United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 08-5508 **September Term, 2009**

FILED ON: DECEMBER 22, 2009

ILENE HAYS,
APPELLEE

v.

KATHLEEN SEBELIUS, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLANTS

Appeal from the United States District Court
for the District of Columbia
(No. 1:08-cv-01032-HHK)

Before: TATEL and KAVANAUGH, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*

J U D G M E N T

This cause came on to be heard on the record on appeal from the United States District Court for the District of Columbia and was argued by counsel. On consideration thereof, it is

ORDERED and **ADJUDGED** that the judgment of the District Court appealed from in this cause is hereby affirmed, in accordance with the opinion of the court filed herein this date.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/

Michael C. McGrail
Deputy Clerk

Date: December 22, 2009

Opinion for the court filed by Circuit Judge Tatel.
Concurring opinion filed by Senior Circuit Judge Randolph.

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Argued November 5, 2009 Decided December 22, 2009

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KATHLEEN SEBELIUS, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLANTS

Appeal from the United States District Court
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Samantha L. Chaifetz, Attorney, U.S. Department of Justice, argued the cause for appellants. On the briefs were *Mark B. Stern* and *Christopher C. Fonzone,* Attorneys.

Stuart M. Gerson argued the cause for appellee. With him on the brief was *Robert E. Wanerman.*

Peter D. Keisler and *Patrick Morrisey* were on the brief for *amicus curiae* Sepracor Inc. in support of appellee.

Before: TATEL and KAVANAUGH, *Circuit Judges,* and RANDOLPH, *Senior Circuit Judge.*

Opinion for the Court filed by *Circuit Judge* TATEL.

Concurring opinion filed by *Senior Circuit Judge* RANDOLPH.

TATEL, *Circuit Judge*: Appellee, a Medicare Part B beneficiary, challenges a decision by a regional Medicare contractor to reimburse for a particular drug only up to the price of its least costly alternative. The district court held that the Medicare Act unambiguously forecloses that determination and requires instead that Medicare pay for covered items or services at a statutorily prescribed rate. Agreeing with the district court, we affirm.

I.

Medicare Part B is a public health insurance program that provides the disabled and elderly with outpatient items and services, including durable medical equipment and certain prescription medications. The threshold for Medicare Part B coverage appears in 42 U.S.C. § 1395y(a)(1)(A), which states that "no payment may be made . . . for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

The Secretary of Health and Human Services administers the Medicare Act and may delegate certain functions to contractors, including the development of local coverage determinations. 42 U.S.C. § 1395kk-1(a)(4). The Medicare Act defines local coverage determinations as decisions "whether or not a particular item or service is covered" in the contractor's geographic area "in accordance with section 1395y(a)(1)(A)." 42 U.S.C. § 1395ff(f)(2)(B). The Secretary has instructed contractors that when determining whether a treatment is "reasonable and necessary" under section

1395y(a)(1)(A), they may apply the so-called least costly alternative policy. Ctrs. for Medicare and Medicaid Servs., Medicare Program Integrity Manual § 13.4.A (Rev. 71, Apr. 9, 2004). Under that policy, Medicare provides reimbursement for treatments only up to the price of their "reasonably feasible and medically appropriate" least costly alternatives. Ctrs. for Medicare and Medicaid Servs., Medicare Benefit Policy Manual § 110.1.C.3 (Rev. 93, July 25, 2008). Application of the policy is discretionary with regard to prescription drugs—the subject of this case—but mandatory with regard to durable medical equipment. *See* Medicare Program Integrity Manual § 13.4.A.

This case arose when Medicare contractors applied the least costly alternative policy to DuoNeb, an inhalation drug used to treat Chronic Obstructive Pulmonary Disease. DuoNeb provides a combination of albuterol sulfate and ipratropium bromide in one dose and can be slightly more expensive than separate doses of the two component drugs. Appellee Ilene Hays is a Medicare Part B beneficiary suffering from Chronic Obstructive Pulmonary Disease who has used DuoNeb for approximately four years. During that time, Medicare, pursuant to a statutory formula, provided reimbursement for DuoNeb at 106% of the drug's average sales price. 42 U.S.C. §§ 1395w-3a(b)(1), 1395u(o)(1)(G)(ii).

In 2008, four Medicare contractors announced that the medical necessity of administering the two drugs in a combined dose, as compared to separate doses, had not been established. *See* NHIC (Region A), LCD for Nebulizers, L11499 (Apr. 10, 2008). Thus, pursuant to the least costly alternative policy, payment for the combination drug "[would] be based on the allowance for the least costly medically appropriate alternative," the two component drugs as administered separately. *Id.* Hays challenged this decision in

the United States District Court for the District of Columbia pursuant to a provision of the statute that allows beneficiaries to proceed without exhausting administrative remedies where "there are no material issues of fact in dispute, and the only issue of law is . . . that a regulation, determination, or ruling by the Secretary is invalid." 42 U.S.C. § 1395ff(f)(3). Hays argued that section 1395y(a)'s "reasonable and necessary" standard modifies "items and services." Accordingly, she contended, the Secretary may determine only whether DuoNeb is reasonable and necessary; if it is, Medicare must reimburse based on the 106% statutory formula. *See* 42 U.S.C. § 1395w-3a. The district court agreed with Hays and granted her motion for summary judgment. *Hays v. Leavitt*, 583 F. Supp. 2d 62, 69, 72 (D.D.C. 2008). The Secretary appeals, and our review is de novo. *See, e.g.*, *Transitional Hosps. Corp. of La., Inc. v. Shalala*, 222 F.3d 1019, 1023 (D.C. Cir. 2000) (reviewing de novo district court's grant of summary judgment to plaintiffs challenging validity of Medicare regulations).

II.

The Secretary argues that section 1395y(a) is ambiguous and that we should defer to her reasonable interpretation of the statute. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Several features of the Medicare statute, however, convince us that it unambiguously forecloses the Secretary's interpretation.

In relevant part, section 1395y provides:

> (a) Items or services specifically excluded. Notwithstanding any other provision of this subchapter, no payment may be made . . . for any expenses incurred for items or services--

> (1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services . . . , are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]

The dispute in this case centers on whether "reasonable and necessary" modifies "expenses" (as the Secretary argues), or "items and services" (as Hays contends). If the Secretary is correct, then Medicare may, as it has here, partially cover an item or service, declining to reimburse expenses associated with the marginal difference in price between a prescribed item or service and its least costly and medically appropriate alternative. If Hays and the district court are correct, then the Secretary may make only a binary coverage decision, namely to reimburse at the full statutory rate or not at all.

We agree with Hays and the district court. As they point out, only a dependent clause separates "reasonable and necessary" from the phrase "items or services." *See* § 1395y(a)(1) ("for any expenses incurred for items or services—which, . . . , are not reasonable and necessary . . ."). "Expenses," by contrast, appears earlier in the sentence. "Ordinarily, qualifying phrases are to be applied to the words or phrase immediately preceding and are not to be construed as extending to others more remote." *United States v. Pritchett*, 470 F.2d 455, 459 (D.C. Cir. 1972). To be sure, this "Rule of the Last Antecedent" "is not an absolute and can assuredly be overcome by other indicia of meaning." *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003); *see also United States v. Villanueva-Sotelo*, 515 F.3d 1234, 1238 (D.C. Cir. 2008). Here, however, section 1395y contains no indication that the rule is inapplicable. Quite to the contrary, not only is the phrase "items or services" much nearer to the phrase

"reasonable and necessary," but subsection (1)(A), which introduces the "reasonable and necessary" standard, is set off from the introductory language and nowhere mentions "expenses."

Several other characteristics of section 1395y(a) reinforce this conclusion. First, subsection (1)(A) prohibits payment for expenses incurred for items or services "which, except for items and services described in a succeeding subparagraph . . . , are not reasonable and necessary . . . ." 42 U.S.C. § 1395y(a)(1)(A). By defining the scope of the word "which," this language provides powerful evidence that "reasonable and necessary" applies to "items and services." Moreover, the "succeeding subparagraph[s]" to which subsection (1)(A) refers discuss coverage of specific items and services including "hospice care," § 1395y(a)(1)(C), "screening mammography," § 1395y(a)(1)(F), "home health services," § 1395y(a)(1)(I), and "ultrasound screening," § 1395y(a)(1)(N).

Second, to be covered something—either expenses or items and services—must be "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). Items and services diagnose, treat, and improve; expenses do not.

Finally, section 1395y(a) is entitled "Items or services specifically excluded." 42 U.S.C. §1395y(a). Although "the title of a statute and the heading of a section cannot limit the plain meaning of the text," they remain "tools available for the resolution of a doubt" about statutory meaning. *Bhd. of R.R. Trainmen v. Baltimore & Ohio R.R. Co.*, 331 U.S. 519, 528–29 (1947). Here, the title, which says nothing about expenses, confirms the obvious: that items or services, not

expenses, must be reasonable and necessary to qualify for Medicare coverage.

Our conclusion finds support elsewhere in the Medicare Act, specifically its mandatory reimbursement formulas. Section 1395w-3a provides that for multiple source drugs like DuoNeb "the amount of payment . . . *is*" 106% of the average sales price, as determined under the statutory formula. 42 U.S.C. § 1395w-3a(b)(1) (emphasis added). The statutory formula is in turn based on the volume-weighted average of the average sales prices of drugs within the same Healthcare Common Procedure Coding System (HCPCS) billing and payment code. 42 U.S.C. § 1395w-3a(b)(6). DuoNeb's HCPCS code includes neither component drug.

The Secretary insists that the least costly alternative policy comports with the Medicare Act's mandatory reimbursement formulas because payment under that policy is based on the statutory rate as applied to an item or service's least costly alternative. But this argument would permit an end-run around the statute. The statutory formula requires the Secretary to reimburse a particular drug at 106% of the average sales price for drugs within its billing and payment code. 42 U.S.C. § 1395w-3a(b)(1). By reimbursing DuoNeb at 106% of the average sales price of its two component drugs—which have different billing and payment codes—the Secretary would fundamentally alter the reimbursement scheme. Like the district court, we think it quite unlikely that "Congress, having minutely detailed the reimbursement rates for covered items and services, intended that the Secretary could ignore these formulas whenever she determined that the *expense* of an item or service was not reasonable or necessary." *Hays*, 583 F. Supp. 2d at 71.

To be sure, Congress could have written the Medicare Act to authorize the least costly alternative policy. For example, if the statute read, "no payment may be made . . . for any expenses which are incurred for items and services *and* which are not reasonable and necessary for the diagnosis or treatment of illness or injury," then the phrase "reasonable and necessary" would indeed modify "expenses." And if the reimbursement formulas were either discretionary or based on the cost of an item or service's therapeutic equivalents, the Secretary would have authority to refuse payment for the difference in cost between a prescribed item or service and its least costly alternative. But this is not the statute Congress wrote. As written, the statute unambiguously authorizes the Secretary 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. Nothing in the statute authorizes the least costly alternative policy.

III.

Amicus Sepracor argues that the statute also prohibits the Secretary from considering cost in making the initial coverage determination. But we need not consider that issue. Even if the Secretary may consider cost in determining whether an item or service is "reasonable and necessary," it does not follow that she has authority to partially cover an item or service based on the price of its least costly alternative.

For the foregoing reasons, we affirm.

So ordered.

RANDOLPH, *Senior Circuit Judge*, concurring: Although I join the court's opinion, one feature of this case, unusual in administrative law, prompts me to add a few words. Invoking *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984), the Secretary asked us to defer to the interpretation of the statute embodied in the local coverage determination of a private contractor. The court rightly declines on the ground that the statute – 42 U.S.C. § 1395y(a)(1)(A) – clearly forecloses application of the least costly alternative policy to DuoNeb. Slip Op. at 4. If the statute had not been so clear, one may wonder whether deference of the *Chevron* variety would have been due. No decision of the Secretary applied the least costly alternative policy to this product. That was the doing of four private contractors the Secretary hired to administer the program. While the Secretary issued guidance instructing the contractors to employ the policy with respect to durable medical equipment, the guidance gave the contractors "discretion to apply this principle to payment for non-DME [durable medical equipment] services as well." Ctrs. for Medicare and Medicaid Servs., Medicare Program Integrity Manual § 13.4.A (Rev. 71, Apr. 9, 2004). DuoNeb is not durable medical equipment and so fell within the scope of the contractors' discretion. The Secretary at one time considered issuing a nationwide opinion regarding the status of DuoNeb but ultimately declined, leaving the issue to the contractors. Ctrs. for Medicare and Medicaid Servs., Decision Memo for Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases, CAG-00354N (Sept. 10, 2007).

Given these circumstances, there is a substantial question whether, in requesting deference, the Secretary was actually asking us to defer to a private contractor's determination of the meaning of the statue as applied to DuoNeb. It is not apparent why the rationale of *Chevron* would support the Secretary's request. *See* 467 U.S. at 844-45, 865-66. Still less is it clear that Congress authorized the Secretary to delegate lawmaking functions to private contractors, *see* 42 U.S.C. §§ 1395u(a), 1395kk-1, or could do so consistently with the Constitution. As

I have said, the court's disposition of the case renders consideration of these issues unnecessary.