4 F.4th 896
United States Court of Appeals, Ninth Circuit.

AGENDIA, INC.,
Plaintiff-Appellee/Cross-Appellant,
v.
Xavier BECERRA, Secretary of U.S.
Department of Health and Human Services,
Defendant-Appellant/ Cross-Appellee.

Nos. 19-56516
|
20-55041
|
Argued and Submitted
January 15, 2021 Pasadena, California
|
Filed July 16, 2021

Appeal from the United States District Court for the Central District of California, David O. Carter, District Judge, Presiding, D.C. No. 8:19-cv-00074-DOC-JDE

Attorneys and Law Firms

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Patric Hooper (argued), Hooper Lundy & Bookman PC, Los Angeles, California, for Plaintiff-Appellee/Cross-Appellant.

Before: Michelle T. Friedland and Mark J. Bennett, Circuit Judges, and Frederic Block,* District Judge.

Dissent by Judge Block

OPINION

FRIEDLAND, Circuit Judge:

Through the Medicare health insurance program, the Department of Health and Human Services ("HHS") reimburses medical providers for the cost of items and services that are "reasonable and necessary" for the treatment of beneficiaries. HHS employs private contractors to process providers' claims for reimbursement, including by making initial determinations as to whether the items or services for which reimbursement is sought are reasonable and necessary. To promote consistency in initial determinations, a contractor can issue a "local coverage determination," which specifies whether or under what conditions that contractor will approve reimbursement for some set of items or services.

Plaintiff Agendia, Inc. ("Agendia") submitted claims for reimbursement for its diagnostic tests, which were denied based on a local coverage determination. Agendia contends that the denial was improper because the local coverage determination was issued without notice and opportunity for comment in

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* The Honorable Frederic Block, United States District Judge for the Eastern District of New York, sitting by designation.

violation of a provision of the Medicare Act—specifically, 42 U.S.C. § 1395hh. We hold that § 1395hh's notice-and-comment requirement does not apply to local coverage determinations, and that the district court erred in interpreting the statute otherwise.

In the alternative, Agendia suggests that the Medicare Act and its implementing regulations have unconstitutionally delegated regulatory authority to Medicare contractors by permitting them to issue local coverage determinations. We hold that, because those contractors act subordinately to the HHS officials implementing Medicare, there is no unconstitutional delegation.

I.

A.

For background, we begin with a summary of the Medicare reimbursement process. Medicare Parts A and B cover only medical items and services that are "reasonable and necessary" for the treatment of beneficiaries. 42 U.S.C. § 1395y(a)(1)(A). Medical providers submit their claims for reimbursement to a Medicare administrative contractor ("MAC"), a private entity that processes claims in a geographic region assigned by HHS. The MAC makes an initial determination as to whether an item or service qualifies for reimbursement in that geographic region. 42 C.F.R. § 405.920; *see also* 42 U.S.C. § 1395kk-1(a)(4)(A). A provider that is dissatisfied with the initial determination can file an administrative appeal. 42 C.F.R. § 405.904.

The administrative appeals process consists of up to four steps: (1) a redetermination by the MAC that originally denied the claim; (2) a review by a different contractor (known as a "qualified independent contractor"); (3) a hearing before an Administrative Law Judge ("ALJ"); and finally, (4) review by the Medicare Appeals Council ("the Council"), an adjudicatory body within HHS. *Id.* § 405.904(a)(2), (b). A provider that exhausts its administrative appeals can seek judicial review in a federal district court. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A).

Congress has authorized two mechanisms to promote consistency in these adjudications: national coverage determinations and local coverage determinations. National coverage determinations are decisions by the Secretary of Health and Human Services ("the Secretary"[1]) as to whether a particular item or service will be covered by Medicare on a nationwide basis. 42 C.F.R. § 405.1060(a)(1); *see also* 42 U.S.C. § 1395y(*l*)(6)(A). National coverage determinations bind HHS at all levels of claims adjudication. 42 C.F.R. § 405.1060(a)(4). Before issuing a national coverage determination, the Secretary must follow a unique notice-and-comment process that the Medicare Act requires only for those determinations. *See* 42 U.S.C. § 1395y(*l*)(3). Specifically, the Secretary must publish a draft version of the national coverage determination online and allow a public comment period of thirty

[1] Xavier Becerra is substituted for his predecessor, Alex M. Azar II, as the Secretary of Health and Human Services. Fed. R. App. P. 43(c)(2).

days. *Id.* § 1395y(*l*)(3)(A)-(B); *see also id.* § 1395y(a) ("In making a national coverage determination . . . the Secretary shall ensure consistent with subsection (*l*) that the public is afforded notice and opportunity to comment.").

Local coverage determinations, by contrast, are issued by MACs. *See id.* § 1395kk-1(a)(1), (4). A local coverage determination governs only the issuing MAC's claims adjudications. *Id.* § 1395ff(f)(2)(B). Unlike a national coverage determination, a local coverage determination is not binding at the higher levels of administrative review conducted by the qualified idependent contractor, an ALJ, or the Council. *Id.* § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. §§ 405.968(b)(2)-(3), 405.1062(a)-(b). Still, qualified independent contractors, ALJs, and the Council all owe "substantial deference" to a relevant local coverage determination and, if they decline to apply that determination, must explain their reasons. 42 C.F.R. §§ 405.968(b)(2)-(3), 405.1062(a)-(b). The primary dispute before us is about what procedures are required before a MAC may issue a local coverage determination.

B.

Agendia is a clinical laboratory that furnishes molecular diagnostic tests to doctors treating breast cancer patients. After Agendia provided such tests for eighty-six Medicare beneficiaries in 2012 and 2013, it sought reimbursement from HHS. The MAC assigned to adjudicate claims in Agendia's region denied

payment based on a local coverage determination the MAC had previously issued. Under that local coverage determination, certain molecular diagnostic tests—including those Agendia provided—were not reasonable and necessary.

Agendia administratively appealed. The qualified independent contractor that reviewed Agendia's claims agreed that payment should be denied. The reviewing ALJ, however, reversed, concluding that the diagnostic tests were reasonable and necessary, notwithstanding the local coverage determination. On its own motion, the Council overturned the ALJ's decision, holding that the tests were not in fact reasonable and necessary. The Council explained that there was "no reason to not apply substantial deference" to the relevant local coverage determination.

Agendia then sued the Secretary in federal district court, asserting that the denial of its reimbursement claims was improper because the process for issuing the relevant local coverage determination was unlawful for two reasons.[2] First, Agendia argued that a provision of the Medicare Act, 42 U.S.C. § 1395hh, requires that a local coverage determination undergo a notice-and-comment process before being adopted. Second, Agendia argued that the portions of the Medicare Act and its implementing regulations that authorize MACs to issue local coverage determinations

[2] Agendia also initially argued that the relevant local coverage determination was arbitrary and capricious. On appeal, Agendia has expressly abandoned this contention.

unconstitutionally delegate regulatory authority to private entities.

The district court rejected Agendia's constitutional challenge but agreed with Agendia's statutory argument, concluding that § 1395hh requires local coverage determinations to undergo notice and comment. Because no such process had occurred, the district court granted summary judgment for Agendia and remanded to the Council to reevaluate the claims for reimbursement without relying on the local coverage determination. The Secretary appealed.[3]

II.

Although the district court remanded this case, the grant of summary judgment is a final order subject to appellate review under 28 U.S.C. § 1291 because it "terminated the civil action challenging the Secretary's final determination" denying Agendia's claims for reimbursement. *Sullivan v. Finkelstein*, 496 U.S. 617,

[3] Agendia filed a putative cross-appeal of the district court's rejection of its constitutional challenge. Instead of cross-appealing, Agendia could have made the same argument in its response to the Secretary's appeal as a proposed alternative ground for affirmance. *Ecological Rts. Found. v. Pac. Gas & Elec. Co.*, 874 F.3d 1083, 1092 n.3 (9th Cir. 2017) ("Where an appellee properly raised an argument in the district court and raises it on appeal in an effort 'seek[ing] to preserve, and not to change, the judgment,' it need not file a cross-appeal." (alteration in original) (quoting *Lee v. Burlington N. Santa Fe Ry. Co.*, 245 F.3d 1102, 1107 (9th Cir. 2001))). We accordingly consider that constitutional argument as a possible alternative reason to affirm. *Spencer v. Peters*, 857 F.3d 789, 797 n.3 (9th Cir. 2017) (treating "arguments on cross-appeal as alternative arguments to affirm the judgment").

625, 110 S.Ct. 2658, 110 L.Ed.2d 563 (1990). We review de novo a grant of summary judgment. *Kaiser Found. Hosps. v. Sebelius*, 649 F.3d 1153, 1157 (9th Cir. 2011).

III.

A.

We first turn to Agendia's principal argument that the process for adopting local coverage determinations requires notice and comment.

The Medicare Act requires the Secretary to follow a notice-and-comment procedure for any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. § 1395hh(a)(2). This process consists of "notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." *Id.* § 1395hh(b)(1). (As discussed above, national coverage determinations have a separate notice-and-comment process that requires that a draft be posted online with thirty days for public comment. *Id.* § 1395y(*l*)(3)(A)-(B).) Agendia argues that the more formal notice-and-comment process contained in § 1395hh(b)(1) is required for local coverage determinations. For clarity, we will refer to that process as the "§ 1395hh notice-and-comment process."

The parties agree that local coverage determinations have never undergone the § 1395hh notice-and-comment process. Agendia contends that this procedural error makes all local coverage determinations

invalid. Because the Council's denial of Agendia's claims for reimbursement rested on a local coverage determination, Agendia insists that denial was improper.

We hold that local coverage determinations are not subject to the § 1395hh notice-and-comment process because such determinations do not "establish[] or change[] a substantive legal standard." *Id.* § 1395hh(a)(2).[4] We have no occasion to define the outer boundaries of "substantive legal standard" today because only one standard is potentially implicated here: an item or service must be "reasonable and necessary" for a provider to have a right to payment. *Id.* § 1395y(a)(1)(A). A local coverage determination does not "establish[] or change[]" that standard. *See*, *e.g.*, *Establish*, Black's Law Dictionary (11th ed. 2019) ("To make or form; to bring about or into existence."); *Change*, Oxford English Dictionary Online, www.oed.com/view/Entry/30468 (last visited July 8, 2021) ("To substitute one thing for (another); to replace (something) with something else.").

A local coverage determination guides the application of that legal standard in a particular claim adjudication. Specifically, it reflects a MAC's view of what qualifies as reasonable and necessary, and accordingly it controls that MAC's claims determination. But although the agency adjudicators reviewing

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[4] Given this holding, we need not decide whether a local coverage determination is a "rule, requirement, or other statement of policy" within the meaning of § 1395hh(a)(2).

a MAC's decision must consider the local coverage determination, they are not bound by it. A qualified independent contractor, an ALJ, and the Council all ultimately must apply the statutory reasonable and necessary standard to determine whether to approve a claim.[5]

This understanding of the effect of local coverage determinations is consistent with our court's precedent. We have previously explained that the reasonable and necessary standard is independent of local coverage determinations because, if such determinations "did not exist, Medicare contractors would still have an overarching duty to deny claims for items and services that are not 'reasonable and necessary.'" *Erringer v. Thompson*, 371 F.3d 625, 631 (9th Cir. 2004) (quoting 42 U.S.C. § 1395y(a)(1)(A)). To be sure, *Erringer* did not interpret § 1395hh. *See* 371 F.3d at 633. But its recognition that the reasonable and necessary standard would remain unaltered if local coverage determinations ceased to exist is consistent with our holding that such determinations neither "establish[]" nor "change[]" that substantive legal standard.

Our conclusion is also driven by the structure of the statute. Congress created a special notice-and-comment

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[5] Citing various dictionaries, our dissenting colleague contends that the word "change" can also mean "to make different in some particular." Dissent at 905-06. Using this definition would not alter our conclusion. A local coverage determination simply reflects one contractor's attempt to apply the reasonable and necessary standard to a given item or service. The application of a statutory standard does not—and could not—make the relevant standard different in any way.

process for *national* coverage determinations, requiring HHS to post a draft on the internet and provide thirty days for public comment. 42 U.S.C. § 1395y(*l*)(3)(A)-(B). Agendia argues that *local* coverage determinations must undergo the more arduous § 1395hh notice-and-comment process from which national coverage determinations are expressly exempt: publication in the Federal Register with at least sixty days for public comment. *Id.* § 1395hh(b)(1). Subjecting local coverage determinations, which are not binding, to a more demanding procedure than their national, binding counterparts would make little sense. *Cf. Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 320, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014) ("[W]ords of a statute must be read in their context and with a view to their place in the overall statutory scheme." (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000))).[6]

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[6] In 2016, Congress amended the Medicare Act by adding a separate public notice requirement specifically for local coverage determinations. *See* 21st Century Cures Act, Pub. L. No. 114-255, § 4009, 130 Stat. 1033, 1185 (2016) (codified at 42 U.S.C. § 1395y(*l*)(5)(D)). Under this new provision, a MAC must post a local coverage determination online at least forty-five days before its effective date, as well as a "response to comments submitted to the contractor with respect to such proposed determination." 42 U.S.C. § 1395y(*l*)(5)(D). Because the amendment is not retroactive, *id.* § 1395y note, it does not govern the local coverage determination challenged by Agendia here.

Nonetheless, we infer from this amendment that local coverage determinations were not previously subject to the § 1395hh notice-and-comment process. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000) ("The classic judicial task of reconciling many laws enacted

over time, and getting them to make sense in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." (quotation marks and citation omitted)). In enacting this provision, Congress sought to "increase transparency" in the development of local coverage determinations. H.R. Rep. No. 114-190, at 127 (2015). Indeed, the amendment is part of a pattern of congressional actions *adding* procedural requirements for local coverage determinations. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 731, 117 Stat. 2066, 2350 (imposing a new consultation requirement for the development of local coverage determinations). This suggests that Congress passed the 2016 amendment with the understanding that local coverage determinations were not subject to any notice-and-comment requirements under the pre-amendment regime.

Our dissenting colleague reads the 2016 amendment as confirming the applicability of § 1395hh because the amendment "arguably reflects congressional intent to *remove* [local coverage determinations] from § 1395hh(a)(2)'s stringent notice provisions." Dissent at 909. The dissent cites no support for this counter-intuitive hypothesis, which contradicts Congress's desire to "*begin* the process of bringing greater accountability" to the adoption of local coverage determinations. H.R. Rep. No. 114-190, at 127 (2015) (emphasis added). Moreover, if the dissent were correct, Congress presumably would have added an express exemption for local coverage determinations to § 1395hh(a)(2) simultaneously—as it already had for national coverage determinations. *Cf. Hillman v. Maretta*, 569 U.S. 483, 496, 133 S.Ct. 1943, 186 L.Ed.2d 43 (2013) ("We have explained that where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent." (quotation marks, alteration, and citation omitted)); *United States v. Johnson*, 529 U.S. 53, 58, 120 S.Ct. 1114, 146 L.Ed.2d 39 (2000) ("When Congress provides exceptions in a statute, . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth."). Congress did not do so, leaving us confident that Congress did not think local coverage determinations were ever subject to the § 1395hh notice-and-comment process.

Agendia's arguments to the contrary are not persuasive. First, Agendia asserts that the Supreme Court's decision in *Azar v. Allina Health Services*, ___ U.S. ___, 139 S. Ct. 1804, 204 L.Ed.2d 139 (2019), compels the opposite result. In that case, the Secretary argued that a Medicare reimbursement policy adopted by HHS was exempt from the § 1395hh notice-and-comment process. 139 S. Ct. at 1811. The Secretary did not argue that the Medicare Act supplied the controlling legal standard, but instead he asserted that the adoption of the policy did not require notice and comment because it was an interpretative, or "gap-filling," rule. *See id.* at 1816-17. The Supreme Court rejected this argument, deciding only that the § 1395hh notice-and-comment process does not contain the same exemption for interpretative rules as does the Administrative Procedure Act, 5 U.S.C. § 553(b). 139 S. Ct. at 1814. Thus, the Court held that "when the government establishes or changes an avowedly 'gap'-filling policy, it can't evade its notice-and-comment obligations under" the Medicare Act simply by claiming that the policy is an interpretative rule. *Id.* at 1817.

The Court, however, explicitly left open another line of argument the Secretary could pursue in future cases: "the government might have sought to argue that the policy at issue . . . didn't 'establis[h] or chang[e]' a substantive legal standard—and so didn't require notice and comment under § 1395hh(a)(2)—because the *statute* itself" provided the relevant standard. 139 S. Ct. at 1816 (alterations in original). In *Allina*, the Secretary did not make that argument, *id.*,

but here the Secretary has done so. And we believe that argument carries the day. Although local coverage determinations help adjudicators apply the reasonable and necessary standard to the facts of a claim, they do not "establish[] or change[]" the standard for reimbursement contained in the statute itself. Agendia's reliance on *Allina* is therefore misplaced.

Nor are we persuaded by Agendia's contention that the phrase "other than a *national* coverage determination" in § 1395hh implies that *local* coverage determinations must undergo the notice-and-comment procedures. 42 U.S.C. § 1395hh(a)(2) (emphasis added). Because local coverage determinations clearly do not "establish[] or change[]" a substantive legal standard, there was no reason for Congress to exempt them from a requirement that does not, by its plain terms, apply.

A local coverage determination is therefore valid without undergoing the § 1395hh notice-and-comment process.

B.

We also reject Agendia's alternative theory that contractors' ability to issue local coverage determinations reflects an unconstitutional delegation of regulatory power to private entities. *See* 42 U.S.C. § 1395kk-1(a)(4) (authorizing MACs to "develop[] local coverage determinations"). The statutory and regulatory scheme is constitutional because the contractors "function subordinately" to the Secretary. *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 399, 60

S.Ct. 907, 84 L.Ed. 1263 (1940). The Secretary retains the relevant decision-making power: although HHS regulations provide that local coverage determinations are entitled to "substantial deference," the regulations also provide that ALJs and the Council can refuse to apply a local coverage determination in any claim appeal if they adequately explain their reasons for departing from it.[7] *See* 42 C.F.R. § 405.1062(a)-(b). Moreover, the Secretary can prescribe requirements for contractors issuing local coverage determinations,[8] and he can issue national coverage determinations that supersede any conflicting local coverage determination, *see* 42 C.F.R. § 405.1060(a)(4). ALJs and the Council can also review and invalidate a local coverage determination in a challenge brought by a Medicare beneficiary. *See id.* §§ 426.400-426.490. Because MACs "function subordinately" to the Secretary, the Constitution does not forbid them from carrying out the administrative function of issuing local coverage determinations.

Agendia resists this conclusion by arguing that the Secretary's oversight is limited. First, it highlights that "unappealed Medicare claims denials based on [local coverage determinations] and other MAC policies

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[7] The ALJ reviewing Agendia's claims did precisely that, even though the Council ultimately concluded that the ALJ's reasoning was unpersuasive.

[8] *See generally* Medicare Program Integrity Manual: Chapter 13—Local Coverage Determinations (rev. 2019), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf (requiring MACs to follow certain procedures when issuing local coverage determinations).

are final." While true, the fact that unappealed decisions are not reviewed does not mean that the Secretary—acting through an ALJ or the Council—cannot approve, disapprove, or modify a contractor's determination if an appeal *is* brought. *Cf. Adkins*, 310 U.S. at 388, 60 S.Ct. 907. That a particular claimant can waive or forfeit its challenge to a contractor's decision does not make the contractor unaccountable to the Secretary.

Second, Agendia contends that because HHS regulations allow ALJs and the Council to invalidate a local coverage determination only in a beneficiary's (rather than a provider's) appeal, Agendia must separately appeal each reimbursement claim denied by a MAC even if each is based on the same local coverage determination. *See* 42 C.F.R. § 405.1062(c) ("An ALJ or . . . the Council may not set aside or review the validity of a[ ] . . . [local coverage determination] for purposes of a claim appeal."); *id.* §§ 426.110, 426.320 (precluding a provider from challenging a local coverage determination directly). Although we recognize that separate appeals are burdensome, Agendia cites no authority for the proposition that burdensome limitations on remedies in an administrative review process can create an unconstitutional delegation.

Finally, Agendia contends that consideration of local coverage determinations in litigation under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, demonstrates that those determinations create regulatory policy that goes unchecked by HHS. False claims, such as fraudulent requests for Medicare reimbursement,

must be material to be actionable. *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017). We have held that the existence of a local coverage determination can be a relevant factor in determining whether a false statement was material to the approval of a Medicare reimbursement, and therefore probative of whether a plaintiff has satisfied her burden under the False Claims Act. *See Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1213 (9th Cir. 2019). Consideration of local coverage determinations in this manner, however, does not demonstrate that the Secretary lacks control over the MACs issuing and applying local coverage determinations.

IV.

Because local coverage determinations do not require notice and comment under 42 U.S.C. § 1395hh, and because the Constitution permits contractors to issue such determinations, judgment must be entered in favor of the Secretary.

REVERSED.

BLOCK, District Judge, dissenting:

Agendia has been trying to secure agency approval for its BluePrint and TargetPrint tests for almost a decade.[1] In 2018, it nearly succeeded. After a hearing, an ALJ issued a detailed decision that was "fully favorable" to Agendia. But Agendia's victory was fleeting. The Medicare Appeals Council decided, on its own motion, to review and reverse the ALJ's decision. Specifically, the Council held that the favorable decision must be reversed because it "was inconsistent with the LCDs in effect during the dates at issue," and there was "no reason not to apply substantial deference to the LCD[s]." It described the ALJ's failure to defer to the LCDs as "an error of law material to the outcome of [Agendia's] claim." That error obviated the need to determine whether the ALJ's decision was supported by sufficient evidence.

Consequently, the Council's own statements reflect that an ALJ can be reversed for failing to follow an LCD, and thus that LCDs significantly alter the nature of appellate review in Medicare cases. *See generally* 42 U.S.C. § 1395y(a)(1)(A) (setting out the statutory "reasonable and necessary" standard). Had there been no LCD applicable to Agendia's tests, the ALJ's determination that they were "reasonable and necessary"—which was supported by a detailed analysis of

[1] I agree with the majority's factual recitations and assume the reader's familiarity with them. I likewise assume familiarity with the shorthand in the majority opinion (e.g., "LCD" for "Local Coverage Determination," "ALJ" for "Administrative Law Judge" etc.).

live physician testimony—might well have been upheld and would at least have been evaluated on its merits. Instead, the ALJ's factual analysis was ignored and his decision reversed due to its "inconsistency" with a purportedly nonbinding LCD.

The majority acknowledges all these facts. Nonetheless, it insists that LCDs neither "establish [nor] change a substantive legal standard" because LCDs merely "guide" and do not replace the statutory "reasonable and necessary" standard. This argument elevates form over substance. In *Allina Health Servs. v. Price (Allina I)*, then Judge Kavanaugh explained that, "a substantive legal standard at a minimum includes a standard that creates, *defines and regulates* the rights, duties and powers of parties." 863 F.3d 937, 943 (D.C. Cir. 2017) (emphasis added) (internal citations omitted). Because LCDs are binding at the initial stage of the Medicare claim adjudication process and can compel the reversal of an ALJ's judgment, they "define and regulate the rights" of parties even if, as the majority says, they also "guide" the application of a statutory standard. *See Azar v. Allina Health Servs.* (*Allina II*), ___ U.S. ___, 139 S. Ct. 1804, 1812, 204 L.Ed.2d 139 (2019) ("if 'a so called policy statement is in purpose *or likely effect* . . . a binding rule of substantive law, . . . it 'will be taken for what it is' ") (quoting *Guardian Fed. Sav. and Loan Ass'n v. Fed. Sav. Loan Ins. Corp.*, 589 F.2d 658, 666-67 (D.C. Cir. 1978)) (emphasis added). Put another way, because LCDs bind initial claim adjudicators and "narrowly limit[ ]" subsequent reviewers' discretion to weigh evidence and consider

arguments, they "establish" a standard at the initial stage of review and "change" the standards applied on appellate review. *Fed. Sav. Loan Ins. Corp.*, 589 F.2d at 666-67; *accord Agendia*, *Inc. v. Azar*, 420 F. Supp. 3d 985, 997-98 (C.D.C.A. 2019) (concluding that a standard can be "substantive [regardless of] whether it is binding or entitled to substantial deference"). *See generally Change*, Merriam Webster Dictionary Online, https://www.merriam-webster.com/dictionary/change (last accessed Jun. 11, 2021) (defining "change" as "to make different in some particular"). They should therefore be subject to notice and comment under 42 U.S.C. § 1395hh(a)(2) (requiring notice and comment when a "rule, requirement, or other statement of policy . . . establishes *or changes* a substantive legal standard") (emphasis added).

Because the majority's selective readings of dictionaries and abstract analysis of the Medicare statute's "structure" do not change the reality of the administrative proceeding below, I respectfully dissent from Part III.A of the majority opinion, which addresses Agendia's statutory claims, and from the reversal of the district court's grant of summary judgment to Agendia. I join in Part III.B of the majority's opinion which rejects Agendia's constitutional, non-delegation argument.

I.

The majority attempts to obscure the reality of the Medicare claims process—and the practical effect LCDs had on Agendia's claim—in two ways.

First, the majority holds that LCDs do not "change substantive legal standards" because, notwithstanding any relevant LCDs, Medicare ALJs and the Appeals Council "ultimately must apply the statutory reasonable and necessary standard." Citing the *Oxford English Dictionary* ("*OED*"), the majority implies that a "change" occurs only when one thing is "substituted for" or "replaced with" another. *See Change*, Oxford English Dictionary Online, www.oed.com/view/Entry/30468 (last visited Jun. 11, 2021). It then reasons that, because LCDs do not "replace" the statutory standard, they do not "change" that standard within the meaning of § 1395hh(a)(2).

Second, the majority contends that its decision to exempt LCDs from 42 U.S.C. § 1395hh(a)(2)'s notice and comment requirements is "driven by the structure of the [Medicare] statute." Specifically, the majority argues that it would not make sense to "[subject] local coverage determinations, which are not binding, to a more demanding procedure than their national, binding counterparts," the NCDs.

Both arguments are flawed. Neither provides more than a fig leaf for the majority's efforts to obscure the fact that the Council reversed an ALJ's decision because his opinion was "inconsistent with the LCDs in effect during the dates at issue."

A. Definitional Arguments

The phrase "substantive legal standard" and its corollary, "change a substantive legal standard," appear to be unique. *See Allina II*, 139 S. Ct. at 1814 ("the phrase 'substantive legal standard' . . . appears in § 1395hh(a)(2) and apparently nowhere else in the U.S. Code"). Thus, the majority was within its rights to analyze those terms' "ordinary meaning" and to consider the dictionary definitions of relevant words. *See United States v. Cox*, 963 F.3d 915, 920 (9th Cir. 2020) (Where "[the] statute does not define [a word] . . . we construe the word pursuant to its ordinary meaning. To determine ordinary meaning, we consider dictionary definitions").

However, the majority's "ordinary meaning" analysis is neither complete nor persuasive. It considers only a single definition for the word "change," drawn from the nonlegal *Oxford English Dictionary*. *Cf. Cox*, 963 F.3d at 920-21 (rejecting a defendant's proposed definition of the undefined term, "notice," because "*most* standard English-language dictionary . . . definitions do not define notice in relation to audience size") (emphasis added); *see also Wisconsin Cent. Ltd. v. United States*, ___ U.S. ___, 138 S. Ct. 2067, 2070-71, 201 L.Ed.2d 490 (2018) (basing "ordinary meaning" analysis on three different dictionary definitions and a prior interpretation drawn from caselaw). Significantly, the word "change" can also mean "to make different in some particular" (*Merriam Webster*), "to make or become different" (*Cambridge Dictionary*), or "to alter; . . . [and] to make different in some particular"

(*Black's Law Dictionary*, 6th ed.). *See Change*, Merriam Webster Dictionary Online, https://www.merriam-webster.com/dictionary/change (last accessed Jun. 11, 2021); *Change*, Cambridge Dictionary Online, https://dictionary.cambridge.org/us/dictionary/english/change (last accessed Jun. 11, 2021); *Change*, Black's Law Dictionary (6th ed. 1990). Indeed, even the majority's use of the *OED* is suspect insofar as it refers to the definition of the term "change" listed under the heading "[s]enses relating to substitution or exchange" but ignores all the definitions under the heading "[s]enses relating to alteration, variation or mutability," several of which mirror the definitions I list above. *See Change*, Oxford English Dictionary Online, www.oed.com/view/Entry/30468 (last visited Jun. 11, 2021).

Had the majority considered these alternative definitions, it might have concluded—as I have—that a standard can "change" even if it is not replaced root and branch. It might also have realized that grafting presumptions and deference regimes onto statutory rules substantially alters the scope of the conduct those rules cover, "making them"—and the outcomes that result from their application to real cases—"different in some particular." Such an interpretation would be consistent with the ordinary meaning of the word "change" and a more accurate reflection of the decisive role LCDs played in the administrative proceeding below.[2]

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[2] The majority's citation to *Erringer v. Thompson*, 371 F.3d 625, 631 (9th Cir. 2004), does not save its deficient analysis. Even

Because the majority's definitional analysis is deficient, I reject its claim that 42 U.S.C. § 1395hh(a)(2)'s notice and comment requirement "does not, by its plain terms, apply" to LCDs. The "plain meaning" of the phrase "change a substantive legal standard" is ambiguous, and the majority offers no compelling reason to favor its interpretation over any other.

B. Structural Arguments

The majority's structural analysis ignores the plain text of the statute, its legislative history and the canons of statutory interpretation.

42 U.S.C. § 1395hh(a)(2) states: "*No* rule, requirement or statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard . . . shall take effect unless it is promulgated by the Secretary by regulation."[3] This language establishes only one exception—for NCDs—

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if that case applied to § 1395hh(a)(2)—and the majority concedes that it does not—the fact that the agency would still have a duty to apply the statutory standard even "if . . . LCDs did not exist" does not imply that existing LCDs have no effect on the underlying standard. As explained above, LCDs can "change" the underlying standard without supplanting it.

[3] The parties "[did] not contest that [an] LCD is at least a statement of policy" at the district court level. *Agendia*, 420 F. Supp. 3d at 997. Accordingly, I assume for the sake of argument that LCDs are at least "statements of policy." *See AMA Multimedia, LLC v. Wanat*, 970 F.3d 1201, 1213-14 (9th Cir. 2020) ("Absent exceptional circumstances, we generally will not consider arguments raised for the first time on appeal") (quoting *In re Am. W. Airlines*, 217 F.3d 1161, 1165 (9th Cir. 2000)).

and expressly provides that *no* other "rule, requirement or statement of policy" shall fall outside its scope. We are therefore left with a statute that expressly exempts NCDs *and nothing else*, along with a congressional record that suggests the legislature meant to give § 1395hh(a)(2) a broad scope. *See* H.R. Rep. No. 100-391(l), at 430 (1987) ("The only explicit exclusion [from § 1395hh rulemaking] would be national coverage determinations. The Committee expects, in any case in which there might be a doubt as to whether a policy is covered by this provision, to treat [the policy] as if [the provision] applied").

The lack of an explicit exemption for LCDs is, however, no obstacle for the majority, which concludes that Congress *must have* intended to exempt LCDs from § 1395hh(a)(2), because it "would make little sense" for it to have done otherwise. But it is not for this Court to tell Congress what it ought to have done or say what it "makes little sense" for Congress to do. Nor should the majority assume, without reason or citation to the congressional record, that Congress left LCDs out of § 1395hh(a)(2) because it obviously thought them insubstantial. "Courts aren't free to rewrite clear statutes under the banner of [their] own policy concerns," even if those statutes appear illogical, are poorly constructed or function sub-optimally. *Allina II*, 139 S. Ct. at 1815. If Congress had wanted to exempt LCDs from § 1395hh(a)(2)'s requirements, it could have easily added the phrase "and LCDs" to that subsection. It has not done so. *Cf.* H.R. Rep. No. 100-391(l), at 430 (1987) (acknowledging that "national

coverage determinations" are § 1395hh(a)(2)'s "*only explicit exclusion*") (emphasis added). If "the government doesn't like Congress's notice and comment policy choices, it must take its complaints there."[4] *Allina II*, 139 S. Ct. at 1815.

But even assuming that the majority is right to look beyond the text of the statute, it fails to show why its interpretation of congressional intent is the right one. *Cf. Epic Sys. Corp. v. Lewis*, ___ U.S. ___, 138 S. Ct. 1612, 1631, 200 L.Ed.2d 889 (2018) ("[L]egislative history is not the law"). As Justice Gorsuch points out in *Allina II*, § 1395hh's "legislative history is ambiguous at best." 139 S. Ct. at 1814. In seeming support of the majority's reading, a 1986 congressional report suggested that § 1395hh would not "require the Secretary to provide an opportunity for public comment for items (such as interpretive rules, general statements of policy, or rules of agency, organization, procedure or practice) that are not currently subject to that requirement." H.R. Conf. Rep. No. 99-1012, at 311 (1986). One year later, however, Congress amended the statute and issued a second report, which expressed "concern that important policies are being developed without the benefit of the public notice and comment period and,

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[4] The majority would likely respond that this critique is inapplicable because "there was no reason for Congress to exempt [LCDs] from a requirement that does not, by its plain terms, apply." I reject the premise of this defense, which assumes the correctness of the majority's selective definitional arguments. The "plain meaning" of the phrase "change a substantive legal standard" is unclear, and the majority's interpretation is not the only plausible one.

with growing frequency, are being transmitted, if at all, through manual instructions and other informal means." H.R. Rep. No. 100-391(l), at 430 (1987). In that Report, the legislature also suggests that "the Committee Bill"—which became the 1987 version of § 1395hh—would "define those policies which must be subject to the rulemaking procedure [in § 1395hh]" to include "all those [policies] which are of general applicability and have a significant effect on Medicare enrollees, on providers, or on the administration of the program," and that § 1395hh's rulemaking requirements are "intended to apply to the duties and responsibilities of . . . [among other entities] carriers and intermediaries who administer the program [i.e. contractors]."[5] *Id.* Such broad language could easily capture LCDs.

In light of the foregoing, I agree with Justice Gorsuch that the legislative history of § 1395hh(a)(2) is ambiguous. While I readily acknowledge that some portions of the congressional record favor the majority's decision to exempt LCDs from notice and comment rulemaking,[6] the more persuasive reading is that

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[5] Before 2003, Medicare's administrative contractors were called "fiscal intermediaries." Dep't of Health & Hum. Servs., *Medicare Administrative Contractors*, https://www.cms.gov/Medicare/MedicareContracting/Medicare-Administrative-Contractors/MedicareAdministrativeContractors (last accessed Jun. 11, 2021).

[6] For instance, the 1987 Report states that "there will still remain policy matters . . . that are not required to go through public rulemaking." H.R. Rep. No. 100-391(l), at 430 (1987). It also discusses "policies . . . adopted by the fiscal intermediaries [i.e. contractors] . . . includ[ing] payment screens applicable only n the area served by the contractor [i.e. LCDs]" in their own

Congress wanted Medicare rules to have the "benefit of notice and comment rulemaking," and therefore that it intended to give § 1395hh's rulemaking provisions the broadest possible scope. *See* H.R. Rep. No. 100-391(l), at 430 (1987). Such intent is consistent with Congress's own statements in the legislative record and aligns with a robust judicial consensus on the salutary effect of notice and comment rulemaking. *See*, *e.g. United States v. Reynolds*, 710 F.3d 498, 517 (3d Cir. 2013) (explaining that "among the purposes [of notice and comment rulemaking] are (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review") (internal citations omitted); *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988) (notice and comment rulemaking "allow[s] the

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paragraph, perhaps implying that these policies are distinct from the "policies of general applicability" that must go through notice and comment rulemaking. *Id.* at 431. However, the case for inferred intent is by no means overwhelming, particularly since the paragraph discussing "payment screens applicable only in [a contractor's area]" suggests that Congress wanted to impose notice requirements on contractors who draft local policies, and thus that it felt some additional process was needed. *Id.* (requiring contractors to develop a process "reasonably designed to provide notice to parties likely to be affected by [contractor-specific] policies"). Because an LCD-specific notice process was not added until 2016, and the Report itself reflects intent to resolve ambiguity in favor of requiring notice and comment rulemaking, I conclude that the Congress of 1987 likely believed that contractor-specific determinations, like LCDs, could be subject to § 1395hh(a)(2)'s rulemaking requirements.

agency to benefit from the expertise and input of parties who file comments . . . and [ensures] that the agency maintains a flexible and open-minded attitude toward its own rules") (internal citations omitted); *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980) ("The essential purpose of . . . notice and comment opportunities is to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies"). The majority fails to show why it would "make little sense" for Congress to seek these benefits for LCDs.

Moreover, Congress's statements in the 1987 Report suggest that it wanted courts to determine which policies are subject to rulemaking requirements based on the "effects" those policies have on stakeholders in the Medicare system. H.R. Rep. No. 100-391(l), at 430 (1987) ("The policies affected would be all those which . . . have a significant effect on Medicare enrollees, on providers, or on the administration of the program"). Because LCDs decide coverage issues as a practical matter, they have "a significant effect" on companies like Agendia and the Medicare beneficiaries they serve, so Congress probably meant them to be subject to rulemaking requirements. At the very least, Congress did not clearly intend to exempt them from such requirements.

Finally, recent changes to the Medicare statute appear to confirm that the LCDs used to deny Agendia's claims should have been subject to § 1395hh(a)(2)'s notice and comment procedure. In 2016, Congress amended the Medicare statute to create a specific notice procedure for LCDs. *See* 42 U.S.C. § 1395y(*l*)(5)(D);

see also 21st Century Cures Act, Pub. L. No. 114-255, § 4009, 130 Stat. 1033, 1185 (2016). The 2016 amendment does not apply to the LCDs at issue in this case, but its passage may shed some light on Congress's understanding of the pre-2016 notice and comment requirements and their application to LCDs. *See*, *e.g.*, *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000) (finding that "a specific policy embodied in a later federal statute should control our construction of the [earlier] statute") (internal citations omitted). Specifically, because "it is a commonplace of statutory construction that the specific governs the general," and courts will typically "construe a specific provision as an exception to the general one," the passage of the 2016 amendment arguably reflects congressional intent to *remove* LCDs from § 1395hh(a)(2)'s stringent notice provisions and subject them to § 1395y(*l*)(5)(D)'s more lenient ones. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645, 132 S.Ct. 2065, 182 L.Ed.2d 967 (2012) (citations omitted). It therefore supports an inference of congressional understanding that, prior to 2016, LCDs fell under § 1395hh(a)(2)'s catchall provision.[7]

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[7] Underscoring the ambiguity of the Medicare statutory scheme—and with it, the imprudence of prioritizing "structure" over text in statutory interpretation—the majority draws the opposite inference from the 2016 amendment, namely "that local coverage determinations were not previously subject to the § 1395hh notice-and-comment requirements." This conclusion rests on (1) legislative materials from 2003 and 2015, which suggest that the amendment is "part of pattern of *adding* procedural requirements for local coverage determinations. . . . [and imply]

that Congress passed the 2016 amendment with the understanding that local coverage determinations were not subject to any notice-and-comment requirements under the pre-amendment regime"; and (2) the principle of statutory interpretation that "when Congress provides exceptions in a statute . . . the proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth." *United States v. Johnson*, 529 U.S. 53, 58, 120 S.Ct. 1114, 146 L.Ed.2d 39 (2000) (cleaned up).

As to the first argument, I agree with the majority that the legislative history of the Medicare Act reflects consistent concern that LCDs and other policies are being enacted without adequate procedural safeguards. *See generally* H.R. Rep. No. 100-391(l), at 430 (1987). However, unlike the majority, I refuse to twist Congress's understandable concern into an argument *against* imposing further safeguards. *See Amalg. Transit Union Local 1398, AFL-CIO v. Laidlaw Transit Servs., Inc.* 448 F.3d 1092, 1093 (9th Cir. 2006) (*en banc*) ("When we interpret a statute, our purpose is always to discern the intent of Congress") (internal quotations and citations omitted). I likewise find it peculiar that the majority relies heavily on the legislative history of the 2016 amendment to refute my "structural" analysis of the Medicare Act but refuses to engage with the history of the provision we interpret today: § 1395hh(a)(2). The majority may not pick and choose when to consider Congress's intentions, and it certainly may not consider only those portions of the legislative record that support its preferred outcome.

The second argument is the product of a selective, outcome-driven application of interpretive canon. If the majority truly believed that Congress's choice to enumerate exceptions to a statute implies intent to "limit[ ] the statute to the [exceptions] set forth," it would agree that Congress's choice to explicitly exempt NCDs—and only NCDs—from § 1395hh(a)(2) suggests that an "additional exception[ ]" for LCDs is "not to be implied in the absence of contrary legislative intent." *Cf. Hillman v. Maretta*, 569 U.S. 483, 496, 133 S.Ct. 1943, 186 L.Ed.2d 43 (2013) (internal quotations and citations omitted); *Johnson*, 529 U.S. at 58, 120 S.Ct. 1114. And of course, the majority offers no competing account of the "legislative intent" behind § 1395hh(a)(2).

In sum, I reject the majority's "structural" analysis because it is not grounded in the text of the Medicare Act or its legislative history. It is also undercut by subsequent amendments to that statute. The "structure" of the Medicare statute is ambiguous and does not clearly support the majority's conclusion.

II.

My disagreement with the majority is fundamentally definitional. Without defining its terms or citing to the congressional record, the majority gives the phrase "substantive legal standard" a narrow construction that excludes LCDs.[8] By contrast, I define the

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To the extent that the majority believes—again without citation or explanation—that the interpretive principle articulated in *Maretta* and *Johnson* applies solely to the 2016 amendment, I respond that my interpretation of the amendment rests on another principle cited by the majority, namely the principle that "the implications of a statute may be altered by the implications of a later statute." *See United States v. Fausto*, 484 U.S. 439, 453, 108 S.Ct. 668, 98 L.Ed.2d 830 (1988). Put another way, my interpretation posits that the 2016 amendment *may* reflect congressional intent to clarify that LCDs should *no longer* be considered "substantive legal standards," thereby altering § 1395hh(a)(2)'s "implications" for LCDs. All that said, I hesitate to draw any strong conclusions from the passage of the 2016 amendment. Unlike the majority, my analysis is not "driven by the structure of the [Medicare] statute," but rather by that statute's text and legislative history. I include the "structural" analysis above not because I believe it is decisive, but simply to show that the "structure" of the Medicare Act is ambiguous and does not lead inevitably to the majority's conclusion.

[8] Because the majority found "no occasion to define the outer boundaries of [what constitutes a] substantive legal standard," it is unclear which administrative rules, if any, the majority would deem "substantive."

term "substantive legal standard" to include all "rules" and "statements of policy" that decide Medicare claims, impact the rights of parties in the Medicare adjudicative process, or otherwise have "a significant effect" on stakeholders in the Medicare system. *See* H.R. Rep. No. 100-391(l), at 430 (1987) ("The policies affected would be all those which . . . have a significant effect on Medicare enrollees, on providers, or on the administration of the program"). I believe my definition takes a more realistic view of the role LCDs played in the proceedings below than does the majority, that it shows proper respect to § 1395hh(a)(2)'s plain language, and that it is consistent with that section's legislative history.

Today's opinion is a missed opportunity. In *Allina II*, Justice Gorsuch opened the door to judicial interpretation of the *sui generis* phrase "change a substantive legal standard." 139 S. Ct. at 1814. This Court could have taken up the Supreme Court's challenge and defined the term "substantive legal standard" in a realistic manner. Perhaps the Supreme Court may now decide to address this important and unresolved issue.

But for now, the majority relies on an overly narrow semantic argument and a "structural" analysis that ignores the text and history of the statute it claims to interpret. In so doing, the majority obscures the substantial effects that LCDs have on companies like Agendia and ultimately, on Medicare beneficiaries.

I respectfully dissent.

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]** (Filed Oct. 29, 2019)

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")

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[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.

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 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(1)(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 Ails 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 Ails 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 ("Ails 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]

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[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 AU or the DAB.

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(1)(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.

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 Ails 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

[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.

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 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 Ails 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(1)(5)(D)(iii) do not in any way imply exclusivity. In fact, though § 1395(y)(1)(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(1)(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

/s/ David O. Carter
DAVID O. CARTER
UNITED STATES
DISTRICT JUDGE

DEPARTMENT OF HEALTH AND
HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
Medicare Appeals Council
Docket No. M-19-123

Agendia Inc., Appellant
ALJ Appeal No. 1-2560274302

DECISION

(Filed Jan. 7, 2019)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge (ALJ)'s decision dated August 22, 2018, because there is an error of law material to the outcome of the claims. 42 C.F.R. § 405.1110. The underlying case concerns Medicare coverage of two molecular diagnostic tests referred to as BluePrint® and TargetPrint®, and related services, furnished to eighty-six beneficiaries during the period from June 25, 2012, through January 25, 2013.[1] The ALJ issued a decision favorable to the

[1] A complete list of beneficiaries, redacted health insurance claim numbers (HICNs), dates of service and HCPCS codes at issue is in Attachment A to this decision. The record is missing addresses for twenty-seven of the beneficiaries who have an asterisk next to their initials in Attachment A; therefore, those beneficiaries will not receive a copy of this decision. In this regard, we note that the appellant's request for hearing is incomplete. The regulations at 42 C.F.R. § 405.1014(a)(1) (effective Jan. 8, 2010), require the appellant to provide the name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed. Because these requirements are not met, dismissal of the request for hearing could be appropriate. However, because the appellant was not provided an opportunity to cure this

appellant, finding the two tests were medically reasonable and necessary.

By memorandum dated October 10, 2018, the Centers for Medicare & Medicaid Services (CMS) has asked the Council to review the ALJ's decision. 42 C.F.R. § 405.1110. The Council limits its consideration of the ALJ's decision to the specific exceptions raised by CMS. We enter the CMS referral memorandum into the record as Exhibit (Exh.) MAC-1. The appellant, through its representative, has filed a response, which the Council enters into the record as Exh. MAC-2.

For the reasons set forth below, the Council reverses the ALJ's decision. We find that the tests are not medically reasonable and necessary, and that the appellant is financially responsible for the non-covered charges.

BACKGROUND AND PROCEDURAL HISTORY

The appellant is a molecular diagnostics company that develops and markets molecular diagnostic tests. *See* www.agendia.com (last visited Dec. 18, 2018). During the period from June 25, 2012, through January 25, 2013, the appellant submitted claims to Medicare for molecular diagnostic tests, including the MammoPrint, BluePrint, and TargetPrint tests, and related services, furnished to the beneficiaries at issue. The MammoPrint test was covered and paid, and is not at

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defect in accordance with the Office of Medicare Hearings and Appeals Case Processing Manual, Chapter 3, and because CMS does not raise the issue in its referral memorandum, we proceed with our review of this case.

issue in the instant case. However, the BluePrint and TargetPrint tests, and related services, were not covered.[2] The Medicare contractor[3] denied the claims, and explained the basis of the denial as follows.

> The Molecular Diagnostic Services Program (MolDx) was developed to identify and establish reimbursement for molecular diagnostic tests. The molecular pathology procedure and the unlisted chemistry procedure [at issue] are molecular diagnostic services, and therefore must be processed using MolDx guidelines. These guidelines require that a unique

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[2] The appellant submitted claims for these tests using the following HCPCS codes: 81479 (TargetPrint; unlisted molecular pathology procedure not otherwise classified (NOC); 84999 (BluePrint; unlisted chemistry procedure). In addition, the appellant's claims also include HCPCS codes 88386 (array-based evaluation of multiple molecular probes; 251 through 500 probes) and 88381 (manual microdissection). *See* Attachment A. We note that many of the claims also include a second HCPCS code 84999 for the MammoPrint test, which was paid and not at issue in this case. *See*, *e.g.*, Exh. 2 at 134.

The CPT is an American Medical Association publication of billing codes for medical services. CMS created the Healthcare Common Procedure Coding System (HCPCS) to develop uniform national definitions of physician services, codes for those services and payment modifiers, in order to process, screen, identify and pay Medicare claims. *See* 42 C.F.R. §§ 414.2 and 414.40. The HCPCS incorporates the CPT coding system and includes additional coding references.

[3] Palmetto CBA issued the majority of the individual redeterminations in this case. Then, on September 16, 2013, Noridian became the contractor for the appellant's jurisdiction. *See* Exh. 4 at 79.

> identifier be provided when submitting claims or appeals for these types of services.
>
> The MolDx identifier is a unique code assigned to describe a specific service or set of services that constitute a molecular diagnostic test. The MolDx identifiers submitted with your claim, PB840 and PB841, have been reviewed for coverage. The Local Coverage Determination (LCD) provides the coverage guidelines for the payment of MolDx services. The LCD has determined that MolDx tests PB840 and PB841 cannot be deemed medically necessary for any indication. Therefore, no payment may be made.
>
> This decision is based on the [LCD] (L32288) for Molecular Diagnostic Tests and the coverage article "Molecular Diagnostics Services (MolDx) Program." These policies provide the coverage criterion that determines whether payment for a service can be made. These policies can be found on the websites, www.cms.gov and www.palmettogba.com.

See, *e.g.*, Exh. 2 at 13.

On reconsideration, the Qualified Independent Contractor (QIC) denied coverage for the tests, and provided the following explanation.

> During a review of the clinical utility component of a MolDX Technical Assessment (TA). Palmetto GBS recognized the need to develop a mechanism to provide rapid patient access, while also generating the evidence necessary

> to assess benefits and risk for test(s)/service(s) that meet the LCD criteria:
>
> Under this approved mechanism, also known as a Coverage with Evidence Development (CED), the MolDX Program may provide coverage for promising, but unproven diagnostic tests contingent on the submission of plans to conduct a clinical study that will generate additional evidence to support their safety, diagnostic performance, and most importantly, clinical utility.
>
> * * *
>
> The Contractor has completed [a] technical assessment on BluePrint® and TargetPrint®. To date, there is insufficient evidence to support the required clinical utility for the established Medicare benefit category. Based on the provided evidence, historical information included with the reconsideration request, the LCD, and review of the provided medical documentation, the QIC determined the services are not eligible for coverage.

Exh. 1 at 5. The QIC found the appellant liable for the denied services, explaining that it should have known about the coverage guidelines for molecular diagnostic tests. *Id.* The QIC dismissed some procedure codes that had not yet received a redetermination, and those procedure codes are not listed in Attachment A of this decision. *Id.* at 5-6.

The ALJ held a hearing at which the appellant's representative and several employees of the appellant

presented their case. The hearing is described in detail in the ALJ's decision, as well as CMS's referral memorandum, so we will not repeat it here. *See* Dec. at 2-4, 20-21; Exh. MAC-1 at 5-6. The contractor, Noridian, submitted a position paper in lieu of attending the hearing. Exh. 4 at 79-81. Thereafter, the ALJ issued a decision fully favorable for the appellant, finding as follows:

> The Appellant clarified that it is not challenging the LCD, but argued that the LCD does allow for genetic testing when medically reasonable and necessary. The Appellant also explained that given the history and context of this case, the assignment of unique identifiers to the MolDx by the Contractor was just another way to state that the tests in question were not medically reasonable and necessary.
>
> 42 C.F.R. 405.1062 provides that ALJs are not bound by LCDs, LMRPs, or CMS program guidance but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. In this case, the medical literature submitted as well as testimony provided at the hearing [] offered evidence that the emerging genetic testing provided to the beneficiaries in these cases were medically reasonable and necessary. The medical literature shows that molecular subtyping of early stage breast cancer is more accurate and helpful in selecting treatment options than conventional

subtyping. Dr. A[ ] explained that prior to the growth of genetic technology, it was known that there were 3 types of breast cancer, all of which were treated with chemotherapy. With the growth in genetic technology, tests were developed to be more precise in identifying the type or classification of the individual's cancer, and accordingly, more precise in how to effectively treat the type of cancer in that individual. Dr. A[ ] noted that prior to the development of the genetic testing, there was a one in 5 error rate in correctly identifying the type of cancer and it appeared that the imperfections in accurately identifying the type of cancer was the result of the timing or handling between the surgeon and the pathologist of the cells for biopsy. Dr. A[ ] noted that in contrast, with genetic tests, there is more precision in the classification of the cancer cells, which leads to more precise treatment options and better results for the cancer patient. Dr. A[ ] explained that BluePrint classifies the three types of cancer cells: 1) cells that are hormone driven (luminal); 2) cells that are HER2 driven; and 3) cells that are basal, and which can be treated by chemotherapy only. Dr. A[ ] stated that the TargetPrint test looks at the 3 types of receptor genes: 1) estrogen receptor gene; 2) progesterone receptor gene; and 3) HER2 gene. He stated that in each case, these tests are not affected by the way the cells are handled by the pathologist. Dr. A[ ] explained that the tests yielded different information in that TargetPrint shows how positive a single gene is, whereas, the

BluePrint gives different information with respect to a pathway analysis. Dr. An noted that in 2012, both these tests were used in conjunction, and the physician used both results to plan the patient's care. Dr. A[ ] summarized that the standard pathology reports have a lot of gray zones, whereas, the BluePrint and TargetPrint tests were more precise and supplement the pathologist report in order to better decide the course of treatment. Dr. A[ ] argued that by 2012, the use of these tests were the standard of care for oncologists.

In addition, Dr. A[ ] discussed three of the beneficiaries in this appeal and explained how the BluePrint and TargetPrint were utilized, how the tests identified the type of cancer the beneficiary had, how the tests yielded different and/or more accurate results than the standard pathology tests, and how the tests were used in plotting the patient's course of treatment.

Mr. V[ ] and Dr. A[ ] testified that the peer-reviewed literature the Appellant submitted showed that the molecular testing was not experimental and investigational, but was used to guide treatment by oncologists as standard practice in early stage breast cancer by the time of the dates of service at issue.

Based on the record and discussion above, I find that the BluePrint and TargetPrint tests were effective in allowing doctors to make more precise educated decisions on how to treat their patients on a long-term basis

> and potentially minimize their exposure to harmful chemotherapy drugs. In each of the individual cases at issue, medical records showed that the patient was diagnosed with early stage breast cancer, that her physician ordered the molecular diagnostic testing at issue, and that the testing was provided as billed. The pathology reports and/or supplemental office notes supported that the BluePrint and TargetPrint results corroborated, supplemented, or contrasted the information in the pathology report, and could be used to guide the physician in plotting the patient's most appropriate course of treatment. In addition, as discussed by Dr. A[ ], in the case of basal type cancers, once a metastatic occurrence occurs, it becomes incurable. Therefore, accurately identifying the type of cancer at the early stages is crucial. In the case discussed above, standard pathology did not accurately identify the type of cancer. By identifying a basal case, the high toxicity of the most powerful chemotherapy was justified by the likelihood of its effectiveness. In other types of cases, the cancer patient might be spared the risks and side effects of undergoing chemotherapy when the cancer cells are hormone driven inasmuch as the chemotherapy would not be effective and hormone therapy would be most effective. In sum, I find that the tests are medically reasonable and necessary.

Dec. at 20-21. The ALJ ordered payment for the tests. *Id.* at 22.

In its referral memorandum, CMS asserts that the ALJ erred as a matter of law by misapplying the applicable LCD, L32288. Exh. MAC-1 at 2, 15-17. CMS asserts the ALJ simply adopted the appellant's characterization of the LCD, i.e., that the LCD does allow for genetic testing when medically reasonable and necessary. CMS asserts the ALJ did not consider the LCD's explicit statement that "[t]his policy confirms 'non-coverage' for *all* molecular diagnostic tests [MDTs] that are not explicitly covered by a National Coverage Determination [NCD], [LCD], a covered article published by Palmetto GBA and excluded per MolDx Exempt tests published on the Palmetto GBA website." *Id.* at 2 (emphasis added by CMS). CMS explains that unless one of those authorities affirmatively covered the MDTs in question, the MDTs are not covered by Medicare. *Id.*

Further, CMS asserts the LCD required the contractor to "review all test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement," and that it "will cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility." *Id.* CMS emphasizes that tests not reviewed or approved are not covered by Medicare and the test assigned identifiers indicate such non-coverage. *Id.* The tests' unique identifiers to the MolDX, PB840 and PB841, went beyond the ALJ's mischaracterization as "just another way to state that these tests . . . were not medically reasonable and necessary," and instead reflect the contractor's review of the tests to determine whether they demonstrated

analytical and clinical validity, and clinical utility. *Id.* CMS asserts that Policy Article A51931, which was in effect on the dates at issue, stated that with respect to the BluePrint assay, "[t]o date, there is insufficient evidence to support reasonable and necessary criteria for Medicare reimbursement. Therefore, Palmetto GBA will deny BluePrint services." Moreover, later versions of the Policy Article, including a revision effective February 26, 2018, continue to find insufficient evidence to support the required clinical utility for the established Medicare benefit category for the BluePrint assay, citing Policy Articles A55115, A55116, and A53484. *Id.* n.3.

In addition, CMS asserts that even if the tests were a covered benefit and considered reasonable and necessary for diagnosing or treating an illness generally, documentation must still support that the services were reasonable and necessary for each patient. *Id.* CMS asserts that the Medicare Benefit Policy Manual (MBPM) requires that clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a), citing MBPM, Ch. 15, § 80.1. *Id.* In this case, CMS asserts, the ALJ found that tests "*allow[ed]* doctors to make more precise educated decisions on how to treat their patients," and the test results "*could be used* to guide the physician in plotting the patients most appropriate course of treatment." *Id.* at 2-3, citing Dec. at 21 (emphasis added by CMS). CMS asserts the ALJ did not consider whether documentation in the administrative record established

whether the ordering physicians in fact used the tests at issue to diagnose or treat the beneficiaries, and the preponderance of the evidence in the record does not support that these tests were used promptly by the beneficiaries' treating physicians in accordance with Medicare regulations and policy. *Id.* at 3.

In its response to CMS's memorandum, the appellant, through its representative, asserts that CMS's referral for own motion review "is based on (1) misinterpretation of the controlling law and regulations, and (2) reliance on a series of *ultra vires* "policies" developed on an *ad hoc* basis by Medicare Administrative Contractors ("MACs") acting well outside of their legal authority." Exh. MAC-2 at 1. The appellant notes that 42 U.S.C. § 1395y(a)(l) excludes from Medicare coverage items and services that are not medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The appellant asserts that Congress mandated in 42 U.S.C. § 1395hh(a)(2) that with the exception of NCDs, no policy that changes or establishes the substantive legal standard governing the scope of Medicare benefits "shall take effect unless it is promulgated by the Secretary by regulation." The appellant then cites to the regulations that expressly cover physician and diagnostic laboratory services under Part B so long as they are ordered by a patient's treating physician.

The appellant emphasizes that CMS asserts the controlling policies governing coverage of MDTs are those established by a MAC, Palmetto GBA, in 2011,

"through an *ad hoc* process that continues to evolve according to the wishes of another private contractor that operates the. 'MolDx' program." *Id.* at 3. The appellant asserts that the MACs have issued LCDs, including LCD L32288, without going through required rulemaking procedures, which flatly prohibit Medicare coverage for any MDT that has not been approved under MolDx's standards for analytic validity, clinical validity, and clinical utility, as subjectively determined by MolDx. The appellant notes that if a test does not meet the MolDx policies, then the MACs deem the test to be "statutorily excluded." *Id.*

The appellant asserts the ALJ did not ignore the LCD or the MolDx decision, and instead, "properly engrafted upon them the statutory requirement that she must follow to determine whether the tests at issue were reasonable and necessary under the controlling and legally enacted Medicare regulations, as applied to the undisputed facts." Exh. MAC-2 at 4. With regard to the reasonable and medically necessary issue, the appellant reiterates the testimony of Dr. A, an expert in oncology, and the testimony of others at the ALJ hearing. Specifically, the appellant emphasizes that Dr. A opined that each test for each patient was medically reasonable and necessary based on the documentation in the record, and that ordering of such testing was consistent with the standard of practice applicable to the treatment of breast cancer patients in 2012; the clinical utility of the tests was described using three sample beneficiary cases; and a summary was provided of the published evidence-based articles in effect

during the dates at issue regarding genetic testing and the testing at issue. *Id.* at 6. The appellant characterizes CMS's position as asserting none of this expert testimony matters here because LCD L32288 provides that no MDT is covered by Medicare unless MolDx approves it, and this has not occurred with respect to Blueprint and TargetPrint. *Id.* Further, the appellant asserts this position ignores the provisions of the Medicare coverage statutes and regulations. *Id.*

In response to CMS's assertion regarding the preponderance of the evidence in this case, the appellant asserts that contrary to the newly raised assertion by CMS, the regulation does not impose a burden on a clinical laboratory to present to an ALJ documentation of how the ordering doctor actually used the test results in the treatment of the patient or whether he or she did so "promptly." *Id.* Instead, the appellant asserts it is the doctor, not the billing laboratory, who must maintain documentation of the medical necessity for ordering the testing. *See id.* at 4-6.

APPLICABLE AUTHORITIES

Medicare is a defined benefit program. In order to be considered for Medicare coverage, an item or service must fall within a statutory benefit category. Medicare Part B covers medical and other health services, defined to include diagnostic laboratory tests and other diagnostic tests. Social Security Act (Act), §§ 1832(a)(2)(B) and 1861(s)(3). Specifically, diagnostic X-Ray tests, laboratory tests, and other diagnostic

tests is a Medicare defined benefit category. *See* MBPM, Ch. 15, § 10. In order to be paid under this benefit category, a diagnostic test must be ordered by a physician who is treating the beneficiary, and the results used in the management of a beneficiary's specific medical problem. 42 C.F.R. § 410.32. In addition, the statutory exclusion of § 1862(1)(A) of the Act, "except for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," must also be applied.

In 2011, the Molecular Diagnostic Services (MolDX) Program was developed by Palmetto GBA in order to identify and establish coverage and reimbursement for molecular diagnostic tests. *See* Palmetto GBA MolDX Hub, General, *available at* https://www.palmettogba.com/palmetto/MolDX.nsf/docsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~General (last visited Dec. 28, 2018). The MolDX program performs the following functions:

- Facilitates detailed and unique identification through registration of molecular diagnostics tests to facilitate claims processing and to track utilization
- Establishes clinical utility expectations
- Completes technical assessments of published test data to determine clinical utility and coverage
- Establishes reimbursement

Palmetto GBA MolDX Hub, *available at* https://www.palmettogba.com/palmetto/MolDX.nsf/docsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~General (last visited Dec. 28, 2018). The MolDX program has three components: (1) test registration and ID assignment, (2) application review, and (3) coverage determination and reimbursement. *Id.*

As explained in more detail below, for molecular diagnostic tests (MDTs), like the ones at issue in this case, Palmetto GBA must review through the MolDX program, all test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement. *See* LCD L32288, effective May 7, 2012, through Sept. 20, 2012; MolDx Manual, version M00106, *available at* https://www palmettogba.com/moldx (last visited Dec. 13, 2018). Palmetto GBA will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility. *Id.* Prior to this technical assessment, Palmetto will consider all tests investigational and therefore, not a covered service. *See* Palmetto GBA MolDX Hub, General, *available at* https://www.palmettogba.com/palmetto/MolDX.nsf/docsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~General (last visited Dec. 28, 2018).

Submitting Claims for MDTs to Medicare/Use of Identifiers

Laboratories must report MDTs with the CPT and/or HCPCS code(s) that most accurately describes the specific test performed. MolDX Manual, Ch. 2, §§ 2, 2.1.

Because the available language in the HCPCS and CPT manuals to describe the pathology and laboratory categories and the tests included in those categories is not specific to the actual tests, all MDT services must include an identifier as additional claim documentation. *Id.* Ch. 1, § 1.4. This is because tests that are not described by a specific code require the use of an unlisted code. *Id.* Ch. 2, § 2.

For this reason, the MolDX Program requires laboratories to obtain a test-specific identifier that is unique to the laboratory's specific test (i.e., the unique test identifier establishes a link to the specific test performed). When reported in conjunction with the appropriate CPT/HCPCS code, the identifier allows payers to determine the exact test that has been performed, facilitating the process of making pricing and/or coverage determinations (subject to Palmetto GBA's analysis of the data supporting the use of the test.) MolDX Manual, Ch. 2, §§ 2, 2.1. In this case, the BluePrint and TargetPrint tests have the identifiers PB841 and PB840, respectively.

The MolDX Program – Technical Assessment of MDTs

MolDX only provides coverage for MDTs and laboratory developed tests (LDTs) that demonstrate analytical validity, clinical validity, and clinical utility. Nonvalidated tests must submit a comprehensive dossier of scientific information and undergo a technical assessment (TA) to substantiate that the test meets

Medicare's requirements for coverage. The MolDX Manual lists all required elements of the TA submission. Laboratories that perform FDA-approved tests with *proven utility* and only perform the test within labeling indications may be exempt from the technical assessment. MolDX Manual, Ch. 2, § 2.2.

During the TA process, subject matter experts (SMEs) and the MolDX team determine if an assay demonstrates clinical utility and fulfills the CMS "reasonable and necessary" criteria. *Id.* SMEs from academia and industry will assess the scientific literature, and the MolDX team will perform the assessment for all other components. *See* Frequently Asked Questions, Technical Assessment, M00086, V22, *available at* https://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Frequently%20Asked%20Questions-8N3ELL4072?open (last visited Dec. 11, 2018). In addition, CMS has directed MolDX to follow the ACCE criteria developed by the Centers for Disease Control and Prevention. MolDX Manual, Ch. 2, § 2.2.1.

Once a coverage determination has been established, the results will be published to the provider community. *Id.* § 2.2. An LCD may also be developed if the test requires administration of reasonable and necessary limitations. *Id.*

Currently, Palmetto GBA provides coverage for MDTs and LDTs that are identified as covered in the LCD for MDTs. Palmetto GBA may also develop and publish specific LCDs, and/or Palmetto GBA coverage articles

as required. MDTs not identified as covered in an NCD, LCD or coverage article are not covered. Coverage for items or services that are outlined in the Medicare Benefit Category may be addressed in an NCD, LCD, or article. Items or services that are *not* considered a Medicare benefit may only be addressed in an article. *Id. §* 2.

LCD L32288 for Molecular Diagnostic Tests

Under Medicare regulations, ALJs and the Council are not bound by LCDs but will give substantial deference to LCDs applicable to a particular case. 42 C.F.R. § 405.1062(a). If the ALJ or the Council decline to follow an LCD or Medicare program guidance, the ALJ or Council must explain the reason for departing from the policy or program guidance. *Id.* at 405.1062(b).

Relevant here, there were two versions of LCD L32288 in effect during the dates of service at issue in this case: one that was effective from May 7, 2012, through September 20, 2012, and one that was effective from September 21, 2012, through April 25, 2013. Both versions state, "This policy confirms 'non-coverage' for all molecular diagnostic tests (MDTs) that are not explicitly covered by a National Coverage Determination (NCD), a Local Coverage Determination (LCD), a coverage article published by Palmetto GBA and excluded per MolDx Exempt Tests published on the Palmetto GBA website." Both versions also include sections titled: Applicable Tests/Assays, Unique Test Identifier Requirement, Technology Assessments (TA), Payment

Rules, and Noncovered Tests, which are described and quoted in the ALJ's decision. *See* Dec. at 19-20.

Policy Article A51931 – MolDx: BluePrint® Billing and Coding Guidelines

Attached to the earlier version of LCD L32288, mentioned above, is Policy Article A51931 for MolDx: BluePrint® Billing and Coding Guidelines, effective Aug. 15, 2012, through Nov. 1, 2012. The Policy Article states: "Palmetto GBA has completed a technical assessment on BluePrint®, a molecular subtyping assay. To date, there is insufficient evidence to support reasonable and necessary criteria for Medicare reimbursement. Therefore, Palmetto GBA will deny Blueprint® services."

According to the FAQs for the Technical Assessment of the MolDX Program on Palmetto GBA's website, laboratories are allowed to resubmit a coverage request six months after the initial non-coverage determination was issued if substantive new information, not included in the initial submission, becomes available. Therefore, this non-coverage determination would still be in effect through the last date of service at issue in this case, which is January 25, 2013.

DISCUSSION

Coverage

Upon careful consideration of the record, CMS's memorandum, and the appellant's exceptions, we find that

the ALJ's decision contains an error of law material to the outcome of the claims. The ALJ's decision is inconsistent with the LCDs in effect during the dates of service at issue, which explicitly provide that these tests are not covered. The ALJ's departure from the LCD was a result of its misapplication and misunderstanding of the MolDX program. Moreover, the ALJ erred by not applying Policy Article A51931, as it was not mentioned in the decision.

The Council finds no reason to not apply substantial deference to the LCD or to question the MolDX program's findings. *See* 42 C.F.R. § 405.1062(a). The record demonstrates that both tests, the BluePrint and TargetPrint, were reviewed by the MolDX program, and neither had sufficient evidence to support the reasonable and necessary criteria for Medicare reimbursement. While the appellant argues the MolDX program was developed by contractors acting outside of their legal authority, and challenges LCDs relating to coverage of MDTs, as the appellant also acknowledges, these assertions are not within the Council's jurisdiction to review. *See* 42 C.F.R. §§ 405.924, 405.926.

The purpose of the MolDX program is specifically to analyze and review the analytical validity, clinical validity, and clinical utility of molecular diagnostic tests. The assessment and review process under the MolDX program is specialized for molecular diagnostic tests, considers applicable statutory and regulatory requirements, and includes the review of scientific literature by independent subject matter experts.

For the BluePrint test, Policy Article A51931 specifically states that Palmetto GBA has completed a technical assessment on this test, and to date, there is insufficient evidence to support reasonable and necessary criteria for Medicare reimbursement. While we note that the policy article for the BluePrint coverage determination is dated August 15, 2012, and there are some dates of service prior to that date, LCD L32288 states, prior to the technical assessment and published coverage determination, Palmetto will consider all tests investigational and therefore, not a covered service.

And while there is not a specific policy article that addresses the TargetPrint test, it is clear from Palmetto GBA's redeterminations that this test also was reviewed by the MolDX program, and also found to not have sufficient evidence to support the reasonable and necessary criteria for Medicare reimbursement. *See*, *e.g.*, Exh. 2 at 142-43. The appellant would have submitted all of the clinical studies available at the time of the technical assessment with its application. *See* MolDX Manual, Ch. 2, § 2.2. While the appellant's expert, who is the appellant's Chief Medical Officer, opined that the tests are medically reasonable and necessary, and met Medicare's coverage criteria for MDTs, the technical assessment performed under the MolDX program determined otherwise.

In accordance with the LCDs and policy article, the Council concludes that both the BluePrint or TargetPrint tests are not covered and we reverse the ALJ's decision. As we have found that the ALJ's decision contains

an error of law material to the outcome of the claims, we need not address whether the ALJ's decision was based on a preponderance of the evidence. 42 C.F.R. § 405.1110.

Liability

When an item or service is denied as not medically "reasonable and necessary" under § 1862(a)(1)(A) of the Act, § 1879 of the Act limits the liability of a beneficiary or supplier that did not know, and could not reasonably have been expected to know, that the item or service would not be covered by Medicare. A beneficiary is considered to have "knowledge" of non-coverage if the supplier provides advance written notice to the beneficiary explaining why it believes that Medicare will not cover the items. 42 C.F.R. § 411.404(b). In this case, there is no evidence that any of the respective beneficiaries were provided with advance written notice of non-coverage.

In contrast, a provider or supplier has actual or constructive knowledge of non-coverage based upon its receipt of CMS notices, manual issuances, bulletins, and other written guides or directives and its knowledge of acceptable standards of practice by the local medical community. *See* 42 C.F.R. § 411.406(c). It is clear from the record that the appellant was aware of the applicable authorities, as the appellant submitted applications for these tests to be reviewed by the MolDX program. The appellant would have received direct notice of the coverage determinations for these tests. *See*

also Palmetto GBA, MoldDX Excluded Tests, *available at* https://www.palmettogba.com/palmetto/MolDX.nsf/docsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Excluded%20Tests (last visited Dec. 18, 2018). In addition, as a Medicare supplier, the appellant is also deemed to have had constructive notice of the coverage criteria (including LCDs and Policy Articles) of the tests for which it submitted Medicare claims.

For these reasons, the Council finds the appellant knew, or could have reasonably been expected to know, that Medicare would not cover the BluePrint and TargetPrint tests, and related services, at issue here. Accordingly, the Council concludes the appellant is financially responsible for the non-covered costs.

DECISION

The Council concludes that the BluePrint and TargetPrint tests, and related services, furnished to the beneficiaries on the dates of service listed on Attachment A are not covered by Medicare. The Council reverses the ALJ's decision. The appellant remains financially responsible for the non-covered tests and related services.

MEDICARE APPEALS COUNCIL

/s/ Debbie K. Nobleman
Debbie K. Nobleman
Administrative Appeals Judge

/s/ Stanley I. Osborne, Jr.
Stanley I. Osborne, Jr.
Administrative Appeals Judge

Date: JAN –7 2019

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

AGENDIA, INC., Plaintiff-Appellee, v. XAVIER BECERRA, Secretary of U.S. Department of Health and Human Services, Defendant-Appellant.	Nos. 19-56516, 20-55041 D.C. No. 8:19-cv-00074-DOC-JDE Central District of California, Santa Ana ORDER (Filed Sep. 2, 2021)

Before: FRIEDLAND and BENNETT, Circuit Judges, and BLOCK,* District Judge.

Judge Friedland and Judge Bennett have voted to deny the petition for rehearing en banc. Judge Block recommends granting the petition for rehearing en banc.

The full court has been advised of the petition for rehearing en banc, and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

* The Honorable Frederic Block, United States District Judge for the Eastern District of New York, sitting by designation.

The petition for rehearing en banc is DENIED.

RELEVANT STATUTES AND REGULATIONS

42 U.S.C. § 1395ff

Determinations; appeals

(f) Review of coverage determinations

* * *

(2) Local coverage determination

* * *

(B) Definition of local coverage determination

For purposes of this section, the term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A) of this title.

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42 U.S.C. § 1395hh

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means,

unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where –

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph **(B)** of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which –

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

(e)[1] **Retroactivity of substantive changes; reliance upon written guidance**

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or

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[1] So in original. No subsec. (d) has been enacted.

otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that –

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case maybe, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If –

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1395zz(g) of this title) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this subchapter or the provisions of subchapter XI insofar as they relate to this subchapter (including interest under a repayment plan under section 1395ddd of this title or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(f) Report on areas of inconsistency or conflict

(1) Not later than 2 years after December 8, 2003, and every 3 years thereafter, the Secretary shall

submit to Congress a report with respect to the administration of this subchapter and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect –

> **(A)** information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman with respect to such areas of inconsistency and conflict; and
>
> **(B)** information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

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42 U.S.C. § 1395kk-1

Contracts with medicare administrative contractors

(a) Authority

(1) Authority to enter into contracts

The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

* * *

(4) Functions described

The functions referred to in paragraphs (1) and (2) are payment functions (including the function of developing local coverage determinations, as defined in section 1395ff(f)(2)(B) of this title), provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

(A) Determination of payment amounts

Determining (subject to the provisions of section 1395oo of this title and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this subchapter to be made to providers of services, suppliers and individuals.

(B) Making payments

Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

(C) Beneficiary education and assistance

Providing education and outreach to individuals entitled to benefits under part A or enrolled under

part B, or both, and providing assistance to those individuals with specific issues, concerns, or problems.

(D) Provider consultative services

Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this subchapter and otherwise to qualify as providers of services or suppliers.

(E) Communication with providers

Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

(F) Provider education and technical assistance

Performing the functions relating to provider education, training, and technical assistance.

(G) Improper payment outreach and education program

Having in place an improper payment outreach and education program described in subsection (h).

(H) Additional functions

Performing such other functions, including (subject to paragraph (5)) functions under the Medicare Integrity Program under section 1395ddd of

this title, as are necessary to carry out the purposes of this subchapter.

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42 U.S.C. § 1395*l*

Payment of benefits

(h) Fee schedules for clinical diagnostic laboratory tests; percentage of prevailing charge level; nominal fee for samples; adjustments; recipients of payments; negotiated payment rate

* * *

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1395cc of this title, payment may be made only to the person or entity which performed or supervised the performance of such test; except that –

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if –

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)),6 receives requests for testing during the year in which the test is performed[6] are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1395x(w)(1) of this title) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic may

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[6] So in original. The comma after "subclause (II))" probably should follow "is performed".

only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1395cc of this title.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1395u(j) of this title in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies[7] to such section.

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42 U.S.C. § 1395m-1

Improving policies for clinical diagnostic laboratory tests

* * *

(d) Payment for new advanced diagnostic laboratory tests

* * *

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[7] So in original. Probably should be "such paragraph applies".

(5) Advanced diagnostic laboratory test defined

In this subsection, the term "advanced diagnostic laboratory test" means a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:

(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.

(B) The test is cleared or approved by the Food and Drug Administration.

(C) The test meets other similar criteria established by the Secretary.

* * *

(g) Coverage

* * *

(2) Designation of one or more medicare administrative contractors for clinical diagnostic laboratory tests

The Secretary may designate one or more (not to exceed 4) medicare administrative contractors to either establish coverage policies or establish coverage policies and process claims for payment for clinical

diagnostic laboratory tests, as determined appropriate by the Secretary.

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42 U.S.C. § 1395y

Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services –

> **(1)(A)** which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

* * *

(1) National and local coverage determination process

* * *

(5) Local coverage determination process

* * *

(D) Local coverage determinations

The Secretary shall require each Medicare administrative contractor that develops a local coverage determination 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, the following information:

(i) Such determination in its entirety.

(ii) Where and when the proposed determination was first made public.

(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

(v) An explanation of the rationale that supports such determination.

* * *

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42 C.F.R. § 410.32

Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) Ordering diagnostic tests. Except as otherwise provided in this section, all diagnostic x-ray tests,

diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(1) Mammography exception. A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(2) Application to nonphysician practitioners. Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(3) Public Health Emergency exceptions. During the Public Health Emergency for COVID-19, as defined in § 400.200 of this chapter, the order of a physician or other applicable practitioner is not required for one otherwise covered diagnostic

laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis when performed in conjunction with COVID-19 diagnostic laboratory test in order to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID-19 and related tests described in the previous sentence are reasonable and necessary when ordered by a physician or nonphysician practitioner in accordance with this paragraph (a), or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. FDA – authorized COVID-19 serology tests are included as covered tests subject to the same order requirements during the Public Health Emergency for COVID-19, as defined in § 400.20 of this chapter, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection.

* * *

Local Coverage Determination (LCD): Molecular Diagnostic Tests (MDT) (L32288)

Contractor Information

Contractor Name	Contract Number	Contract Type
Palmetto GBA opens in new window	01192	MAC – Part B

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LCD Information

Document Information

LCD ID
L32288

LCD Title
Molecular Diagnostic Tests (MDT)

Jurisdiction opens in new window
California – Southern

Original Effective Date
For services performed on or after 05/07/2012

Revision Effective Date
For services performed on or after 05/10/2013

Revision Ending Date
N/A

Retirement Date
ANTICIPATED 09/15/2013

Notice Period Start Date
03/12/2013

Notice Period End Date
N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA) §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of malformed body member."

Title XVIII of the Social Security Act (SSA) §1833(e), prohibits Medicare payment for any clam lacking the necessary documentation to process the claim.

Title XVIII of the Social Security Act (SSA) §1862(a)(1)(D), Investigational or Experimental.

CMS Manual System, Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §80.1, 80.1.1, 80.1.2, 80.1.3, laboratory services must meet applicable requirements of CLIA.

Pub 100-08 PIM, Ch. 13, Sec 13.1.3, Program Integrity Manual, "*LCDs consist of only "reasonable and necessary"* information.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

This coverage policy provides the following information:

- defines tests required to register for a unique identifier
- defines tests required to submit a complete technical assessment (TA) for coverage determination
- defines the payment rules applied to covered tests that are not reported with specific CPT codes
- lists specific covered tests that have completed the registration and TA process and meet Medicare's reasonable and necessary criteria for coverage

As per Pub 100-08 PIM, Ch. 13, Sec 13.1.3, tests not covered due to benefit category or statutory exclusion provisions will not be listed in this LCD. The following

test types are considered not covered due to statutory exclusion or no Medicare benefit category:

- Tests considered screening in the absence of clinical signs and symptoms of disease
- Tests that do not provide the clinician with actionable data (information that will improve patient outcomes and/or change physician care and treatment of the patient)
- Tests that confirm a diagnosis or known information
- Tests to determine risk for developing a disease or condition
- Tests without diagnosis specific indications
- Tests performed to measure the quality of a process or for Quality Control/Quality Assurance (QC/QA), i.e., tests performed to ensure a tissue specimen matches the patient
- Tests considered investigational or experimental

MDT Policy Specific Definitions

MDT: Any test that involves the detection or identification of nucleic acid(s) (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolite(s). The test may or may not include multiple components. A MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.

LDT: Any test developed by a laboratory developed without FDA approval or clearance.

Applicable Tests/Assays

In addition to the MDT definition, this coverage policy applies to all tests that meet at least one of the following descriptions:

- All non-FDA approved/cleared laboratory developed tests (LDT)
- All modified FDA-approved/cleared kits/tests/assays

  All tests/assays billed with more than one CPT code to identify the service, including combinations of method-based, serology-based, and anatomic pathology codes

  All tests that meet the first three bullets and are billed with an NOC code

Unique Test Identifier Requirement

Because the available language in the HCPCS and CPT manuals to describe the pathology and laboratory categories and the tests included in those categories are not specific to the actual test results provided, all MDT services must include an identifier as additional claim documentation. Test providers must apply for an identifier specific to the applicable test and submit the test assigned identifier with the claim for reimbursement. The assigned identifier will provide a crosswalk between the test's associated detail information on file

and the submitted claim detail line(s) required to adjudicate each test's claim. The unique identifier limits the need to submit the required additional information about the test on each claim.

Laboratory providers who bill MDT services must register services with one of the following methods:

- Z-Code Identifier Application
- Palmetto GBA Test Identifier (PTI) Application

Technology Assessments (TA)

Palmetto GBA must review all test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement. Labs must submit a comprehensive dossier on each new test/assay prior to claim submission. Palmetto GBA will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility. Prior to this tech assessment and published coverage determination, Palmetto will consider all tests investigational and therefore, not a covered service. Palmetto GBA will consider the minimum coverage effective date to be the date that Palmetto GBA publishes the coverage decision.

Payment Rules

Palmetto GBA will apply the following payment rules:

- Tests submitted and paid that have NOT been reviewed and approved through the process

outlined in this policy will be considered investigational and therefore denied as not a covered service.

- Approved tests will be effective for dates of service on and after the approval date of a coverage determination. Dates of service prior to the approval effective date are subject to this non-coverage policy.
- To obtain a unique identifier for a test, to request a technical assessment, or for additional MDT information, go to the Medicare home page ©PalmettoGBA.com and enter MolDx in the search window.

Covered Tests

To date, Palmetto GBA has reviewed the MolDx application and/or the MolDx Technical Assessment and determined the following tests meet the Medicare reasonable and necessary criteria:

Test Name	Test Developer	Test ID	CPT Code(s)	Publish Date	Effective Date
Afirma™	Veracyte	ZB846	84999	10/31/12	03/05/12
Allomap	Expression Diagnostics	ZB863	86849	10/31/12	2/28/12*
Avise PG	Exagen Diagnostics, Inc.	PBD31	84999	10/31/12	04/25/12
Cancer TYPE ID	bioTheranostics	PBU00	84999	10/31/12	07/25/11*
cobas® 4800 BRAF V600	Roche	ZB794	84999	10/31/12	09/07/12
Corus® CAD	CardioDx, Inc.	ZB854	84999	10/31/12	01/01/12
HERmark®	Monogram	PB839	84999	10/31/12	04/19/12
MammaPrint™	Agendia	PB864	84999	10/31/12	11/16/09*
Oncotype DX® Breat	Genomic Health	PR008	84999	10/31/12	09/02/08*
Oncotype DX® Colon	Genomic Health	PR861	84999	10/31/12	03/26/12
Progensa® PCA3	Gen-Probe Incorporated	ZBA41	84999	10/31/12	05/07/12
therascreen	Qiagen	ZBT98	81479	04/30/13	04/30/13
Tissue of Origin	Pathworks	ZB798	84999	10/31/12	07/25/11*
Vectra™ DA	Crescendo	ZBC85	84999	5/10/13	4/11/13
	Abbot	ZB976	88367(2)OR 88368(2)	04/29/13	04/29/13

* indicates test specific retired/active LCD coverage prior to identifier assignment

Palmetto GBA expects laboratory providers to follow test indications published by the developer.

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[LOGO] [LOGO]

PALMETTO GBA® **PALMETTO GBA®**

MolDX® A CELERIAN GROUP COMPANY
A CMS Medicare
Administrative Contractor

Molecular Diagnostic Program (MolDX®)

Coverage, Coding, and Pricing Standards and Requirements (M00106)

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[i] **DOCUMENT VERSION CONTROL**

Version No.	Date	Purpose/Changes	Author
1.0	08/02/2013	Original document	Becke Turner
2.0	020/7/2014	Regular program updates	MolDX Team
3.0	09/03/2014	Updated trademark, CPT codes, CTEP information, language for statutory excluded tests, replace CED with CDD, changed MEF from quarterly to weekly, add MolDX tracker#	Becke Turner
4.0	12/31/2014	2015 CPT code update	Becke Turner

5.0	03/06/2015	Added Mod 22 explanation to 3.1	Becke Turner
6.0	05/04/2015	Added panel definition, corrected format errors, updated TA component with new guidance documents on M00095, V5	Becke Turner
7.0	07/29/2015	Updated cover page w/new corporate logos	Becke Turner
8.0	09/09/2015	Updated1.2. Current Scope of the Palmetto GBA MolDX to include multiple jurisdictions, removed references to addition of 2015 MAA codes, added form #5 Analytical Performance Specifications for Comprehensive Genomic Profiling(M00018)	Becke Turner
9.0	10/19/2015	Add Utah to 1.2 JF and Updated with new MolDX icon	Kathy Brannon
10.0	12/23/2015	Corrected typo page 7 “is” to “if’	Tina Houser
11.0	5/17/2016	Add WPS to 1.1, corrected codes/descriptions in MolDX table, 1.2.1 corrected claim form to 835P	Tina Houser
12.0	3/2/2017	Updated the following sections: 1.2, 1.2.1,	Tina Houser

		2.2.1 2.2.2(Deleted) and 2.3	
13.0	9/27/2017	Deleted HCPCS Code G0452 from table	Alston Meetze
14.0	10/24/2017	Added microbiology codes, deleted empty row from CPT table, added parenthesis to section1:3, fixed spacing in 2.2.1	Alston Meetze
15.0	12/8/2017	Deleted CDD, added cytology codes, changed DEX website, revised TA information	Alston Meetze
16.0	1/8/2018	Removed FISH (cytology) codes from table	Alston Meetze
17.0	1/11/2018	Updated CPT table, updated DEX address	Alston Meetze
18.0	2/1/2018	2018 CPT code update	Alston Meetze
19.0	2/6/2018	Reformatted bullets, changed 2017 to 2018	Alston Meetze
20.0	3/1/2018	Removed microbiology codes from CPT table	Alston Meetze
21.0	3/26/2018	Removed 22 modifier information	Alston Meetze
22.0	6/13/2018	Removed NOC codes 88399 and 89398 from CPT table	Alston Meetze
23.00	7/12/2018	Updated CPT table to specify which PLA, MAAA, and NOC codes require Z-codes; removed 88199 and 88299	Alston Meetze

24.00	7/27/2018	Corrected list of states for JF territory; removed "CDD" from list of possible coverage determinations	Alston Meetze
25.00	3/27/2019	Changed the year on CPT chart to 2019	Alston Meetze
26.00	12/16/19	Replaced CPT chart with link to MDT Article	Alston Meetze

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[i] **TABLE OF CONTENTS**

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[1] **CHAPTER I: BACKGROUND**

1. Background

1.1. Objective

The objective of this document is to describe the process that Palmetto GBA (Palmetto GBA) uses to determine coverage, coding, and pricing for molecular diagnostic tests and other molecular pathology services administered through the Molecular Diagnostic Services (MolDX®) Program.

1.2. Current Scope of the Palmetto GBA MolDX program

The following Medicare Jurisdictions have implemented the MolDX program:

- JE A/B MAC, which covers California, Nevada, Hawaii and the US Pacific Territories of Guam, American Samoa and the Northern Marianas, administered by Noridian Healthcare Solutions
- JF A/B MAC, which covers Oregon, Washington, Idaho, Utah, Montana, Wyoming, Arizona, North

Dakota, South Dakota, Alaska, and the Aleutian Islands, administered by Noridian Healthcare Solutions

- JM A/B MAC, which covers North Carolina, South Carolina, Virginia, and West Virginia, administered by Palmetto GBA
- J5 A/B MAC, which covers Iowa, Kansas, Missouri, and Nebraska, administered by WPS Government Health Administrators
- J8 A/B MAC, which covers Michigan and Indiana, administered by WPS Government Health Administrators
- J15 A/B MAC, which covers Ohio and Kentucky, administered by CGS Administrators, LLC
- JJ MAC, which covers Georgia, Tennessee, and Alabama, administered by Palmetto GBA

Please review Local Coverage Article: Billing and Coding: MolDX Molecular Diagnostic Tests (MDT) (A56853) for a list of diagnostic services that fall within the scope of MolDX.

https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56853

Tier 1 molecular pathology services that are not covered in the Medicare Clinical Laboratory Fee Schedule, Tier 2 codes, and NOC codes will be subject to the coverage, coding, and pricing processes outlined in the MolDX Program. MolDX codes published in the Medicare Clinical Laboratory Fee Schedule or in the MDFSB will be priced and covered as published.

MDTs and LDTs present challenges because the Clinical Laboratory Fee Schedule pricing methodology does not account for the unique characteristics of these tests. As such, Palmetto GBA's MolDX Program strives to create a consistent approach to coverage and pricing decisions for MDTs and LDTs.

*As a group, all CPT PLA codes are inclusive in MolDX and are not listed individually.

[2] ***1.2.1. MolDX Program and AB MAC roles:***

Palmetto GBA will maintain and provide MACs, which have established operating agreements with Palmetto GBA, a weekly Master Edit File (MEF). In addition to the MEF, Palmetto GBA will coordinate appropriate LCD development and provide educational articles to support the coverage decisions as necessary. This model will be used as the MolDX Program is expanded to additional AB MACs (MACs).

MolDX will administer MoPath claims in the following manner.

- Per policy (see Chapter II), services within the scope of this program require a test identifier (DEX Z-Code™) and this identifier must be submitted as additional information at the time of claim submission in order to be fully adjudicated. MACs will use the DEX Z-Code as the identifier to align coverage and/or payment with the MEF.
- MACs will receive and implement weekly updates of the MolDX MEF to adjudicate claims

- For CPT NOC codes (81479, 81599, 84999, 85999, 86849, 87999, 88199, and 88299), this additional information (Test identifier/Z-Code) is submitted in the SV101-7 (5010A1-837P) or SV202-7 (5010A1-8371) claim line detail field.
- For CPT non-NOC codes, Labs may either use the SV101-7 or SV202-7 (preferred) or the NTE field to submit this required information.
- If the identifier is not on file, MAC forwards claim information to MolDX for review and determination.
    - MolDX processes for coverage, correct coding, and price (see section 3)
    - MolDX submits information to MAC for adjudication
    - MAC adjudicates claim
    - MolDX generates an article and/or, LCD as appropriate to support decision
    - MolDX updates MEF with new information for weekly release

1.3. Definitions

- *Common Procedure Terminology (CPT) Code:* Level I codes in the Health Care Common Procedure Coding System (HCPCS) CPT, a uniform coding system consisting of descriptive terms and identifying codes, used to identify medical services and procedures furnished by physicians and other health care professionals. The American Medical Association (AMA) establishes CPT codes, which are used by payers under license.

- *Health Care Common Procedure Coding System (HCPCS):* The HCPCS Code Set is one of the standard code sets used to process claims in an orderly and consistent manner The HCPCS is divided into two principal subsystems, referred to as level I and level II of the HCPCS.

- *Health Care Common Procedure Coding System (HCPCS) Level II:* Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.

- *Laboratory developed test (LDT):* A test developed by a laboratory for the use of its own clients. Typically, LDTs are not approved or cleared by the FDA.

- *Part A/Part B Medicare Administrative Contractor (MAC):* Private entities delegated authority to receive, review, price and pay Medicare claims for items and services, including clinical laboratory services, under Medicare Part A and Part B.

[3] • *Molecular Diagnostic Services Program (MolDX):* A program designed and operated by Palmetto GBA to identify and establish coverage on existing tests, newly developed LDTs, tests using pathology NOC codes, and other molecular diagnostic tests that fall within the scope of the Molecular Diagnostic Test (MDT) LCD.

- *Molecular diagnostic test (MDT):* A test that involves the detection or identification of nucleic

acids (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolites. The test may or may not include multiple components. An MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.

- *Molecular Pathology Codes (MoPath):* A series of CPT codes published by the AMA describing molecular diagnostic tests. MoPath codes are found in the 80000 series of CPT codes. Certain MoPath codes are subject to unique coverage, coding and pricing provisions of Palmetto GBA's MolDX program. MoPath codes are subject to gapfill pricing at the request of CMS.

- *National Limitation Amount (NLA):* Calculated as a percentage of the median of all contractor-determined prices for services paid under the Clinical Laboratory Fee Schedule, the NLA serves as a ceiling rate, above which no MAC may pay in excess.

- *Not Otherwise Classified Codes (NOC):* Codes used to report an item or service for which no specific code exists. Sometimes referred to as "unlisted" or "miscellaneous" codes.

- *Test Panel:* A predetermined set of medical tests composed of individual laboratory tests, related by medical condition, specimen type, frequency ordered, methodology or types of components to aid in the diagnosis/treatment of disease.

1.4. Coverage for Clinical Laboratory Services under Medicare

Medicare provides coverage for items or services that:

- Fall within a defined Medicare benefit category
- Are not excluded from coverage by statute, regulation, National Coverage Determination (NCD), or Local Coverage Determination (LCD)
- Are determined to be reasonable and necessary for the treatment of illness or injury

Section 1833(a)(1) of the Social Security Act establishes coverage for "medical and other health services" under Medicare Part B. Section 1861(s)(3) of the Act defines "medical and other health services" as including "diagnostic laboratory tests".

The CMS may outline conditions and limitations in which an item or service may be covered by Medicare in a National Coverage Decision (NCD).

Section 1862(a)(1)(A) of the Act excludes from coverage any item or service which is not reasonable and necessary for the treatment of illness or injury or is a replacement for a missing or non-functioning body member. Reasonable and necessary limitations are administered through an LCD. An individual MAC may outline conditions and limitations in which an item or service may be covered by Medicare in a Local Coverage Determinations (LCDs). An LCD covers the MAC geographical jurisdiction and complies with Section 1862(a)(1)(A) of the Social Security Act (i.e., a

determination as to whether the item or service is reasonable and necessary).

Coding

Services (including clinical laboratory services) must be reported using the alpha-numeric HCPCS code (e.g., CPT code) that best describes the service. The AMA's CPT workgroup establishes CPT codes, which are grouped into series of related codes. CPT codes in the 80000 – 89999 series describe clinical laboratory services.

[4] Clinical laboratory services not described by a specific procedure code should be reported using a NOC (or unlisted) procedure code. Because NOC codes may potentially be used to report many different types of services, claims processing systems are not capable of automatically assigning service-specific pricing to NOC codes. As such, NOC claims require review of additional information in order to identify the service provided, determine coverage, and make a pricing determination.

Because the available language in the HCPCS and CPT manuals to describe the pathology and laboratory categories and the tests included in those categories are not specific to the actual test results provided, all MDT services must include an identifier as additional claim documentation. Test providers must apply for an identifier specific to the applicable test and submit the test assigned identifier on the claim for reimbursement. The assigned identifier will provide a crosswalk

between the test's associated detail information on file and the submitted claim detail line(s) required to adjudicate each test's claim the unique identifier limits the need to submit the required additional information about the test on each claim.

Laboratory providers who bill MDT services must obtain a test ID (as described in Chapter II).

[5] **CHAPTER II: COVERAGE**

2. Coverage Policy

As set forth in Palmetto GBA's "Molecular Diagnostic Tests (MDT)" LCD, Palmetto GBA provides coverage for MDTs and LDTs that are identified as covered in the LCD. Palmetto GBA may also develop and publish specific LCDs, and/or Palmetto GBA coverage articles as required. MDTs and LDTs not identified as covered in an NCD, LCD, or coverage article are not covered. Coverage for items or services that are outlined in the Medicare Benefit Category may be addressed in an NCD, LCD, or article. Items or services that are *not* considered a Medicare benefit may only be addressed in an article.

To obtain coverage for an established MDT or LDT, laboratories must apply for and obtain a unique test identifier. For newly developed tests or for established tests that have not been validated for clinical and analytical validity and clinical utility, labs/developers must submit a detailed dossier of clinical data to

substantiate that the test meets Medicare's requirements for coverage.

2.1. Unique Test Identifier

Labs must report LDTs and MDTs with the CPT and/or HCPCS code(s) that most accurately describes the specific test performed. Tests that are not described by a specific code require the use of an unlisted code. Although many of the MoPath codes were assigned descriptions, these descriptions do NOT identify a specific test. Therefore, MoPath codes must be processed in the same manner as an unlisted code and require additional documentation.

For this reason, the MolDX Program requires laboratories to obtain a test-specific identifier — a DEX Z-Code – that is unique to the laboratory's specific test (i.e., the unique test identifier establishes a link to the specific test performed). When reported in conjunction with the appropriate CPT/HCPCS code, the identifier allows payers to determine the exact test that has been performed, facilitating the process of making pricing and/or coverage determinations (subject to Palmetto GBA's analysis of the data supporting the use of the test).

Laboratories seeking coverage for the following types of tests must obtain a test ID:

- LDT or MDT reported using an unlisted code
- Test reported with a Tier 1 or Tier 2 CPT code

- FDA-approved version of an MDT test (if multiple, identical versions of the test are available, including tests that have not been approved by the FDA)
- All versions of a single test performed in multiple laboratories (to the extent that each laboratory performs the test differently)
- Modified version of an FDA-approved IVD

2.1.1. Registration

To submit claims on tests reported with the CPT/HCPCS codes in 1.2 of this manual, laboratories must register and receive a test ID. To access the online MolDX registry, laboratories should follow the following steps:

- For laboratory providers that have not registered a test for a DEX Z-Code:
- Go to the DEX TM Diagnostics Exchange: https://app.dexzcodes.com
    - Select 'Register My Organization' and follow the prompts to register your organization, including participation in the MolDX program

[6] • An email with a user name and a link for activating your account will be sent to you once McKesson activates your account. You will choose a password when you activate your username

- Once you've completed the registration of your organization, and activation of your

account you will have access to add test information

- For laboratory providers that currently have a DEX Z-Code™ assigned to a test:
    - Log into the Diagnostics Exchange using your existing username and password combination

This access enables the following functions:

- Review specific test information
- Review each DEX Z-Code™
- Request edits for tests
- Register new tests

2.1.2. Registration Review Timelines

Within 30 days of receiving a valid submission, the applicant will receive notice of one or more of the following:

- Additional information or clarification needed
- Assigned ID
- Suspension of claims pending technical assessment (TA) submission and favorable decision

2.2. Technical Assessment (TA)

MolDX only provides coverage for MDTs and LDTs that demonstrate analytical validity, clinical validity (AVCV), and clinical utility (CU). Non-validated tests must submit a comprehensive dossier of scientific information.

Laboratories that perform FDA-approved tests with *proven utility* and only perform the test within labeling indications may be exempt from TA.

The dossiers are reviewed by unbiased subject matter experts. Once a coverage determination has been established, the results will be published to the provider community An LCD may also be developed if the test requires administration of reasonable and necessary limitations.

Only tests assigned a test ID will be accepted for TA. During the review period of the TA, claims submission for the service should be suspended in order to avoid denial.

2.2.1. Clinical Dossier Requirements

To determine coverage, a TA is required for molecular assays that are laboratory developed tests (LDT), employ new or novel technology, or have undefined or unproven clinical utility. During the TA period, developers should suspend claims submission for the test service. TA submissions should be submitted to MolDX@palmettogba.com.

During the TA process, subject matter experts (SME) and the MolDX Team determine if an assay demonstrates clinical utility (CU) and fulfills the CMS "reasonable and necessary" criteria. In order to receive favorable review results, the assay must also meet analytical and clinical validity (AV/CV) standards. In addition to these three broad categories of evidence, CMS

has directed MolDX to follow the ACCE criteria developed by the Centers for Disease Control and Prevention. Reference (M00096)

[7] In order to reduce delays and unfavorable determinations, please ensure that the TA submission is complete. The table below lists all required elements. To ensure submission accuracy, reference the assigned identifier on all documents and in the subject line of email exchanges.

Executive Summary	Other	A concise summary with description of assay, intended patient population(s), and intended purpose
Technical Assessment (TA) Summary Form (M00116)	Other	Complete this form if assay is performed by all platforms except NGS.
Analytical Performance Specifications for Comprehensive	Other	Complete this form, in addition to M00116, if assay is performed using NGS technology
Clinical Utility Studies	Clinical Utility	All CU articles must be submitted as completed and published work. Abstracts and non-

		published studies are not accepted.
Analytical Performance Specifications for Quality Tumor-only Somatic Variant Detection Using Circulating Tumor DNA (M00135)	Other	Complete this form, in addition to M00116, if testing circulating tumor DNA (ctDNA)
Clinical Validity Studies	Clinical Validity	Submit all relevant data supporting CV.
Analytic Validity Materials	Analytical Validity	Submit all relevant AV data
Economic Value Studies	Economic Value	Submit relevant economic impact studies

Possible LCD coverage determinations:

- Full coverage; and pricing review initiated after LCD drafted
- Limited coverage
- Non-coverage – does not meet Medicare "reasonable and necessary" criteria-

2.3. Excluded Tests

Medicare is a defined benefit program. In order to be considered for Medicare coverage, an item or service must fall within a statutory benefit category. Although TOM 100-2, Ch. 15, Sec 10 identifies "Diagnostic X-Ray

tests, laboratory tests, and other diagnostic tests;" as a benefit category; Sec. 1862 (1)(A) Statutory Exclusion "except for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," must also be applied. In order to be paid under this benefit category, a diagnostic test must be ordered by a physician who is treating the beneficiary and the results used in the management of a beneficiary's specific medical problem.

Step 1 for test assessment: Does the test fall within a Medicare benefit category?

Although many molecular diagnostic tests may provide valid and useful information, they do not meet this definition. Based on the Medicare Benefit requirements, the following test types are examples of services that may not be considered a benefit (statutory excluded) and therefore would be denied as Medicare Excluded tests:

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law
- Tests that confirm a diagnosis or known information

[8]
- Tests to determine risk for developing a disease or condition
- Tests performed to measure the quality of a process
- Tests without diagnosis specific indications

- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial

2.3.1. Excluded Test Reconsiderations

This section applies to a specific gene that may include different tests from multiple labs. To reconsider a decision on a specific laboratory test, please follow the Technical Assessment Process covered in 2.2.

Although the Program Integrity Manual (PIM Chapter 13.11.E.2) does NOT allow reconsideration requests for NCDs, coverage provisions in interpretive manuals, draft, template or retired LCDs, individual claims, bulletins, articles, training material, and any instance in which an LCD doesn't exist, Palmetto GBA will continue to accept and consider requests on excluded genetic tests. The following reconsideration requirements have been modeled from the LCD reconsideration PIM language and will be used in support of this excluded service reconsideration process:

1. Requests shall be submitted in writing with all attachments (email or hardcopy), and shall identify the language the requestor wants added to or deleted from the Excluded Test determination. Requests shall include a justification supported by new evidence, which may materially affect the determination or basis. Copies of published evidence shall be included. The level of evidence required for SE reconsideration is the same as that required for new/revised LCD development. (PIM Chapter 13 Section 13.7.1)

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
    - Scientific data or research studies published in peer-reviewed medical journals;
    - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
    - Medical opinion derived from consultations with medical associations or other health care experts. Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community The broad range of available evidence must be considered, and its quality shall be evaluated before a conclusion is reached.

2. Any reconsideration request for an Excluded test determination that, in the judgment of the contractor, does not meet these criteria is invalid
3. Contractor will have the discretion to consolidate valid requests if similar requests are received

[9] ***2.3.2.*** Excluded Test Reconsideration Process

- Submit a valid Excluded Test Reconsideration request by one of the following methods:
    - **Email** (Preferred): MolDX@palmettogba.com
    - **Regular mail**:
      Palmetto GBA, Attn: MolDX
      17 Technology Circle, Mail Code AG-315
      Columbia, SC 29203
- Within 30 days of the request receipt date, Palmetto GBA will determine whether the request is valid or invalid
    - If invalid, Palmetto GBA will notify requestor of the reason for the invalid determination
    - If valid, Palmetto GBA will make one of the following decisions within 90 days of a valid request receipt date:
        - Continue to exclude coverage
        - Allow coverage and retire article, if applicable
        - Allow limited coverage through the LCD process

2.3.3. MolDX-Specific Exclusions from Coverage

The MolDX Program will also deny coverage for the following tests:

- Tests that have not been reviewed and approved through the MolDX process outlined in this document.

- Tests provided with dates of service prior to the effective date of an approval.

[10] CHAPTER III: PRICING AND CODING REQUIREMENTS

3. Pricing and Coding Under the MolDX Program

To determine the price for established tests, the data submitted with the MolDX application was reviewed. Tests were categorized into "like tests" using the CPT descriptions for each gene/allele/or gene component as outlined in the CPT. The submitted CPT stacking codes, used by CPT prior to 2012, were used to standardize the process for various labs. Each stack was reviewed for accuracy and labs contacted as needed for clarification. Once the correct stack had been validated, "like tests" were collected and compared. An example of "like tests" would be tests for full gene sequence of the APC gene. Whenever possible, the simple average of the like tests was used to calculate the MolDX price per test. As more "like" tests are added to the universe of tests, the average may be recalculated and submitted to CMS as requested.

For new MDTs and LDTs, the MolDX Program uses the 2011 stacking codes if applicable to establish a baseline for new tests consistent with values developed for established tests. Because of the unique nature of these tests, the MolDX Program considers a variety of factors, including but not limited to the following:

- Innovator tests, such as those performed by a single lab or offered by an in vitro diagnostic test kit manufacturer, have different cost structures because the innovator must develop the test and provide evidence of the clinical validity and utility of the test Innovator tests include, those tests performed using kits cleared by the FDA under a de novo 510(k) application or approved by the FDA under a Pre-Market Approval application as well as proprietary laboratory tests offered by a single laboratory.
- Economic Impact-In addition to considering the resources required to develop and furnish a test, the MolDX Program considers the value of the information provided by test in patient management decision making and in achieving improvement in health outcomes and the overall impact to all patient costs.

3.1. MolDX NOC Claims Pricing

To allow for varied values for an LDT and an innovator tests, the MolDX Program validates a lab only uses the FDA-approved for an unmodified FDA-approved test. Once validated, the MolDX Program instructs these specified labs to use a NOC code so the payer systems can identify and correctly price the FDA-approved test.

Since the fees are based on the ID and not the CPT reported code, the MolDX program can vary prices of "like tests." Palmetto GBA's MolDX edit processes all NOC codes according to tables by specific test identifier. This system is used to process MolDX claims

submitted with NOC codes and the identifier submitted on the claim (SV101-7 or SV202-7).

3.2. Pricing Tests Using NOC Codes

The MolDX Program considers the following factors to establish values reported with unlisted codes or for innovator tests:

- Laboratory charges and discounts from charges
- Allowed rates established by other payers for the same test including median or geometric mean rates on fully-adjudicated claims and/or median or geometric mean rates for contracted claims

[11] • Validated resources to furnish the test including the price of the kit, the cost of the kits and other supplies combined with clinical labor, equipment and overhead factors based on cost-per test

- Independent health care economic information supporting the value of the test in patient management and/or improvement of health outcomes

3.3. Additional MolDX Information

- All information regarding the MolDX Program may be reviewed from the MolDX website located at https://www.PalmettoGBA.com/Palmetto/MolDX.nsf/DocsCatHome/MolDx
- Select “Email Updates” to receive notifications of current updates to the program