No. 21-584

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

PETITIONER'S BRIEF IN REPLY TO OPPOSITION BRIEF

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I. INTRODUCTION

In *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1812 (2019) ("*Allina*"), this Court confirmed that "[a]gencies have never been able to avoid notice and comment simply by mislabeling their substantive pronouncements." Instead, "courts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*, when deciding whether notice-and-comment demands apply." *See also Mt. Diablo Hosp. Dist. v. Bowen*, 860 F. 2d 951, 956 (9th Cir. 1988) (In determining the procedural validity of a Medicare manual provision, the "label an agency gives to a particular statement of policy is not dispositive" and instead the "court must inquire into the substance and effect of the policy pronouncement.").

Here, the Ninth Circuit's majority opinion mechanically accepted the label given the policy statement at issue. The policy statement pronounces that all molecular diagnostic laboratory tests are "investigational" and therefore not covered by Medicare until and unless Palmetto, GBA, a private Medicare Administrative Contractor ("MAC"), holds otherwise. And, unlike the typical administrative law case, here the government agency responsible for administering the Medicare program, the Centers for Medicare & Medicaid Services ("CMS"), neither established nor labeled the policy. Rather, the MAC established the policy and labeled it a Local Coverage Determination ("LCD").

Instead of analyzing the contents and effects of the specific LCD at issue, L32288, the Ninth Circuit's majority issued a sweeping decision holding that **no** LCD is, or ever has been, subject to the notice-and-comment rulemaking requirements of 42 U.S.C. § 1395hh. Despite a strong dissenting opinion by Judge Block, the Secretary fully embraces the majority opinion in its Opposition Brief. In fact, like the Ninth Circuit majority, the Secretary insists that no policy statement labeled as an LCD by a MAC can ever establish or change a legal standard for Medicare coverage, because the legal standard of "reasonable and necessary" has already been established by the controlling Medicare statute, 42 U.S.C. § 1395y(a)(1)(A).

In so holding, the Secretary disregards the fact that this same conclusion could be made about virtually any Medicare sub-regulatory policy. The detailed and voluminous provisions of the Medicare statutes set forth numerous legal standards, which serve as "intelligible standards" but nevertheless contemplate implementation through "gap-filling" regulatory policy making. *Allina*, 139 S. Ct. 1817. These gap-filling Medicare policy pronouncements must be promulgated by CMS through notice-and-comment rulemaking under Section 1395hh. They may not be established by private contractors through veiled placement on a list of Medicare LCDs.

Indeed, the fact that Congress has delegated to MACs, private non-governmental entities, the authority to establish Medicare coverage and payment policy in the first place is offensive to the Constitution. And,

it should not matter that the policy is not "absolutely binding" on the Secretary's government adjudicators because Medicare agency adjudicators are required in all instances to give LCDs "substantial deference." As this case illustrates – where an agency adjudicator does not do so, her decision will be reversed by the final agency adjudicator.

If the Ninth Circuit's overly broad decision is not reversed, MACs can thus establish or change legal standards for Medicare coverage on an *ad hoc* basis simply by labeling the new standards as LCDs, as the MAC did here.

II. *ALLINA* IS IMPLICATED BY THE MAJORITY OPINION HERE

In his opposition, the Secretary insists that *Allina* is not "implicate[d]" in this case, because in *Allina* this Court expressly reserved judgment on the issue presented. Opposition, page 25. And, the Secretary argues further that the Ninth Circuit's majority opinion does not conflict with the District of Columbia's Court of Appeals' reasoning in *Allina*, because "the government did not argue that the statute, not the agency's policy at issue there, supplied the substantive legal standard." Opposition, page 26. Thus, the Secretary insists that the Ninth Circuit's majority opinion creates no actual conflict with this Court's decisions or those of courts of appeals. Supreme Court review is therefore unnecessary according to the Secretary. Opposition, page 15.

Even if the Secretary's argument that there is a lack of conflict among the courts is accurate, which is

questionable, grounds for review exist because the majority opinion presents important questions of federal law that have not been, but should be, resolved by this Court in this case, as Judge Block eloquently concluded in his dissenting opinion. Judge Block disagreed with the proposition that the statutory standard of "reasonable and necessary" established the substantive legal standard for purposes of construing 42 U.S.C. § 1395hh. And, he therefore stressed that the majority opinion is a "missed opportunity" to address the meaning of the phrase "change a substantive legal standard." He even expressed his hope that "[p]erhaps the Supreme Court may now decide to address this important and unresolved issue." Pet. App. page 33. Judge Block further cautioned that the Majority's blanket ruling exempting LCDs from rulemaking requirements "obscures the substantial effects that LCDs have on companies like Agendia and ultimately, on Medicare beneficiaries."[1]

III. LCDs HAVE OVERSIZED IMPACT ON THE MEDICARE PROGRAM

Two recent events, postdating the filing of the Petition, support Judge Block's statement about the

[1] In *Allina*, Justice Gorsuch pointed out that "[o]ne way or another, Medicare touches the lives of nearly all Americans," which is why the public must be afforded public notice and a chance to comment if the government wishes to establish or change a "substantive legal standard." Indeed, "even seemingly modest modifications to the program to the program can affect the lives of millions." 139 S. Ct. at 1808.

substantial effects of LCDs on Medicare providers of services and the Medicare beneficiaries they treat. The first is a November 3, 2021 Administrative Law Judge ("ALJ") decision, and the second is a November 15, 2021 Notice of Final Rule issued by CMS.

A. The November 3, 2021 ALJ Decision

Only Medicare beneficiaries (and their estates) may challenge the validity of LCDs. Providers and suppliers of Medicare items and services do not have standing to do so under the controlling statutes and regulations. 42 U.S.C. § 1395ff(f)(2)(A); 42 C.F.R. §§ 426.400 *et seq*. Providers must therefore pursue administrative appeals on a claim-by-claim basis, and agency adjudicators, including ALJs, may not set aside or review the validity of an LCD in such appeals. 42 C.F.R. § 1062(c). This is why Agendia has fourteen pending administrative appeals on the same issue involving thousands of Medicare beneficiaries. Petition, page 14, note 2.

On November 3, 2021, the Secretary's ALJ issued an "**UNFAVORABLE**" decision in Agendia's fourth administrative appeal. A copy is appended hereto at "App." pages 1-9. The decision involves the same two molecular diagnostic laboratory tests at issue here for more than one hundred different Medicare beneficiaries. During the administrative hearing, Agendia presented uncontradicted expert testimony from a highly experienced oncologist, Dr. William Audeh. In the ALJ's findings of fact and analysis, the ALJ found that

the tests at issue provide "more precision in the classification of the [breast] cancer cells, which leads to more precise treatment options and better results for the cancer patient." The ALJ also found that by 2012, the use of Agendia's tests was "the standard of care for oncologists." App., page 12. The ALJ accepted Dr. Audeh's analysis of the clinical utility of the tests at issue for five representative Medicare beneficiaries. App., pages 12-14. Yet, the ALJ concluded that the testing was not covered by Medicare because of LCD L32288 and the related lack of approval by the MAC's MolDX program. App., pages 14-15.

Of particular significance is the ALJ's discussion of the "Policy and Guidance," including LCD L32288, and the related MolDX program and MAC coverage article. The ALJ begins by citing the requirements of Social Security Act 1871(a)(2), (42 U.S.C. § 1395hh), that "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." Yet, the ALJ adds that "in lieu of binding regulations with the full force and effect of law," CMS and its contractors have issued "policy guidance" describing the criteria for coverage of selected items and services in the form of manuals and LCDs. App., pages 4-5.

The ALJ's observation is accurate, especially in the instant case. Rather than issuing a regulation embodying the MACs' "statement of policy" concerning Medicare coverage for molecular diagnostic laboratory

tests, CMS and the MAC have been able to circumvent the requirements of Section 1395hh by using the label "LCD" to establish the standard of coverage for molecular diagnostic testing. As a result, the ALJ used the LCD and its related policies to disallow coverage for laboratory testing that the uncontradicted expert evidence supported as being reasonable and necessary for the diagnosis and treatment of breast cancer.

B. The November 15, 2021 Notice of Final Rule

CMS, the agency charged with administering the Medicare program on a day-by-day basis, took a position in a November 15, 2021 Federal Register notice (86 Fed. Reg. 62944-62958) that is different from the position taken by the Secretary in his Opposition Brief concerning the impact of *Allina*. The Federal Register notice announced that CMS was repealing a Medicare rule defining the "reasonable and necessary" standard for "innovative technology" that had been published on January 14, 2021, and was to become effective on December 15, 2021.

This November 15, 2021 notice pertains to the very same "reasonable and necessary" statutory standard the Ninth Circuit decided was so definite that it essentially could not be changed by the interpretations in LCDs or other sub-regulatory guidance. Opposition, page 16. Among the 115 items of correspondence in response to its earlier September 2021 notice of the proposed rule, CMS noted that "[s]everal commenters

asked that CMS prohibit concurrent NCD and LCD processes" for determining Medicare coverage for innovative technology. 86 Fed. Reg. at 62950.

In responding to the comments, CMS expressly acknowledged that "it is **not** clear that CMS has legal authority under the *Allina* Supreme Court ruling to use subregulatory (*sic*) guidance to modify aspects of the [innovative technology] final rule as some commenters suggested." Emphasis added. 86 Fed. Reg. at 62951. Yet, the sub-regulatory policy at issue here, the LCD and the MolDX Program, have done just that – they "modified" (established/changed) the definition of reasonable and necessary for molecular diagnostic laboratory testing.

This recently expressed concern of CMS regarding the use of sub-regulatory policy, including LCDs, to modify the reasonable and necessary standard is different from the position currently being advocated by the Secretary regarding the issue of whether *Allina* is implicated for LCDs.[2]

IV. CLARIFICATIONS AND OTHER RECENT EVENTS

In his Opposition (at pages 14-15), the Secretary characterizes an LCD as a MAC's explanation of "how it will apply the statutory reasonable-and-necessary standard in its own adjudication of individual claims,

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[2] In its November 15, 2021 notice, CMS also points out that in 2020, MACs finalized 31 LCDs. 86 Fed. Reg. at 62957.

and which bind only that contractor. . . ." He also repeats (at page 17) that LCDs "by definition apply on an intermediary-or carrier-wide basis. . . ." These assertions grossly understate the impact of the LCD at issue by overlooking the facts (1) that the policy at issue here has been adopted by other MACs covering more than one-half of the "jurisdictions" in the Country (Palmetto MolDX Policy Manual, Pet. App. 117-18, and Pet., page 6), and (2) that Respondent Agendia Inc.'s testing has been ordered by different doctors for each of the eighty-six Medicare beneficiaries regardless of where each resides. Pet., page 7.

Moreover, effective January 1, 2015, a single MAC (and in any event no more than four MACs) establishes Medicare coverage policies for all clinical diagnostic laboratory services throughout the Country (Pet., page 3). Thus, at least for clinical diagnostic laboratory services, LCDs are hardly "local." And, given that Medicare is a national health insurance program, LCDs should be uniform throughout the Country. Pet., page 13. Indeed, there is no Medicare statute or regulation allowing Medicare coverage policies, themselves, to vary based on the location of a beneficiary or provider.

Additionally, while this case pertains to Medicare Part B, it must be emphasized that the Medicare Advantage Program, Medicare Part C, 42 U.S.C. § 1395w-21 et al. and 42 C.F.R. § 400.202, now uses Palmetto GBA's policies, including the MolDX program, to determine benefits for those Medicare beneficiaries who chose the managed care benefits of the Medicare

Advantage program. *See* United Healthcare Medicare Advantage, *Coverage Summary*, November 26, 2021 report accessible at *Genetic Testing – Medicare Advantage Coverage Summary (uhcprovider.com)*. Thus, the Ninth Circuit's ruling is not limited to Parts A and B of the Medicare program.

The Secretary discusses none of the above critical facts in his opposition. Rather, he repeats the Ninth Circuit's mischaracterization of LCDs as mere "guides" MACs use to apply the statutory "reasonable and necessary" standard when they "adjudicate" Medicare claims involving item or services. Opposition, page 16. But, as the Secretary must know, the development of an LCD is a quasi-legislative process, not a quasi-judicial process. Indeed, LCDs make the Medicare quasi-judicial processes robotic by removing the discretion of the adjudicators from the determination of whether items or services meet the statutory standard of being reasonable and necessary. Without LCDs, government adjudicators, including ALJs, determine whether the statutory standard of reasonable and necessary is met (their "overarching duty," Opposition, page 17) by applying their expertise and discretion to the facts of particular cases rather than substantially deferring to policies developed by private contractors outside of the usual notice-and-comment rulemaking process.

V. THERE IS NO RELIABLE EVIDENCE THAT CONGRESS INTENDED TO EXEMPT LCDs FROM THE REQUIREMENTS OF SECTION 1395hh

Rather than concluding that Congress's express exemption of National Coverage Determinations, but not LCDs, from the requirements of Section 1395hh is evidence that Congress intended for LCDs to be promulgated under Section 1395hh, the Secretary embraces the Ninth Circuit's contrary conclusion. Opposition, pages 19-20. And, once again taking his cue from the Ninth Circuit, the Secretary also argues that certain 2003 amendments and "Congress's enactment of a specific process for Administrative Contractors to follow in promulgating local coverage determinations [reinforce] the conclusion that local coverage determinations have never been subject to Section 1395hh's more formalized approach." Opposition, pages 20-21.

However, given the lack of uniformity and myriad other problems with LCDs, it does not follow that one should presume Congress intended to make it easier for a private contractor to establish policy than a government agency. As mentioned above, labels should not be determinative of whether a policy statement should be promulgated as a rule. And, if after MAC goes through the process authorized for LCDs in 2016, the Secretary (or CMS) determines that the resulting policy establishes or changes a substantive legal standard for an item or service, the LCD should be promulgated as a regulation pursuant to 42 U.S.C. § 1395hh. Such a process should not be considered duplicative. Instead,

it should be considered to be consistent with Congress' intent concerning the enactment of policies that establish or change Medicare substantive legal standards regardless of the label given the policy. And, if as a result, two processes rather than one is pursued, Congress expressly provided for this result.

The Secretary's administrative feasibility argument must be rejected here for the same reason it was rejected in *Allina*, 139 S. Ct. at 1816. Not all LCDs establish or change legal standards. However, the one at issue here, LCD L32288, does. In any event, the administrative feasibility issue only arises here because the Ninth Circuit's majority opinion treats all LCDs the same based solely on the label given them by the MACs. In actuality, some LCDs do establish or change substantive legal standards, and some do not. The LCDs that do establish or change substantive legal standards should be promulgated under Section 1395hh. Others do not have to be so promulgated.

VI. LCDs ARE OUTCOME DETERMINATIVE REGARDLESS OF PURPORTEDLY BEING NON-BINDING

This Petition is necessary because the Medicare Appeals Council decided that the ALJ did not give sufficient deference to LCD L32288 and its related subregulatory policies. If there had been no such LCD, the appeal process would have been resolved based on the judgment of the adjudicators and evidence in the record. The Appeals Council could have reviewed the

ALJ's favorable decision applying its own judgment to the facts in the record. The same can be said about the November 3, 2021 ALJ decision discussed above. Indeed, in the latter appeal, the findings and analysis, exclusive of those pertaining to the LCD, were favorable to Agendia. The unfavorable outcome was due solely to LCD L32288 and its progeny.

Notwithstanding the Secretary's support for the Ninth Circuit majority's conclusion that LCDs are not binding on the government agency, the reality is to the contrary, as this case clearly demonstrates. The ALJ gave no deference to LCD L32288. As a result, the Medicare Appeals Council reversed the ALJ's decision and remanded the matter to the ALJ for the purpose of giving the LCD its due deference.

In Medicare claims review, the Secretary's regulation, 42 C.F.R. § 1062(c), expressly prohibits ALJs and the Medicare Appeals Council from invalidating LCDs. Instead, Medicare providers and suppliers must engage in a seemingly never-ending appeal process on a claim-by-claim basis. For Agendia, this process has been ongoing for nearly ten years with no end in sight.

The 2016 amendment simply codifies procedures that MACs must follow in the first instance to establish or change LCDs. In addition to not being applicable here because LCD L32288 was established five years before the 2016 amendment, the new procedures do not involve CMS. As pointed out previously, Petition, page 4, while MACs must establish "Contractor

Advisory Committees" to provide information to professionals about proposed LCDs, the Committees are "advisory only." And, the amendment is silent about any involvement or control by the Secretary or CMS.

CONCLUSION

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

Respectfully submitted,

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