UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

TWILA SHAKESPEARE, Plaintiff, v. SCAN HEALTH PLAN, INC. a corporation; and DOES 1, through 20, inclusive Defendants.	Case No.: 3: 17-CV-568-BTM-MDD **ORDER GRANTING DEFENDANT'S MOTION TO DISMISS** **ECF NO. 4**

Defendant SCAN Health Plan ("SCAN") has filed a motion to dismiss Plaintiff Twila Shakespeare's complaint. (ECF No. 4). For the reasons discussed below, the Court grants Defendant's motion.

I. BACKGROUND

Under the Medicare Advantage ("MA") program, created under Part C of the Medicare Act, Medicare enrollees can receive Medicare benefits through private organizations called Medicare Advantage Organizations ("MAOs"). *See* 42 U.S.C. § 1395 *et seq*. The federal government pays MAOs monthly fees and, in exchange, the MAOs offer MA plans that accord with applicable requirements and standards. 42 U.S.C. § 1395w-23.

Defendant SCAN is a public-benefit nonprofit corporation domiciled in California. (ECF No. 1-3 ("Complaint") ¶ 3). Defendant is a MAO that offers MA plans for "seniors and other Medicare eligible beneficiaries." *See id.*

Plaintiff Twila Shakespeare, a resident of San Diego County, California, became a member of Defendant's MA Health Maintenance Organization ("HMO") plan in 2013. *Id.* ¶¶ 2, 11. In June 2014, Plaintiff underwent an operation to treat her atrial fibrillation. *Id.* ¶ 14. As a result of the operation, Plaintiff alleges she was put "at risk for suffering a life threatening stroke caused by blood clots forming in her heart." *Id.* ¶ 15. According to Plaintiff, her medical providers "ordered that it was critically necessary that [she] have a 'Watchman Device' implanted in her heart which would prevent strokes caused by clots in her heart." *Id.* ¶ 15. From October 2015 to June 2016, Defendant denied Plaintiff's request that she receive the Watchman Device. *Id.* ¶¶ 17, 18. On June 28, 2016, Plaintiff "suffered a major stroke." *Id.* ¶ 20. According to Plaintiff, her physicians "stated that had the Watchman Device been timely implanted she would never have suffered the stroke." *Id.* On October 12, 2016, Defendant approved the Watchman Device for Plaintiff. *Id.* ¶ 22.

Plaintiff alleges that "as a result of the stroke caused by [Defendant's] failure to timely approve the Watchman Device," she "suffered extreme pain, debilitating fear, overwhelming anxiety, and lost a substantial amount of work and income opportunities." *Id.* ¶ 23. On February 15, 2017, Plaintiff brought the following causes of action against Defendant in the Superior Court of the State of California for the County of San Diego: (1) breach of contract; (2) negligence; (3) willful misconduct; and (4) breach of covenant of good faith and fair dealing. *Id.* ¶¶ 24-49. On March 22, 2017, Defendant removed the action to this Court pursuant to 28 U.S.C. §§ 1441(a), 1442(a)(1), and 1446. (ECF No. 1). Defendant now moves to dismiss Plaintiff's complaint under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). (ECF No. 4). First, Defendant argues that Plaintiff's complaint should be

dismissed for lack of subject matter jurisdiction because Plaintiff failed to exhaust the Medicare administrative review process. *Id.* Second, Defendant argues that Plaintiff's complaint should be dismissed for failure to state a claim upon which relief may be granted because Plaintiff's claims are preempted by the Medicare Act's express preemption provision, 42 U.S.C. § 1395w-26(b)(3). *Id.*

II. STANDARD

A. F.R.C.P. 12(b)(1) Lack of Subject Matter Jurisdiction

"A Rule 12(b)(1) jurisdictional attack may be facial or factual. In a facial attack, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004) (internal citations omitted). Failure to exhaust administrative remedies may be a barrier to federal jurisdiction under Rule 12(b)(1). *See, e.g.*, *Munns v. Kerry*, 782 F.3d 402, 413 (9th Cir. 2015); *Benson v. JPMorgan Chase Bank, N.A.*, 673 F.3d 1207, 1209 (9th Cir. 2012).

B. F.R.C.P. 12(b)(6) Failure to State a Claim

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) should be granted only where a plaintiff's complaint lacks a "cognizable legal theory" or sufficient facts to support a legal claim. *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1988). When reviewing a motion to dismiss, the allegations of material fact in plaintiff's complaint are taken as true and construed in the light most favorable to the plaintiff. *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Although detailed factual allegations are not required, factual allegations "must be enough to raise a right to relief above the speculative level." *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). Only a complaint that states a plausible claim for relief will survive a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

III. DISCUSSION

A. Exhaustion

The Medicare Act has an exhaustion requirement, "42 U.S.C. § 405(h), [which] makes judicial review under a related provision, 42 U.S.C. § 405(g), the sole avenue for judicial review for claims arising under the Medicare Act." *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1140 (9th Cir. 2010) (internal quotations omitted). "The Supreme Court has held that the exhaustion requirement of § 405(g) consists of 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 pursued fully by the claimant. Only once the Secretary has issued a final decision may the individual seek judicial review of that determination. A final decision is rendered only after the individual has pressed his claim through all levels of administrative review." *Id.* (internal quotations and citations omitted).

"The key inquiry in determining whether § 405(h) requires exhaustion before [this Court] can exercise jurisdiction is whether the claim 'arises under' the [Medicare] Act." *Id.* at 1141. "The Supreme Court has identified two circumstances in which a claim 'arises under' the Medicare Act: (1) where the 'standing and the substantive basis for the presentation of the claims' is the Medicare Act; and (2) where the claims are 'inextricably intertwined' with a claim for Medicare benefits." *Id.* (internal citations omitted). As Plaintiff asserts state common law claims, the Medicare Act is not the standing or substantive basis for Plaintiff's claims. *See* Complaint ¶¶ 24-49. However, "even a state law claim may 'arise under' the Medicare Act." *Do Sung Uhm*, 620 F.3d at 1142. Therefore the remaining question is whether Plaintiff's claims are 'inextricably intertwined' with a claim for Medicare benefits.

"One category of claims that [courts] have found to arise under the Act are those cases that are cleverly concealed claims for benefits." *Id.* at 1141 (internal

quotations omitted). Further, "whether or not [a plaintiff seeks] reimbursement of benefits is not 'strongly probative' of whether a claim 'arises under' the Medicare Act" as "the remedy sought [is not] dispositive of the 'arising under' question." *Id.* at 1142. As the Ninth Circuit has explained, "our case law establishes that where, at bottom, a plaintiff is complaining about the denial of Medicare benefits . . . the claim 'arises under' the Medicare Act." *Id.* at 1142-43.

Plaintiff alleges four causes of action: (1) breach of contract, (2) negligence, (3) willful misconduct, and (4) breach of covenant of good faith and fair dealing. Complaint ¶¶ 24-49. All are premised on and centered around Defendant's allegedly wrongful denial and delay in approving the Watchman Device for Plaintiff. Plaintiff is therefore, at bottom, complaining about a denial and delay of Medicare benefits. Courts in this circuit have held that similar delays in administering Medicare benefits "arise under" the Medicare Act and therefore require exhaustion. *See Dicrescenzo v. UnitedHealth Grp. Inc.*, 2015 WL 5472926, at *3 (D. Haw. Sept. 16, 2015) ("[i]nsofar as [plaintiff's] claims relate to the delay or mishandling of the coordination of benefits with respect to his eyeglasses, they are inextricably intertwined with a Medicare benefits decision, and [plaintiff] must first present them to the Secretary of Health and Human Services"); *Quinones v. UnitedHealth Grp. Inc.*, 2015 WL 3965961, at *4 (D. Haw. June 30, 2015) ("insofar as Plaintiff's claims relate to the [year long delay in preauthorizing plaintiff for a new personal mobility device], they are inextricably intertwined with the Medicare benefits decision, and Plaintiff must first present them to the Secretary"). Plaintiff does not allege that, after Defendant's initial denial, she presented her claim to the Secretary of Health and Human Services or engaged at all in Medicare's administrative review process.[1]

[1] Because Plaintiff has not overcome the initial non-waivable hurdle of first presenting her claims to the Secretary of Health and Human Services, the Court need not address whether the requirement that she pursue her claims through all levels of administrative review was waived.

Furthermore, Plaintiff's claims could have been appropriately remedied through the Medicare Act's administrative review process had she timely engaged with it after Defendant's initial denial decision in October 2015, a factor that the Ninth Circuit has given some weight to in favor of finding that claims arise under the Medicare Act. In *Do Sung Uhm v. Humana, Inc.*, plaintiffs submitted a prescription drug enrollment form to defendant, who provided prescription drug plans under Medicare Part D. 620 F.3d at 1138. Even though premiums were deducted from plaintiffs' social security checks, plaintiffs never received any information on how to obtain their drug benefits and were forced to buy their prescription medication out-of-pocket at costs greater than those provided by defendant's plan. *Id.* at 1139. In their complaint, plaintiffs alleged, among other actions, breach of contract and unjust enrichment, demanding that their premiums be returned. *Id.* at 1140. The Ninth Circuit held that the district court did not have jurisdiction over plaintiffs' breach of contract and unjust enrichment claims until § 405(h)'s requirements had been met. *Id.* at 1144. In addition to characterizing plaintiffs' claims as, "at bottom, merely creatively disguised claims for benefits," the Ninth Circuit explained that "at the time [plaintiffs'] claims arose . . . [the Medicare] Act's administrative remedial mechanisms—including the coverage determination and grievance processes—were available to them. The coverage determination process, in particular, would have allowed [plaintiffs] to secure the benefits to which they were entitled as enrollees. The coverage determination process is meant for disputes arising from [a] decision not to provide or pay for a Part D drug." *Id.* (internal citations and quotations omitted). Here, Plaintiff's failure to engage with § 402(h)'s requirements does not now allow her to circumvent them entirely.

Plaintiff argues that her claims do not arise under the Medicare Act by analogizing her case to the wrongful dealth claim in *Ardary v. Aetna Health Plans of California, Inc.*, 98 F.3d 496 (9th Cir. 1996). In *Ardar*y, Defendant, a private Medicare provider, explicitly promised a Medicare beneficiary and her family that

under Defendant's plan, should the need arise, Defendant would immediately authorize transfer to a larger hospital for emergency care (the Medicare beneficiary lived in a relatively isolated area). *Id.* at 497. The Medicare beneficiary enrolled in Defendant's plan based on these representations. *Id.* However when the Medicare beneficiary subsequently suffered a heart attack, Defendant refused to authorize airlift transportation to a proper facility, resulting in the death of the Medicare beneficiary. *Id.* at 497-98. Plaintiffs, the surviving family members of the Medicare beneficiary, filed a wrongful death suit alleging negligence, intentional and/or negligent infliction of emotional distress, intentional and/or negligent misrepresentation, and professional negligence. *Id.* at 498. The Ninth Circuit characterized the jurisdictional question as follows:

> [D]oes the Medicare Act, which provides for exclusive administrative review of all claims "arising under" that Act, apply to preclude the heirs of a deceased Medicare beneficiary from bringing state law claims for wrongful death against a private Medicare provider when those claims do not seek recovery of Medicare benefits but instead seek compensatory and punitive damages on the grounds that the provider both improperly denied emergency medical services and misrepresented its managed care plan to the beneficiary?

Id. at 499. The Ninth Circuit held that even though plaintiffs' claims were "predicated on [defendant's] failure to authorize the airlift transfer, the claims [were] not inextricably intertwined because [plaintiffs were] are bottom not seeking to recover benefits" and the death "[could not] be remedied by the retroactive authorization or payment of the airlift transfer." *Id.* at 500 (internal quotations omitted).

Here, however, Plaintiff's claims are not simply "predicated" on Defendant's Medicare benefits decision, they are "inextricably intertwined" with the decision. In *Ardar*y, the question of "whether the provider both improperly denied emergency medical services and misrepresented its managed care plan to the beneficiary" could be answered largely independent of the underlying Medicare law because

defendant made an explicit representation to the beneficiary that an emergency transfer would immediately be authorized. *See id.* at 497. Here, Plaintiff does not allege that Defendant made any such representations that they would authorize the Watchman Device for her. Aside from alleging that Defendant's Medicare benefits decision was wrong, Plaintiff does not allege any additional action on Defendant's part that would support claims wholly collateral to the decision itself. Plaintiff's claims of breach of contract, negligence, willful misconduct, and breach of covenant of good faith and fair dealing would all require a determination that Plaintiff was entitled to the Watchman Device and Defendant was wrong to deny approval prior to October 12, 2016. Plaintiff's claims are therefore inextricably tied to a claim for Medicare benefits. *See Kaiser v. Blue Cross of California*, 347 F.3d 1107, 1115 (9th Cir. 2003) ("Hearing most of the [plaintiffs'] claims would necessarily mean redeciding [defendant's related] Medicare decisions."); *Dicrescenz*o, 2015 WL 5472926, at *3 ("Critically, [plaintiff's] ability to prevail on this state law cause of action inevitably turns upon a determination that [plaintiff] was entitled to a Medicare benefit, i.e., a new pair of eyeglasses, in the first place, and that [defendant] had no right to deny such a benefit because it was 'reasonable and necessary' for treatment of [plaintiff's] condition. . . . That being the case, [plaintiff's] claim is 'inextricably intertwined' with a Medicare benefits determination and is subject to Medicare's administrative review process.").

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Because Plaintiff has already been granted the Watchman Device and seeks damages resulting from Defendant's Medicare benefits decision, the Court acknowledges that engaging in the administrative review process will not provide the relief Plaintiff seeks.[2] However the Ninth Circuit has stated that even if "the administrative action may in some sense be futile for [plaintiffs] (if the administrative process cannot provide the damages [plaintiffs] seek), administrative exhaustion of [plaintiffs'] claims would still serve the purpose of exhaustion and not be futile in the context of the system." 347 F.3d at 1115. The Ninth Circuit has elaborated that:

> [C]ases may "arise under" Medicare under § 405(h) and yet contain issues which are not suitable for resolution by the [administrative review process]. This disconnect, while at first puzzling, makes sense in the context of the purposes of exhaustion. "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." If a court were to prematurely tackle a question inextricably intertwined with an issue properly resolved by an agency, the court would defeat the purposes of § 405(g) and (h) even if the question was not one that the agency has the authority to answer fully. More specifically, even if the claims raised here are broader than those suitable for resolution by the [administrative review process], deciding [plaintiff's] claims would mean also passing judgment on questions which are appropriately first answered by the [administrative review process]. This is why all inextricably intertwined claims must first be raised in an administrative process. In that process, the agency, with the benefit of its experience and expertise, can resolve whatever issues it can, limiting the number of issues before judicial review (and limiting review on those issues

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[2] Where a plaintiff has sought damages for a wrongly denied or delayed Medicare benefit, some courts have found the inadequacy of the administrative review process to be dispositive of whether a claim is "inextricably intertwined" with a claim for Medicare benefits. *See Woodruff v. Humana Pharmacy Inc.*, 65 F. Supp. 3d 588 (N.D. Ill. 2014); *Kennedy v. Health Options, Inc.*, 329 F. Supp. 2d 1314 (S.D. Fla. 2004); *Kovach v. Coventry Health Care, Inc.*, 2011 WL 284174 (W.D. Pa. Jan. 25, 2011); *Kelly v. Advantage Health, Inc.*, 1999 WL 294796 (E.D. May 11, 1999). The Court declines to follow these lines of cases, given the Ninth Circuit guidance on the purpose of the administrative review process.

according to the appropriate standard of deference).

Kaiser, 347 F.3d at 1116 n.4. Here, allowing the administrative review process to first answer whether it was proper for Defendant to deny approval of the Watchman Device for Plaintiff prior to October 12, 2016 fulfills the purpose of § 405(h) exhaustion.

Because the Court finds that Plaintiff's claims arise under the Medicare Act and therefore require exhaustion, Defendant's motion to dismiss pursuant to F.R.C.P. 12(b)(1) is granted.

B. Preemption

Defendant also argues that Plaintiff's complaint should be dismissed pursuant to F.R.C.P. 12(b)(6) because Plaintiff's claims are preempted by the Medicare Act's express preemption provision. Assuming that even if Plaintiff had satisfied § 405(h)'s exhaustion requirement, the Court agrees.

The Secretary of Health and Human Services delegated to the Centers for Medicare & Medicaid Services ("CMS"), the responsibility for administering Medicare. Under Part C of the Medicare Act, CMS contracts with MAOs to provide MA plans to eligible Medicare beneficiaries. 42 U.S.C. § 1395w-23. MAOs are required to comply with the standards set forth under Part C of the Medicare Act. 42 U.S.C. § 1395w-27(a). In making Medicare benefits decisions, MAOs follow a specified procedure on the standards they must adhere to:

> CMS issues national coverage determinations (NCDs) that specify whether certain items, services, procedures or technologies are reasonable and necessary under §1862(a) (1) (A) of the Act. In the absence of an NCD, [MAOs] are responsible for determining whether services are reasonable and necessary. If no local coverage determination (LCD) exists for a particular item or service, the [MAO] shall consider an item or service to be reasonable and necessary if the item or service meets [a specified set of criteria].

Medicare Program Integrity Manual, CMS Pub. 100-08, ch. 3 (November 9, 2017).

The Medicare Act's preemption provision, 42 U.S.C. § 1395w-26(b)(3), states that "[t]he standards established under this part shall supercede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." "The plain language of the statute therefore provides that CMS 'standards' supersede 'any State law or regulation . . . with respect to' a [MA plan] offered by a [MAO]." *See Do Sung Uhm*, 620 F.3d at 1148–49. "[C]ommon law claims fall within the ambit of the Act's preemption clause." *Id.* at 1156.

On February 8, 2016, CMS issued a NCD for the Watchman Device. The NCD provided detailed criteria for when the device would be covered by Medicare.[3] *See* Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy, CAG-00445N (Feb. 8, 2016). Prior to the issuance of the NCD, approval of the Watchman Device as a Medicare benefit was governed by whether the device was "reasonable and necessary" as defined by CMS.[4]

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[3] The patient must have: **(1)** A CHADS2 score = 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score = 3 (Congestive heart failure, Hypertension, Age = 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category); (**2)** A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record; **(3)** A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program. **(4)** The procedure must be performed by an interventional cardiologist(s), electrophysiologst(s) or cardiovascular surgeon (s) that meet the following criteria: **(a)** Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and **(b)** Has performed = 25 interventional cardiac procedures that involve transeptal puncture through an intact septum; and **(c)** Continues to perform = 25 interventional cardiac procedures that involve transeptal puncture through an intact septum, of which at least 12 are LAAC, over a two year period. Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy, CAG-00445N (Feb. 8, 2016)

[4] "Reasonable and necessary" if: **(1)** It is safe and effective; **(2)** It is not experimental or investigational; and **(3)** It is appropriate, including the duration and frequency in terms of whether the service or item is: **(a)** Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member; **(b)** Furnished in a setting appropriate to the beneficiary's medical needs and condition; **(c)** Ordered and furnished by qualified personnel; and, **(d)** One that meets, but does not exceed, the beneficiary's medical need. Medicare Program Integrity Manual, CMS Pub. 100-08, ch. 3 (November 9, 2017).

The impetus behind Plaintiff's complaint appears to stem from the disconnect between her physician's recommendation and Defendant's Medicare benefit determination. Plaintiff's alleges that her physician "ordered that it was critically necessary that [she] have a 'Watchman Device' implanted in her heart which would prevent strokes caused by clots in her heart." Complaint ¶ 15. Plaintiff further alleges that "[w]ith knowledge of [plaintiff's] medical condition and without regard to her physician's orders and recommendations, Defendant denied the request." *Id.* ¶ 17. However, in making its decision on the Watchman Device, Defendant was required to follow the standards set by CMS rather than when Plaintiff's physician deemed it to be "critically necessary." Plaintiff does not allege that she satisfied the criteria set by CMS for a Watchman Device nor does does she allege that Defendant failed to adhere to the applicable CMS standards.

In *Do Sung Uhm*, plaintiffs' fraud and fraud in the inducement claims were based on allegations that defendant's Medicare marketing materials were misleading. 620 F. 3d at 1150. The Ninth Circuit held those claims to be preempted by 42 U.S.C. § 1395w-26(b)(3) because "CMS promulgated detailed regulations governing how Part D sponsors market their plans" and had to "approve all PDP marketing materials before they [were] made available to Medicare beneficiaries." *Id.* at 1150-51. The Ninth Circuit explained that

> [I]n order to determine whether [defendant] committed a fraud or fraud in the inducement, a court would necessarily need to determine whether the written and oral statements were misleading. Were a state court to determine that [defendant's] marketing materials constituted misrepresentations resulting in fraud or fraud in the inducement, it would directly undermine CMS's prior determination that those materials were not misleading and in turn undermine CMS's ability to create its own standards for what constitutes "misleading" information about Medicare Part D. Thus, [plaintiffs'] fraud and fraud in the inducement claims must be preempted.

Do Sung Uhm, 620 F.3d at 1157.

Similarly, in order to determine Plaintiff's tort claims, the Court would necessarily need to determine whether Plaintiff was entitled to the Watchman Device in the first place, a decision that is governed by detailed CMS standards. Beyond alleging that Defendant's benefit decision was wrong, Plaintiff fails to allege any other action on Defendant's part that would support Plaintiff's claims of breach of contract, negligence, willful misconduct, and breach of covenant of good faith and fair dealing. Therefore, deciding on Plaintiff's claims would directly undermine the standards set by CMS on when the Watchman Device is covered by Medicare. As such, Plaintiff's claims are preempted. Defendant's motion to dismiss pursuant to F.R.C.P. 12(b)(6) is granted.

IV. CONCLUSION AND ORDER

For the foregoing reasons, the Court GRANTS Defendant's motion to dismiss with prejudice.

IT IS SO ORDERED.

Dated: January 8, 2018

Barry Ted Moskowitz, Chief Judge
United States District Court