UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL HOME INFUSION ASSOCIATION, *Plaintiff*, v. XAVIER BECERRA, *in his official capacity as Secretary of Health and Human Services,* *Defendant*.	Civil Action No. 19-393 (TJK)

MEMORANDUM OPINION

Plaintiff National Home Infusion Association (NHIA) is a nonprofit organization of member companies that provide home infusion medical services, which allow some patients to receive certain drugs at home instead of in a hospital. NHIA sues Defendant, the Secretary of Health and Human Services, alleging that his regulation defining "drug administration calendar day" under the relevant benefit program conflicts with the Medicare Act and violates the Administrative Procedure Act in several ways. The Secretary has moved to dismiss, arguing that the Court lacks subject-matter jurisdiction because NHIA's members have not exhausted their administrative remedies, and in the alternative, seeks summary judgment because the regulation is otherwise lawful. For the reasons explained below, the Court will dismiss the complaint because it lacks subject-matter jurisdiction.

I. Background

A. Legal and Regulatory Background

The Medicare Act, 42 U.S.C. § 1395 *et seq.*, establishes a program of health insurance for the elderly and the disabled. Under Medicare Part B, the federal government pays for certain outpatient infusion drugs that are "incident to" a physician's services, as long as the drugs are not usually self-administered by a patient. 42 U.S.C. § 1395x(s)(2)(A), (B). The Center for Medical Services (CMS), an agency housed within the Department of Human Health and Services (HHS), administers the Medicare program through private contractors known as Medicare Administrative Contractors (MACs). 42 U.S.C. §§ 1395u(a), 1395kk-1(a)(4).

Congress created a new Medicare benefit for home infusion therapy services in 2016. *See* 21st Century CURES Act, Pub. L. No. 114-255, § 5004, 130 Stat. 1033, 1190 (2016). That legislation authorized CMS to promulgate a payment scheme for certain items and services associated with home infusion therapy, effective January 1, 2021. *See* 42 U.S.C. § 1395m(u)(1)(A).

In later legislation, Congress instructed the Secretary of HHS ("the Secretary") to establish a temporary transitional benefit program to compensate eligible home infusion therapy suppliers for certain designated drugs until CMS established the permanent program. *See* Bipartisan Budget Act of 2018, Pub. L. No. 115-123, § 50401, 132 Stat. 64, 214 (2018). The Act specifically ordered the Secretary to "establish a single payment amount for each such payment category . . . for each infusion drug administration calendar day in the individual's home for drugs assigned to such category." 42 U.S.C. § 1395m(u)(7)(B)(iv). The Act also clarified that "a reference to payment to [an eligible home infusion supplier or a qualified home infusion therapy supplier] for an infusion drug administration calendar day in the individual's home shall refer to payment only for the date on which professional services [as described elsewhere in the statute] were furnished to administer such drugs to such individual." 42 U.S.C. § 1395m(u)(7)(E)(i).

In devising the temporary transitional benefit program, the Secretary defined "infusion drug administration calendar day" as the "day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration." 42 C.F.R. § 486.505 ("Final Rule"); 83 Fed. Reg. 56,406, 56,579–583 (Nov. 13, 2018). Under the Final Rule, whether or not a professional is "skilled" turns on whether the services they provide are "so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel." *Id.*

B. Procedural Background

National Home Infusion Association (NHIA) is a not-for-profit association that represents home infusion therapy companies. ECF No. 1 ¶ 11. Under Medicare, its members are reimbursed for medical services they provide to patients. *Id.* Three of NHIA's members—BioScrip, Inc., Intramed Plus, and Paragon Healthcare, Inc.—presented claims to the Secretary for Medicare reimbursement. *Id.* ¶ 13. BioScrip requested Medicare reimbursement from a MAC on February 7, 2019. ECF No. 15-1 ¶ 5. On February 13, 2019, Intramed Plus also presented claims to a MAC. *Id.*¶ 4. The next day, February 14, 2019, Paragon Healthcare presented its claims to a MAC. *Id.* ¶ 6. All three providers' claims sought "payment for days where the patient was infused but a nurse or other skilled professional was not present in the home." ECF No. 9-2 ¶¶10–14. All three sets of claims were denied. William Noyes, Senior Vice President of Reimbursement Policy at NHIA, submitted to the Court remittance notices dated between February 13 and February 21, 2019, which he asserts are "representative of the DME MAC's claims processing decisions" of NHIA's members' claims. ECF No. 15-1 ¶¶ 4–6. Most of the notices contain two codes explaining why the MAC denied the claim. *See, e.g.*, *id.*

at 11. The first code, M25, means that "[t]he information furnished does not substantiate the need for this level of service." *Id.* The second code, N180, signifies that the provided "item or service does not meet the criteria for the category under which it was billed." *Id.* A minority of the notices only contain the N180 code, *see, e.g.*, *id.* at 12, but, like all the notices, they do not explain why the item or service did not meet the criteria for the category under which it was billed. NHIA filed a separate exhibit showing that of the fifty claims the three members submitted, forty-two led to remittance notices containing both codes and eight resulted in notices containing only the N180 code. ECF No. 9-2 at 118. NHIA represents that all three companies sought redetermination of the denied claims and that, at the time it moved for summary judgment, those appeals remained pending. ECF No. 15-1 ¶¶ 4–6.

NHIA filed this lawsuit on behalf of its members on February 14, 2019—within days of all three of its members' first request for reimbursement—alleging that the Final Rule conflicts with § 1395m(u)(7) of the Medicare Act and otherwise violates the Administrative Procedure Act. ECF No. 1. NHIA then moved for summary judgment, and Defendant moved to dismiss for lack of subject-matter jurisdiction, or in the alternative, for summary judgment. ECF No. 13. After the motions had been pending for about a year, the case was reassigned to the undersigned. *See* ECF No. 24.

II. Legal Standards

"Federal courts are courts of limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). The plaintiff bears the burden of establishing that the court has subject-matter jurisdiction. *Colorado Heart Inst., LLC v. Johnson*, 609 F. Supp. 2d 30, 34 (D.D.C. 2009) (citing *Kokkonen*, 511 U.S. at 377). In assessing whether a plaintiff has met its burden, "the Court must scrutinize the complaint, treating its factual allegations as true and granting the plaintiff the benefit of all reasonable inferences that can be drawn from those facts."

Arriva Med. LLC v. U.S. Dep't of Health & Human Servs., 239 F. Supp. 3d 266, 276 (D.D.C. 2017). The Court may also "consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." *Jerome Stevens Pharms., Inc. v. Food & Drug Admin.*, 402 F.3d 1249, 1253 (D.C. Cir. 2005) (citation omitted).

Under Federal Rule of Civil Procedure 56, a court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Summary judgment is appropriately granted when, viewing the evidence in the light most favorable to the non-movants and drawing all reasonable inferences accordingly, no reasonable jury could reach a verdict in their favor." *Lopez v. Council on Am.-Islamic Relations Action Network, Inc.*, 826 F.3d 492, 496 (D.C. Cir. 2016).

III. Analysis

The Court begins, as it must, with the question of subject-matter jurisdiction. "Federal jurisdiction is extremely limited for claims arising under the Medicare Act." *Porzecanski v. Azar*, 943 F.3d 472, 480 (D.C. Cir. 2019). Three statutes lay out the scheme that governs judicial review of Medicare Act claims. "First, 42 U.S.C. §°405(h) divests the district courts of federal-question jurisdiction 'on any claim arising under' Title II of the Social Security Act, and it bars any 'decision of the Commissioner of Social Security' from being judicially reviewed, 'except as herein provided' in other Title II provisions." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018). "Second, 42 U.S.C. § 405(g) provides for judicial review of Social Security Act claims, thus creating the exception 'herein provided.' In pertinent part, it permits any person to file a civil action, 'after any final decision of the Commissioner of Social Security made after a hearing to which he was a party,' to 'obtain a review of such decision' in federal district court." *Id.* "Third, 42 U.S.C. §°1395ii states that certain provisions in § 405 and elsewhere in Title II 'shall also apply with respect to' Title XVIII of the Social Security Act—*i.e.*, the Medicare Act—'to the same extent as they are applicable with respect to' Title II, with any reference to the 'Commissioner of Social Security' considered as one to the Secretary of HHS." *Id.* "Although § 1395ii does not specifically enumerate § 405(g) as one of the incorporated Title II provisions," the Supreme Court and the D.C. Circuit have treated it as such, "presumably on the theory that expressly incorporating the judicial-review bar in § 405(h) also effectively incorporates the exception 'herein provided' in § 405(g)." *Id.*

The parties agree on a few aspects of their dispute that substantially narrow it. First, although federal question jurisdiction may exist at times to preserve an opportunity for judicial review of Medicare claims, *see, e.g.*, *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 19–20 (2000), the parties agree that is not the case here, because "the question presented . . . is not *whether* they may obtain review of their challenges to the [Final Rule], but *when* and *how* they may do so." *Am. Hosp. Ass'n*, 895 F.3d at 825 (emphasis in original). Thus, the parties agree that the Court's subject-matter jurisdiction, if it exists at all, flows from § 405(g). Second, although "the Supreme Court has held that § 405(g) imposes two distinct preconditions for obtaining judicial review of covered Medicare claims," only one is at issue. *Id.* A plaintiff must have presented her claim to the Secretary to obtain review, and this requirement "is not waivable because without presentment there can be no decision of any type, which § 405(g) clearly requires." *Id.* (cleaned up). The parties agree that BioScrip, Inc., Intramed Plus, and Paragon Healthcare, Inc. have done so. Their dispute focuses on the the second requirement: that a plaintiff fully exhaust all administrative remedies before suing, thus receiving a final decision, which the Supreme Court has held is waivable in limited circumstances. *See Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). Third, the parties' dispute can be narrowed even more: they agree that NHIA's members did not, in fact, fully exhaust their administrative remedies; in fact, NHIA sued within days of its members presenting their claims to the agency. Thus, the heart of their dispute is whether waiver of the exhaustion requirement is appropriate.

Some background on the particulars of the exhaustion requirement at issue is helpful. Typically, to exhaust administrative remedies under the Medicare Act, a healthcare provider must submit a reimbursement claim to a MAC. The MAC issues an initial determination about whether the services provided are covered by Medicare and, if so, the payment amount. 42 U.S.C. § 1395ff(a)(1); 42 C.F.R. §§ 405.904(a)(2), 405.920. If the claimant disagrees with the MAC's decision, it can request a redetermination from the MAC. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.904(a)(2), 405.940. If the claimant remains dissatisfied with the MAC's redetermination, it can request that a qualified independent contractor (QIC) reconsider the MAC's redetermination. 42 U.S.C. § 1395ff(b), (c); 42 C.F.R. §§ 405.904(a)(2), 405.960. The QIC's decision is subject to review by an Administrative Law Judge (ALJ) if the amount-in-controversy requirements are met. 42 U.S.C. §§ 405(b), 1395ff(b)(1)(A), (d)(1); 42 C.F.R. §§ 405.1000–405.1058. If a claimant wishes to challenge the ALJ's decision, it must seek review by the Medicare Appeals Council of the Departmental Appeals Board. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100–405.1140. The Medicare Appeals Council's decision is the Secretary's final decision and is subject to judicial review. 42 U.S.C. §§ 405(g), 1395(ff)(b)(1)(A); 42 C.F.R. §§ 405.1130, 405.1136. As noted earlier, NHIA sued within days of BioScrip, Inc., Intramed Plus, and Paragon Healthcare, Inc., presenting their claims. And even at the time of the briefing of the instant motions, it appears that its members' claims had only progressed to the MAC redetermination phase, the second step in the process. *See* ECF No. 15-1 ¶¶ 4–6.

Under 42 U.S.C. § 1395ff(b), the Secretary has established the expedited access to judicial review (EAJR) process that allows a claimant to bypass the ALJ and Medicare Appeals Council review stages and proceed directly to federal court if, relevant here, the Secretary agrees that (1) "material facts involved in the claim are not in dispute," (2) the "sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation, CMS Ruling, or national coverage determination," and (3) "[b]ut for the provision challenged, the requestor would receive a favorable decision on the ultimate issue." 42 C.F.R. § 405.990(g). If the Secretary so certifies, that constitutes a final decision for purposes of judicial review, and if other conditions are met, the claimant has sixty calendar days to sue in district court. *Id.* § 405.990(h)(2). The parties agree that BioScrip, Inc., Intramed Plus, and Paragon Healthcare, Inc. did not pursue this expedited review process before they sued.

For the reasons explained below, the Court holds that waiver of the administrative exhaustion requirement is not appropriate here, and so it lacks subject-matter jurisdiction. To begin with, this is so because of the nature of the requirement imposed by the relevant statutory provisions. The concept of "exhaustion" exists under typical administrative law principles, but in *Illinois Council,* the Supreme Court explained that § 405(h)'s channeling mechanism imposes an even more stringent exhaustion requirement. The Court held that "the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies.'" *Ill. Council on Long Term Care, Inc.*, 529 U.S. at 12. The Court then explained that this exacting exhaustion requirement reflects a judgment made by Congress:

> Insofar as § 405(h) prevents application of the "ripeness" and "exhaustion" exceptions, *i.e.,* insofar as it demands the "channeling" of virtually all legal attacks through the agency, it assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying "ripeness" and "exhaustion" exceptions case by case. But this assurance comes at a price, namely, occasional

> individual, delay-related hardship. In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified.

Id. at 13.

Additionally, in general, the Court saw no reason to apply the requirement to different types of claims differently. "[The Court's past decisions] foreclose distinctions based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought." *Id.* at 13–14. "There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h). Section 1395ii's blanket incorporation of that provision into the Medicare Act as a whole certainly contains no such distinction." *Id.* at 14. The Court went so far as to say that channeling was required even if the agency had no power to provide relief to the claimant. "The fact that the agency might not provide a hearing for that *particular contention*, or may lack the power to provide one . . . is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Id.* at 23. And only "[a]fter the action has been so channeled," the Court noted, a court—which "has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide" may resolve the dispute. *Id.* at 23–24.

Several years later, the D.C. Circuit applied *Illinois Council* in *Three Lower Counties Cmty. Health Servs., Inc. v. U.S. Dep't of Health and Human Services*, 317 Fed. App'x 1 (D.C. Cir. 2009). In that case, the district court had dismissed claims challenging how HHS calculated two payment rates under the Medicare program. *See Three Lower Counties Cmty. Health Servs.*

Inc. v. U.S. Dep't of Health & Human Servs., 517 F. Supp. 2d 431, 433–34, 437 (D.D.C. 2007). In dismissing the claims, the district court reasoned that it did not have § 405(g) jurisdiction because the plaintiffs had not exhausted their administrative remedies. *Id.* at 435 ("The Supreme Court has made clear that if this process is available, it must be followed, even if it is time-consuming . . . and even if the agency cannot grant the relief sought.") (citing *Ill. Council*, 529 U.S. at 20, 22–23). On appeal, the Circuit affirmed. The court rejected the argument that "'facial' challenge[s] need not follow the administrative appeals procedures for Medicare reimbursement claims," and held that "[p]arties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge." 317 Fed. App'x at 2 (citing *Ill. Council*, 529 U.S. at 5).

To be sure, *Illinois Council* and *Three Lower Counties* do not control the outcome here because the plaintiffs in those cases did not even *begin* the channeling process by presenting their claims to the agency nor did they argue for waiver along the lines NHIA does. Still, they illustrate the uphill climb that NHIA faces because of the statutory regime's exacting exhaustion requirement, and because BioScrip, Inc., Intramed Plus, and Paragon Healthcare, Inc. had not come close to exhausting their administrative procedures when NHIA sued only days after they presented their claims.

Despite the sweeping language the Court used in *Illinois Council,* in prior cases, it had recognized waiver of the exhaustion requirement in a few narrow situations. *See, e.g.*, *Mathews v. Eldridge*, 424 U.S. 319, 329–32 (1976). But none provided a particularly clear rule for lower courts to follow. Generally, in the wake of those cases, in evaluating whether waiver of the exhaustion requirement is appropriate, courts have looked to whether "(1) the issue raised is entirely collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; and (3) exhaustion would be futile." *Triad at Jeffersonville I, LLC v. Leavitt*, 563 F. Supp. 2d 1, 16 (D.D.C. 2008) (citing *Bowen v. City of New York*, 476 U.S. 467, 483–85 (1986)); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). Again, the case law is not altogether clear as to which combination of these factors is required for waiver, or whether they might each provide an independent ground. The Court need not wade into that thicket, though, because NHIA relies only on futility. In short, it argues that "there is nothing to indicate that the administrative review process could result in the Secretary overturning his Final Rule." ECF No. 15 at 11.

Under traditional waiver-of-exhaustion principles, that might well be enough. But in *Ryan v. Bentsen*, 12 F.3d 245 (D.C. Cir. 1993), the D.C. Circuit considered a situation like this one and affirmed the district court's refusal to find waiver of the § 405(g) administrative process to exhaust a plaintiff's Social Security claims, in part because he had failed to follow expedited review procedures. In that case, the court noted two situations in which the Supreme Court had found waiver of the exhaustion requirement appropriate. In one such circumstance, "the claimant's constitutional challenge [was] collateral to his claim of entitlement and he [stood] to suffer irreparable harm if forced to exhaust his administrative remedies." *Ryan*, 12 F.3d at 248. "In such a case, 'deference to the agency's judgment [was] inappropriate,' and the court itself [could] waive the exhaustion requirement." *Id.* (citing *Eldridge*, 424 U.S. at 330–31). But in *Ryan*, the court noted, that precedent was inapt. And similarly, NHIA does not assert that its claim is collateral, nor does it argue it will suffer irreparable harm.

The second instance the *Ryan* court identified in which the Supreme Court had held that waiver was appropriate was when "the Secretary determine[d] that the only issue before him is one of the constitutionality of a provision of the Act and that he [could not] allow or disallow benefits on any ground other than the constitutional ground. Because the constitutionality of a statutory provision is an issue beyond his competence to decide, exhaustion [was] futile." *Id.* at 247 (citing *Weinberger v. Salfi*, 422 U.S. 749, 765–66 (1975)). The Circuit emphasized, however, that the decision to waive exhaustion in that case was the Secretary's and stemmed from his authority under the statute to define finality:

> When exhaustion is futile, the *Salfi* Court held, the Secretary may waive the exhaustion requirement. The Court further indicated that "[t]he term 'final decision' is not only left undefined by the Act, but its meaning is left to the Secretary to flesh out by regulation." The Secretary heeded the Court and has by regulation enabled a benefit claimant to bypass the final two stages of administrative review by creating an expedited appeals process (EAP) the claimant can use if he contends, and the SSA agrees, that the only obstacle preventing him from receiving benefits is a provision of the Act he alleges is unconstitutional. Agreement to use the EAP constitutes a "final decision" for the purpose of judicial review.

Id. at 247–48 (citations omitted).[1]

The *Ryan* court found that the plaintiff met this second exception, with the important caveat that the plaintiff had not followed the expedited appeals process thorough which the Secretary may deem the exhaustion requirement met. *Id.* at 248. Thus, the court reasoned, it had to consider "whether [it] may effectively waive the requirement and, if so, whether [it] should." *Id.* The court found that it could, noting that Circuit precedent had extended the term waiver "to situations where the Secretary staunchly demand[ed] that the claim be dismissed for want of exhaustion, but the Court itself [] excused non-compliance." *Id.* (citing *Tataranowicz*, 959 F.2d at 274). But the

[1] Indeed, in *Salfi*, the Court had emphasized that the § 405(g) exhaustion requirement is "something more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility." 422 U.S. at 766.

Circuit declined to do so, concluding that the plaintiff's resort to the expedited appeal process would not have been futile. *Id.* The court's reasoning is worth laying out in full:

> The EAP procedure benefits both the parties and the court. First, it allows the claimant to circumvent full Department review. At the same time, when a claimant has availed himself of the EAP, the parties come to court in agreement as to the facts and the applicable law; only the statute's constitutionality remains in dispute. This means that when the case reaches the district court there will be no question regarding exhaustion of remedies or applicability of the futility doctrine . . . . Additionally, the court will benefit from the parties' use of the EAP. When the procedure is used, a case will come before the court in a posture that facilitates review on the merits . . . . Although cases may well arise in which a district court is required to consider the appropriateness of the SSA's refusal to agree to expedited review, they should be rare and the overall utility of the EAP to the judicial system and to the Department's effectiveness in responding to claimants will be tangible. Compliance with the EAP, it should be emphasized, is not another wall constructed to stymie a claimant's efforts to obtain judicial review of his claim. Indeed, the EAP is an "expedited" procedure. It merely requires a claimant to agree with the SSA in writing that no facts are in dispute, and to allege that the provision of the Act prohibiting his receipt of benefits is unconstitutional and that he does not otherwise challenge the SSA's interpretation of the Act. *See* 20 C.F.R. § 404.926. These are matters a claimant would ordinarily be required to establish before invoking the futility doctrine in district court. The added burden that a claimant reach written agreement with the SSA is not itself futile because the agreement does not involve review of the merits of his claim to benefits. Once the agreement is reached, the claimant "may go directly to a Federal district court without first completing the administrative review process that is generally required" before judicial review. *Id.*

Ryan, 12 F.3d at 248–49. The Circuit concluded that "our decision to require a claimant mounting a constitutional challenge to utilize the EAP reflects both considerations already embodied in the Supreme Court's futility decisions and our own prudential concerns. When an agency has provided an abbreviated procedure that accelerates the decision-making process, it is in the best interests of the court, the agency and the claimant that the procedure be utilized." *Id.* at 249.[2]

[2] Similarly, in *Three Lower Counties*, the Circuit appears to have reiterated the point, noting that because the plaintiff had the ability to "seek 'expedited judicial review' of the reimbursement determination" it had to "pursue its challenge . . . in th[at] manner." 317 Fed. App'x at 3.

So too here. HHS has established the EAJR process for Medicare claims. *See* 42 C.F.R. § 405.990. Like the EAP in *Ryan*, the EAJR procedure allows a "benefit claimant to bypass the final two stages of administrative review"—here, the ALJ and Medicare Appeals Council—and proceed directly to federal court if the claimant "contends, and [the Secretary] agrees, that the only obstacle preventing him from receiving benefits is a provision of the [regulation] he alleges is [invalid]," *Ryan*, 12 F.3d at 247–48, and there are no material facts in dispute. 42 C.F.R. §§ 405.990(c), (g). And the parties agree that NHIA's members did not avail themselves of the EAJR process. And, as in *Ryan*, the Secretary has not waived the exhaustion requirement on futility grounds here. *See* 12 F.3d at 248.

Thus, the same "considerations [ ] embodied in the Supreme Court's futility decisions and [the D.C. Circuit's] prudential concerns" that guided the *Ryan* court apply here as well, even though this case involves a statutory rather than constitutional question. *Id.* at 249. The expedited appeal procedure "benefits both the parties and the court." *Id.* at 248. "[W]hen a claimant has availed himself of the [EAJR procedure], the parties come to court in agreement as to the facts and the applicable law; only the [regulation's validity] remains in dispute. . . . Hence, the [regulatory] issue will be isolated for thorough analysis" and the Court will not need to "expend[] judicial effort on the applicability of the futility doctrine." *Id.* at 248–49. These benefits are highly relevant here, as the parties do not appear to agree as to how the Final Rule applies to NHIA's members. *See, e.g.*, ECF No. 15 at 7 (asserting that nurses are "the only 'skilled professional' that could practically meet the Secretary's definition"); ECF No. 18 at 7–8 ("Plaintiff's characterizations of the final rule call into question whether it correctly understands how the CMS will apply the rule to the underlying claims" and arguing that social workers or dieticians could also qualify as skilled professionals).[3]

In addition, requiring NHIA to use the EAJR procedure gives the agency "greater opportunity" to "revise policies [or] regulations" without the need to worry about different district courts waiving the exhaustion requirement on a "case by case" basis. *Ill. Council*, 529 U.S. at 13. When promulgating the Final Rule, HHS noted that its "best course of action [was] to monitor the effects on access to care of finalizing this definition and, if warranted and within the limits of [its] statutory authority, engage in additional rulemaking or guidance regarding this definition for temporary transitional payments." 83 Fed. Reg. at 56,583. But NHIA, by filing suit merely days after its members presented claims to the MACs—private contractors that are not even part of the agency—short-circuited the opportunity for the agency to do so without this concern. Thus, waiving the exhaustion requirement here would deprive the agency of a fuller "opportunity to reconsider its policies, interpretations, and regulations in light of [NHIA's members'] challenges." *Ill. Council*, 529 U.S. at 24.

In arguing that waiver is appropriate, NHIA relies on *Tataranowicz v. Sullivan*, 959 F.2d 268 (D.C. Cir. 1992) and a litany of district court cases citing *Tataranowicz* for the proposition that exhaustion is not required when a plaintiff's claim is "a 'purely legal challenge to the agency's established interpretation' of the Medicare statute." ECF No. 15 at 10 (quoting *Nat'l Ass'n for Home Care & Hospice Inc. v. Burwell*, 77 F. Supp. 3d 103, 112 (D.D.C. 2015); *see also*, 348 F. Supp. 3d 62, 75 (D.D.C. 2018), *rev'd on other grounds* 967 F.3d 818 (D.C. Cir.

[3] Clarification as to how the Final Rule applies to NHIA's members will also inform whether NHIA's members—and therefore, NHIA—have standing to bring a facial challenge in the first place. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (plaintiff challenging agency action must show injury, causality, and redressability).

2020); *Hall v. Sebelius*, 689 F. Supp. 2d 10, 24 (D.D.C. 2009) ("[E]xhaustion may be excused where 'an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law.'").

NHIA misreads *Tataranowicz.* To begin with, unlike in *Ryan*, that case did not consider the effect of the availability of expedited review in its exhaustion analysis, a procedure that the *Ryan* court explained would not have been futile. *See Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 144 (2011) ("When 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."). And *Tataranowicz* predates the expansive reading of § 405(g)'s channeling requirements the Supreme Court articulated in *Illinois Council* and the D.C. Circuit's application of *Illinois Council* in *Three Lower Counties*. *Cf. Three Lower Counties* 317 Fed. App'x at 2 (rejecting view that a "'facial' challenge need not follow the administrative appeals procedures for Medicare reimbursement claims.").

Moreover, even taken on its own terms, *Tataranowicz* does not support a finding that the Court should waive the exhaustion requirement on futility grounds. In that case, class action plaintiffs sought injunctive and declaratory relief from a Medicare regulation but failed to exhaust their administrative remedies. 959 F.2d at 274. The Circuit held that requiring exhaustion in that instance would be "wholly formalistic" because the case presented no factual disputes, the regulation at issue was the sole obstacle to the plaintiffs' obtaining relief, the Secretary gave no reason to believe that the agency would accede to the plaintiffs' claims, and he acknowledged that review by the Appeals Council was "in essence review by the Secretary himself." *Id.* at 274.

None of that is so here. As the Secretary notes, "there is no record upon which the Court can review the rule's application (if any) to the underlying reimbursement claims." ECF No. 13-1 at 22. That is significant because there may well be reasons apart from the Final Rule that justify denying NHIA's members' claims. Certainly, the Secretary has not agreed (as the EAJR procedure contemplates)—and the Court has no basis to conclude—that the sole issue in dispute is the validity of the Final Rule, and that but for the Final Rule, NHIA's members would prevail on the ultimate issue of reimbursement. In addition, unlike the Secretary's representations in *Tataranowicz*, the Secretary here has not given NHIA or the Court reason to believe he will refuse to reconsider the merits of NHIA's members' claims or the Final Rule. *See* 83 Fed. Reg. at 56,583 (HHS would monitor effect of Final Rule).

IV. Conclusion

For all these reasons, the Court holds that futility does not excuse the requirement that NHIA's members exhaust their administrative remedies under § 405(g), and because they failed to do so, the Court lacks subject-matter jurisdiction over NHIA's claims. Thus, the Court will deny NHIA's Motion for Summary Judgment, ECF No. 9, grant Defendant's Motion to Dismiss, ECF No. 13, and deny NHIA's Motion for a Scheduling Order, ECF No. 26, as moot. A separate order will issue.

/s/ Timothy J. Kelly
TIMOTHY J. KELLY
United States District Judge

Date: June 15, 2021