FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE 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 D.C. No. 8:19-cv-00074-DOC-JDE OPINION

Appeal from the United States District Court
for the Central District of California
David O. Carter, District Judge, Presiding
Argued and Submitted January 15, 2021
Pasadena, California

Filed July 16, 2021

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

Opinion by Judge Friedland;
Dissent by Judge Block

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

SUMMARY[**]

Medicare

The panel reversed the district court's summary judgment in favor of Agendia, Inc. in its action alleging that the Secretary of Health and Human Services ("HHS") wrongfully denied its claims for reimbursement for diagnostic tests under the Medicare health insurance program.

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. 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. Agendia's claims for reimbursement were denied based on a local coverage determination.

Agendia argued that the denial of reimbursement was improper because it was issued without notice and opportunity for comment. The panel held that the Medicare Act's notice-and-comment provision – 42 U.S.C. § 1395hh – did not apply to local coverage determinations because such determinations did not establish or change a substantive legal standard, and the district court erred in interpreting the statute otherwise. A local coverage determination is

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

therefore valid without undergoing the § 1395hh notice-and-comment process.

Agendia also argued that the Medicare Act and its implementing regulations unconstitutionally delegated regulatory authority to Medicare contractors by permitting them to issue local coverage determinations. The panel held that, because those contractors acted subordinately to the HHS officials implementing Medicare, there was no unconstitutional delegation.

District Judge Block dissented from Part III.A of the majority opinion, which addressed Agendia's statutory claims, and from the reversal of the district court's grant of summary judgment to Agendia. He would hold that the "structure" of the Medicare statute was ambiguous and did not clearly support the majority's conclusion. Judge Block joined in Part III.B of the majority's opinion, which rejected Agendia's constitutional, non-delegation argument.

COUNSEL

Stephanie R. Marcus (argued) and Michael S. Raab, Appellate Staff; Nicola T. Hanna, United States Attorney; Ethan P. Davis, Acting Assistant Attorney General; Civil Division, United States Department of Justice, Washington, D.C.; for Defendant-Appellant/Cross-Appellee.

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

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 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 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 independent 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.

[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).

§§ 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 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]

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

[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

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, 625 (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

"arguments on cross-appeal as alternative arguments to affirm the judgment").

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.

[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).

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 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

[5] Citing various dictionaries, our dissenting colleague contends that the word "change" can also mean "to make different in some particular." Dissent at 22. 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 (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 (2000))).[6]

[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 (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.

Agendia's arguments to the contrary are not persuasive. First, Agendia asserts that the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (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

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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 28–29. 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 (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 (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.

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 (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

[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

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 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. 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

(requiring MACs to follow certain procedures when issuing local coverage determinations).

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

[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.).

Agendia's tests, the ALJ's determination that they were "reasonable and necessary"—which was supported by a detailed analysis of 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*), 139 S. Ct. 1804, 1812 (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*, 138 S. Ct. 2067, 2070–71 (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]

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

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

Secretary by regulation."[3] This language establishes only one exception—for NCDs—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

[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 (2d 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)).

§ 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*, 138 S. Ct. 1612, 1631 (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, with growing frequency, are being transmitted, if at all, through manual instructions and other

[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.

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

[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/Medicare-Contracting/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 in the area served by the contractor [i.e. LCDs]" in their own 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

persuasive reading is that 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 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

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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.

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 (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 (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 (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

In sum, I reject the majority's "structural" analysis because it is not grounded in the text of the Medicare Act or

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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 (2013) (internal quotations and citations omitted); *Johnson*, 529 U.S. at 58. And of course, the majority offers no competing account of the "legislative intent" behind § 1395hh(a)(2).

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 (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.

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 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

[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."

"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.