plaintiffs focus on (hypothetical) RAC determinations that Part A claims were improper because inpatient admission and treatment were inappropriate. But the central question in any such determination — whether admission to the hospital for inpatient treatment is "reasonable and necessary" in a given case — may be heavily fact dependent. Unfavorable RAC determinations that Plaintiffs appeal may not stand upon further review, and Plaintiffs could well obtain the relief they seek through the administrative process, obviating the need for judicial involvement.

C. The Court Lacks Jurisdiction to Review the Discretionary Decisions Whether To Reopen Part A Payment Determinations or To Extend the Statutory Deadline for Untimely Part B Claims

Even if Plaintiffs could establish standing and had exhausted their administrative remedies, the Court would still lack jurisdiction over Plaintiffs' challenge to the one-year deadline for rebilling denied Part A claims under Part B. Plaintiffs argue that the Secretary has the discretion to reopen denied Part A claims, Compl. ¶ 107, or to extend the deadline for

untimely Part B claims, id. ¶ 108, and that her "refusal" to do so was arbitrary and capricious, id. ¶¶ 107-08.[12] But Plaintiffs identify no Medicare claims for which they have requested either form of relief, and even if they had, the Court would lack jurisdiction over Plaintiffs' challenges to those discretionary claims processing decisions.

The parties agree that 42 U.S.C. § 405(g)-(h) govern the scope of the Court's jurisdiction over this action. Compl. ¶ 20; see supra at 15-16. Congress has spoken precisely in those provisions, incorporated as relevant here by 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ii, about whether and when the Court has jurisdiction. Section 405(g) provides for judicial review of certain claims arising under the Medicare statute, specifically, those challenging a "final decision of the [Secretary] . . . made after a hearing." 42 U.S.C. § 405(g). Section 405(h) separately forbids the Court from exercising general federal question jurisdiction over claims arising under the Medicare statute. Id. § 405(h) ("No action against the United States, the [Secretary] or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter."). But neither a decision denying a request for reopening nor a decision refusing to extend the one-year time limit — had Plaintiffs ever made such a request — could ever be a "final decision of the [Secretary] . . . made after a hearing" within the meaning of § 405(g). Thus, neither decision is reviewable in federal court.

[12] Plaintiffs purport to challenge the Secretary's anticipated refusal to "adjust" or "supplement" their claims, rather than the anticipated refusal to "reopen" them. Compl. ¶¶ 54, 107. But the adjustment Plaintiffs seek is possible only if an unfavorable payment determination is first reopened. When a provider fails to appeal an unfavorable payment determinations within 120 days, 42 C.F.R. § 405.942, that determination becomes "binding upon all parties," id. § 405.928(b), and remains so unless "revised as a result of a reopening in accordance with [42 C.F.R.] § 405.980," id. § 405.928(b)(2) (emphasis added). But, as discussed above, regardless of the terms Plaintiffs use to describe it, actions refusing to reopen are not reviewable even where there is standing and all administrative remedies have been exhausted.

1. The Court lacks jurisdiction to review a refusal to reopen

The Ninth Circuit recently addressed jurisdiction under § 405(g) over the first sort of claim processing decision Plaintiffs challenge (whether to reopen a Medicare Part A payment determination) in Palomar Medical Center v. Sebelius, 693 F.3d 1151 (9th Cir. 2012), and both its reasoning and its holding are directly applicable here. Relying on Supreme Court decisions holding that analogous reopening decisions are not subject to judicial review, see Your Home Visiting Nurse Servs., Inc. v. Shalala, 525 U.S. 449, 456 (1999) ("We also reject petitioner's fallback argument that it is entitled to judicial review of the intermediary's refusal to reopen."); Califano v. Sanders, 430 U.S. 99, 107-08 (1977) ("[§ 405(g)] cannot be read to authorize judicial review of alleged abuses of agency discretion in refusing to reopen claims for social security benefits. . . . [A] petition to reopen a prior final decision may be denied without a hearing[.]"), the Ninth Circuit held that the decision to reopen a Medicare Part A payment determination is not reviewable because it is not a "final decision . . . made after a hearing" within the meaning of § 405(g). Palomar, 693 F.3d at 1165-1166 (citing Your Home and Califano). That decision fully comports with the Medicare statute and the Supreme Court's cases interpreting the "final decision" requirement.

The Ninth Circuit began by noting that, while § 405(g) "limits judicial review of the Secretary's decisions to 'final decisions . . . made after a hearing," id. at 1165 (quoting § 405(g)-(h)), "[t]he statute does not define 'final decision,'" id. Rather, whether and when the Secretary has made a "final decision . . . is left to the Secretary to flesh out by regulation." Id. Therefore, the Ninth Circuit properly looked to the Secretary's regulations to decide whether a reopening decision is a "final decision of the [Secretary]" for purposes of § 405(g). In doing so, it followed binding Supreme Court precedent instructing it to defer to the Secretary's interpretation of her

own regulations unless "plainly erroneous or inconsistent with the regulation." Id. at 1159 (quoting Auer v. Robbins, 519 U.S. 452, 461 (1997)). The Ninth Circuit then concluded that, "[b]ecause the . . . decision to reopen Palomar's claim is not a 'final decision of the [Secretary] made after a hearing,' the district court and this court lack jurisdiction to review it." Id. at 1166 (quoting § 405(g)).

So too here. As authorized by Congress, the Secretary has issued regulations that govern the processing of Medicare payment claims. See 42 U.S.C. § 1395ff(a)(1) ("The Secretary shall promulgate regulations and make initial determinations with respect to benefits . . . in accordance with those regulations."); 42 C.F.R. § 405.900 et seq. (claim processing regulations). Those regulations allow for an "initial determination" on payment made by a contractor to be appealed all the way to the MAC, which, after a statutorily mandated hearing, issues a "final" decision of the Secretary that is subject to judicial review under § 405(g). See 42 U.S.C. § 1395ff(b)(1)(A) (providing for hearing to challenge initial determination); 42 C.F.R. § 405.900 et seq. (administrative appeal process); § 405.1130 (decision of MAC is "final"); § 405.1136 (judicial review of MAC's final decision). But those regulations do not allow for appeal of certain discretionary claim processing decisions made by contractors that are not initial determinations, including the decision whether to reopen a determination that was not appealed. See 42 C.F.R. § 405.926(*l*) ("Actions that are not initial determinations and are not appealable under this subpart include . . . [a] contractor's . . . determination or decision to reopen or not to reopen[.]"); see also 70 Fed. Reg. at 11,453 (explaining that regulations reflect determination that contractor reopening determinations should be policed internally by CMS through audits and performance evaluations, rather than externally via administrative and judicial review). As a result, decisions whether to reopen a Part A payment determination never lead to a "final decision of the

[Secretary]," let alone one made after a hearing, and are therefore not reviewable under § 405(g).[13] Palomar, 693 F.3d at 1165 ("The decision to reopen a paid Medicare claim . . . is discretionary and does not constitute a "final decision" for purposes of § 405(g)."); see also Your Home Visiting Nurse Servs., 525 U.S. at 456 (no judicial review of refusal to reopen yearly Medicare cost report); Califano, 430 U.S. at 107-08 (no judicial review of decision whether to reopen social security benefit claim).[14]

2. The Court lacks jurisdiction to review a refusal to extend the one-year timely filing requirement

The reasoning of Palomar also compels the conclusion that the Court lacks jurisdiction to review the claims processing decision whether to extend the one-year statutory limitation period for Medicare payment claims. Like the decision whether to reopen a determination already made, a contractor's decision whether to extend the limitation period is, per the Secretary's regulations, not an "initial determination" appealable to the MAC. 42 C.F.R. § 405.926(n) ("Actions that are not initial determinations and are not appealable under this subpart include . . . [d]eterminations that a provider or supplier failed to submit a claim timely[.]"). But the only determination in the administrative process that is "final" is the MAC's decision on a properly-

[13] By contrast, if the contractor decides to reopen a payment determination, the resulting determination on reopening is subject to appeal and ultimate judicial review to the extent it revises the original determination. 42 C.F.R. §§ 405.984(a), (f).

[14] Moreover, the nature, scope, and timing of Plaintiffs' hypothetical reopening requests and new Part B claims are entirely speculative. Medicare regulations permit reopening of a Part A claim determination for "good cause," but only as that concept is defined in 42 C.F.R. § 405.986, and only if such a request is made within "4 years from the date of initial determination or redetermination." 42 C.F.R. § 405.980(b)(2). It is unclear whether Plaintiffs' hypothetical reopening requests would satisfy these regulatory requirements. Likewise, the time for filing a new claim for payment may be extended due to certain "error or misrepresentation of an . . . agent of HHS," 42 C.F.R. § 424.44(b)(1), but even this ground for extension of the one-year filing requirement is limited to no more than "4 years after the date of service," id. § 424.44(b)(5)(i).

filed-and-appealed claim for payment. Id. § 405.1130 ("The MAC's decision is final and binding"). Because a claims processing decision rejecting a claim as untimely is neither a "final" decision nor one made "after a hearing," the Court does not have jurisdiction to review it under § 405(g).

Thus, even if Plaintiffs had requested reopening of a denied Part A claim, or an extension of the deadline to rebill such a claim under Part B, the Court would lack jurisdiction to review the denial of such a request. Whether for that reason, lack of standing, or failure to exhaust administrative remedies, the Court should therefore dismiss Plaintiffs' challenge to the one-year time limit to rebill denied Part A claims under Part B.

CONCLUSION

For the foregoing reasons, the Court should grant Defendant's motion to dismiss and dismiss this case in its entirety.

Dated: July 16, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 16, 2014, I filed the foregoing document with the Clerk of Court via the CM/ECF system, causing it to be served electronically on Plaintiff's counsel of record.

/s/ *Eric Beckenhauer*
ERIC B. BECKENHAUER