UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE, INC., Plaintiff, v. **SYLVIA MATHEWS BURWELL, Secretary, U.S. Department of Health and Human Services, et al.,** Defendants.	Case No. 1:14-cv-00950 (CRC)

MEMORANDUM OPINION

What does it mean to "document" that a meeting occurred? That is the ultimate question in this case. Under the Affordable Care Act, in order for a provider of home health services to receive payment for services rendered to a Medicare patient, the physician who ordered the services must "document" that he or she has had a "face-to-face encounter" with the patient. The Secretary of Health and Human Services issued a regulation interpreting that requirement to mean that the doctor must, in addition to certifying that the encounter took place, explain in writing why the encounter supports the conclusion that the patient is homebound and requires the services in question. This explanation has become known as the "narrative requirement."

The National Association for Home Care and Hospice, Inc. ("NAHC")—a trade association representing some 6000 home health service providers—brought suit, contending that the Secretary exceeded her statutory authority in issuing the regulation and that the narrative requirement violates the Fifth Amendment rights of its members by making it "nearly impossible" to achieve compliance. The Secretary has moved to dismiss NAHC's complaint for lack of standing and failure to exhaust administrative remedies, as well as for failure to state a claim. The Court finds that NAHC has standing because it has identified at least one member that was denied Medicare

payments based on a failure to comply with the narrative requirement. The Court also finds that NAHC has failed to exhaust administrative remedies with respect to all of its claims. The Court will nonetheless assert jurisdiction over NAHC's facial challenge to the Secretary's statutory authority to issue the regulation because it concludes exhaustion of that claim would be futile. The Court will reserve judgment on the merits of NAHC's statutory-authority claim, however, in order to allow the parties an opportunity to brief the issues more fully on cross-motions for summary judgment.

I. Background

Title XVIII of the Social Security Act, known as the Medicare Act, provides medical insurance to individuals eligible for Social Security benefits. See 42 U.S.C. § 402(a). These benefits include payments for health services provided to homebound individuals. See id. § 1395k(a)(2). In the Patient Protection and Affordable Care Act ("ACA"), Pub. L. 111-148 (2010), Congress amended the provisions of the Medicare Act governing the documentation that providers must submit to receive payment for home health services provided to Medicare patients. The statute previously required that a physician certify that home care services "are or were required because the individual is or was confined to his home[.]" 42 U.S.C. § 1395f(a)(2)(C) (governing Medicare Part A benefits); accord id. § 1395n(a)(2)(A) (governing Medicare Part B benefits). Along with that requirement, it now also requires that a physician "document that the physician . . . has had a face-to-face encounter . . . with the individual within a reasonable timeframe as determined by the Secretary [of HHS.]" Id. § 1395f(a)(2)(C); accord id. § 1395n(a)(2)(C). The Secretary implemented this new face-to-face meeting requirement through a regulation requiring that the documentation of the meeting include an explanation, now known as the narrative requirement, "of why the clinical findings of such encounter support that the patient is homebound and in need of [home health services.]" 42 C.F.R. § 424.22(a)(1)(v).

Ordinarily, an unsuccessful Medicare claimant must take a denial of a claim for benefits through the administrative appeals process before filing suit in federal court. Administrative exhaustion of a Medicare claim is a lengthy process. An HHS contractor initially determines whether to approve the claim for payment. 42 C.F.R. § 405.904(a)(2). If payment is denied, the claimant can request a redetermination. Id. If still unsuccessful, the claimant can demand reconsideration by a Qualified Independent Contractor. Id. The claimant then may request a hearing before an Administrative Law Judge, and may appeal the result of that hearing to the Medicare Appeals Council of the Departmental Appeals Board. Id. The decision of the Medicare Appeals Council is the agency's final word on the claim. Id. Only after completing this process may a claimant bring suit in federal court.

NAHC is a trade organization representing approximately 6,000 home healthcare providers. Compl. ¶ 5. It has brought suit to challenge the Secretary's interpretation of the new documentation provision. It contends that the narrative requirement is not authorized by the underlying statutory provision in the ACA; that it is unconstitutionally vague; and that HHS should consider the entire patient record, not solely the narrative requirement, in determining whether a patient needs home health services. Id. ¶¶ 45–58. NAHC alleges that its members have experienced a high percentage of Medicare denials due to the narrative requirement, id. ¶¶ 34, 39, citing eleven examples of claims made by members that were denied solely because of the requirement, nine of which were later reversed by administrative appeal, id. ¶ 33. NAHC seeks declaratory and injunctive relief but not payment of claims as to any member. Id. at 22–23. The Secretary has responded with a motion to dismiss NAHC's complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) and for failure to state a claim under Rule 12(b)(6).

II. Standard of Review

In response to a motion to dismiss a complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), the plaintiff must prove by a preponderance of the evidence that the Court has jurisdiction. E.g., Biton v. Palestinian Interim Self-Gov't Auth., 310 F. Supp. 2d 172, 176 (D.D.C. 2004). The court "assume[s] the truth of all material factual allegations in the complaint and 'construe[s] the complaint liberally, granting [the] plaintiff the benefit of all inferences that can be derived from the facts alleged.'" Am. Nat'l Ins. Co. v. FDIC, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quoting Thomas v. Principi, 394 F.3d 970, 972 (D.C. Cir. 2005)). But a "court must give [the] plaintiff's factual allegations closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion for failure to state a claim." Byrum v. Winter, 783 F. Supp. 2d 117, 122 (D.D.C. 2011) (citing Macharia v. United States, 334 F.3d 61, 64, 69 (D.C. Cir. 2003)). In determining whether it has jurisdiction, a court "may consider materials outside of the pleadings." Jerome Stevens Pharm., Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005).

"To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). While the court must "assume [the] veracity" of any "well-pleaded factual allegations" in the complaint, conclusory allegations "are not entitled to the assumption of truth." Id. at 679.

III. Analysis

As noted above, the Secretary urges dismissal of NAHC's complaint for three separate reasons. First, she contends that NAHC—which does not itself submit claims for payment to Medicare—lacks standing because it has not pled that any of its members have standing. Second, she argues that the Court lacks subject matter jurisdiction because NAHC and its members have not

followed administrative review procedures—namely "presentment" of a claim and exhaustion of administrative remedies—that generally must precede a Medicare-related federal suit. And third, she asserts that NAHC has failed to state a claim because the narrative requirement is consistent with the new documentation provision of the ACA and otherwise satisfies the requirements of the Fifth Amendment. The Court addresses each of the Secretary's arguments below.

A. Standing

To maintain Article III standing, a plaintiff must demonstrate: (1) an injury in fact that is concrete and particularized, and actual or imminent, as opposed to conjectural or hypothetical; (2) that the plaintiff's injury is fairly traceable to the defendant's conduct; and (3) that the plaintiff's injury likely can be redressed through judicial action. Bennett v. Spear, 520 U.S. 154, 167 (1997). Because NAHC asserts standing on behalf of its members, "it is not enough to aver that unidentified members have been injured. . . . Rather, [NAHC] must specifically 'identify members who have suffered the requisite harm.'" Chamber of Commerce of U.S. v. EPA, 642 F.3d 192, 199–200 (D.C. Cir. 2011) (quoting Summers v. Earth Island Inst., 555 U.S. 488, 497–498 (2009)).

NAHC alleges in its complaint that an unspecified member presented a claim to a Medicare contractor, who denied the claim solely for failing to satisfy the narrative requirement. Compl. ¶¶ 35–38. In response to the Secretary's argument that identifying an unspecified member is insufficient for a membership organization to establish standing, NAHC has provided the declaration of its Vice President for Law, William A. Dombi, who explains that the member referenced in the complaint is Liberty Healthcare Corporation of North Carolina. Declaration of William A. Dombi ¶ 4 (Oct. 10, 2014). The Secretary has not challenged this affidavit. Because the Court may consider materials outside of the pleadings in determining whether NAHC has standing to bring its claims, see, e.g., Jerome Stevens Pharm., 402 F.3d at 1253, it concludes that

NAHC has met its burden to identify at least one specific member that has been injured by the challenged regulation. NAHC itself therefore has standing.

B. Jurisdiction under the Medicare Act

The Secretary next argues that the Court lacks jurisdiction to entertain NAHC's suit. 42 U.S.C. § 405 creates an exclusive right of action for "claim[s] arising under" the Social Security Act, including its Medicare provisions. See id. §§ 504(g)–(h), 1395ii. A challenge that arises under the Medicare Act must be brought via Section 405 irrespective of whether it may be equally framed as a challenge under other laws or the Constitution. Heckler v. Ringer, 466 U.S. 602, 615 (1984) (citing Weinberger v. Salfi, 422 U.S. 749, 760–61 (1975)). A claimant may not seek judicial review under Section 405, however, without first receiving a final decision from the Secretary. 42 U.S.C. § 405(g); Mathews v. Eldridge, 424 U.S. 319, 326 (1976). The Supreme Court has interpreted these requirements to go beyond the ordinary antecedents to a suit under the Administrative Procedures Act ("APA"). Shalala v. Illinois Council on Long Term Care, Inc. ("Illinois Council"), 529 U.S. 1, 12–13 (2000) ("the bar of § 405(h) reaches beyond ordinary administrative law principles of ripeness and exhaustion of administrative remedies[;] it demands the channeling of virtually all legal attacks through the agency" (internal quotations omitted)). There are two elements of the finality requirement: a non-waivable "requirement that a claim for benefits shall have been presented to the Secretary[;]" and a waivable "requirement that the administrative remedies prescribed by the Secretary be exhausted." Eldridge, 424 U.S. at 328. Determining whether to waive exhaustion is not a mechanical exercise "but should also be guided by the policies underlying the exhaustion requirement." Bowen v. City of New York, 476 U.S. 467, 484 (1986).

i. Presentment

Section 405 requires a plaintiff to have first presented "a claim for benefits" to the Secretary. Eldridge, 424 U.S. at 328. Here, the Secretary contends that NAHC does not satisfy the presentment requirement simply because its members have filed claims that were rejected. Instead, according to the Secretary, NAHC must present its specific constitutional and statutory arguments to the agency before raising them in federal court. In Eldridge itself, however, the Supreme Court instructed that the plaintiff need not "raise with the Secretary his constitutional claim" to satisfy either presentment or exhaustion because Section "405(g) requires only that there be a 'final decision' by the Secretary *with respect to the claim of entitlement to benefits*." Id. at 329 & n.10 (emphasis added). Accordingly, because at least one member of NAHC has submitted a claim for payment to the agency that was rejected due to an insufficient narrative, NAHC has satisfied the presentment requirement.[1]

ii. Exhaustion of Administrative Remedies

NAHC, through its members, must also establish that it has exhausted administrative remedies. The Secretary has discretion to waive the exhaustion requirement and permit a claimant to proceed directly to federal court. Id. at 329. The Secretary's decision not to do so in a given case ordinarily is entitled to deference by the Court. But under certain circumstances "a claimant's interest in having a particular issue resolved promptly is so great that deference to the agency's judgment is inappropriate." Id. at 329–30. In determining whether to excuse the exhaustion

[1] Along with arguing that its members should be excused from exhausting administrative proceedings for their individual claims, NAHC argues that it satisfied the presentment requirement by submitting comments to the agency and by meeting with agency officials to voice disagreement with the rule. Pl. Opp'n to Mot. Dismiss at 9. But a generalized opposition to agency action or regulations is insufficient to establish standing. E.g., Summers, 555 U.S. at 493–94. Moreover, Illinois Council established that an association may not challenge the constitutionality of Medicare regulations in the abstract on the basis that its members are likely to confront those regulations in the future. 529 U.S. at 5. As such, the Court only has jurisdiction if NAHC's members have satisfied administrative requirements.

requirement, courts consider (1) whether the claim is collateral to a demand for benefits, (2) whether delay would cause irreparable harm, and (3) whether exhaustion would be futile. Tataranowicz v. Sullivan, 959 F.2d 268, 274 (D.C. Cir. 1992) (citing among others Eldridge, 424 U.S. at 330–31); see also Ringer, 466 U.S. at 617–18.

To demonstrate irreparable harm, a plaintiff generally must demonstrate more than economic distress, even if severe. See Eldridge, 424 U.S. at 331 (plaintiff's dependency on disability payments for basic necessities meant plaintiff would suffer more than mere economic harm and thus retroactive payment after-the-fact would not provide adequate compensation); see also Illinois Council, 529 U.S. at 22–23 ("added inconvenience or cost" is not sufficient; instead, a plaintiff demonstrates irreparable harm when "what appears to be simply a channeling requirement [becomes] *complete* preclusion of judicial review" (emphasis in original)). In urging the Court to find irreparable injury here, NAHC points only to the allegations in its complaint that the narrative requirement will cause financial harm leading to closure or bankruptcy for NAHC members. Pl.'s Opp'n to Mot. Dismiss at 17; Compl. ¶ 40. NAHC provides no evidentiary support for its assertion, such as affidavits or declarations from members describing the narrative requirement's specific effect on their businesses. NAHC instead asks the Court to assume that the requirement must be so costly that it inevitably will cause members to go bankrupt. But plenty of regulations impose significant compliance costs on the healthcare industry without forcing affected companies into bankruptcy. NAHC's unsupported assertion of financial hardship is not sufficient to meet its burden to prove by a preponderance of the evidence that it will suffer irreparable injury. Bennett, 520 U.S. at 167–68. Moreover, even if the Court were to accept NAHC's assertion that some of its members are likely to go bankrupt as a result of the narrative requirement, even extreme financial difficulty does not necessarily satisfy the irreparable harm requirement. See Triad at Jeffersonville I, LLC v. Leavitt, 563 F. Supp. 2d 1, 13–14 (D.D.C. 2008) (rejecting argument that plaintiff's

impending bankruptcy due to a Medicare denial, supported by the affidavit of plaintiff's CEO, could establish irreparable injury as a result of delay and economic harm).

NAHC makes a stronger argument that exhaustion would be futile. Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with the other factors laid out in Eldridge. Tataranowicz, 959 F.2d at 274 (citing among others Mathews v. Diaz, 426 U.S. 67, 76–77 (1976)). The ordinary standard for futility in administrative law cases is inapplicable in Medicare cases, however. See Salfi, 422 U.S. at 766 (section 405(g) was "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"). Instead, the court must consider whether judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record. Tataranowicz, 959 F.2d at 275 (citing Salfi, 422 U.S. at 765). Applying these standards, the Court finds that requiring exhaustion of NAHC's constitutional claims would not be futile, but that requiring exhaustion of its statutory-authority claim would.

NAHC's Fifth Amendment claims are premised on the arguments that the narrative requirement is unconstitutionally vague and fails to consider the entire patient record. To properly resolve these arguments, the Court would need to consider the particular facts of the denied claims, including the content of the narratives, the other documents submitted to the agency, and the agency's justifications for denying these claims. The policies underlying the exhaustion requirement would be furthered, and the Court's task made easier, by channeling these individual claims through the administrative appeals process. By reviewing NAHC's members' claims in the first instance, the agency will have the necessary opportunity to correct improperly denied claims, ensuring that the Court will not review narratives that the agency ultimately would have determined were satisfactory. Administrative review would also enable the Court and the parties to rely on

HHS's expertise, as the agency can better explain in further proceedings why certain narratives are insufficient. Perfecting the record in this manner will ensure that the Court can properly determine whether the Secretary's actual implementation of the narrative requirement is sufficiently clear to survive Fifth Amendment scrutiny. See Salfi, 422 U.S. at 765 ("Exhaustion is generally required as a matter of preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review"). Moreover, NAHC's members have succeeded in appealing denials of Medicare payments based on insufficient narratives. Compl. ¶ 33. These successful claims demonstrate that the appeals process is far from futile despite the alleged vagueness of the narrative requirement. See Am. Orthotic & Prosthetic Assoc., Inc. v. Sebelius, No. 13-697, 2014 WL 3817124, at *6 (D.D.C. Aug. 4, 2014) ("Proving futility requires demonstrat[ing] that defeat is certain, which the plaintiff cannot demonstrate if its members are succeeding in appeals before the agency.").

Finally, NAHC asserts that it should not be forced to exhaust administrative remedies on its Fifth Amendment claims because the appeals process does not permit its members to raise constitutional claims on the forms it must submit to ask for reconsideration. But "there is no exception to exhaustion due to limited options—even limited options, however imperfect, must be exhausted before a federal court can interfere with the Secretary's right to apply, interpret, and/or revise agency regulations and policies in the context of concrete factual claims." Id. at *6. As stated above, requiring NAHC's members to proceed through the appeals process will enable both the parties and the Court to narrow the issues raised by NAHC's Fifth Amendment claims in light of the factual record. Accordingly, these claims will be dismissed for lack of subject matter jurisdiction.

By contrast, NAHC's statutory claim—that the Secretary exceeded her authority under the ACA in promulgating the narrative requirement—is a purely legal challenge to the agency's established interpretation of the Medicare Act. See Hall v. Sebelius, 689 F. Supp. 2d 10, 23–24 (D.D.C. 2009) ("exhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law" (quotation omitted)); see also Diaz, 426 U.S. at 76. The D.C. Circuit considered similar circumstances in Tataranowicz, where it confronted HHS claims manual provisions that plaintiffs argued were incompatible with the underlying Medicare Act amendment. 959 F.2d at 269–270. The parties acknowledged that no factual disputes would impede judicial resolution of the claim. Id. at 274. And, although the Secretary "ha[d] *authority* to decide the legal issue in plaintiffs' favor . . . . [he gave] no reason to believe that the agency machinery might accede to plaintiffs' claims." Id. (emphasis in original). For those reasons, the court excused the exhaustion requirement. Id.

Likewise here, the Secretary does not contend that this claim will turn on any disputed facts, as it requires the Court to consider nothing more than the statute, its legislative history, and the regulation. See Am. Bankers Ass'n v. Nat'l Credit Union Admin., 271 F.3d 262, 266 (D.C. Cir. 2001). And, nothing indicates that administrative appeals might result in the agency overturning its regulation. In fact, in responding to comments to a new version of the regulation—which eliminated the narrative requirement for claims based on services provided after January 1, 2015—HHS flatly stated that "we do not agree that the narrative requirement goes beyond Congressional intent." Medicare and Medicaid Programs; CY 2015 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies, 79 Fed. Reg. 66032-01, 66043. Moreover, the agency's interpretation of the Medicare Act here would appear to be even more embedded than the claims manual provisions in Tataranowicz, which were not promulgated by regulation after notice and

comment rulemaking. See 959 F.2d at 270–71. For these reasons, the Court will excuse the exhaustion requirement with respect to NAHC's statutory authority claim.

C. Statutory Authority

The Secretary also asks the Court to dismiss NAHC's APA claim on the merits. Recall, the ACA requires that a physician "document that the physician . . . has had a face-to-face encounter . . . with the individual[,]" 42 U.S.C. § 1395f(a)(2)(C); accord id. § 1395n(a)(2)(C). The Secretary contends that the narrative requirement is a reasonable interpretation of that statutory provision because the term "document" is ambiguous and fairly encompasses explaining why the encounter supports the conclusion that the patient requires home health services. NAHC responds that the overall phrase unambiguously forecloses requiring doctors to supply the narrative required by the regulations.

Although a court may resolve an APA claim on a motion to dismiss when review of the administrative record is unnecessary, Am. Bankers Ass'n, 271 F.3d at 266, such challenges are typically decided on summary judgment, see, e.g., Apotex Inc. v. FDA, 414 F. Supp. 2d 61, 66 (D.D.C. 2006), aff'd sub nom., 226 F. App'x. 4 (D.C. Cir. 2007). NAHC's statutory argument and the surrounding regulatory regime are complex, and the parties' briefing on this motion to dismiss has focused predominantly on the question of exhaustion. Accordingly, to give the parties a greater opportunity to brief this issue, the Court will deny the Secretary's motion to dismiss under Rule 12(b)(6) and set a briefing schedule for cross-motions for summary judgment.

IV. Conclusion

For the reasons stated above, the Court will grant the Secretary's motion to dismiss in part and deny it in part. The Court will issue an Order consistent with this Memorandum Opinion.

CHRISTOPHER R. COOPER
United States District Judge

Date: January 6, 2015