No. 16-808

In the Supreme Court of the United States

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A., PETITIONER

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly upheld a determination by the Department of Health and Human Services that petitioner overbilled Medicare by nearly $9 million because it extracted three doses of a drug from each single-use vial, but then billed Medicare as if it had purchased a separate vial for each dose.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-26) is not published in the *Federal Reporter* but is reprinted at 649 Fed. Appx. 684. The order of the district court (Pet. App. 31-45) is not published in the *Federal Supplement* but is available at 2015 WL 1608458.

JURISDICTION

The judgment of the court of appeals was entered on April 29, 2016. A petition for rehearing was denied on August 22, 2016 (Pet. App. 27-30). On November 3, 2016, Justice Thomas extended the time within which to file a petition for a writ of certiorari to and including December 21, 2016, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Medicare is a federally subsidized system of health insurance for the aged and disabled. Under Medicare Part B, drugs administered by a physician may be covered if (as relevant here) they are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. 1395y(a)(1)(A). To qualify as "reasonable and necessary," a drug must be administered in accordance with "accepted standards of medical practice." Ctrs. for Medicare & Medicaid Servs. (CMS), *Medicare Benefit Policy Manual* Ch. 15, § 50 (rev. 228, Oct. 13, 2016) (*MBPM*); see CMS, *Medicare Program Integrity Manual* § 13.5.1 (rev. 608, Aug. 14, 2015) (*MPIM*); Pet. App. 9, 86.

This case concerns the accepted standards of medical practice for administering the drug Lucentis, which is injected into the eye.[1] Lucentis is packaged as a sterile solution in single-use vials designed to deliver a 0.5-milligram (mg) dose. Pet. App. 2, 87. Although each vial contains excess solution (a total of 2.0 mg), the label approved by the Food and Drug Administration (FDA) instructs that "[e]ach vial should only be used for the treatment of a single eye." *Id.* at 2; see C.A. App. 172 ("VIALS ARE FOR SINGLE EYE USE ONLY"). The label "requires the healthcare professional to extract the *full contents* of the 2.0-mg vial into a syringe" and then expel the excess solution before administering a 0.5-mg dose. Pet. App. 2.

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[1] Technically, Lucentis is a biological product as well as a drug. See FDA, *FDA Approves New Biologic Treatment for Wet Age-Related Macular Degeneration* (June 30, 2006), http://www.fda.gov/newsevents/newsroom/pressannouncements/2006/ucm108685.htm. Like petitioner and the decisions below, we refer to it as a drug for simplicity.

Medicare Part B drug reimbursements are capped at the lower of the amount the healthcare provider billed the patient or an amount based on the drug's average sales price. 42 U.S.C. 1395w-3a; see Pet. App. 3. During the period at issue here, the average price of Lucentis was roughly $2025 per 2.0-mg vial. Pet. App. 3-4. Consistent with the FDA-approved label, the Medicare reimbursement rate for Lucentis presumed that each vial would be used to administer only one 0.5-mg dose. *Ibid.* That yielded a reimbursement rate of approximately $405 per 0.1 mg administered, or $2025 per dose. *Ibid.*

2. Petitioner is a single-physician ophthalmology practice that treated Medicare Part B patients using Lucentis. Pet. App. 2, 31-32. Petitioner "did not follow the Lucentis label's instructions limiting dosage to one per vial." *Id.* at 3. Instead, it "treated up to three patients from a single vial" and then sought to be reimbursed at the full $2025 rate for each of the three doses. *Ibid.*; see *id.* at 3-4. As a result, petitioner was "reimbursed" approximately $6075 for each vial—roughly triple its actual cost. *Id.* at 4.

In June 2009, a Medicare contractor that audited claims issued a preliminary notice of overpayment determining that, in 2007 and 2008 alone, petitioner had overbilled Medicare for Lucentis by nearly $9 million. Pet. App. 4. The contractor concluded that petitioner's practice of extracting additional doses of Lucentis from a single vial was contrary to both the instructions on the FDA-approved label and the governing local coverage determination, which reiterated those instructions. *Id.* at 2-3, 5, 61. A Medicare Administrative Contractor then sought to recoup the overpayment. *Id.* at 5; see 42 U.S.C. 1395ff(a)(1).

The initial determination of overpayment was affirmed at each of four levels of administrative review: first upon further review by the Medicare Administrative Contractor itself, Pet. App. 63-64; see 42 U.S.C. 1395ff(b)(1)(A); then on reconsideration by a Qualified Independent Contractor, Pet. App. 64-65; see 42 U.S.C. 1395ff(c); then on review before an administrative law judge, Pet. App. 65-72; see 42 U.S.C. 1395ff(d)(1); and, finally, on de novo review before the Medicare Appeals Council within the Department of Health and Human Services (HHS), Pet. App. 52-100; see 42 U.S.C. 1395ff(d)(2).

In its final decision, HHS concluded that petitioner had failed to "show[] that it was medically reasonable and necessary to extract and administer more than a single dose of Lucentis from a single use vial." Pet. App. 85. HHS determined that Lucentis injections are reasonable and necessary only "to the extent the drug [is] administered consistent with its FDA-approved label." *Ibid.* Thus, HHS concluded that a provider administering Lucentis may not bill Medicare for more than one injection per vial. *Id.* at 85-95.

3. Petitioner sought review of HHS's decision in district court. See 42 U.S.C. 1395ff(b)(1)(A). The court entered summary judgment for the government, Pet. App. 48-51, and then denied petitioner's motion for reconsideration, *id.* at 31-45.

4. The court of appeals affirmed in an unpublished per curiam opinion. Pet. App. 1-26. As relevant here, the court upheld HHS's decision on two independent grounds.

First, the court of appeals held that petitioner's billing for Lucentis impermissibly overstated its expenses. Pet. App. 13-17. The court explained that Medi-

care policy provides for reimbursement for the cost of a drug only if that cost is "an expense to the physician." *Id.* at 14 (quoting *MBPM* Ch. 15, § 50.3) (emphasis omitted). The court concluded that "[n]othing in the statute forbids [HHS] from relating Medicare reimbursement to the physician's expense." *Ibid.*

Second, and in the alternative, the court of appeals upheld HHS's determination that "multiple doses of Lucentis from a single vial were medically unreasonable" and therefore ineligible for reimbursement. Pet. App. 17; see *id.* at 17-23. The court explained that "[b]ecause administering more than one dose of Lucentis from one vial violated the drug's FDA-approved labeling, [HHS] reasonably could have concluded that multi-dosing was medically inappropriate." *Id.* at 17.

5. The court of appeals denied rehearing en banc with no judge requesting a vote. Pet. App. 29-30.

ARGUMENT

Petitioner renews its contention (Pet. 14-29) that HHS lacked authority to determine that it overbilled Medicare. The court of appeals correctly rejected that argument, and neither of the two independent grounds for the court's factbound, nonprecedential decision conflicts with any decision of this Court or another court of appeals. Further review is unwarranted.

1. HHS's final decision determined that petitioner's extraction of multiple doses of Lucentis from a single vial was not "reasonable and necessary" because it departed from accepted standards of medical practice. Pet. App. 85-95. The court of appeals correctly upheld that determination. *Id.* at 17-23.

a. As HHS emphasized, the FDA-approved label for Lucentis specifically instructed doctors to use the entire contents of a vial to prepare a single dose and

to discard the excess solution. Pet. App. 2, 87-88; see C.A. App. 172. Those explicit instructions provided strong evidence of the accepted standard of medical practice. Pet. App. 86-88. That evidence was reinforced by the local coverage determination for Lucentis issued by the Medicare contractor for Florida, which reflected the medical judgment of advisory groups including "representatives from the Connecticut Society of Eye Physicians and the Florida Society of Ophthalmology." *Id.* at 40 & n.3 (citation omitted). The *Physician's Desk Reference* likewise instructed that the excess solution from each vial should be discarded rather than used for additional doses. *Id.* at 23. And HHS noted that the single-use instruction is "consistent with general guidelines for injection safety promulgated by the [Centers for Disease Control and Prevention (CDC)]," which state that "medications labeled as 'single dose' or 'single use'" should be "used for only one patient" to "protect patients from life-threatening infections that occur when medications get contaminated from unsafe use." *Id.* at 89 (citation omitted).

During the administrative proceedings, petitioner "presented no evidence of a contrary accepted medical practice" for the administration of Lucentis. Pet. App. 23. Indeed, petitioner has not identified any other physician who extracted multiple doses of Lucentis from a single vial.[2] The court of appeals thus correctly declined to disturb HHS's decision—particularly given the deferential substantial-evidence standard of review that applies to HHS's factual find-

[2] Petitioner now asserts (Pet. 2, 7-8) that "many" other doctors engaged in the same practice. Those assertions are neither supported by any evidence in the record nor accompanied by citations.

ings about accepted medical practice. *Id.* at 22-23; see *id.* at 6-7.

b. Petitioner provides no sound reason to question HHS's determination that the extraction of multiple doses of Lucentis from single-use vials was ineligible for reimbursement because it was not "reasonable and necessary" under 42 U.S.C. 1395y(a)(1)(A).

First, petitioner asserts (Pet. 22-23) that the court of appeals failed to "explain how [HHS] could deem the 'first' 0.5-mg dose obtained from a vial of Lucentis to be medically reasonable and necessary, but reach a different conclusion as to the 'second' and 'third' doses obtained from that same vial." But as HHS explained, the extraction of the second and third doses from a single vial was unreasonable because it was inconsistent with accepted medical practice—in part because the second and third doses extracted from the vial carry a risk of infection. Pet. App. 89-90 (citing CDC guidelines).

Second, petitioner notes (Pet. 22-23) that Medicare contractors initially relied on the ground that its billing overstated its actual expenses rather than on the alternative ground that extracting multiple doses of Lucentis from a single-use vial is inconsistent with accepted medical practice—the basis for HHS's final decision. But an administrative agency is not limited to the rationales initially adopted by its contractors. See 42 U.S.C. 1395ff(d)(2)(B) (providing that the Medicare Appeals Council "shall review the case de novo"); *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 658-659 (2007).

Third, petitioner appears to suggest (Pet. 23-24) that HHS lacks authority to deny reimbursement for drugs that are not administered in accordance with

accepted medical practice. But Medicare reimbursement is limited to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. 1395y(a)(1)(A). As HHS has long concluded, a drug that is not administered in accordance with accepted medical practice is not "reasonable and necessary." Pet. App. 17; see *MBPM* Ch. 15, § 50; *MPIM* § 13.5.1. Petitioner does not cite any decision reaching a contrary conclusion.[3]

Fourth, petitioner asserts (Pet. 24, 27-28) that HHS's decision improperly gave dispositive weight to the instructions on an FDA-approved label. But HHS specifically recognized that a use of a drug that is not consistent with its FDA-approved label may nonetheless qualify as "reasonable and necessary" if that off-label use is consistent with "accepted standards of medical practice." Pet. App. 79 (quoting *MPIM* § 13.13). Here, petitioner simply failed to offer any evidence of such an accepted off-label practice.

Finally, petitioner contends (Pet. 27-28) that HHS's determination regarding accepted medical practice for Lucentis is inconsistent with the way HHS and the FDA treat a different drug, Avastin. But as the court of appeals explained, a practice may be medically appropriate for one drug but not another. Pet. App. 20-21. Avastin is sold in much larger vials

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[3] Petitioner has also forfeited this argument by failing to raise it below. In the court of appeals, petitioner did not question HHS's authority to deny reimbursement for drugs that were administered in a medically unreasonable manner; it argued only that extracting multiple doses from a single vial of Lucentis was consistent with accepted medical practice. See Pet. C.A. Br. 28-54. And even in this Court, petitioner elsewhere acknowledges (Pet. 22) that reimbursement for a drug is required only if "its administration was *medically* 'reasonable and necessary.'"

than Lucentis, and there is an "accepted medical practice" of "us[ing] multiple doses from a single vial of Avastin." *Ibid.* Petitioner failed to establish any such practice for Lucentis.[4]

2. The court of appeals' alternative holding—that petitioner's billing for Lucentis improperly overstated its costs—was also correct. Pet. App. 13-17. As the court explained, every time a physician buys a single 2.0-mg vial of Lucentis, Medicare reimburses the physician for the vial's full cost, even though the instructions require the physician to discard all contents not used for a single dose. *Id.* at 16. Here, by contrast, petitioner billed Medicare multiple times for a single vial, and thus received "reimbursement" for vials that it never purchased. As the court of appeals explained, "[n]othing in the statute forbids the Secretary from relating Medicare reimbursement to the physician's expense." *Id.* at 14. "On the contrary, the very concept of 'reimbursement' contemplates payment for money that was actually spent." *Ibid.*; see 42 U.S.C. 1395y(a) (contemplating reimbursement for expenses "incurred").

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[4] Petitioner also relies (Pet. 25) on a draft FDA guidance document providing for the repackaging of drugs such as Avastin. But the guidance is only a draft describing conditions under which FDA would not pursue enforcement of certain requirements that might otherwise apply. And among the conditions listed in the draft are provisions that the repackaging be done in specified facilities and in accordance with practices designed to maintain the sterility of the drug and avoid contamination. FDA, *Draft Guidance Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry*, 2015 WL 1735391, at *7-*9 (Feb. 1, 2015). Petitioner does not allege that it followed such procedures.

Petitioner contends (Pet. 16-17) that if a drug qualifies for Medicare coverage, then the applicable statute mandates that it be reimbursed according to the statutory formula—that is, at 106% of the average sales price. See 42 U.S.C. 1395w-3a(b)(1). But the court of appeals did not purport to authorize HHS to deviate from the statutory formula, and the decision below permits petitioner to seek reimbursement for 106% of the average sales price of each vial of Lucentis that it actually purchased. See Pet. App. 3-4, 92-94. The court simply held that petitioner was not entitled to have the per-milligram price of Lucentis calculated as if it was extracting only one 0.5-mg dose from each vial when it was in fact extracting three—a practice that allowed petitioner to obtain "reimbursement" for triple its actual costs.

3. Petitioner contends (Pet. 1-4, 16-23) that the court of appeals' decision conflicts with *Hays* v. *Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009). Even if that were correct, the unpublished decision below could not create a circuit conflict warranting this Court's review. See 11th Cir. R. 36-2 ("Unpublished opinions are not considered binding precedent."). And in any event, both of the court of appeals' alternative rationales are entirely consistent with *Hays*.

Hays was a challenge to HHS's "least costly alternative policy," which provided that even if a drug or service otherwise qualified as reasonable and necessary, Medicare would decline to provide full reimbursement if a less-costly alternative was available. 589 F.3d at 1280. In *Hays*, Medicare contractors applied the policy to limit reimbursement for a drug called DuoNeb, which was a combination of two other drugs. *Ibid.* Because it was more expensive to pur-

chase DuoNeb than to purchase the two component drugs separately, Medicare contractors applied the least costly alternative policy to provide that reimbursement for DuoNeb would be based on the average cost of the component drugs rather than the actual cost of DuoNeb itself. *Ibid.* The D.C. Circuit held that the least costly alternative policy was impermissible because the statutory term "reasonable and necessary" modifies "items and services," not "expenses." *Id.* at 1281-1283; see 42 U.S.C. 1395y(a)(1)(A). The court therefore concluded that "the statute unambiguously authorizes [HHS] to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all." *Hays*, 589 F.3d at 1283.

As the court of appeals explained, *Hays* is "inapposite" to the court's conclusion that petitioner impermissibly overstated its billing for Lucentis. Pet. App. 13. "*Hays* construed the Medicare statute to require Medicare to pay for any drug it deems reasonable and necessary, without regard to alternative methods that would save Medicare money." *Ibid.* "Here," in contrast, HHS "did not demand that [petitioner] administer a cheaper alternative than Lucentis," *ibid.*, and it did not reimburse petitioner at less than the statutory rate for the vials that petitioner actually purchased. It simply determined that petitioner was not entitled to have the per-milligram price of Lucentis calculated as if it was extracting only one 0.5-mg dose from each vial when it was in fact extracting three.

Hays has even less relevance to the court of appeals' alternative holding that HHS permissibly con-

cluded that extracting multiple doses of Lucentis from the same vial is not "reasonable and necessary." HHS determined that such second and third injections from a single vial are not reasonable and necessary because they are inconsistent with accepted medical practice and risk the spread of infection. Pet. App. 85-95. That conclusion is entirely consistent with the "binary choice" described in *Hays*: HHS determined that second and third injections are "unreasonable or unnecessary," and thus that they "may not be covered at all." *Hays*, 589 F.3d at 1283.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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