JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

AGENDIA, INC.,

Plaintiff,

vs.

ALEX AZAR,

Defendants.

Case No.: SA CV 19-0074-DOC (JDEx)

ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT [18]

Before the Court is Plaintiff Agendia, Inc.'s ("Agendia" or "Plaintiff") Motion for Summary Judgment ("Motion") (Dkt. 18) against Alex Azar ("Azar" or "Defendant") the Secretary of Health and Human Services ("Secretary"). The Motion asks the Court to set aside the January 7, 2019 decision of the Medicare Appeals Council ("Council") denying Medicare coverage and payment for clinical laboratory tests. Oral arguments were held in this matter on October 28, 2019. After considering the papers and hearing the arguments raised by the parties, the Court **GRANTS** Plaintiff's Motion.

I. BACKGROUND

A. Facts[1]

Medicare is the federal health insurance program for the aged and disabled. 42 U.S.C. §§ 1395 *et seq*. and 42 C.F.R. Part 400 *et seq.*; *see also* Plaintiff's Statement of Uncontroverted Facts and Conclusions of Law ("SUF") (Dkt. 20) ¶ 1. Of relevance here is Part B of the Medicare Program, known as the "supplementary medical insurance program" ("Medicare Part B"). 42 U.S.C. §§ 1395j -1395x and 42 C.F.R. Part 410 *et seq*. Medicare Part B covers "medical and other health care services," including physician services and diagnostic laboratory tests. SUF ¶ 1, 3. To be covered and paid by Medicare, a diagnostic laboratory test must be ordered by a physician who is treating the beneficiary and using the test results in the management of the patient's specific medical condition. *Id*. ¶ 3. Medicare Part B does not cover "services that are not reasonable and necessary" for treatment. *Id*. ¶ 4; 42 U.S.C. § 1395y(a)(1)(A).

The Secretary administers the Medicare Program through the Centers for Medicare and Medicaid Services ("CMS"). SUF ¶ 2. CMS, in turn, contracts with private Medicare Administrative Contractors ("MACs") to administer portions of Medicare Part B. 42 U.S.C. § 1395u(a). Section 1395u(a) states that Medicare Part B "shall be conducted through contracts

[1] Unless indicated otherwise, to the extent any of these facts are disputed, the Court concludes they are not material to the disposition of the Motion. Further, to the extent the Court relies on evidence to which the parties have objected, the Court has considered and overruled those objections. As to any remaining objections, the Court finds it unnecessary to rule on them because the Court does not rely on the disputed evidence.

with medicare administrative contractors under section 1395kk-1 of this title." *Id.* Congress expressly delegated to MACs the "function of developing local coverage determinations, as defined in section 1395ff(f)(2)(B) of this title." 42 U.S.C. § 1395kk-1(a)(4). A local coverage determination ("LCD") is defined as a determination of whether or not a particular item or service is covered on a contractor-wide basis under Section 1395y(a)(1)(A). *Id.* § 1395ff(f)(2)(B).

In contrast to LCDs, the Secretary (as opposed to MACs) develops National Coverage Determinations ("NCDs"). SUF ¶ 6. NCDs are a "determination by the Secretary with respect to whether or not a particular item or service is covered nationally." *Id.* § 1395ff(f)(1)(B). CMS establishes NCDs through a process similar to that required under the notice and comment rulemaking provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. section 553. Congress requires the Secretary to provide a public comment period, including publishing a proposed draft of any NCD, and to respond publicly to comments received. *See* 42 U.S.C. § 1395y(l)(3). The Secretary does not have to promulgate NCDs as regulations even though NCDs establish or change the legal standards governing the scope of Medicare benefits. *Id.* § 1395hh(a)(2) ("No rule, requirement, or other statement of policy (other than a [NCD]) that establishes or changes a substantive legal standard governing the scope of benefits . . . shall take effect unless it is promulgated . . . by regulation . . . .").

LCDs are not promulgated by regulation. SUF ¶ 7. Instead, MACs internally establish the policies. *Id.* Furthermore, the Secretary requires ALJs and the Council to give MAC policies "substantial deference" in the Medicare administrative appeal process. *See* 42 C.F.R. 405.1062(a) ("ALJs . . . and the Council are not bound by LCDs . . . but will give substantial deference to these policies if they are applicable to a particular case."). In a Medicare supplier's claim appeal, such as here, an ALJ and the Council may not set aside or review the validity of an LCD. *See* 42 C.F.R. § 1062(c).

Agendia is an independent clinical laboratory that may be certified as a "supplier" of Medicare Part B services. 42 C.F.R. § 400.202; *see also* SUF ¶ 1. Agendia furnishes molecular diagnostic tests at the requests of doctors throughout the country who treat breast cancer

patients. *Id*. ¶ 18. At issue here are two tests furnished by Agendia, the BluePrint and TargetPrint tests. *Id*. ¶ 20. Upon the written order of the doctors for each of the 86 Medicare beneficiaries whose claims are at issue in this case, Agendia furnished BluePrint and/or TargetPrint tests between June 2012 and January 2013, the period at issue in this case. *Id*. ¶ 21.

Palmetto GBA ("Palmetto") was the MAC for Agendia's geographic region in 2011. *Id*. ¶ 15. That year, Palmetto developed the Molecular Diagnostic Services ("MolDX") Program to identify and establish coverage and reimbursement for molecular diagnostic tests. *Id*. Under MolDX, Palmetto requests clinical information about a test to determine if a test meets Medicare's reasonable and necessary requirement. *Id*. Prior to this technical assessment, Palmetto considers all molecular diagnostic tests investigational and not a covered service. *Id*.

Between June 2012 through January 2013 Palmetto established LCD L32288, confirming "non-coverage" for all molecular diagnostic tests that were not explicitly covered by a NCD, a LCD, a Palmetto Coverage Policy Article, or approved through the MolDX program. *Id*. ¶ 16. Palmetto also issued a "Policy Article" (Policy Article A51931) indicating there was "insufficient evidence to support" the reasonable and necessary criteria for Medicare reimbursement for Agendia's BluePrint test. *Id.* LCD L32288 and MolDX are administered by Palmetto, and all MACs rely on MolDX to determine coverage for molecular diagnostic lab services across the United States. *Id* ¶ 17. The tests Agendia furnished between June 2012 and January 2013 were denied payment on the grounds the tests were not covered by Medicare based on LCD L32288 and lack of MolDX approval. *Id*. ¶ 21.

B. Procedural History

After the denial of payment, Agendia requested reconsideration on November 1, 2013 from a private Medicare contractor called a Qualified Independent Contractor ("QIC") as required by law. *Id*. ¶ 22. On December 31, 2013, the QIC informed Agendia that it was also denying coverage because the MolDX program had completed technical assessments of BluePrint and TargetPrint showing that, to date, there is insufficient evidence to support the required clinical utility for the established Medicare benefit category. *Id*.

After the QIC denial, Agendia requested a hearing before an ALJ on February 28, 2014. *Id*. ¶ 23. The Secretary's appeals office scheduled an ALJ hearing for July 19, 2018, more than four years after Agendia's request for a hearing. *Id*. The ALJ issued a fully favorable decision for Agendia based on the record and testimony provided at the hearing. *Id*. ¶ 24. The ALJ found that the testing was medically reasonable and necessary. *Id*. On October 12, 2018, a second QIC wrote to the council asserting that the ALJ misapplied the LCD at issue in this case. *Id*. ¶ 26. Agendia countered, but the Council issued a decision on January 7, 2019 reversing the ALJ and concluding that the tests were not medically necessary based on the LCD, Palmetto policy, and the lack of approval by MolDX. *Id*. The Council concluded that the ALJ erred as a matter of law by departing from the LCD, the relevant policies, and MolDX, and the Council found no reason "not to apply substantial deference to the LCD or to question the MolDX program's findings." *Id*. ¶ 27; Administrative Record ("A.R.") at 3333–34.

On January 14, 2019, more than five years since the first denial of payment, Agendia filed a complaint in the Central District of California asking for judicial review of the agency decision described. Dkt. 1. First, the Complaint alleges that the administrative process at issue is an unconstitutional delegation of lawmaking authority to private contractors in violation of the Fifth Amendment Due Process Clause. Compl. at 11. Next, the Complaint alleges that the administrative process depended on an LCD, policy article, and MolDX program that were adopted without complying with the rulemaking requirements in the Medicare Act. *Id*. Finally, Agendia argues that the decision in this matter is arbitrary and capricious and not in accordance with the law or supported by substantial evidence. *Id.*

On June 17, 2019 Agendia filed the instant Motion for Summary Judgment. Dkt. 18. On July 29, 2019 Defendant opposed ("Opp'n"). Dkt. 21. On August 5, 2019 Plaintiff replied. Dkt. 23.

II. LEGAL STANDARD

A. Summary Judgment

Summary judgment is proper if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is to be granted cautiously, with due respect for a party's right to have its factually grounded claims and defenses tried to a jury. *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A court must view the facts and draw inferences in the manner most favorable to the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1992); *Chevron Corp. v. Pennzoil Co.*, 974 F.2d 1156, 1161 (9th Cir. 1992). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact for trial, but it need not disprove the other party's case. *Celotex*, 477 U.S. at 323. When the non-moving party bears the burden of proving the claim or defense, the moving party can meet its burden by pointing out that the non-moving party has failed to present any genuine issue of material fact as to an essential element of its case. *See Musick v. Burke*, 913 F.2d 1390, 1394 (9th Cir. 1990).

Once the moving party meets its burden, the burden shifts to the opposing party to set out specific material facts showing a genuine issue for trial. *See Liberty Lobby*, 477 U.S. at 248–49. A "material fact" is one which "might affect the outcome of the suit under the governing law." *Id.* at 248. A party cannot create a genuine issue of material fact simply by making assertions in its legal papers. *S.A. Empresa de Viacao Aerea Rio Grandense v. Walter Kidde & Co., Inc.*, 690 F.2d 1235, 1238 (9th Cir. 1982). Rather, there must be specific, admissible, evidence identifying the basis for the dispute. *See id.* The Court need not "comb the record" looking for other evidence; it is only required to consider evidence set forth in the moving and opposing papers and the portions of the record cited therein. Fed. R. Civ. P. 56(c)(3); *Carmen v. S.F. Unified Sch. Dist.*, 237 F.3d 1026, 1029 (9th Cir. 2001). The Supreme Court has held that "[t]he mere existence of a scintilla of evidence … will be insufficient; there must be evidence on which the jury could reasonably find for [the opposing party]." *Liberty Lobby*, 477 U.S. at 252.

III. DISCUSSION

In the instant Motion, Plaintiff and Defendant agree on the essential facts. *See generally* SUF and Plaintiff's Response to SUF (Dkt. 21-1); Mot. at 14 (characterizing the facts in the case as "essentially undisputed"). Plaintiff asks for summary judgment invalidating the administrative decision. Defendant responds that the administrative decision should be affirmed and summary judgement granted for the Defendant under F.R.C.P. 56(f)(1).

Plaintiff makes three broad challenges to the January 7th, 2019 decision by the Council. First, Plaintiff argues that the policies that grounded the decision were established by private contractors, whom were impermissibly delegated lawmaking authority in violation of the Fifth Amendment Due Process Clause. Mot. at 1. Second, Plaintiff argues that these same policies were enacted under improper procedure in violation of the APA and Medicare Act. *Id*. Finally, Plaintiff argues that the decision and underlying policies are inconsistent with Medicare coverage statutes and regulations. *Id*. The Court will take Plaintiff's challenges in turn.

A. Impermissible Delegation to a Private Party

Plaintiff describes the Council's decision as erroneous because the decision relied on an impermissible delegation of authority to a private contractor—Palmetto. Mot. at 14. Defendant concedes Palmetto issued the LCD, created MolDX, and issued a policy article. Opp'n at 2–4. These policies were referenced in the Council's decision, which found that Agendia's tests "were reviewed by the MolDX program, and neither had sufficient evidence to support the reasonable and necessary criteria for Medicare reimbursement" and "the ALJ erred by not applying Policy Article A51931." A.R. at 3333. Plaintiff argues that the "Council's decision squarely raises the question of whether Congress and the Secretary may delegate discretionary regulatory policy making to a private contractor." Mot. at 13. Because the Council's decision rested on the finding that the ALJ erred by not substantially deferring to the LCD, MolDX, and relevant Palmetto policy article, Plaintiff argues that this Court should decide whether Congress' delegation to MACs to establish these policies is an unconstitutional delegation of power to a private party. *Id*. at 14.

Plaintiff also focuses this Court on 42 C.F.R. section 405.1062. The regulation states that "ALJs . . . and the Council are not bound by LCDs . . . but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). If an ALJ does decline to follow a policy, the ALJ must explain the reasons for doing so. § 405.1062(b). Furthermore, "an ALJ . . . or the Council may not set aside or review the validity of an . . . LCD for purposes of a claim appeal" but may only review its validity if a Medicare *beneficiary* initiates a review. § 405.1062(c). Plaintiff argues that the relevant LCD, program, and policies at issue are not only issued by a private party, but also are given substantial deference by the agency and may not be reviewed unless a beneficiary (as opposed to a supplier, like Agendia) challenges the policy. Mot. at 14. Therefore, Plaintiff argues, "MAC policies do, in fact, establish legal standards for determining coverage for molecular diagnostic tests." *Id*.

Defendant argues that the Plaintiff is incorrect because (1) LCDs are not legislative and (2) MACs function subordinately to the Secretary. Opp'n at 6. The Defendant concedes that the Secretary contracts with MACs to develop LCDs in accordance with the Secretary's Program Integrity Manual ("PIM"). *Id*. at 2. However, Defendant argues that PIM provisions do not have legislative force, therefore it "follows that the LCDs developed in accordance with the PIM guidelines do not have any legislative force as well." *Id*. at 6–7.

Defendant next argues that MACs function subordinately to the federal agency and the agency has authority over MAC activities. *Id*. at 7. Defendant details that LCDs may be challenged and reviewed by ALJs and the Departmental Appeals Board of the Department of Health and Human Services ("DAB") and are subject to judicial review. *Id*. at 7–8; *see also* 42 C.F.R. § 426.400 (allowing aggrieved parties—defined as a Medicare beneficiary and not a supplier of services—to challenge LCDs). Therefore, Defendant argues that the Council was not bound by the LCD and the MAC did not establish a legal standard for determining coverage of the molecular diagnostic test. Opp'n at 7.

The Fifth Amendment's Due Process Clause prohibits federal lawmakers from delegating regulatory authority to a private entity. To do so would be "legislative delegation in its most obnoxious form." *Carter v. Carter Coal Co*., 298 U.S. 238, 311 (1936). To establish a

due process violation, the Court must find (1) a self-interested private party (2) given power by Congress to regulate other private parties who may have adverse interests. *Ass'n of Am. Railroads v. United States Dep't of Transportation*, 896 F.3d 539, 545 (D.C. Cir. 2018).

"Any delegation of regulatory authority 'to private persons whose interests may be and often are adverse to the interests of others in the same business' is disfavored." *Pittston Co. v. United States*, 368 F.3d 385, 394 (4th Cir. 2004) (quoting *Carter*, 298 U.S. at 311). However, private parties may assist an agency provided the party functions subordinately to the agency and the agency "has authority and surveillance over the activities" of the party. *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 399 (1940). Private parties do not act subordinately to an agency when they "occupy positions of authority" and the agency is "powerless to overrule" the private party. *See Ass'n of Am. Railroads v. U.S. Dep't of Transp.*, 821 F.3d 19, 35 (D.C. Cir. 2016) (invalidating a scheme where Amtrak developed metrics affecting other parties that could not be overruled by the Federal Railroad Administration without intervention from a private arbitrator).

A brief comparison of cases involving delegations to private entities illuminates the line between permissible assistance private entities may provide in enacting a regulatory scheme and impermissible delegation of authority to a private party. In *Carter*, the Supreme Court invalidated a scheme that *mandated* all coal producers accept maximum labor hours and minimum wages negotiated by a majority of coal producers and representatives of mine workers. *Carter*, 298 U.S. at 310–11. The scheme was invalid because the *private* majority was able to "regulate the affairs of an unwilling minority" and had unfettered ability to pursue their interests unfairly. *Id.* at 311. The *Carter* Court was especially concerned because here the delegation was to private persons who interests were likely "adverse to the interests of others in the same business." *Id*.

In contrast, in *Sunshine*, the Supreme Court upheld a scheme that allowed private coal producers to assist in setting prices for coal because the producers were subordinate to the National Bituminous Coal Commission, which ultimately determined the prices at issue. *Sunshine*, 310 U.S. at 399. The statute at issue in *Sunshine* allowed coal producers to *propose*

minimum prices for coal pursuant to statutory standards which the Commission then would approve, disapprove, or modify. *Id*. at 388. The Court found that this supervision was sufficient to survive a challenge under the due process clause. *Id*. at 399.

Circuits courts have also addressed the issue and upheld or invalidated delegations to private entities or otherwise self-interested entities. For example, in *Pittston* the Fourth Circuit applied *Sunshine* to find that the Coal Act, which gave power to a private entity to collect premiums, was not unconstitutional when the Social Security Commissioner defined the premiums, determined who was eligible to receive them, and designates the amount of the benefits. *Pittston*, 368 F.3d at 396. The private parties who collected the premiums were simply performing an administrative or advisory role. *Id*.

Similarly, in *United States vs. Frame*, the Third Circuit upheld a statutory scheme where a private Cattleman's Board develops budgets and plans under the Beef Promotion Act and collects assessments under the Act. 885 F.2d 1119, 1123 (3d Cir. 1989). However, the Board is under the supervision of the Secretary of Agriculture, "who must finally approve all budgets, plans, expenditures, and contracts for them to become effective." *Id*. The Third Circuit found this scheme squarely within *Sunshine* because of the considerable oversight of the Secretary of Agriculture and because the Board had no lawmaking authority. *Id*. at 1128–29.

The D.C. Circuit in *Association of American Railroads vs. U.S. Department of Transportation* ("AAR") went the other way. In *AAR*, the Circuit found that Amtrak was economically self-interested in the content of metrics that it was allowed to "jointly" create with the Federal Railroad Administration ("FRA") that affected Amtrak's competitors. *AAR*, 896 F.3d at 545. The statutory scheme provided that, if Amtrak and the FRA could not jointly agree on the metrics, Amtrak could petition for a *private* arbitrator to resolve the dispute (and force Amtrak's preferred metrics) without any check from the FRA. *Id*. The *AAR* Court reasoned that Amtrak's involvement in creating the metrics was not constitutionally improper, but the fact that the FRA has no "independent ability to temper or prevent Amtrak from adopting measures that promoted its own self-interest" was the constitutional issue. *Id*.

This Court adopts the reasoning in *Carter* and *Sunshine* and its application in *Pittston*, *Frame,* and *AAR*. Congress may delegate regulatory authority to a private party when there is agency authority and supervision over the activities of those private parties. *See Sunshine*, 310 U.S. at 399. However, a statutory scheme that empowers private parties to regulate the affairs of other parties without an independent check is unlawful. *See Carter*, 298 U.S. at 310–11 (invalidating a scheme where a private majority was able to regulate an unwilling minority of coal producers). Finally, this Court will closely scrutinize the role of a private entity when the entity has authority over others whose interests may be adverse to the interests of the private decisionmaker. *See id*. at 311 ("[O]ne person may not be intrusted with the power to regulate the business of another, and especially of a competitor.").

The Court assumes that Palmetto is self-interested as Plaintiff asserts in passing. Mot. at 16 (MACs are typically owned or controlled by private insurance companies, which have an economic inventive to restrict coverage . . . ."). Even assuming that Palmetto is self-interested in a way that may affect their decisions in creating LCD and other programs and policies, the Court finds there is a sufficient independent check on the MACs through the claims appeal process that was fully utilized here. *See* 42 C.F.R. § 405.1062 ("ALJs and . . . the Council are not bound by LCDs").

Plaintiff's argument that the "substantial deference" that LCDs are entitled to in the administrative appeals process does not support the contention that MACs "establish legal standards for determining coverage" in a way that violates the Due Process Clause. Mot. at 14. The agency review at issue here, even if substantial deference is given to LCDs, shows that the agency "has authority and surveillance over the activities" of the MACs. *Sunshine*, 310 U.S. at 399. The MAC does not "occupy [a] position of authority" where the agency is "powerless to overrule" its decision. *AAR*, 821 F.3d at 35. Instead, the ALJ and the Council are free to disregard the LCD created by the MAC provided they "explain the reasons why the policy was not followed." 42 C.F.R. § 405.1062(b).

For these reasons, the Court finds that the Due Process Clause is not violated by the statutory scheme at issue in this case.[2]

B. Promulgation Challenge

Plaintiff argues that the MAC policies, including the LCD, were not promulgated in accordance with the procedure required by the Medicare Act and the APA. Mot. at 17. Therefore, the Council erred in issuing its decision asking the ALJ to give substantial deference to the invalid policies. *Id*. 42 U.S.C. section 1395hh prohibits any "rule, requirement, or other statement of policy (other than a [NCD]) that establishes or changes a substantive legal standard governing the . . . payment for services" from taking effect unless it is promulgated by the Secretary by regulation." Plaintiff argues that the LCD at issue here "establishes or changes a substantive legal standard" governing payment of molecular diagnostic tests. Mot. at 17–18. Therefore, the LCD should have been established by the Secretary by regulation. *Id*.

Defendant argues that section 1395hh does not apply to LCDs because LCDs do not establish or change a substantive legal standard. Opp'n at 9. Instead, an LCD simply determines coverage "in accordance with" the reasonable and necessary standard. 42 U.S.C. § 1395ff(f)(1)(B). Next, Defendant argues that the Medicare Act provides a special process for LCDs separate from 1395hh. 42 U.S.C. § 1395y(l)(5)(D)(iii) provides that "[t]he Secretary shall require each [MAC] that develops a [LCD] to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination," "[h]yperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination." Therefore, neither the APA or section 1395hh apply to LCDs. Opp'n at 9–10.

[2] Plaintiff also argues that the agency is powerless to review the validity of LCDs. This is not the case. LCDs may be challenged and reviewed by ALJs and the DAB. 42 C.F.R. § 426.400 (allowing aggrieved parties to challenge LCDs). The fact that Agendia cannot challenge the policy on its own does not mean that the LCD is entirely unchecked. Agendia can challenge claims determinations in the appeal process and beneficiaries can separately challenge the validity of an LCD in front of an ALJ or the DAB.

A. APA Challenge

Plaintiff argues that the "LCD, the MAC's policy article, and its MolDX program are not guidelines or mere interpretative rules." Mot. at 18. Plaintiff seems to suggest that this means that these policies should have been promulgated through notice and comment rulemaking requirements of the APA. *Id*. ("Case law in this Circuit . . . compel the conclusion that the MAC policies at issue here were required to have been promulgated under the notice and comment rulemaking requirements of the APA to be implemented.").

Defendant argues that the APA does not apply, and if it does, the Ninth Circuit has already found that LCDs are interpretive and "not subject to notice and comment under the APA." Opp'n at 9; *see Erringer v. Thompson*, 371 F.3d 625, 631 n.10 (9th Cir. 2004) (describing LCDs as "only binding in the initial adjudication and during the preliminary appeals stages. They do not bind ALJs or the federal courts").[3] In its Reply, Plaintiff does not directly address the argument that *Erringer* forecloses the policies at issue from having to go through notice and comment under the APA. Instead, Plaintiff argues that *Erringer* does not answer whether interpretive statements are exempt from rulemaking requirements under the *Medicare Act*. Reply at 4.

Notice and comment under the APA does not apply to "interpretative rules, general statements of policy, or rules of agency organization procedure, or practice." 5 U.S.C. § 553(b)(3)(A). A rule is interpretive if it "merely explain[s], but does not add to, the substantive law that already exists in the form of a statute or legislative rule." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003). In *Erringer*, the Ninth Circuit found that the guidelines issued in the Program Integrity Manual ("PIM") that direct contractors in creating LCDs were interpretative and do not have the force of law because the "Medicare statute does contain a standard for approval of claims apart from the PIM . . . and the LCDs." *Erringer*, 371 F.3d at 631. The standard is "reasonable and necessary." *See* 42 U.S.C. § 1395y(a)(1)(A). Thus, the

[3] The Court does not need to answer whether or not the APA applies to the policies at issue because, even assuming the APA applies, the policies are interpretive.

PIM (and by extension the LCD) simply "interpret the reasonable and necessary standard contained in the statute." *Erringer*, 371 F.3d at 631 (internal quotations omitted).

Here, the same analysis applies. The LCD and other policies at issue "interpret the reasonable and necessary standard contained in the statute." *Id.* They do not have the force of law because they do not have a binding effect on tribunals outside the agency. *Id*. at 631 n.10 ("[LCDs] do not bind ALJs or the federal courts."). Plaintiff is correct in pointing out that *Erringer* does not answer whether the same analysis applies to the rulemaking provisions in the *Medicare Act*. However, as it pertains to the APA, the policies at issue are interpretive.

B. Medicare Act Challenge

Plaintiff argues that the policies at issue "change[] a substantive legal standard governing the scope of benefits" and therefore should be promulgated through the process described in 42 U.S.C. section 1395hh(a). However, "during the period at issue here, MACs did not follow such rulemaking requirements when promulgating LCDs and other coverage policies." Mot. at 17. Plaintiff also argues that the Supreme Court in *Azar v. Allina Health Services* rejected the argument that "interpretative rules were exempt from the requirements" of 1395hh(a) even if they are exempt from APA requirements. *Id*. at 18.

Defendant argues that "an LCD does not establish or change a substantive legal standard" and therefore section 1395hh does not apply. Opp'n at 9. Defendant reasons that an LCD must determine coverage in accordance with the statutory standard and therefore cannot establish or change the standard. *Id*. Further, Defendant argues that the Medicare Act has a separate notice and comment process for LCDs and therefore § 1395hh cannot apply to LCDs. *Id*. at 10; *see also* 42 U.S.C. § 1395y(1)(5)(D)(iii) (mandating contractors make available certain information describing the LCD, including public comments submitted about the LCD).

The Medicare Act contains a notice and comment provision that allows "[n]o rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits [or] the payment for services" to take effect unless promulgated as a regulation. 42 U.S.C. § 1395hh(a)(2). In *Azar v. Allina Health Services*, the Supreme Court answered whether the phrase "substantive legal standard" under the Medicare

Act tracked the phrase "substantive rule" under the APA. 139 S.Ct. 1804 (2019). The Court reasoned that under the APA, "substantive rules are those that have the force and effect of law, while interpretive rules . . . merely advise the public of the agency's construction of the statutes and rules which it administers." *Id*. at 1811. However, the Medicare Act contemplates that a statement of policy *can* "establish[] or change[] a substantive legal standard." 42 U.S.C. § 1395hh. Therefore, the APA and the Medicare Act do not use the term "substantive" in the same way. An interpretive rule exempt from notice and comment under the APA may still require notice and comment under the Medicare Act. *Azar*, 139 S.Ct. at 1811 ("[B]y definition under the APA, statements of policy are not substantive; instead they are grouped with and trusted as interpretive rules.").

Though the *Allina* Court did not find it necessary to define what a change to a substantive legal standard means, the Court described the outer limitations of a definition. For example, the Court noted that that the defendant in *Allina* did not argue that the statute at issue "required" the policy created by the agency. *Id*. at 1816 (discussing how the government did not argue that the statute required the challenged agency action and instead argued that the statute "does not speak directly to the issue."). Then the Court, assuming that the statute did not speak directly to the issue, held that "when the government establishes or changes an avowedly 'gap'-filling policy, it cannot evade its notice-and-comment obligations under 1395hh(a)(2) on the strength of the arguments it has advanced in this case." *Id*. at 1817.

As a preliminary matter, though the Defendant argues that 1395hh cannot apply because the Medicare Act "provides a specialized notice and comment process for LCDs . . . apart from" 1395hh, the Court finds that the provision is applicable to LCDs and the policies at issue. The requirements provided in 42 U.S.C. § 1395y(l)(5)(D)(iii) do not in any way imply exclusivity. In fact, though § 1395(y)(l)(5)(D) requires posting "responses to comments submitted to the contractor," there is no provision that describes a *process* for the contractor to receive those comments. In contrast, Congress explicitly exempted NCDs (but not LCDs) from § 1395hh. *See* 42 U.S.C. §1395hh(a)(2). Then, at § 1395y, Congress detailed a separate notice and comment process for NCDs. *Id*. at § 1395y(l)(3) (describing the "[p]rocess for public

comment in national coverage determinations"). The statute does not describe a separate notice and comment process for LCDs. Thus, both § 1395y and § 1395hh may work simultaneously as requirements for LCDs. LCDs that establish or change a substantive legal standard must comply with both § 1395hh and § 1395y. LCDs that do not establish or change a substantive legal standard must only comply with § 1395y.

Here, though the LCD and policies at issue simply "interpret the reasonable and necessary standard contained in the statute," *Erringer*, 371 F.3d at 631, the question is whether the LCD is nevertheless a "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard." 42 U.S.C. § 1395hh. Neither party argues that the policies at issue are not at least statements of policy. *See* Opp'n at 9 (arguing that § 1395hh did not apply because the LCD did not establish or change the substantive legal standard). The disagreement, however, is over whether the LCD as an interpretive rule establishes or changes the legal standard at issue—whether the diagnostic tests are "reasonable and necessary." *See* 42 U.S.C. § 1395y(a)(1)(A).

The Court finds that the LCD is a (1) "rule, requirement, or other statement of policy" that (2) "establishes or changes" (3) a "substantive legal standard" that (4) governs "payment for services." *Id*. § 1395hh(a)(2). The parties do not contest that the LCD is at least a requirement or other statement of policy that governs payment for services. Thus, the Court will address whether a LCD establishes or changes a substantive legal standard under the Act.

First, the LCD represents an *establishment* of an agency standard. As both parties agree, a LCD is defined as a determination of whether or not a particular item or service is covered on a contractor-wide basis under section 1395y(a)(1)(A). *Id*. § 1395ff(f)(2)(B). Palmetto was the MAC for Agendia's geographic region in 2011, and between June 2012 through January 2013 Palmetto established LCD L32288, confirming "non-coverage" for all molecular diagnostic tests that were not explicitly covered by an NCD, an LCD, a Palmetto Coverage Policy Article, or approved through the MolDX program. SUF ¶¶ 15, 16. Thus, the LCD *established* that the Agendia tests would not be covered by Medicare.

Next, the standard that the LCD established is a *substantive* legal standard. "A substantive legal standard at a minimum includes a standard that creates, defines, and regulates the rights, duties, and powers of parties." *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017) (internal quotations omitted). Here, the LCD and related policies do exactly that. The LCD, though not binding on the agency, is binding on the private contractors and are entitled to substantial deference in the administrative process. Therefore, the LCD establishes a standard that defines Agendia's right to payment throughout the administrative process. At the preliminary stages, the standard is binding. *See Erringer*, 371 F.3d at 631 n.10. As the appeal process continues, the standard established by the LCD is entitled to substantial deference. *See* 42 C.F.R. 405.1062(a) ("ALJs . . . and the Council are not bound by LCDs . . . but will give substantial deference to these policies if they are applicable to a particular case."). However, the Court finds the standard is *substantive* during the entire process, whether it is binding or entitled to substantial deference.

Furthermore, as in *Allina*, the Defendant here is not arguing that the statute itself *compels* the LCD. Instead, the Defendant admits that LCD determines "whether or not a particular item or service" is reasonable and necessary and therefore entitled to payment. Opp'n at 9. The statute itself does not compel the determination that the molecular diagnostic tests are not reasonable and necessary. Instead, it is the LCD that makes that determination. This is the kind of "gap-filling policy" that cannot "evade notice-and-comment obligations under § 1395hh(a)(2)." *Allina*, 139 S.Ct. at 1817.

C. Arbitrary and Capricious or Otherwise Unlawful Challenge

Because the Court finds that the LCD and policies at issue were unlawfully promulgated without notice and comment, whether the agency decision was arbitrary and capricious or otherwise unlawful is moot.

IV. DISPOSITION

For the aforementioned reasons, the Court **GRANTS** Plaintiff's Motion for Summary Judgment. The action is **REMANDED** to the Medicare Appeals Council for further hearing in accordance with this opinion.

DATED: October 29, 2019

David O. Carter

DAVID O. CARTER
UNITED STATES DISTRICT JUDGE