No. 21-584

In the Supreme Court of the United States

AGENDIA, INC., PETITIONER

v.

XAVIER BECERRA,
SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

Part B of the Medicare program, 42 U.S.C. 1395j *et seq.*, provides for payment to healthcare providers and suppliers that furnish certain healthcare items and services for Part B enrollees. Congress has generally limited Part B coverage to items or services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. 1395y(a)(1)(A). Congress has directed the Centers for Medicare & Medicaid Services (CMS) to administer Part B through contracts with Medicare Administrative Contractors, which determine in the first instance whether an item or service in a provider's claim should be covered by applying regulations and national coverage determinations adopted by CMS pursuant to statutory notice-and-comment procedures. 42 U.S.C. 1395u(a), 1395ff(f)(1)(B), 1395hh(a)(1) and (2). If no regulation or national coverage determination applies to an item or service, an Administrative Contractor may issue a local coverage determination specifying how that Administrative Contractor will apply the statutory "reasonable and necessary" standard to that item or service. 42 U.S.C. 1395ff(f)(2)(B). A local coverage determination does not bind CMS or other Administrative Contractors. The questions presented are as follows:

1. Whether an Administrative Contractor's local coverage determination must be adopted pursuant to the statutory notice-and-comment requirements applicable to CMS's Medicare regulations.

2. Whether an Administrative Contractor's ability to issue a local coverage determination explaining how that Administrative Contractor will apply the statutory standard for coverage represents an unconstitutional delegation of regulatory authority to a private entity.

ADDITIONAL RELATED PROCEEDINGS

United States District Court (C.D. Cal.)

Agendia, Inc. v. *Azar*, No. 19-cv-74 (Oct. 29, 2019)

United States Court of Appeals (9th Cir.):

Agendia, Inc. v. *Becerra*, No. 19-56516 (July 16, 2021)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-33) is reported at 4 F.4th 896. The order of the district court (Pet. App. 34-59) is reported at 420 F. Supp. 3d 985. The decision of the Medicare Appeals Council (Pet. App. 60-84) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 16, 2021. A petition for rehearing was denied on September 2, 2021 (Pet. App. 85-86). The petition for a writ of certiorari was filed on October 19, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Part B of the Medicare program, established in 1965 by Title XVIII of the Social Security Act (Medicare Act), see Health Insurance for the Aged Act, Pub. L. No. 89-97, Tit. I, Pt. 1, sec. 102(a), §§ 1831 *et seq.*, 79 Stat. 301-313 (42 U.S.C. 1395j *et seq.*), provides for payment by the federal government to healthcare providers and suppliers who furnish covered items or services to Part B enrollees. Part B covers a range of services and other items, such as certain physician services, home health services, outpatient physical therapy, durable medical equipment, diagnostic tests, and related services. See 42 U.S.C. 1395k(a)(2)(A)-(C) and (G), 1395m(a)(13), 1395x(s). Congress has generally limited Part B (and Part A) coverage, however, to services and items that 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). The Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS) administers the Medicare program. See *Maine Med. Ctr.* v. *Burwell*, 841 F.3d 10, 13-14 (1st Cir. 2016); see also *Schweiker* v. *McClure*, 456 U.S. 188, 189 (1982).

Congress has specified that "[t]he administration of [Part B] shall be conducted through contracts with [M]edicare administrative contractors." 42 U.S.C. 1395u(a). Congress has authorized CMS to "enter into contracts with" Medicare Administrative Contractors (Administrative Contractors) to perform a variety of functions, including processing claims presented by and making payment to providers and suppliers that have furnished items or services to Part B enrollees. 42 U.S.C. 1395kk-1(a)(1); see 42 U.S.C. 1395kk-1(a)(4). CMS has

entered such contracts with Administrative Contractors, which are assigned to process Part B claims in particular geographic regions.

Among other functions, Administrative Contractors render initial determinations about whether Part B covers items or services for which payment is sought by (or on behalf of) a Part B enrollee. 42 U.S.C. 1395ff(a); 42 C.F.R. 405.920. If an Administrative Contractor denies a claim, an individual beneficiary—or, as in this case, a provider or supplier representing a beneficiary or presenting a claim assigned by a beneficiary—can appeal that denial pursuant to a four-level scheme of administrative review: (1) redetermination by the Administrative Contractor that made the decision, 42 C.F.R. 405.940; (2) reconsideration by a different, independent contractor, 42 C.F.R. 405.960; (3) a hearing before an administrative law judge (ALJ), 42 C.F.R. 405.1002; and (4) an appeal to the Medicare Appeals Council (Appeals Council), 42 C.F.R. 405.1100. In addition, "CMS or any of its contractors may refer a case to the [Appeals] Council," and the Council itself may review a determination on its own motion. 42 C.F.R. 405.1110(a); see 42 C.F.R. 405.1110(b)-(e).

b. In determining whether Medicare Part B covers an item or service for which a supplier claims payment, every adjudicator in the Part B claims-review process, from an Administrative Contractor to the Appeals Council, is bound by the Medicare Act—including the provision limiting coverage to services and items that are "reasonable and necessary," 42 U.S.C. 1395y(a)(1)(A). 42 C.F.R. 405.1063(a). Those adjudicators also are bound by CMS's regulations, *ibid.*, which the Medicare Act expressly authorizes the agency to promulgate "as may be necessary to carry out" the Medicare program. 42 U.S.C. 1395hh(a)(1). The Medicare Act requires such

regulations to be adopted pursuant to a specified notice-and-comment process, including publication of a proposed regulation in the *Federal Register*, followed by a public comment period of at least 60 days. 42 U.S.C. 1395hh(b)(1). The Medicare Act generally makes such regulations the exclusive means by which CMS may adopt a "rule, requirement, or other statement of policy * * * that establishes or changes a substantive legal standard governing," among other things, "the scope of benefits" and "the payment for services." 42 U.S.C. 1395hh(a)(2).

In addition to regulations, however, the Medicare Act provides for two other mechanisms by which CMS or its contractors may explain how they intend to apply the statute and regulations to adjudication of claims for particular items or services. First, CMS itself may issue "national coverage determination[s]," which identify on a nationwide basis whether particular items or services are covered. 42 U.S.C. 1395ff(f)(1)(B). Like CMS's regulations, national coverage determinations are binding on all contractors and agency adjudicators. See 42 U.S.C. 1395ff(c)(3)(B)(ii)(I); 42 C.F.R. 405.1060(a)(4). Also like regulations, the Medicare Act requires CMS to provide advance public notice of national coverage determinations and to invite and consider public comment, but the notice-and-comment procedures that Congress specified for national coverage determinations differ from those applicable to regulations. See 42 U.S.C. 1395y(*l*).

Section 1395y(*l*) provides that CMS must post proposed national coverage determinations on its website or make them public by "other appropriate means," and must provide for a 30-day public-comment period. 42 U.S.C. 1395y(*l*)(3)(A) and (B). That provision also requires CMS to make public the factors it considers in deciding whether to adopt national coverage determinations, to

respond to requests for national coverage determinations and render a final decision within specified periods, and to consult with outside experts in certain circumstances. See 42 U.S.C. 1395y(*l*)(1)-(2), (3)(A), (C), and (4). The Medicare Act expressly excludes national coverage determinations from the requirement that CMS proceed by regulation to "establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services," and certain other topics. 42 U.S.C. 1395hh(a)(2). The Medicare Act provides for administrative and judicial review of a national coverage determination, see 42 U.S.C. 1395ff(f)(1)(A)(iii)-(v) and (5), but a national coverage determination cannot be set aside on the ground that it was not promulgated in the manner required for regulations, see 42 U.S.C. 1395ff(f)(1)(A)(ii).

Second, if no CMS regulation or national coverage determination applies, an Administrative Contractor may issue a "[l]ocal coverage determination." 42 U.S.C. 1395ff(f)(2) (emphasis omitted). The Medicare Act defines a local coverage determination as a "determination * * * respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under [Medicare Parts A and B], in accordance with section 1395y(a)(1)(A)." 42 U.S.C. 1395ff(f)(2)(B), As noted above, Section 1395y(a)(1)(A) is the provision limiting coverage to items and services that are "reasonable and necessary." 42 U.S.C. 1395y(a)(1)(A).

Unlike regulations and national coverage determinations, which are binding on the agency and all of its contractors, 42 C.F.R. 405.1060(a)(4), a local coverage determination binds only the specific Administrative Contractor (*i.e.*, "intermediary") that issued it. 42 U.S.C. 1395ff(f)(2)(B). If a party seeks reconsideration of an

Administrative Contractor's claim determination (following a redetermination) by an independent contractor, the Administrative Contractor's "local coverage determination * * * shall not be binding on [that] independent contractor," but the independent contractor "shall consider" it. 42 U.S.C. 1395ff(c)(3)(B)(ii)(II). And CMS's regulations expressly provide that "ALJs and attorney adjudicators and the [Appeals] Council are not bound by [local coverage determinations]." 42 C.F.R. 405.1062(a). Instead, an independent contractor or an agency adjudicator must give "substantial deference" to an Administrative Contractor's local coverage determinations in reviewing claims determined by that contractor, but the adjudicator may "decline[] to follow" a local coverage determination "in a particular case," so long as the adjudicator "explain[s] the reasons why the [local coverage determination] was not followed." 42 C.F.R. 405.968(b)(2), 405.1062(b).

The Medicare Act also provides for administrative and judicial review of a local coverage determination. An aggrieved party—*i.e.*, a beneficiary or the estate of a beneficiary who is in need of coverage for an item or service that was denied based on a local coverage determination—may seek review before an ALJ, whose decision can be reviewed by the Departmental Appeals Board and, in turn, by a court. See 42 U.S.C. 1395ff(f)(2)(A); 42 C.F.R. 426.400 *et seq.* Although a provider or supplier itself cannot directly challenge a local coverage determination, it may argue in an appeal from the denial of a particular claim for payment that the local coverage determination should not be applied in that specific case, see 42 U.S.C. 1395ff(b)(1)(A); 42 C.F.R. 405.1136, as petitioner did here, see Pet. App. 5-6.

In 2003, Congress directed the agency to "develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, sec. 731(a)(1), § 1862, 117 Stat. 2350 (42 U.S.C. 1395y(*l*)(5)(A)). Congress instructed CMS to require that contractors in a given area "consult" with one another "on all new local coverage determinations within the area" and directed the agency to "serve as a center to disseminate information on local coverage determinations" among its contractors. *Ibid.* (42 U.S.C. 1395y(*l*)(5)(B) and (C)); see H.R. Conf. Rep. No. 391, 108th Cong., 1st Sess. 733 (2003).

In addition, in 2016—after the period covering the claims at issue in this case—Congress specified procedures for Administrative Contractors to promulgate local coverage determinations. See 21st Century Cures Act, Pub. L. No. 114-255, sec. 4009(a), § 1862(*l*)(5), 130 Stat. 1185 (42 U.S.C. § 1395y(*l*)(5)(D)). Those procedures require an Administrative Contractor to provide notice of the determination on its own website and "on the Medicare Internet website, at least 45 days before the effective date" of that determination. *Ibid.* The notice must include the determination itself, a statement of "[w]here and when the proposed determination was first made public," "[h]yperlinks to the proposed determination and a response to comments," "[a] summary of evidence that was considered," and "[a]n explanation of the rationale that supports [the] determination." *Ibid.*

2. a. Petitioner is a clinical laboratory that uses methods of molecular diagnostic testing for breast cancer, known as the "MammoPrint," "BluePrint" and "TargetPrint" tests, and furnishes such tests to doctors. Pet. App. 61; see *id.* at 5, 37. In 2011, the Administrative Contractor for petitioner's region at the relevant times (Palmetto GBA) developed a Molecular Diagnostic Services Program (Molecular-Testing Program) "to identify and establish coverage and reimbursement for molecular diagnostic tests." Pet. App. 37-38. Under that Program, Palmetto "request[ed] clinical information about a test to determine if [the] test meets Medicare's reasonable and necessary requirement." *Id.* at 38.

Palmetto then issued Local Coverage Determination L32288, which explained that Palmetto would not find a molecular diagnostic test to be covered by Medicare Part B unless the test either (i) was expressly covered by a national coverage determination, another local coverage determination, or a Palmetto Coverage Policy Article, or (ii) had been approved through the Molecular-Testing Program. Pet. App. 38. Palmetto considered molecular diagnostic tests that satisfied none of those criteria to be "investigational and not a covered service." *Ibid.*

b. Between June 2012 and January 2013, petitioner submitted claims for all three tests that it had provided to patients. Pet. App. 61. The claims for petitioner's MammoPrint tests were covered and paid. *Ibid.* Palmetto denied petitioner's claims for BluePrint, TargetPrint, or both tests that it provided to 86 patients. *Id.* at 37-38. Those two tests were not covered by an existing national or local coverage determination or any Palmetto Coverage Policy Article; both had been reviewed through Palmetto's Molecular-Testing Program but

had not been approved. *Id.* at 38, 80. And a Palmetto Policy Article indicated that there was "insufficient evidence to support" finding that petitioner's BluePrint test met the reasonable-and-necessary standard. *Ibid.*

c. After unsuccessfully seeking redetermination by Palmetto, petitioner sought reconsideration by an independent contractor, which was also denied. C.A. Supp. E.R. 36; see Pet. App. 38-39, 62-64 & n.3.

Petitioner requested a hearing before an ALJ, who ruled for petitioner. Pet. App. 6, 65-68. The ALJ declined to defer to Local Coverage Determination L32288. Instead, the ALJ reviewed medical literature and testimony presented by petitioner and concluded that they "offered evidence" that petitioner's tests "were medically reasonable and necessary," and therefore were covered under Part B. *Id.* at 65 (citation omitted).

d. The Appeals Council, on its own motion, reviewed the ALJ's decision and reversed that decision. Pet. App. 60-83. The Appeals Council held that the ALJ had erred by failing to accord appropriate deference to Local Coverage Determination L32288. *Id.* at 80. The Appeals Council recognized that neither it nor the ALJ was "bound by" that or any local coverage determination. *Id.* at 78. But it "f[ound] no reason to not apply substantial deference" to that local coverage determination in the circumstances of this case. *Id.* at 81.

The Appeals Council explained that "[t]he purpose of" Palmetto's Molecular-Testing Program "is specifically to analyze and review the analytical validity, clinical validity, and clinical utility of molecular diagnostic tests." Pet. App. 80. The Appeals Council observed that the Program "is specialized for molecular diagnostic tests, considers applicable statutory and regulatory

requirements, and includes review of scientific literature by independent subject matter experts." *Ibid.* The Appeals Council explained that petitioner's tests had been reviewed through that specialized process—in which petitioner "would have submitted all of the clinical studies available at the time"—and had been found "to not have sufficient evidence" that the tests were reasonable and necessary. *Id.* at 81.

3. Petitioner sought review in the district court, which granted summary judgment to petitioner. Pet. App. 34-59. The court rejected petitioner's contention that the development by Administrative Contractors of local coverage determinations is an unconstitutional delegation of regulatory authority to private entities in violation of Due Process Clause of the Fifth Amendment. *Id.* at 45-49. The court also determined that Palmetto's issuance of Local Coverage Determination L32288 did not violate the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 701 *et seq.*, applicable to agency regulations, see 5 U.S.C. 553. The court explained that local coverage determinations are "interpretive" in nature because they "simply 'interpret the reasonable and necessary standard'" in the Medicare Act, and therefore are not subject to the APA's requirements. Pet. App. 52-53 (quoting *Erringer* v. *Thompson*, 371 F.3d 625, 631 (9th Cir. 2004)).

The district court concluded, however, that local coverage determinations were required, but had failed, to comply with the Medicare Act's own notice-and-comment requirements, set forth in 42 U.S.C. 1395hh. Pet. App. 54-58. The court held that those requirements applied to Local Coverage Determination L32288 because, in the court's view, that determination "established * * *

a substantive legal standard" about the coverage of particular services. *Id.* at 57 (citing *Allina Health Servs.* v. *Price*, 863 F.3d 937 (D.C. Cir. 2017), aff'd, 139 S. Ct. 1804 (2019) (emphasis omitted); see *id.* at 56-58. The court acknowledged that local coverage determinations are "not binding on the agency," but noted that they do bind the Administrative Contractors that issue them and "are entitled to substantial deference in the administrative process." *Id.* at 57.

4. The court of appeals reversed. Pet. App. 1-33.*

a. The court of appeals rejected petitioner's contention that local coverage determinations are "subject to the § 1395hh notice-and-comment process." Pet. App. 9; see *id.* at 8-14. The court explained that "such determinations" fall outside Section 1395hh because they "do not 'establish[] or change[] a substantive legal standard.'" *Id.* at 9 (quoting 42 U.S.C. 1395hh(a)(2)) (brackets in original). The court found it unnecessary to "define the outer boundaries of 'substantive legal standard'" in this case "because only one standard is potentially implicated here": the Medicare Act's requirement that "an item or service must be 'reasonable and necessary' for a provider to have a right to payment" under Part A or Part B. *Ibid.* (quoting 42 U.S.C. 1395y(a)(1)(A)). The court explained that "[a] local coverage determination does not 'establish[] or change[]' that standard" but merely "guides the application of that legal standard in a particular claim adjudication." *Ibid.* (citations omitted; second and third sets of brackets in original).

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* The court of appeals construed petitioner's constitutional argument as an alternative basis for affirmance, Pet. App. 7 n.3, which it rejected, *id.* at 14-17; see p. 13-14, *infra*.

The court of appeals observed that a local coverage determination "reflects [an Administrative Contractor's] view of what qualifies as reasonable and necessary, and accordingly it controls that [Administrative Contractor's] claims determinations," but it does not bind other contractors or agency adjudicators. Pet. App. 9; see *id.* at 9-10. The court noted that, if local coverage determinations "'did not exist,'" the statutory "reasonable and necessary standard would remain unaltered," and Administrative Contractors "'would still have an overarching duty to deny claims for items and services'" that fall short of that standard. *Id.* at 10 (quoting *Erringer*, 371 F.3d at 631).

The court of appeals further explained that "the structure of the statute" reinforces that interpretation. Pet. App. 10. The court noted that Congress has "created a special notice-and-comment process for *national* coverage determinations" that is streamlined, requiring drafts of those determinations to be posted online with a 30-day comment period. *Id.* at 10-11. The court found it incongruous to subject local coverage determinations to "the more arduous," "more demanding" "notice-and-comment process" under Section 1395hh, "from which national coverage determinations are expressly exempt." *Id.* at 11. The court noted the parties' agreement that local coverage determinations "have never undergone th[at] § 1395hh notice-and-comment process," and observed that petitioner's position would "make[] all local coverage determinations invalid." *Id.* at 8-9.

The court of appeals additionally observed that Congress's 2016 amendment specifying procedures for the development of local coverage determinations—although not retroactively applicable here—provided further ev-

idence that Section 1395hh's procedures have never applied to local coverage determinations. Pet. App. 11 n.6. The court explained that, in prescribing those new procedures, "Congress sought to 'increase transparency' in the development of local coverage determinations," indicating that such determinations were not already governed by Section 1395hh's more demanding notice-and-comment requirements. *Id.* at 12 n.6 (citation omitted).

The court of appeals rejected petitioner's contention that this Court's decision in *Azar* v. *Allina Health Services*, 139 S. Ct. 1804 (2019), compelled a contrary conclusion. Pet. App. 13. The court of appeals explained that this Court in *Allina* had held "only that the § 1395hh notice-and-comment process does not contain the same exception for interpretative rules as does the [APA]." *Ibid.* The court noted that *Allina* had "explicitly left open" the argument that the government advanced in this case: "'that the policy at issue . . . didn't "establis[h] or chang[e]" a substantive legal standard.'" *Ibid.* (quoting *Allina*, 139 S. Ct. at 1816) (brackets in original).

The court of appeals also rejected petitioner's contention that Section 1395hh(a)(2)'s express exclusion of national coverage determinations implies that local coverage determinations are subject to that provision. Pet. App. 14. The court observed that, "[b]ecause 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." *Ibid.* (brackets in original).

b. The court of appeals rejected petitioner's separate contention that Administrative Contractors' "ability to issue local coverage determinations reflects an unconstitutional delegation of regulatory power to private

entities." Pet. App. 14; see *id.* at 14-17. The court explained that "[t]he statutory and regulatory scheme is constitutional because the contractors 'function subordinately' to the Secretary." *Id.* at 14 (quoting *Sunshine Anthracite Coal Co.* v. *Adkins*, 310 U.S. 381, 399 (1940)). The court observed that "[t]he Secretary retains the relevant decision-making power" because the agency's adjudicators (ALJs and the Appeals Council) are not bound by local coverage determinations, and they "can refuse to apply" one so long as "they adequately explain their reasons." *Id.* at 15. In addition, the court noted, the agency can "prescribe requirements for contractors issuing local coverage determinations," supersede them by issuing national coverage determinations, and review a local coverage determination directly at the request of a Medicare beneficiary. *Ibid.*

c. District Judge Block, sitting by designation, dissented in part. Pet. App. 18-33. Judge Block agreed with the majority's rejection of petitioner's constitutional challenge to Administrative Contractors' authority to issue local coverage determinations. *Id.* at 20. But he disagreed with the majority's conclusion that local coverage determinations are not subject to Section 1395hh's notice-and-comment requirements that govern regulations. *Id.* at 18-33. In Judge Block's view, local coverage determinations do "'establish' a standard at the initial stage of review and 'change' the standards applied on appellate review." *Id.* at 20 (citation omitted).

ARGUMENT

Petitioner contends (Pet. 15-19) that a local coverage determination under Medicare Part B—in which a Medicare Administrative Contractor explains how it will apply the statutory reasonable-and-necessary standard in its own adjudication of individual claims, and which bind

only that contractor—should be subject to the same notice-and-comment procedures as CMS's Medicare regulations under 42 U.S.C. 1395hh. Petitioner further contends (Pet. 19-23) that an Administrative Contractor's ability to issue a local coverage determination is an unconstitutional delegation of regulatory authority to a private entity. The court of appeals correctly rejected both contentions, and its decision does not conflict with any decision of this Court or of another court of appeals. Further review is not warranted.

1. The court of appeals determined that a local coverage determination issued by a Medicare Administrative Contractor is not subject to the rulemaking procedures set forth in Section 1395hh applicable to CMS's Medicare regulations. Pet. App. 8-14. That conclusion is correct and does not warrant review.

a. Section 1395hh of the Medicare Act authorizes the Secretary to issue regulations to administer the Medicare program, 42 U.S.C. 1395hh(a)(1), and it prescribes the procedures by which the agency may do so, see 42 U.S.C. 1395hh(a)(3), (b), and (c). Section 1395hh generally makes those rulemaking procedures the exclusive avenue by which the agency may make certain determinations. Section 1395hh(a)(2) provides that "[n]o rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services," or certain other specified topics, "shall take effect unless it is promulgated by the Secretary by regulation under [Section 1395hh(a)(1)]." 42 U.S.C. 1395hh(a)(2). The court of appeals correctly determined that Section 1395hh's notice-and-comment rulemaking procedures

do not apply to a local coverage determination that embodies only the views of, and is binding only upon, the particular Administrative Contractor that issued it.

A local coverage determination is not an agency "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard." 42 U.S.C. 1395hh(a)(2). The Medicare Act defines a local coverage determination as "a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A)." 42 U.S.C. 1395ff(f)(2)(B). As the court of appeals recognized, the cross-referenced statutory provision itself supplies the relevant "'substantive legal standard'": "an item or service must be 'reasonable and necessary' for a provider to have a right to payment.'" Pet. App. 9 (quoting 42 U.S.C. 1395y(a)(1)(A)). "A local coverage determination does not," and cannot, "'establish[] or change[]' that standard"; it merely "guides the application of that standard" by the Medicare Administrative Contractor that issued the determination when it adjudicates a claim involving that item or service. *Ibid.* (citation omitted; brackets in original). By issuing a local coverage determination, an Administrative Contractor simply articulates its "view of what qualifies as reasonable and necessary." *Ibid.*

As the court of appeals additionally observed, that "understanding of the effect of local coverage determinations" is confirmed by considering how claims adjudications would proceed "if such determinations 'did not exist.'" Pet. App. 10 (quoting *Erringer* v. *Thompson*, 371 F.3d 625, 631 (9th Cir. 2004)). "[I]f local coverage

determinations ceased to exist," Administrative Contractors "would still have an overarching duty to deny claims for items and services that are not 'reasonable and necessary.'" *Ibid.* (quoting *Erringer*, 371 F.3d at 631, in turn quoting 42 U.S.C. 1395y(a)(1)(A)). And Administrative Contractors would bring their own judgment to bear in determining whether an item or service satisfies that statutory standard in the context of an individual claim adjudication. Cf. 42 U.S.C. 1395ff(c)(3)(B)(ii)(III) (providing that, "[i]n the absence of * * * a national coverage determination or local coverage determination," an independent contractor conducting reconsideration "shall make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence"). Petitioner does not suggest that an Administrative Contractor's reasoning in determining in such an adjudication whether an item or service is reasonable and necessary itself constitutes a "rule, requirement, or other statement of policy * * * that establishes or changes a substantive legal standard governing" a topic listed in Section 1395hh(a)(2) that must be promulgated pursuant to that provision's notice-and-comment procedure. 42 U.S.C. 1395hh(a)(2). The same conclusion follows for local coverage determinations, which merely provide advance notice of a contractor's views that it will apply in individual cases, enhancing the transparency, predictability, and consistency of its adjudications.

Moreover, although an Administrative Contractor that has issued a local coverage determination is bound to apply it while the determination remains in effect, no other adjudicator is bound by it. Because local coverage determinations by definition apply on an "intermediary- or carrier-wide basis," 42 U.S.C. 1395ff(f)(2)(B), they do

not apply to claims adjudicated by other Administrative Contractors. And even on review of a claim adjudication made by the Administrative Contractor that issued a local coverage determination, the determination does not bind the agency or third-party adjudicators. Congress has specified that a local coverage determination "shall not be binding" on an independent contractor conducting reconsideration of an Administrative Contractor's decision. 42 U.S.C. 1395ff(c)(3)(B)(ii)(II); see 42 C.F.R. 405.968(b)(2). And CMS's regulations confirm that "ALJs and attorney adjudicators and the [Appeals] Council are not bound by [local coverage determinations]." 42 C.F.R. 405.1062(a). An individual contractor's statement of how *it* will apply the statutory reasonable-and-necessary standard in adjudicating a claim in the first instance, which every adjudicator at all subsequent levels of review can decline to apply, does not "establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services," or other topics specified in Section 1395hh(a)(2). 42 U.S.C. 1395hh(a)(2).

Petitioner errs in contending (Pet. 19) that a local coverage determination issued by a particular Administrative Contractor does establish or change a substantive legal standard because other adjudicators must accord the determination "deference." To be sure, Congress has directed independent contractors to "consider [a] local coverage determination" when conducting reconsideration of an Administrative Contractor's decision. 42 U.S.C. 1395ff(c)(3)(B)(ii)(II). And CMS's regulations direct independent contractors, ALJs, and the Appeals Council to accord "substantial deference" to local coverage determinations at later stages of review.

42 C.F.R. 405.968(b)(2), 405.1062(a). But at the same time the regulations make clear that each of those subsequent adjudicators may "disregard" and "decline[] to follow" a local coverage determination, so long as they "explain the reasons why the [local coverage determination] was not followed." 42 C.F.R. 405.1062(b); see 42 C.F.R. 405.968(b)(2) and (3). That a subsequent adjudicator must give a local coverage determination appropriate consideration does not transform the determination into a binding legal standard, especially where that adjudicator is free to reject the determination.

Indeed, as the court of appeals noted, "[t]he ALJ reviewing [petitioner's] claims did precisely that." Pet. App. 15 n.7; see *id.* at 65-68. Although the Appeals Council "ultimately concluded that the ALJ's reasoning was unpersuasive," *id.* at 15 n.7, it recognized that it and the ALJ "are not bound by [local coverage determinations]," *id.* at 78. The Appeals Council simply "f[ound] no reason to not apply substantial deference to" Palmetto's Local Coverage Determination L32288 "or to question the [Molecular-Testing Program's] findings" with respect to petitioner's particular tests. *Id.* at 80.

b. The statutory structure and history strongly reinforce the conclusion that local coverage determinations are not subject to Section 1395hh's rulemaking procedures. Pet. App. 10-11 & n.6.

As the court of appeals observed, Congress has expressly excluded national coverage determinations—which are issued by CMS itself, are binding on all contractors and agency adjudicators, and apply nationwide, see 42 U.S.C. 1395ff(c)(3)(B)(ii)(I); 42 C.F.R. 405.1060(a)(4)—from Section 1395hh's rulemaking procedures, and instead subjected them to a less formalized, more streamlined public-comment process. Pet. App. 10-11; see

42 U.S.C. 1395y(*l*)(3)(A) and (B), 1395hh(a)(2). In contrast to Section 1395hh's procedures—which entail publication in the *Federal Register*, a 60-day comment period, and adherence to a predetermined regulatory timeline developed in ongoing consultation with the Office of Management and Budget, 42 U.S.C. 1395hh(a) and (b)—Congress provided for CMS to post draft national coverage determinations on its website (or make them available by "other appropriate means"), allow 30 days for public comment, and issue a decision addressing comments received, see 42 U.S.C. 1395y(*l*)(3)(A)-(C). Given Congress's decision to exclude *national* coverage determinations from the Section 1395hh rulemaking protocol applicable to regulations and instead to craft a more streamlined procedure for such determinations, it is implausible that Congress intended to subject *local* coverage determinations to Section 1395hh's "more demanding procedure than their national, binding counterparts." Pet. App. 11.

Other provisions of the Medicare Act enacted in 2003 bolster that conclusion. Section 1395y(*l*)(5)(A) directs CMS to "develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally," *i.e.*, to *become* national coverage determinations. 42 U.S.C. 1395y(*l*)(5)(A); see p. 7, *supra*. It would be incongruous to require more formalized rulemaking procedures for local coverage determinations that serve as the raw material for future national coverage determinations than for national coverage determinations themselves.

In addition, the next two subparagraphs of Section 1395y(*l*)(5) direct CMS to require its contractors "providing services within the same area to consult on all new local coverage determinations within the area," and instruct CMS to "serve as a center to disseminate

information on local coverage determinations among [contractors] to reduce duplication of effort." 42 U.S.C. 1395y(*l*)(5)(B) and (C). If local coverage determinations were already subject to Section 1395hh's rulemaking procedures, as petitioner contends (*e.g.*, Pet. 19), those additional provisions would be perplexing. Section 1395hh's notice-and-comment process, including publication of proposed and final rules in the *Federal Register*, would render unnecessary those provisions calling for coordination among contractors at the local or regional level and for CMS to serve as a clearinghouse for information. Under the court of appeals' interpretation, in contrast, those provisions make perfect sense.

Similarly, Congress's enactment in 2016 of a specific process for Administrative Contractors to follow in promulgating local coverage determinations reinforces the conclusion that local coverage determinations have never been subject to Section 1395hh's more formalized approach. See 42 U.S.C. 1395y(*l*)(5)(D). That process for local coverage determinations differs starkly from Section 1395hh's more formalized approach, and it is even more streamlined than the procedure Congress crafted for national coverage determinations. An Administrative Contractor must post a local coverage determination on the Internet at least 45 days before it takes effect, along with information about where and when the proposed determination was made public, a response to comments, and the evidence and rationale on which it is based. *Ibid.*; see p. 7, *supra*.

As the court of appeals recognized, although that 2016 amendment postdated and does not apply to the claims here, it strongly indicates that local coverage determinations are not and have never been subject to Section 1395hh's more rigorous rulemaking procedures. Pet.

App. 11 n.6. The 2016 "amendment is part of a pattern of congressional actions *adding* procedural requirements for local coverage determinations," which "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." *Id.* at 12 n.6. No sound basis exists to conclude that Congress enacted that amendment to *reduce* procedural requirements, which would be at odds with Congress's purposes of increasing accountability and transparency. *Ibid.* Moreover, if Congress had viewed local coverage determinations as previously covered by Section 1395hh(a)(2) and intended the 2016 amendment to remove them from that provision, Congress presumably would have amended Section 1395hh(a)(2) to exclude local coverage determinations expressly—as it has done for national coverage determinations—rather than remove them from its scope by oblique implication. *Ibid.* The far more plausible explanation is that Congress in 2016 accurately perceived that the Medicare Act did not specify particular procedures for adopting local coverage determinations and amended the statute to establish such procedures—and that, in keeping with the nature of local coverage determinations as the work of individual contractors and not binding on other adjudicators, Congress fashioned a correspondingly less formal process to be undertaken by the contractor, not CMS.

Petitioner contended below that, given the express exclusion of national coverage determinations in Section 1395hh(a)(2), the omission of a similar express exclusion of local coverage determinations shows that they are covered by that provision. Pet. App. 14. The dissenting opinion below embraced that argument. See *id.* at 24-26. As the court of appeals majority explained,

however, that omission is unremarkable. *Id.* at 14. Local coverage determinations do not fall within the category of agency actions that Section 1395hh(a)(2) identifies in the first place, because they "clearly do not 'establish[] or change[]' a substantive legal standard." *Ibid.* And "there was no reason for Congress to exempt" local coverage determinations "from a requirement that does not, by its plain terms, apply." *Ibid.* Moreover, when Section 1395hh(a)(2) was enacted in 1987, the Medicare Act did not refer directly to local coverage determinations at all. It is especially unsurprising that Congress did not find it necessary to state expressly that a type of contractor determination not mentioned elsewhere in the statute, and that does not satisfy Section 1395hh(a)(2)'s criteria, is not covered.

c. The practical implications of petitioner's contrary approach further support the conclusion that the court of appeals' interpretation is sound. Requiring publication in the *Federal Register* of each proposed local coverage determination by each individual Administrative Contractor, and inviting input from the nationwide public at large, would needlessly complicate and render more burdensome an already-complex process. That approach also might create the misimpression that local coverage determinations embody CMS's official position rather than the non-binding view of a single contractor. Cf. 1 C.F.R. 5.4(c) ("The Director of the Federal Register may not accept any document for filing and publication unless it is the official action of the agency concerned."). Difficulties would arise, moreover, if multiple Administrative Contractors were to propose inconsistent local coverage determinations on the same item or service.

The interpretation adopted by the district court, which petitioner defended in the court of appeals, would

compound those difficulties. The district court posited that the procedures enacted in 2016 for adopting local coverage determinations and the rulemaking procedures in Section 1395hh are not mutually exclusive, but complementary, and that Congress intended to require an Administrative Contractor to "comply with both § 1395hh and § 1395y." Pet. App. 56; see *id.* at 55-56. Petitioner endorsed that interpretation below. Pet. C.A. Br. 15 ("[T]he district court correctly held that the promulgation process of Section 1395hh and the new processes specific to [local coverage determinations] are not mutually exclusive and each must be followed."). That approach would subject local coverage determinations going forward to *two separate* notice-and-comment processes, with different timelines and procedures. Neither petitioner nor the district court has identified any reason why Congress would adopt those duplicative, conflicting processes for local coverage determinations.

Finally, as the court of appeals noted, it is common ground that "local coverage determinations have never undergone the § 1395hh notice-and-comment process." Pet. App. 8. Petitioner's position "that this procedural error makes all local coverage determinations invalid," *id.* at 8-9, would call into question approximately one thousand such determinations currently in force. See CMS, HHS, *MCD Search Results*, https://go.usa.gov/xet6F. Adopting petitioner's position thus could result in substantial disruption of the Medicare payment process.

d. Petitioner does not contend that the court of appeals' determination that local coverage determinations are not subject to Section 1395hh's notice-and-comment rulemaking process directly conflicts with any decision of this Court or of another court of appeals. Petitioner suggests (Pet. 17-18) that the decision below is in tension

with this Court's decision in *Azar* v. *Allina Health Services*, 139 S. Ct. 1804 (2019). That is incorrect.

Allina held that Section 1395hh, unlike the APA, does not include an exception for interpretive rules. 139 S. Ct. at 1810-1816. The Court determined that the CMS policy at issue in that case was invalid because it had not been promulgated in accordance with Section 1395hh's procedures. See *id.* at 1816-1817. But as the court of appeals observed, Pet. App. 13-14, and as petitioner acknowledges, the *Allina* Court expressly reserved judgment on an argument that the government did not advance in that case: that the policy did not "'establish or change' a substantive legal standard—and so didn't require notice and comment under § 1395hh(a)(2)—because the *statute* itself" supplied the relevant standard. 139 S. Ct. at 1816 (brackets omitted); see Pet. 17 ("The panel majority correctly states that this Court explicitly left open [that] line of argument," which "HHS could have made in *Allina*."). As the court of appeals explained, the government did advance that argument in this case, and "that argument carries the day." Pet. App. 14. Moreover, the court found it unnecessary in this case "to define the outer boundaries of 'substantive legal standard'" within the meaning of Section 1395hh(a)(2) because the court determined that the Medicare Act itself supplies the only standard that is "potentially implicated": the reasonable-and-necessary requirement set forth in Section 1395y(a)(1)(A). *Id.* at 9.

Petitioner disagrees (Pet. 18) with the court of appeals' conclusion that Section 1395y(a)(1)(A), not a local coverage determination, establishes the relevant legal standard. The court of appeals' conclusion is correct for the reasons explained above. In any event, petitioners' disagreement on that point does not implicate *Allina*, which expressly reserved judgment on the issue.

Petitioner also suggests (Pet. 15-17) that tension exists between the decision below and the reasoning of the D.C. Circuit in the decision affirmed in *Allina*. See *Allina Health Servs.* v. *Price*, 863 F.3d 937 (D.C. Cir. 2017), aff'd, 139 S. Ct. 1804 (2019). That contention does not warrant review. In *Allina*, as noted, the government did not argue that the statute, not the agency's policy at issue there, supplied the substantive legal standard. The D.C. Circuit thus had no occasion to address that issue.

Petitioner nevertheless asserts (Pet. 16-17) that "it is reasonable to assume" that the D.C. Circuit would conclude that a local coverage determination does establish or change a legal standard and so is "required to have been issued as a regulation under Section 1395hh." Petitioner relies on the D.C. Circuit's definition of a "substantive legal standard" as "includ[ing] a standard that creates, defines[,] and regulates the rights, duties, and powers of parties." Pet. 16 (emphasis omitted); see *Allina*, 863 F.3d at 943. But that definition would not encompass a local coverage determination for the reasons set out above: such a determination does not create, define, or regulate a provider's entitlement to receive and CMS's duty to make payment (through its contractors). A local coverage determination embodies only the first-line adjudicator's view of how the statutory standard applies—a view that subsequent adjudicators in the same proceeding are free to reject. See pp. 15-19, *supra*.

Petitioner's effort (Pet. 16) to analogize a local coverage determination to the agency policy at issue in *Allina* also fails. That policy was one made by the agency itself and, as petitioner acknowledges (*ibid.*), was binding on all contractors. See *Allina*, 863 F.3d at 943. A

local coverage determination is adopted by an individual contractor and binds no other adjudicator. See pp. 15-19, *supra*. Further review is not warranted.

2. The court of appeals unanimously rejected petitioner's separate contention that an Administrative Contractor's ability to develop local coverage determinations represents an unconstitutional delegation of regulatory authority to a private entity. Pet. App. 14-17; *id.* at 20 (Block, J., dissenting). That conclusion is also correct and does not warrant further review.

a. As explained above, local coverage determinations do not establish or modify substantive legal standards, but merely provide advance notice of how a particular contractor will apply the statutory reasonable-and-necessary standard in its initial review of claims. See pp. 15-19, *supra*. Petitioner's argument (Pet. 19-20) that local coverage determinations embody an exercise of substantial regulatory power to prescribe Medicare payment policies fails for many of the same reasons as its contention that they are subject to Section 1395hh.

In any event, as the court of appeals recognized, Administrative Contractors that issue local coverage determinations "function subordinately" to the Secretary. Pet. App. 14 (quoting *Sunshine Anthracite Coal Co.* v. *Adkins*, 310 U.S. 381, 399 (1940)). Because the agency "has authority and surveillance over the activities" of the contractors and makes the final determination, the "statutory scheme is unquestionably valid." *Sunshine Anthracite Coal*, 310 U.S. at 399. As the court explained, CMS can review a local coverage determination directly at the request of an aggrieved Medicare beneficiary. Pet. App. 15. And although in an appeal by a provider or supplier, the agency's adjudicators accord deference to a local coverage determination, those adjudicators are free

to reject such a determination so long as they adequately explain their reasons. *Ibid.* Moreover, CMS can "prescribe requirements for contractors issuing local coverage determinations" or countermand them by issuing national coverage determinations. *Ibid.*

b. Petitioner does not identify any decision of this Court or of another court of appeals that conflicts with the court of appeals' rejection of petitioner's constitutional challenge to local coverage determinations. Petitioner asserts (Pet. 21) that the D.C. Circuit in *Association of American Railroads* v. *United States Department of Transportation*, 721 F.3d 666 (2013), held invalid a "delegation of regulatory power to a private entity." But this Court vacated the decision in that case, holding that the entity at issue (Amtrak) "is a governmental entity, not a private one, for purposes of determining the constitutional issues." *Department of Transp.* v. *Association of Am. R.R.*, 575 U.S. 43, 55 (2015); see *id.* at 55-56; Pet. 22. Moreover, the D.C. Circuit concluded that the statute at issue "empower[ed] private parties to wield regulatory authority." *Association of Am. R.R.*, 721 F.3d at 670-671. The statutory framework enabling Administrative Contractors to issue local coverage determinations does not confer such authority. See pp. 15-19, 27, *supra*. Further review is not warranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 2021