UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

* * *

ROBERT H. ODELL, JR., *et al*.,

Plaintiffs,

v.

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

Case No. 2:15-cv-1793-RFB-GWF

**ORDER**

Motion to Dismiss (ECF No. 103) & Motion for Preliminary Injunction (ECF No. 104)

## I. INTRODUCTION

Before the Court is Defendant's Motion to Dismiss (ECF No. 103) and Plaintiff's Motion for Preliminary Injunction (ECF No. 104). For the reasons stated below, Defendant's Motion to Dismiss is denied and Plaintiff's Motion for Preliminary Injunction is granted.

## II. PROCEDURAL BACKGROUND

Plaintiff filed the original Complaint on September 18, 2015, seeking injunctive relief for violations of procedural due process, the Administrative Procedure Act ("APA"), and the Medicare Act, stemming from an alleged unwritten policy to improperly deny Medicare coverage for certain forms of treatment. ECF No. 1. At a hearing on August 4, 2016, the Court granted Defendant's Motion to Dismiss without prejudice and gave Plaintiff 30 days to amend the Complaint. Plaintiff filed an Amended Verified Complaint on September 9, 2016, in which he clarified that he does not seek to recuperate previous claim denials on behalf of individual patients, but rather seeks declaratory and injunctive relief. ECF No. 57. Defendant moved to dismiss the Amended Complaint and the Court held a hearing on August 17, 2017, in which it denied the Motion to

Dismiss without prejudice and allowed Plaintiff limited jurisdictional discovery to provide evidence of the alleged "unwritten rule." ECF No. 79. Defendant filed the instant Motion to Dismiss and Plaintiff filed the instant Motion for Preliminary Injunction on February 16, 2018. ECF Nos. 103, 104. The Court held a hearing on these motions on July 17, 2018, and took the matter under submission.

## III. FACTUAL BACKGROUND

This case entails a relatively complex factual background, which the Court summarizes based on the pleadings and motions.

### a. Statutory and Regulatory Background

#### *i. Medicare Coverage Determinations*

Title XVIII of the Social Security Act of 1965 established Medicare, a federal health insurance program for the elderly and disabled. 42 U.S.C. § 1395 *et seq*. Medicare covers certain inpatient and outpatient treatments for eligible participants. Under the Medicare statute, no payment may be made for expenses incurred for items or services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Congress delegated discretion over coverage decisions to the Secretary of Health and Human Services ("the Secretary"). There is an intricate administrative infrastructure in place to determine whether services are reasonable and necessary, and thus covered by Medicare.

Congress requires the Secretary to enter into contracts with private contractors to administer the Medicare statute. 42 U.S.C. §§ 1395u;1395kk-1. The Center for Medicare and Medicaid Services ("CMS") is the federal agency that administers the Medicare statute by entering into contracts with Medicare Administrative Contractors ("MACs"). 42 C.F.R. § 421.200. Each MAC is responsible for administering the Medicare program in a discrete geographical location. Within this administrative apparatus, there are four ways that the Secretary can determine whether a given service is covered by Medicare: (1) the Secretary can promulgate a regulation, 42 U.S.C. § 1395hh; (2) the Secretary can issue a National Coverage Determination ("NCD"), which is binding on all Medicare contractors and adjudicators and determines coverage on a nationwide

basis, 42 U.S.C. § 1395ff(f)(1)(B); (3) a MAC can issue a Local Coverage Determination ("LCD"), which identifies items or services that are covered or not covered under particular circumstances and mandates automated initial determinations in those cases, 42 U.S.C. § 1395ff(f)(2)(B); (4) if no regulation, NCD, or LCD applies, the MAC will determine coverage on a case-by-case basis.

An LCD is defined in the Medicare statute as "a determination by [a contractor] … respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with [42 USCS § 1395y(a)(1)(A)]." 42 U.S.C. § 1395ff(f)(2)(B). 42 U.S.C. § 1395y(a)(1)(A) is the "reasonable and necessary" standard described above, indicating that LCDs established by MACs must comply with this standard. Only the MAC that created the LCD is bound by it and LCDs "are only binding in the initial adjudication and during the preliminary appeals stages. They do not bind [Administrative Law Judges] or the federal courts." Erringer v. Thompson, 371 F.3d 625, 634 & n.10 (9th Cir. 2004). An aggrieved party can submit a complaint to challenge an LCD, which must then be reviewed by an Administrative Law Judge ("ALJ") who "shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination." 42 U.S.C. § 1395ff(f)(2). Only those entitled to benefits under the Medicare statute are considered "aggrieved parties" who can challenge an LCD. 42 U.S.C. § 1395ff(f)(5). Providers of services to Medicare beneficiaries are not aggrieved parties and cannot challenge an LCD. Id.

Starting in 2006, Congress directed the Secretary to enter into contracts with Recovery Audit Contractors ("RACs") to identify underpayments and overpayments of Medicare benefits and recoup overpayments. 42 U.S.C. § 1395ddd(h). RACs are paid on a contingency basis. Id. RACs can obtain overpayments by withholding future Medicare payments to the provider until the amount owed is paid off, a process known as recoupment.

***ii. Administrative Appeals Process***

There is a multi-step administrative appeals process in place, should a claimant believe that coverage of a service was improperly denied. A supplier, defined as "a physician or other practitioner, a facility, or other entity…that furnishes items or services under this title," 42 U.S.C. § 1395x(d), may file a claim if they have accepted assignment for items or services furnished to a

beneficiary.[1] 42 C.F.R. § 405.906(a)(2). A claimant first submits a claim to their MAC for an initial determination. 42 U.S.C. § 1395ff(a); 42 C.F.R. § 405.920. If the claimant is dissatisfied with the initial determination, they may seek redetermination by the same MAC. Id. § 1395ff(a)(3); 42 C.F.R. § 405.940. If the claimant is still dissatisfied, they may seek reconsideration by a Qualified Independent Contractor ("QIC"). Id. §§ 1395ff(b) and (c); 42 C.F.R. § 405.960. If the claim is denied on reconsideration, the claimant may seek a hearing before an ALJ, in which they can testify and present evidence. Id. § 1395ff(d)(1). Finally, the claimant can appeal the ALJ's decision to the Medicare Appeals Council ("the Council"), which largely bases its decision on the evidence in the record from the proceedings before the ALJ. Id. § 1395ff(d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council's decision (or the ALJ's decision, if not reviewed by the Council) represents the final decision of the Secretary. 42 C.F.R. §§ 405.1130, 405.1132. Once the Council either issues a decision or fails to issue a decision within the applicable time period, an appellant may file an action in federal district court within 60 days. Id.

As discussed above, only the MAC that promulgated an LCD is bound by it. However, the QIC, ALJ, and Council will give "substantial deference" to an LCD if it is applicable to a particular case. 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow an LCD, they must explain why. Id. § 405.1062(b). The ALJ or Council's decision to disregard an LCD only applies to the specific claim being considered and has no precedential effect. Id. An ALJ or the Council may not set aside or review the validity of an LCD for purposes of a claim appeal. Id. § 405.1062(c). The only way to review or set aside an LCD is through the process described in 42 U.S.C. § 1395ff(f)(2), in which an "aggrieved party" (not a supplier) may submit a complaint and have an ALJ review an LCD.

**b. Factual Findings**

Having described the regulatory scheme in which this case takes place, the Court makes

---

[1] Medicare requires payment to suppliers to be made on an assignment-related basis, which means that Medicare pays the supplier directly, rather than the beneficiary. 42 U.S.C. §§ 1395u(h)(1); 1395u(b)(3)(B)(ii). A supplier who reasonably believes that Medicare will deny coverage may attempt to transfer liability for non-coverage to a Medicare beneficiary by first obtaining, before providing any items or services, the beneficiary's signature on an Advanced Beneficiary Notice of Non-coverage ("ABN"). 42 U.S.C. § 1395pp.

the following factual findings regarding Plaintiff's claims.[2]

***i. Dr. Odell's Treatment***

Plaintiff Odell is a physician who routinely provides a treatment ("the treatment") for a condition known as neurological ischemia, which causes pain, numbness, and loss of functionality in the lower extremities. Dr. Odell has successfully used the treatment on hundreds of patients over the past several years to restore functionality to their lower extremities. The treatment consists of nerve blocks for pain combined with electrical stimulation. It is routine and applied in a similar fashion to each patient who receives it.

***ii. The "Unwritten Rule"***

Dr. Odell alleges that Nevada's MAC is applying a default policy or "unwritten rule," by which Medicare coverage is automatically denied for his treatment. Noridian is the local MAC that provides Medicare services in Nevada. Noridian has created two LCDs that are relevant to this case: "LCD L28271 Injections – Tendons, Ligament, Ganglion Cyst, Tunnel Syndromes and Morton's Neuroma" and "LCD L28240 Blocks and Destruction of Somatic and Sympathetic Nerves." As the name suggests, LCD L28271 describes which services are presumptively necessary and reasonable – or not – in various circumstances involving injections for problems with tendons and ligaments, ganglion cysts, tunnel syndromes, and Morton's Neuroma. LCD L28240 describes which treatments are presumptively necessary and reasonable for the treatment of somatic and sympathetic nerve damage. Under the alleged unwritten rule, Noridian categorizes every claim involving Dr. Odell's treatment as falling under LCD L28271 and automatically denies coverage because the claimant did not meet the criteria for coverage under that LCD. Plaintiff Odell argues that his treatment is more accurately categorized under LCD L28240, and that under this LCD, most claimants receiving his treatment would satisfy the criteria for Medicare coverage. Dr. Odell points out that at least one ALJ has agreed with him. In a case with fifteen consolidated Medicare coverage appeals, ALJ Wein held that Dr. Odell's treatment was necessary and reasonable in thirteen claims. ECF No. 57, Ex. B. ALJ Wein reasoned:

---

[2] The following facts are taken from Plaintiffs' Amended Complaint (ECF No. 57).

> The undersigned finds that Local Coverage Determination LCD L28420 is the applicable provision that governs Medicare coverage of the Appellant's claims as it more broadly references nerve blocks. The Appellant billed CPT code 64450 for the treatment of diabetic polyneuropathy and other medical conditions which fall under L28240. On the contrary, L28271 does not reference diagnostic codes which cover more systemic causes of severe nerve dysfunction [e.g. neuropathy affecting multiple nerves], and thus does not list diabetic neuropathy as an indication for the procedure.

Id. at 16. Noridian did not appeal ALJ Wein's decision.

Dr. Odell has submitted evidence that RACs performing audits of past Medicare payments have followed Noridian's unwritten rule and retroactively denied claims involving his treatment as unnecessary and unreasonable, costing him hundreds of thousands of dollars in recouped payments. Dr. Odell submitted records of RAC audits for the years 2012 and 2013. The 2012 audits required Dr. Odell to pay the Secretary a total of $170, 418.88 in alleged overpayments for hundreds of treatments performed on dozens of patients. ECF No. 57, Ex. D at 19. The 2013 audits similarly required Dr. Odell to pay the Secretary a total of $172,413.66 in overpayments. Id., Ex. E at 36.

## IV. DISCUSSION

### A. Subject Matter Jurisdiction

#### *1. Legal Standard*

Federal question and diversity jurisdiction is specifically disclaimed in cases involving the Medicare Act. This is because, "[t]he third sentence of 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." Heckler v. Ringer, 466 U.S. 602, 614-15 (1984). The Supreme Court has interpreted the "arising under" language to mean that no claim may be brought through the traditional federal question or diversity jurisdiction statutes if "both the standing and the substantive basis for the presentation" of the claim is the Medicare statute. Shalala v. Ill. Council on Long Term Care, 529 U.S. 1, 12 (2000) (internal citation omitted). In Heckler, the plaintiffs argued that policies regarding Medicare coverage for certain treatments violated the Due Process Clause of the Constitution and the APA,

in addition to violating the reasonable and necessary standard of the Medicare statute. Heckler, 466 U.S. at 610-11. The Court noted that in its previous decision in Weinberger v. Salfi, 422 U.S. 749 (1975), "we held that a constitutional challenge … was a 'claim arising under' Title II of the Social Security Act within the meaning of 42 U.S.C. § 405(h), even though we recognized that it was in one sense also a claim arising under the Constitution." Id. at 615. Under that "broad test," the Court held that all of the plaintiffs' claims arose under the Medicare statute and needed to meet the requirements for jurisdiction under that statute. Id. Additionally, the Supreme Court has held that the APA is not an independent grant of subject matter jurisdiction. Califano v. Sanders, 430 U.S. 99, 105 (1977) ("[T]he APA is not to be interpreted as an implied grant of subject-matter jurisdiction to review agency actions."). Rather, Courts generally have jurisdiction under another statute, such as the federal question statute, to review agency action under the APA. Because the Medicare statute explicitly bars jurisdiction under the federal question statute, the only way that a court can have jurisdiction over cases arising under it is if the plaintiffs meet the requirements for jurisdiction under 42 U.S.C. § 405(g).

Generally, to obtain judicial review of a Medicare claim, a provider must first exhaust the administrative review procedures set forth in the Medicare statute, 42 U.S.C. § 1395oo. Heckler, 466 U.S. at 627. "[A]dherence to the procedures of 42 U.S.C. § 1395oo is a prerequisite to the Court's very jurisdiction." Pacific Coast Medical Enterprises v. Harris, 633 F.2d 123, 138 (1980). The Ninth Circuit has held that the exhaustion requirement is waivable by courts in certain limited circumstances, however. Johnson v. Shalala, 2 F.3d 918 (9th Cir. 1993). The Ninth Circuit applies a three-part test to determine whether to waive administrative exhaustion: "The claim must be (1) collateral to a substantive claim of entitlement (collaterality), (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability), and (3) one whose resolution would not serve the purposes of exhaustion (futility)." Id. at 921.

***a. Collaterality***

A plaintiff's claim is collateral if it is not essentially a claim for benefits. Id. Claims which have been found to be collateral include those in which the plaintiffs were not seeking to have Medicare benefits awarded, but rather were challenging one of the Secretary's policies or alleging

that the Secretary failed to follow applicable regulations in creating a policy. See, e.g. Bowen v. City of New York, 476 U.S. 467, 483 (1985); Johnson, 2 F.3d at 920 (9th Cir. 1993). Generally, a claim is collateral if it is "not bound up with the merits so closely that [the court's] decision would constitute interference with agency process." Johnson, 2 F.3d at 922 (internal citations and quotation marks omitted).

***b. Irreparability***

A plaintiff must also have a colorable claim of irreparable injury. A claim of irreparable injury is colorable if the claim is not "wholly insubstantial, immaterial, or frivolous." Johnson, 2 F.3d at 920. An injury is irreparable if the plaintiff "could not be made whole by retroactive payments at a later time." Briggs v. Sullivan, 886 F.2d 1132, 1140 (9th Cir. 1989). Economic hardship may constitute irreparable harm in certain circumstances. "Back payments cannot erase the experience or the entire effect of several months without food, shelter or other necessities." Johnson, 2 F.3d at 922 (internal citation and quotation marks omitted).

***c. Futility***

It is futile for a district court to require plaintiffs to exhaust their administrative remedies when it would be impossible for the plaintiffs to receive the relief they seek through the administrative process, or when there is little to be gained from compiling a detailed factual record through the administrative process or from relying on agency expertise. Id. One such example is a "straightforward statutory challenge," in which the court does not need a detailed factual record from each plaintiff to decide the issue and will not benefit from agency expertise because the issue posed is "one purely of statutory construction." Id.

***2. Discussion***

The sole basis for jurisdiction over this case is through the Medicare statute. Under the broad test established by the Supreme Court, all of Plaintiffs' claims "arise under" the Medicare statute, and thus Plaintiff must satisfy the jurisdictional requirements of that statute. See Heckler, 466 U.S. at 615. Plaintiff does not claim to have exhausted administrative remedies, but argues

/ / /

that he has met the requirements to waive exhaustion. The Court will analyze each of these requirements in turn.

***a. Collaterality***

Plaintiff amended his Complaint to indicate that he does not seek monetary damages for denied Medicare claims, but only injunctive and declaratory relief regarding the alleged unwritten rule. ECF No. 57. Any injunctive or declaratory relief the Court could order regarding the impropriety of the unwritten rule would certainly impact the adjudication of past and future Medicare claims. A claim can be collateral even if it may impact future adjudications of benefits, however, as long as it is "not essentially a claim for benefits." Johnson, 2 F.3d at 921. Although this case involves the adjudication of claims and Dr. Odell's loss of revenue as a supplier of services to Medicare beneficiaries, the primary focus is on a specific policy that allegedly violates statutory, regulatory, and Constitutional requirements. Therefore, the Court finds that Plaintiff's claims are collateral to a claim for benefits.

***b. Irreparability***

Plaintiff argues that the unwritten rule is causing irreparable harm because the mass audits are costing Dr. Odell's practice hundreds of thousands of dollars at a time, forcing him to close clinics, causing reputational harm to his practice, damaging his relationships with patients, and leaving patients without a means to continue receiving Dr. Odell's relatively uncommon treatment. Should the unwritten rule continue and should Dr. Odell continue to be audited in the future, it is likely that these audits will cost him so much that he will be forced to close his practice or stop offering the treatment. If the treatment is in fact helping restore functionality and relieve pain, this would constitute irreparable harm to both Dr. Odell and his patients. The Court finds that Plaintiff has alleged a colorable claim for irreparability.

***c. Futility***

The most important question in determining whether jurisdiction is proper in this case is whether it would be futile for Plaintiff to seek further administrative relief before pursuing this case in federal court. It is clearly not futile for Dr. Odell to appeal claim denials one at a time through the administrative process. His own evidence indicates that agency actors have agreed

with him and overturned denied claims for the treatment in the past. Dr. Odell has no means to challenge the unwritten rule as a policy matter, however, for two reasons. First, because he is a supplier, and not a beneficiary, he cannot submit a complaint and have an ALJ review the LCD. 42 U.S.C. § 1395ff(f)(5). Dr. Odell can appeal an individual claim as a supplier, but an ALJ or the Council cannot review the validity of an LCD for purposes of a claim appeal. 42 C.F.R. § 405.1062(c). Second, Dr. Odell is not actually attempting to challenge a particular LCD, but rather the routine and continuous improper application of an LCD to claims involving his treatment. Even if Dr. Odell could request review of LCD L28271 under § 1395ff(f), it is not clear from the statute that an ALJ would have the power to dictate the future application of that LCD to particular treatments. As the statute and regulations are written, the only way for Dr. Odell to challenge the unwritten rule is by appealing the automatically denied claims one at a time through the administrative process.[3] Given the volume of claims that are being audited *en masse* and automatically overturned under the unwritten rule, Dr. Odell argues that individual appeals are impractical.

Jurisdictional discovery indicates that Noridian does not intend to modify the unwritten rule of its own accord. Noridian's corporate representatives testified that, as ALJ opinions are not binding on them, they do not look to previous final agency decisions when deciding which LCDs apply to which treatments. ECF No. 105, Exs. A and B. Their testimony indicates that Noridian will continue to categorize all of Plaintiff Odell's treatments as falling under LCD L28271, and presumptively not covered by Medicare, despite final agency decisions to the contrary. Furthermore, Noridian will do so without needing to review medical records or other evidence on

---

[3] The Court notes that a recent regulation allows the Chair of the Department of Health and Human Services Departmental Appeals Board ("the DAB Chair") to designate decisions by the Council as precedential and binding on all CMS components. 42 C.F.R. § 401.109(a); Changes to Medicare Claims and Entitlement, 82 Fed. Reg. 4974, 4977-81 (Jan. 17, 2017). This authority appears to be entirely discretionary, however. The regulation merely states, "In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest." 42 C.F.R. § 401.109(a). Thus, there is no guarantee that the unwritten rule would be adjudicated in a binding decision, even if Dr. Odell appealed many times. As there is no set procedure in place for Dr. Odell to even request that a certain decision be made precedential, the Court does not find that this recent authority has a significant impact on the futility analysis.

an individualized basis. Based on this system, it is likely that Noridian will continue to apply the unwritten rule to claims for Dr. Odell's treatment in the future, no matter how many agency actors overrule these decisions. To be clear, under the current regulatory scheme, Noridian is not required to consider the decisions of ALJs or other agency adjudicators whose decisions are not binding on MACs. This is all the more reason to find that Dr. Odell cannot receive relief through the administrative process, however.

The Court finds that it is futile for Dr. Odell to continue to challenge the unwritten rule through the administrative process. It is impractical for Dr. Odell to appeal hundreds of claims on a piecemeal basis, when no amount of adjudications in his favor will impact future decisions by Noridian. Additionally, the Court will not benefit from gathering a detailed factual record on each of the denied claims. It is the policy as a whole that is at issue, and whether Noridian violates its legal obligations by automatically denying all claims for Dr. Odell's treatment without reviewing them on an individualized basis or reviewing their routine rejection of his claims based upon an application of a particular LCD. The Court can review this default rule without needing to know whether the treatment is factually necessary and reasonable in each individual instance. Because this is primarily a question of legal interpretation, the Court also does not need to rely on the benefit of agency expertise. Johnson, 2 F.3d at 922. Therefore, the Court finds that Plaintiff has satisfied all of the requirements to waive administrative exhaustion, and the Court will exercise jurisdiction over this case.

**B. Failure to State a Claim**

***1. Legal Standard***

In order to state a claim upon which relief can be granted, a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In ruling on a motion to dismiss for failure to state a claim, "[a]ll well-pleaded allegations of material fact in the complaint are accepted as true and are construed in the light most favorable to the non-moving party." Faulkner v. ADT Security Servs., Inc., 706 F.3d 1017, 1019 (9th Cir. 2013). To survive a motion to dismiss, a complaint must contain "sufficient factual matter,

accepted as true, to state a claim to relief that is plausible on its face," meaning that the court can reasonably infer "that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citation and internal quotation marks omitted).

***2. Discussion***

Defendant argues generally that Plaintiff has failed to state a claim because the allegations regarding the unwritten rule are conclusory and he has submitted no evidence that the alleged unwritten rule exists. The Court does not find this argument convincing. As described above, Plaintiff submitted the testimony of Noridian's representatives, who stated that they would continue to classify Dr. Odell's treatment as falling under LCD L28271 and presumptively not being covered by Medicare, regardless of decisions or evidence to the contrary. ECF No. 105, Exs. A and B. Defendant has largely conceded that this policy exists by arguing that it has the right to promulgate and apply LCDs and that as the MAC, it is not bound by the decisions of ALJs or other adjudicators. At this point, there is strong evidence in favor of Noridian's policy of classifying Dr. Odell's treatment under LCD L28271. Whether this default rule violates the Medicare statute, the APA, or the Due Process Clause remains to be seen. The Court does not find that Plaintiff has established any sort of improper motive or intent on Noridian's behalf in creating this policy, but Plaintiff has sufficiently alleged that the policy exists. As Defendant did not make specific arguments regarding the elements of the different claims, the Court will not analyze each claim in detail at this time, but will allow the parties to brief those issues in future dispositive motions.

**C. Motion for Preliminary Injunction**

Based on the jurisdictional discovery that has taken place so far, Plaintiff moved the Court for a preliminary injunction to protect his interests during the pendency of this case. ECF No. 104.

***1. Legal Standard***

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 22 (2008). To obtain a preliminary injunction, a plaintiff must establish four elements: "(1) a likelihood of success on the merits, (2) that the plaintiff will likely suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in its favor, and (4) that

the public interest favors an injunction." Wells Fargo & Co. v. ABD Ins. & Fin. Servs., Inc., 758 F.3d 1069, 1071 (9th Cir. 2014), as amended (Mar. 11, 2014) (citing Winter, 555 U.S. at 20). A preliminary injunction may also issue under the "serious questions" test. Alliance for the Wild Rockies v. Cottrell, 632 F.3d 1127, 1134 (9th Cir. 2011) (affirming the continued viability of this doctrine post-Winter). According to this test, a plaintiff can obtain a preliminary injunction by demonstrating "that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," in addition to the other Winter elements. Id. at 1134-35 (citation omitted).

***2. Discussion***

***a. Likelihood of Success on the Merits***

As discussed, the jurisdictional discovery that has taken place has produced strong evidence that the unwritten rule exists and that Noridian is applying LCD L28271 to claims for Dr. Odell's treatment by default and presumptively denying all of these claims. There is little chance that this unwritten rule will change under the current regulatory scheme, given the fact that ALJ decisions are not binding and that the MAC and the QIC testified that they do not look to previous adjudications in determining the reasonableness of the application of LCDs to specific treatment scenarios. The question is whether Noridian violates any statutory or constitutional rights by doing so. MACs certainly have the statutory right to promulgate and apply LCDs, in order to conserve resources and make the Medicare adjudication process more efficient. 42 U.S.C. § 1395ff(f)(2)(B). All LCDs must be created in accordance with the reasonable and necessary standard described in 42 U.S.C. § 1395y(a)(1)(A), however. Id. While MACs are permitted to create timesaving shortcuts, they are still expected to act within the overarching principle that Medicare claims are only to be denied when they are not reasonable and necessary. If the continuous application of an LCD to a particular treatment scenario was so nonobvious or divergent from the plain meaning of the LCD that the MAC was consistently denying claims that were reasonable and necessary, such an application could potentially be arbitrary and capricious in violation of the APA. 5 U.S.C. § 706(2)(A). Such a nonobvious application could also

effectively constitute a new, unwritten LCD or a substantial restriction to an existing LCD, which did not go through the notice and comment period required under agency regulations and the APA. See U.S. Dep't of Health and Hum. Servs., Ctr. for Medicare & Medicaid Servs., Pub. 100-08, Medicare Program Integrity Manual ("MPIM") ch. 13, § 13.7.2; 5 U.S.C. § 553.

In determining the likelihood that the unwritten rule is arbitrary and capricious or constitutes a new substantive rule that did not go through the required notice and comment period, the Court gives significant consideration to ALJ Wein's opinion in Dr. Odell's favor. While there have been many MAC and QIC adjudications that ruled against Dr. Odell, Defendant has not presented the Court with any ALJ opinions that contradict that of ALJ Wein. ALJ Wein's decision is particularly persuasive at this point in the proceeding because he lays out in some detail the difference between the two LCDs and the reason why LCD L28240 is more appropriate for Dr. Odell's treatment than LCD L28271.[4]

In reviewing the two LCDs, the opinion cites to LCD L28271, which "addresses the injection of chemical substances, such as local anesthetics, steroids, sclerosing agents and/or neurolytic agents into ganglion cysts, tendon sheaths, tendon origins/insertions, ligaments, costochondral areas, or near nerves of the feet (e.g. Morton's neuroma) to affect therapy for a pathological condition." ECF No. 57, Ex. B at 11. The LCD contains guidelines for when injections into these specific areas are presumed to be reasonable and necessary. For example, injection of a tarsal tunnel is presumed reasonable and necessary "for the patient with a mild case of tarsal tunnel syndrome if oral NSAIDs and orthoses have failed or are contraindicated." Id. In another example, the LCD states that "'[d]ry needling' of ganglion cysts, neuromas, tendon sheaths and their origins/insertions are non-covered procedures." Id. at 12. The LCD goes on to clarify that "[m]edical necessity for injections of more than two sites at one session or for frequent or repeated injections is questionable. Such injections are likely to result in a request for medical records which must evidence careful justification of necessity." Id.

/ / /

[4] LCD L28271 was previously called LCD L27702, but it has since been renumbered and is substantively the same.

The opinion also cites to LCD L28240, which addresses nerve block injections – injections of anesthetics into somatic or sympathetic nerves. Id. That LCD explains that nerve block injections can be used for several reasons, including diagnostic, therapeutic, prognostic, and preemptive pain management reasons. Id. at 13. The LCD describes various expectations for the prudent application of nerve blocks. For example, "[i]t would be expected that the least invasive modality should be tried first, advancing to more invasive modalities, if needed." Id. According to the LCD, "[n]erve blocks are indicated in patients who are not adequately controlled by appropriate doses of medications or who are refractory to medical therapy." Id. It also indicates that generally, up to three injections or sets of injections in a 60-day period are sufficient for a course of treatment and that additional injections may require further documentation. Id. LCD L28240 goes on to describe guidelines for the surgical destruction of nerves, which are not relevant here.

In reaching his conclusion, ALJ Wein noted that Dr. Odell submitted peer reviewed medical literature indicating that electrical stimulation in conjunction with nerve block injections can be beneficial for the treatment of ischemic disorders to the lower extremities. Id. at 16. He then explained his reasoning as follows:

> The undersigned finds that Local Coverage Determination LCD L28420 is the applicable provision that governs Medicare coverage of the Appellant's claims as it more broadly references nerve blocks. The Appellant billed CPT code 64450 for the treatment of diabetic polyneuropathy and other medical conditions which fall under L28240. On the contrary, L28271 does not reference diagnostic codes which cover more systemic causes of severe nerve dysfunction [e.g. neuropathy affecting multiple nerves], and thus does not list diabetic neuropathy as an indication for the procedure.

Id. ALJ Wein went on to find that Dr. Odell had submitted sufficient documentation in the form of medical records and progress notes to justify the nerve block injections for all but two of the fifteen beneficiaries whose claims he appealed. Id. at 17. He also found that "[t]he record further establishes that the least invasive modality was used first, and then the procedures advanced to more invasive modalities as needed." Id. ALJ Wein reversed denials for thirteen claims and upheld denials for the two claims that did not include sufficient information regarding medical necessity. Id. at 18.

Based on the information the Court has regarding the two LCDs, the Court finds that Dr. Odell has established a likelihood of success on the merits for his claims that the continuous default application of LCD L28271 to his treatment is arbitrary and capricious in violation of the APA and/or constitutes a new substantive rule that did not go through the required rulemaking process. Other than arguing that the MAC has the right to promulgate LCDs and that ALJ opinions are not precedential, Defendant has not presented many substantive arguments regarding why LCD L28271 is actually the appropriate LCD to apply to Dr. Odell's treatment, rather than LCD L28240. Based on the plain language of the two LCDs and the evidence that the Court has before it, it appears that LCD L28271 is not the most appropriate LCD to apply to Dr. Odell's treatment. While the Court is by no means ruling on Dr. Odell's substantive causes of action at this point, it finds ALJ Wein's reasoning to be persuasive as to the record here, and the Court does not find that the record supports the unwritten rule.

***b. Irreparable Harm***

There is significant irreparable harm at issue in this case if the unwritten rule continues. Dr. Odell has submitted evidence indicating that he has been audited multiple times and that each time he has had hundreds of thousands of dollars recouped. He states that he has had to close clinics in the past due to these audits. Although pure financial harm can be compensated with monetary damages at a later date, it is easy to see how the harm in this case could extend beyond economic damage. Besides limiting the availability of the treatment to Medicare beneficiaries, Dr. Odell also argues that he has suffered and will continue to suffer damage to his relationships with patients and the significant reputational harm that stems from being accused of Medicare fraud. The Court finds that in the absence of injunctive relief, the unwritten rule will likely continue during the pendency of this action, and if it does, Dr. Odell will likely continue to suffer harm to his practice, which he may not be able to recover from.

***c. Balance of Equities***

The Court finds that the balance of equities tips in Dr. Odell's favor. The RACs performing these audits are paid on a contingency basis, and thus are incentivized to recoup as many payments as possible. 42 U.S.C. § 1395ddd(h). Although Defendant points out that RACs are not paid if a

recoupment is overturned, the evidence indicates that Dr. Odell's claims have been recouped *en masse*. Even if a recoupment is overturned from time to time, a RAC will still likely be incentivized to follow the unwritten rule when performing audits. On the other hand, Dr. Odell is suffering significant financial and reputational harm, with no available process to challenge the unwritten rule in the current regulatory scheme.

***d. Public Interest***

The Court finds that it is in the public interest to grant a preliminary injunction in this case. There is a public interest in allowing MACs to create LCDs to efficiently adjudicate Medicare claims and allowing RACs to recover unjustified Medicare payments. However, efficiency and the prevention of waste do not outweigh the provision of medical treatments to patients suffering from pain and loss of functionality. The Court is also aware that is has an obligation to exercise discretion and not interfere unnecessarily with agency affairs. In this case, however, the Plaintiff is suffering significant financial and reputational harm due to a policy that has no apparent justification. Under these circumstances, the Court finds that it is appropriate to intervene and provide limited preliminary injunctive relief.

***e. Appropriate Relief***

Because the Court does not want to intervene with agency affairs to a greater extent than necessary, however, it will allow the parties the opportunity to present arguments regarding the appropriate scope of injunctive relief. The Court will schedule a hearing to decide what specific relief is necessary. The parties are ordered to provide proposed orders regarding injunctive relief no later than October 10, 2018. The Court will finalize the form of injunctive relief after reviewing the submissions of the parties.

## V. CONCLUSION

**IT IS ORDERED** that Defendant's Motion to Dismiss (ECF No. 103) is DENIED.

**IT IS FURTHER ORDERED** that Plaintiff's Motion for Preliminary Injunction (ECF No. 104) is GRANTED. The parties are ordered to submit proposed orders regarding injunctive relief no later than **October 10, 2018.**

**IT IS FURTHER ORDERED** that a hearing regarding the proposed orders as to injunctive relief is set for October 26, 2018 at 11:00 AM in LV Courtroom 7C.

**DATED:** September 26, 2018.

**RICHARD F. BOULWARE, II**
**UNITED STATES DISTRICT JUDGE**