No. _____

In The
Supreme Court of the United States

AGENDIA, INC.,

Petitioner,

v.

XAVIER BECERRA,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019) ("*Allina*"), this Court confirmed that the Department of Health and Human Services ("HHS") must use notice-and-comment rulemaking to promulgate rules, requirements, or statements of policy that "establish[] or change[]" a "substantive legal standard" governing the scope of benefits and payment for services under the Medicare Act, 42 U.S.C. § 1395hh(a)(2). *See* 42 U.S.C. § 1395hh(b)(1).

In the instant case, an HHS private contractor established a Medicare "coverage policy," known as a Local Coverage Determination ("LCD"). The LCD was not promulgated as a regulation under 42 U.S.C. § 1395hh(a)(2). The Court of Appeals' majority decided that "1395hh's notice-and-comment requirement does not apply to" LCDs. The dissent disagreed, characterizing the majority's opinion as a "missed opportunity" and urged that "[p]erhaps the Supreme Court may now decide to address th[e] important and unresolved issue" presented by this case.

The two questions presented for review are therefore:

Whether the rulemaking requirements of 42 U.S.C. § 1395hh(a)(2) apply to a Medicare policy deeming all molecular diagnostic laboratory tests "investigational" and thus not covered by Medicare because it was issued by a Medicare Administrative Contractor ("MAC") as an LCD.

QUESTIONS PRESENTED – Continued

Whether Congress' delegation of policy-making authority to a MAC, a non-governmental entity, to establish LCDs is permissible because HHS adjudicators are not absolutely bound by LCDs even though they must give LCDs "substantial deference," as the final agency decision maker did in this case.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, petitioner Agendia, Inc. ("Agendia") states it is not a publicly owned corporation and no publicly owned company owns more than ten percent of its stock.

RELATED CASES

Agendia knows of no pending proceedings in any state or federal court that is directly related to the instant case.

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

PETITION FOR WRIT OF CERTIORARI

Petitioner respectfully seeks a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The opinion of the Court of Appeals (Petitioner's Appendix ("App.") 1-33) is reported at 4 F.4th 896 (9th Cir. 2021). The opinion of the District Court (App. 34-59) is reported at 420 F. Supp. 3d 985 (C.D. Cal. 2019). The decision of the HHS Medicare Appeals Council (App. 60-84) is unreported.

JURISDICTION

The judgment of the Court of Appeals was entered on July 16, 2021. A petition for rehearing en banc was denied on September 2, 2021. App. 85-86. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS

The relevant statutory and regulatory provisions are reproduced in the appendix to this petition. App. 87-104.

STATEMENT OF THE CASE

A. The Relevant Medicare Principles

This case involves the notice-and-comment rulemaking requirements that HHS must follow under the Medicare Act, 42 U.S.C. § 1395hh (App. 87-94), as well as the authority of Congress to delegate and HHS to "sub-delegate" regulatory authority to MACs to establish Medicare policies and rules governing the scope of, and payment for, Medicare covered services.

Medicare Part B provides payment for the costs of physician services, medical supplies, diagnostic tests, and related services. 42 U.S.C. § 1395j-1395x. Clinical Laboratory services are covered and paid for as diagnostic tests under 42 U.S.C. § 1395*l*(h)(5); App. 97-99.

HHS characterizes molecular diagnostic tests, like those furnished by Agendia in this matter, as "advanced diagnostic laboratory" tests, meaning they are offered or furnished only by a single laboratory and are not sold for use by a laboratory other than the original developing laboratory. Such testing is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result. 42 U.S.C. § 1395m-1(d)(5); App. 99-100.

Medicare covers expenses of clinical laboratory services and other Part B items and services if they are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A); App. 101.

HHS has issued regulations to implement this "reasonable and necessary" standard, including 42 C.F.R. § 410.32(a) for clinical laboratory services, which limits reasonable and necessary clinical laboratory services to those that are ordered by a beneficiary's treating or consulting physician. App. 102-103.

Under 42 U.S.C. § 1395kk-1(a)(1) and (4) (App. 94-97), Congress authorizes HHS to enter into contracts with private entities, MACs, to perform various payment functions for services furnished to Medicare beneficiaries enrolled in Part B. One such function is "developing local coverage determinations," as defined in 42 U.S.C. § 1395ff(f)(2)(B). App. 87. This latter provision defines an LCD as a determination by a MAC (formerly known as fiscal intermediary or a carrier) "respecting whether or not a particular item or service is covered" by Medicare on a contractor-wide basis.

For clinical diagnostic laboratory services, Congress has authorized HHS to choose one or more (not to exceed four) MACs "to establish coverage policies" beginning in January 1, 2015. 42 U.S.C. § 1395m-1(g)(2); *Id.* 100.

In December 2016, well after the LCD at issue in this case was established, Congress authorized a new and separate LCD review process codified at 42 U.S.C. § 1395y(*l*)(5)(D). App. 102. This new process is applicable prospectively only. In fact, the new statute is not self-executing. Thus, HHS has issued guidelines as part of the Medicare Program Integrity Manual to implement the new process that became effective

February 12, 2019. Medicare Program Integrity Manual ("Program Integrity Manual"): Chapter 13-Local Coverage Determinations (Rev. 863, 02-12-19), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

Under the new LCD process, MACs continue to have full policy-making authority for LCDs. While MACs must establish "Contactor Advisory Committees" ("CACs") to provide a formal mechanism for healthcare professionals to be informed of evidence used in developing LCDs, the CACs are "advisory only . . . the final decision on all issues resting with the MACs." Program Integrity Manual at § 13.2.4.3. As under the former *ad hoc* process, MACs "shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under [42 U.S.C. § 1395y(a)(1)(A)]." Program Integrity Manual section at § 13.5.4.

B. The Medicare Part B Claims Appeals Process

Congress has authorized a Medicare administrative appeal process for clinical laboratories and other Medicare providers and suppliers to challenge the denial of payment for Medicare claims by MACs. The first step is to request redetermination with the MAC which denied the claim. The second step is to request reconsideration of the denied claim with another MAC, known as a Quality Improvement Contractor. The third step is to request a hearing before an HHS Administrative Law Judge ("ALJ"). And, the fourth and

final step is an appeal of an adverse ALJ decision to the HHS Medicare Appeals Council. 42 U.S.C. § 1395ff(a) and (b); 42 C.F.R. §§ 405.901–405.1134.

In 2005, HHS amended its administrative appeal regulations for denied Medicare claims to require the Quality Improvement Contractors, HHS ALJs, and the HHS Medicare Appeals Council to give "substantial deference" to a relevant local coverage determination, and, if they decline to apply that determination, they must explain their reasons for doing so. Additionally, the agency adjudicators may not set aside or review the validity of an LCD in a claims appeal. 42 C.F.R. § 405.1062.[1]

Only after a Medicare provider/supplier exhausts its administrative appeals may it seek judicial review of the final HHS agency decision in federal district court pursuant to 42 U.S.C. § 1395ff(b)(1)(A); 42 U.S.C. § 405(g).

C. The LCD at Issue

In 2011, Palmetto GBA, a MAC located in South Carolina, developed and issued LCD L32288, entitled "Molecular Diagnostic Tests." App. 105-112. By its own

[1] A separate administrative appeal process is available to Medicare beneficiaries, only, to challenge an LCD. The providers and suppliers of the services, such as Agendia, lack standing to assert their rights under this process. 42 C.F.R. § 426.100. Thus, Agendia must file appeals of each denied claim through the claims appeals process and challenge the application, rather than the validity, of LCD 32288 and its successors to each claim. Agendia has fourteen such administrative appeals pending.

terms, LCD L32288, constitutes a Medicare "coverage policy" containing "payment rules" for molecular diagnostic tests. App. 107, 111-112.

This coverage policy "defines the payment rules" applied to covered tests that are not reported with specific CPT codes and lists specific covered molecular diagnostic tests that have completed the process designated by Palmetto as meeting Medicare's reasonable and necessary criteria for coverage. *Id.* 107, 112. One such payment rule, the one at issue here, is that tests "that have NOT been approved through the process outlined in this policy will be considered investigational and therefore denied as not a covered service." *Id.* 110-111.

Palmetto calls its process for approving molecular diagnostic testing "MolDX." In August 2013, Palmetto published a MolDX manual, which sets forth the coverage, coding and pricing "Standards and Requirements" for its process. App. 113-138. The process is now used in thirty-one different States and territories. *Id.* 117-118.

D. Agendia's Administrative Appeal

During the period at issue, 2012-2013, Agendia furnished three different molecular diagnostic tests to patients whose doctors ordered such testing for the diagnoses and ongoing treatment of breast cancer. One of its tests, MammaPrint, had been covered and paid for by Medicare since November 2009. *Id.* 112. However, its other two tests, TargetPrint and BluePrint

have not been approved by Palmetto and were thus deemed investigational by Palmetto pursuant to LCD L32288 and the MolDX program.

Nevertheless, physicians across the Country ordered such testing for their breast cancer patients in 2012-2013, including the 86 Medicare beneficiaries who received the testing at issue. To preserve its appeal rights, Agendia submitted bills to Palmetto, its MAC, knowing that Palmetto would deny payment pursuant to LCD L32288. *Id*. 60-62.

Palmetto did, in fact, deny payment for all the TargetPrint and BluePrint testing performed on behalf of the 86 beneficiaries pursuant to LCD L32288 and upheld that denial on redetermination. *Id*. 62. Agendia timely requested reconsideration with a different private contractor, which upheld the payment denial pursuant to LCD L32288. *Id*. 63-64.

Agendia timely requested a hearing before an HHS ALJ, which, through no fault of Agendia, did not take place until several years after Agendia filed its request for a hearing. Based on undisputed expert testimony, the ALJ found that the "genetic testing provided to the beneficiaries in these cases were medically reasonable and necessary." App. 65. Specifically, the ALJ concluded that "molecular subtyping of early stage breast cancer is more accurate and helpful in selecting treatment options than conventional subtyping." The testing was "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." Based on the record of the hearing, the ALJ found "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." *Id*. 65-68.

On its own motion, the Medicare Appeals Council chose to review the ALJ's decision. After recounting the record of the previous administrative steps, the Appeals Council held that the ALJ erred as a matter of law by not deferring to the LCD and the MolDX program. The Appeals Council found "no reason to not apply substantial deference" to the LCD or to question the MolDX program's findings. The Appeals Council concluded that the ALJ's departure from the LCD was a result of the ALJ's "misapplication and misunderstanding of the MolDX program." *Id.* 80.

E. The District Court Decision

Agendia sought judicial review of the Medicare Appeals Council's decision on various grounds, including its reliance on and deference to LCD L32288. Agendia contended that LCD L32288 was unenforceable because it had not been enacted pursuant to the notice-and-comment rulemaking requirements of Section 1395hh, and that the LCD was invalid because it was the product of an unlawful delegation of regulatory policy making by Congress.

The District Court rejected the delegation argument because HHS has sufficient authority and surveillance over the MAC's activities, which provide sufficient independent check on the MACs through the claims appeals process. App. 42-49.

However, the District Court found that although the LCD interpreted the reasonable and necessary standard, it is nevertheless a "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard" that governs Medicare payment for services. App. 56. And, because it was not enacted as a regulation, the Court concluded it was unenforceable. *Id.* 53-58.

F. The Court of Appeals' Opinion

The Ninth Circuit's opinion was unanimous on rejecting Agendia's delegation challenge, concluding that MACs act subordinately to HHS officials. However, the appellate panel split on the Section 1395hh notice-and-comment rulemaking issue.

On the latter issue, the majority concluded that the LCD was not subject to Section 1395hh because the LCD does not "establish[] or change[] a substantive legal standard." The Court held that only one legal standard is applicable here and that is the statutory standard of "reasonable and necessary." Relying on its decision in *Erringer v. Thompson*, 371 F.3d 625, 631 (9th Cir. 2004), a decision that did not involve Section 1395hh, the majority pointed out that if the LCD did not exist, the MACs would have "an overarching duty

to deny claims for items and services that are not 'reasonable and necessary.' " App. 10.

The majority characterized the LCD as "one contractor's attempt to apply the reasonable and necessary standard to a given item or service." And, the majority added that the "application of a statutory standard does not – and could not – make the relevant standard different in any way." *Id*. 10, footnote 5.

After emphasizing that HHS did not make the argument in *Allina* that the statute, itself, contained the controlling standard and therefore nothing the agency did could alter that standard, the majority concluded that HHS did make this argument in this case and it "carries the day." *Id*. 13-14.

Judge Block dissented. He reasoned that 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." As support for this interpretation of Section 1395hh, Judge Block cited this Court's opinion in *Allina*, 139 S. Ct. at 1812. *Id*. 19-20. He pointed out that if there had been no LCD, the ALJ's determination that the tests were "reasonable and necessary," which was "supported by a detailed analysis," might well have been upheld and "at least have been evaluated on its merits by the Medicare Appeals Council." *Id*. 18-19. He further noted that "LCDs can 'change' the underlying standard without

supplanting it," thus requiring them to be enacted as regulations under Section 1395hh. *Id*. 24, footnote 2.

After refuting each of the majority's arguments, Judge Block concluded that he "define[d] 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." In doing so, he relies on the plain language of Section 1395hh and its legislative history as well as this Court's reasoning in *Allina*. *Id*. 32-33.

Judge Block ends his dissent by characterizing the majority's opinion as "an overly narrow semantic argument and a 'structural' analysis that ignores the text and history of the statute it claims to interpret" to the detriment of "companies like Agendia and ultimately, on Medicare beneficiaries." *Id*. 33.

REASONS FOR GRANTING THE PETITION

A. The Panel Majority's Opinion Impacts All LCDs.

Although Agendia reminded the Court in its opening brief (Ninth Circuit Dkt. Entry 19, page 9 of 62) and at oral argument that this case involved a single LCD, the panel majority broadly held that "1395hh's notice-and-comment requirement does not apply to local coverage determinations." *Id*. 3.

In reaching this conclusion, the panel majority not only ignores the outsized importance of LCD L32288 and its successors, it also incorrectly minimizes the widespread effect of LCDs in general by characterizing them as "help[ing] adjudicators apply the reasonable and necessary standard to the facts of a claim. . . . " *Id*. 14. And, the panel majority has little concern about the fact that the LCDs are binding on MACs when they decide whether to pay a claim in the first place, and at the first stage of the appeal process. The panel majority also suggests that Congress has been adding procedural requirements to protect suppliers, providers and beneficiaries since imposing a new consultation requirement for LCDs in 2003. *Id*. 11-12, footnote 6.

The reality, however, is very different. Most Medicare claims denials are **not** appealed through the claims appeal process. Therefore, millions of Medicare claims that are denied by the MACs do not proceed beyond the initial determination stage. For example, in 2007, of the 186 million Medicare claims furnished by hospitals, skilled nursing facilities, home health agencies and other providers processed by MACs and Fiscal Intermediaries ("FIs"), 14.5 million were denied and 240,000 were appealed to the first level of appeal. This means that more than 14 million denials in 2007 were not appealed. *See* CMS Fact Sheet: Original Medicare (Fee-For-Service) Appeals Data – 2007, https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/downloads/appealsfactsheet2008.pdf. And, these figures do not include claims that are not even submitted for payment by providers/suppliers who fear being

subjected to False Claims Act liability if they submit a claim for a service that is disallowed by an LCD.

Moreover, in January 2014, more than ten years after Congress directed HHS to develop a plan to evaluate which LCDs should be adopted nationally, the HHS Office of Inspector General ("OIG") issued a report criticizing the lack of consistency among LCDs and found that HHS had not yet developed a plan for evaluating LCDs that should be adopted nationally. *See* Local Coverage Determinations Created Inconsistency In Medicare Coverage, DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL (Jan. 2014), https://oig.hhs.gov/oei-01-11-00500.pdf, at page 13. Agendia has found no evidence showing that HHS has developed such a plan.

In this same report, at page 10, the OIG called out the practices of those MACs that issue LCDs imposing "blanket" denials of Medicare coverage for new technology deeming all such new technology to be "experimental." This is precisely the policy Palmetto GBA adopted for molecular diagnostic testing in LCD L32288 and the MolDX program.

B. The Continuing Impact of Pre-2019 LCDs.

The impact of the Ninth Circuit's decision continues indefinitely. As indicated above, while Congress now requires MACs to abide by a new process for establishing LCDs (*see* 21st Century Cures Act, Pub. L. No. 114-255 § 4009, 130 Stat. 1033, 1185, codified at 42 U.S.C. § 1395y(*l*)(5)(D)), the new procedure became

effective February 12, 2019, and is not retroactive. It is thus not applicable to LCD L32288 or its successors and the many other LCDs issued prior to February 12, 2019. *See Program Integrity Manual*, Chapter 13 – Local Coverage Determinations.

Because LCDs are only effective prospectively – they only apply to services and items furnished after the effective date of the LCDs, these pre-2019 LCDs will have long lasting impact on Medicare providers, suppliers and beneficiaries. And, because of the enormous backlog of Medicare claims appeals (*see H. Babaali, M.D., Medical Inc. v. Azar*, 798 Fed. Appx. 56, 58 (9th Cir. 2019)), the issue of the enforceability of such LCDs remains a very important ongoing issue for Agendia and others.[2]

Moreover, LCDs not only affect Medicare claims processing and administrative appeals, they are also being used as standards to determine falseness and materiality in False Claims Act (31 U.S.C. § 3729 *et seq.*) cases, as the panel majority recognized, citing *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1213 (9th Cir. 2019). The panel majority, however, brushed aside the impact of this development, concluding that this fact "does not demonstrate that [HHS] lacks

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[2] Indeed, Agendia currently has fourteen other administrative appeals pending involving the same issues raised here involving more than one thousand beneficiaries. *See* ALJ Nos. 1-2812694169; 1-2621162021; 1-1729677740; 1-280637309; 1-2899285920; 1-2643188292R1; 1-3148028764; 3-2912323743; 3-378733338R1; 3-3935618441; 3-4029908451;3-3250079314; 3-3165747142; and 3-3488262674.

control over the MACs issuing and applying" LCDs. App. 17.[3]

C. The Ninth Circuit's Interpretation of Section 1395hh Differs from the D.C. Circuit's Interpretation.

As Judge Block states in his dissenting opinion (App. 19), the majority opinion in the case insists that LCDs, including L32288, do not establish nor change a substantive legal standard because they merely "guide" and do not replace the "reasonable and necessary" standard for determining Medicare coverage and payment for items and services.

In addition to characterizing this holding as elevating form over substance, Judge Block (App. 19) contends the interpretation is different from that applied by then Judge Kavanaugh in *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017) ("*Price*"). Judge

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[3] The panel majority did not address other cases involving this issue, including *United States v. Anesthesia Services Associates*, No. 16-cv-0549, 2019 WL 7372510, at *14-*16 (M.D. Tenn. Dec. 31, 2019), where the court discusses the impact of a 2015 LCD affecting coverage of laboratory testing, and concludes that it "agrees with those courts that have found violation of an LCD may give rise to" FCA liability. *See also United States ex rel. Gray v. Mitias Orthopaedics, PLLC*, No. 3:15-CV-000127, 2021 WL 79615, at *13 (N.D. Miss. Jan. 11, 2021). Nor did the panel majority discuss the False Claims Act lawsuit filed by Elaine Jeter, M.D., the Former Pametto GBA Medical Director who established LCD 32288 and the MolDX program, in *United States ex rel. Jeter v. Myriad Genetics, Inc.*, No. 3:17-cv-02945 (D. S.C. 2017), which was based on the alleged violations of a version of LCD L32288. Ninth Circuit Dkt. Entry 20, pages 11-37.

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." Here, Judge Block pointed out that LCDs are binding at the initial stage of the Medicare Claim adjudication and can compel the reversal of an ALJ's decision, which was the case here.

Significantly, in *Price*, the policy decision under review was to include Medicare Part C days in the 2012 Medicare fractions used by the Medicare Part A MACs to calculate hospitals' disproportionate share payments. 863 F.3d at 942. Because that decision was binding on the Part A MACs (previously known as fiscal intermediaries, 42 U.S.C. § 1395kk-1), the Court considered the decision to be a "requirement" of the Medicare program. *Price*, 863 F.3d at 943. The requirement thus was required to be enacted as a regulation under Section 1395hh. It did not matter that the requirement was not binding on HHS. This same reasoning is applicable here, yet the majority did not apply it.

Just as the requirement to include Part C days in the relevant Medicare fractions in *Price* defined and regulated the rights of the parties, LCDs "define and regulate the rights" of parties even if they also "guide" the application of a statutory standard. Indeed, they "establish" a standard at the initial stage of agency review and "change" the standard applied at the subsequent stages of the agency appeal process. 863 F.3d at 943. Thus, under the D.C. Circuit's interpretation of Section 1395hh, it is reasonable to assume that the

LCD at issue here would have been required to have been issued as a regulation under Section 1395hh.[4]

Finally, the fact that an LCD cannot change a statutory standard by replacing it does not mean an LCD cannot affect the outcome of an agency adjudication. Indeed, this is exactly what happened in this case. The Medicare Appeals Council reversed a favorable ALJ decision solely because the ALJ did not give substantial deference to LCD L32288, as Judge Block stresses. App. 18-19.[5]

D. The Ninth Circuit's Majority Opinion Extends This Court's Holding in *Allina* Well Beyond Any Reasonable Limit on the Scope of 1395hh.

The panel majority correctly states that this Court explicitly left open another line of argument HHS could have made in *Allina*: that the policy at issue did not establish or change a substantive legal standard because the statute, itself, provided the substantive standard. And, the majority proceeds to conclude that this argument "carries the day" in the instant case

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[4] It is also worth noting that Congress uses the word "establish" coverage policies when describing MACs responsibilities with respect to developing Medicare coverage policies for LCDs affecting clinical laboratory diagnostic tests as of January 1, 2015.

[5] The holding that a policy must "replace" a statutory standard to constitute a change under Section 1395hh cannot be correct. Only Congress can replace a statutory standard. An agency's attempt to do so would likely be considered *ultra vires* and thus void. 5 U.S.C. § 706(2)(A)(C).

because LCDs help adjudicators apply the "reasonable and necessary standard." App. 13-14.

As Judge Block remarked – this conclusion by the majority of the panel actually "missed an opportunity" to define the phrase "change a substantive standard" in a "realistic manner." App. 33. While there certainly are situations in which agencies (or private contractors) provide guidance that actually mirrors the specific criteria expressed by Congress in a statute, this is not one such situation.

Indeed, the "reasonable and necessary" standard of the statute at issue, 42 U.S.C. § 1395y(a)(1)(A), is a classic example of a statute by which Congress intends to furnish an intelligible principle to guide a government agency in enacting regulations to fill in the gaps in such a broadly worded statutory phrase. Unfortunately, here, Congress delegated that gap filling task to MACs. As this situation shows, the private contractor, Palmetto GBA, took advantage of this opportunity to establish a policy that no molecular diagnostic tests will be approved for Medicare coverage and payment until Palmetto GBA approves the tests in an assessment process also established by Palmetto known as the MolDX program. And, this requirement is binding on the first level of adjudicators.

Nothing in the "reasonable and necessary" standard of the statute, itself, addresses specific types of services, including clinical laboratory standards. Yet, HHS contends, and the majority panel held, that Palmetto GBA and the other MACs which have

incorporated the provisions of LCD L32288 and the MolDX program, are simply mirroring the "reasonable and necessary" standard.

The fact that government adjudicators must give LCDs "substantial deference" makes LCD L32288 even more impactful and provides more reason to conclude that it should have been subjected to Section 1395hh's notice-and-comment requirement. As Justice Gorsuch said in his concurring opinion in *Kisor v. Wilkie*, 139 S. Ct. 2400, 2425, 2434-2440 (2019), affording this level of deference even to government agencies policies has been criticized recently by a "legion of academics, lower court judges, and Members of [the Supreme Court]" as being undeserved and constituting an intrusion on the doctrine of separation of powers even when a government agency is interpreting a duly promulgated regulation. Yet, here, the panel majority allows a private contractor to enact a policy which is afforded substantial deference by agency adjudicators even though it was not promulgated as a regulation.

E. Whether Congress Has Impermissibly Delegated Regulatory Authority to MACs Is an Important Question of Federal Law that Has Not Been but Should Be Settled by This Court.

Congress has expressly delegated to MACs the authority to establish LCDs under 42 U.S.C. § 1395kk-1(a)(1) and (a)(4). And, as stressed above, in 2005, HHS issued a regulation, 42 C.F.R. § 405.1062, that requires

government adjudicators to give "substantial deference" to LCDs in the claim appeal process. And, in this case, Medicare Appeals Council reversed the favorable decision of the ALJ for failing to give deference to LCD L32288.

Congress has continued to delegate Medicare policy making to MACs for LCDs as of January 1, 2015. As discussed above, for clinical diagnostic laboratory tests, Congress authorizes HHS to designate one or more (not to exceed four) MACs to "establish coverage policies" effective January 1, 2015. 42 U.S.C. § 1395m-1(g)(2).

The Ninth Circuit found this delegation of policy making authority to MACs to be valid because the MACs "function subordinately" to HHS. And, according to *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 399 (1940), this fact saves the delegation from being unconstitutional. App. 15.

Agendia is aware of the precedent supporting the Ninth Circuit's conclusion and is aware of HHS' need for private contractors to help administer the massive Medicare program. However, even with the complexities of the Medicare program, an important distinction exists between ministerial and discretionary policy-making responsibilities.

For example, HHS' use of contractors to audit payments made to providers/suppliers involves ministerial responsibilities, which Congress may delegate to MACs. *See Gentiva Healthcare Corp. v. Sebelius*, 723 F.3d 292, 296 (D.C. Cir. 2013) ("*Gentiva*") (distinguishing

between delegations of regulatory authority to private contractors, and delegations to private contractors to help a government agency make its regulatory decisions). *Gentiva* did not involve LCDs. However, four years earlier, in a concurring opinion in *Hays v. Sebelius*, 589 F.3d 1279, 1283 (D.C. Cir. 2009), a case that did involve LCDs, Judge Randolph expressly questioned whether Congress could delegate to private contractors "lawmaking functions" – specifically, the power to make coverage policies through the issuance of LCDs.

And, three weeks before *Gentiva* was published, the D.C. Circuit issued *Ass'n of Am. R.R. v. United States DOT*, 721 F.3d 666, 668 (D.C. Cir. 2013), in which the Court concluded that Section 207 of the Passenger Rail Investment and Improvement Act of 2008 constituted an unlawful delegation of regulatory power to a private entity.

Among other important principles, the D.C. Circuit Court of Appeals confirmed that Congress cannot delegate regulatory authority to a private entity and that to do so, according to this Court, is "legislative delegation in its most obnoxious form (citation omitted)." The Court of Appeals added that "[e]ven an intelligible principle cannot rescue a statute empowering private parties to wield regulatory authority." *Id.* at 670-671.

In another case, the D.C. Court of Appeals ultimately decided that the private entity, Amtrak, had too much involvement in the administrative process to

satisfy the Constitution. This Court granted review, but did not decide the delegation issue, because it concluded that Amtrak was a governmental entity and not a private entity. *See Dep't of Transp. v. Ass'n of Am. R.R.s*, 135 S. Ct. 1225, 1242 (2015). Yet, in concurring with the Court's judgment, Justice Alito admonished that "[w]hen it comes to [a legislative delegation to] private entities, however, there is not even a fig leaf of constitutional justification." *Id*. at 1237 (Alito, J., concurring).

More recently, the Fifth Circuit reversed a district court decision that had found the certification rule of the Affordable Care Act to be invalid due to an unlawful delegation of legislative authority. *State v. Rettig*, 987 F.3d 518, 531-532 (5th Cir. 2021). Basically, the Fifth Circuit decided that the private actuary furnished HHS with necessary "input" for fulfilling its obligations under the ACA.

The Fifth Circuit denied a petition for a rehearing en banc. However, five of the Court's judges dissented from the denial of rehearing en banc. The dissenters pointed out that the case involved a double delegation – a delegation from Congress to HHS and HHS' delegation to a private entity. They objected to such delegation as lacking any precedential support and characterized it as lawmaking being "exercised by private interests colluding with agency bureaucrats." *Texas v. Rettig*, 993 F.3d 408, 410 (5th Cir. 2021).

Respectfully, Agendia contends that a similar double delegation has occurred here. Congress delegated

to MACs the authority to establish LCDs, and HHS effectively "subdelegated" additional authority to the MACs by enacting a regulation requiring government adjudicators to give the LCDs "substantial deference." The instant case shows the impact of this scheme. Congress gave the MAC authority to establish LCD L32288, and HHS, in turn, delegated additional authority to the MAC by requiring even government adjudicators to give the LCD "substantial deference." When the ALJ did not do so, the Medicare Appeals Council reversed her decision.

The situation here is very different from an agency using a private party to obtain input for agency's policy and decision making. Here, the private party is establishing the policy to be applied and the government agency must substantially defer to that policy – meaning that absent compelling reasons for not doing so, the LCD policy must be applied. In reality, HHS may give the MACs input but the MACs, and not the agency, make the policy.

CONCLUSION

Based on the foregoing, Agendia respectfully requests the Court to grant this petition.

Respectfully submitted,

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