United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 22, 2011 Decided June 17, 2011

No. 10-5201

UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER,
APPELLANT

v.

KATHLEEN SEBELIUS,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:08-cv-00946)

Christopher L. Keough argued the cause for appellant. With him on the briefs were *Daniel J. Hettich*, *Paul D. Clement*, *Ashley C. Parrish*, and *Erin E. Murphy*.

Jorge Lopez, Jr. and *Patricia A. Millett* were on the brief for *amicus curiae* Memorial Sloan-Kettering Cancer Center in support of appellant.

Mark D. Polston, Deputy Associate General Counsel for Litigation, U.S. Department of Health & Human Services, argued the cause for appellee. With him on the brief were *Ronald C. Machen, Jr.*, U.S. Attorney, and *R. Craig Lawrence* and *Mitchell P. Zeff*, Assistant U.S. Attorneys.

Before: SENTELLE, *Chief Judge*, BROWN and KAVANAUGH, *Circuit Judges*.

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

KAVANAUGH, *Circuit Judge*: In 1965, Congress passed and President Johnson signed the Act creating Medicare. Medicare was primarily designed to ensure adequate health care for Americans who are 65 or older.

Paying for Medicare has posed a massive challenge for the U.S. Government, as the costs of Medicare have grown significantly over time. For several decades now, Congress has intermittently attempted to rein in Medicare costs.

This case involves cost-saving tools that Congress has devised for Medicare payments to cancer hospitals. The case specifically concerns Medicare reimbursements paid to one cancer hospital – M.D. Anderson in Texas – in 2000 and 2001 for inpatient and outpatient costs.

The first issue on appeal relates to cancer hospitals' inpatient costs. Medicare reimburses cancer hospitals for the reasonable costs of inpatient services for Medicare patients up to a target amount. If a cancer hospital proves that its actual costs exceeded the target amount because of "events beyond the hospital's control," the target amount is increased, and Medicare reimburses the cancer hospital for costs attributable to those events. In this case, M.D. Anderson requested an increase to its target amount in 2000 and 2001 due to the high cost of certain new cancer drugs. The Department of Health and Human Services denied that request, and the District Court affirmed HHS's decision.

On appeal, the Hospital claims that HHS, after an administrative hearing on the Hospital's claim, imposed a new requirement that the Hospital expressly prove the *net* financial impact of the new drugs – as opposed to its simply showing the *gross* cost of the new drugs. The Hospital argues that it did not receive proper notice of the new net financial impact requirement and thus did not have a fair opportunity to satisfy the requirement at the administrative hearing. We agree. The Hospital did not receive timely notice of the requirement and, on remand to HHS, must be given an opportunity to satisfy it.

The second issue concerns cancer hospitals' outpatient costs. Since 2000, Medicare has typically reimbursed cancer hospitals for outpatient care based on a statutory formula that provides the hospitals a fraction of their reasonable costs. One component of that formula is the reasonable cost of the hospital's outpatient care in 1996. The overarching idea is to ensure that cancer hospitals can receive Medicare reimbursement for at least the same proportion of their actual costs that the hospitals received in 1996. In this case, the Hospital contends that HHS misapplied the formula and undercompensated the Hospital. The problem for the Hospital is that its interpretation of the statute would actually give cancer hospitals *higher* reimbursements in 2000 and later years than they would have received in 1996 for the same actual costs. We do not believe that the statute *unambiguously* says that, or that the Secretary's interpretation of ambiguous language is unreasonable. The Hospital, of course, must show one or the other in order to overcome HHS's interpretation. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984). The District Court granted summary judgment to HHS on this issue, and we affirm the District Court's decision.

In sum, we reverse the District Court's decision regarding the Hospital's request to raise the target amount for inpatient costs. The District Court should remand the matter to HHS. On remand, HHS must provide the Hospital an opportunity to show the net financial impact of the new cancer drugs. We affirm the District Court's decision granting summary judgment to HHS with respect to cancer hospitals' outpatient costs.

I

We first analyze M.D. Anderson's argument concerning its Medicare reimbursements for inpatient costs in 2000 and 2001. We review the statutory and regulatory framework, and we then address the merits of the Hospital's challenge to its Medicare reimbursement for inpatient services.

A

Congress has repeatedly attempted to slow the increase in Medicare costs for hospitals' inpatient services. In 1982, Congress set a ceiling – known as the "target amount" – on the annual reimbursement that Medicare would permit for hospitals' inpatient costs. *See* 42 U.S.C. § 1395ww(b)(3). Although most hospitals are now subject to a different Medicare system, the regime created in 1982 continues to apply to cancer hospitals – that is, hospitals such as M.D. Anderson that integrate cancer research with patient care. *See* 42 U.S.C. § 1395ww(d)(1)(B)(v)(I).

The target amount is usually based on the previous year's reasonable inpatient costs plus an inflation-based rate of increase. But there is an exception: HHS must increase the

target amount by more than the inflation-based rate when there are "events beyond the hospital's control."

Under HHS regulations, to obtain an increase to the target amount greater than the standard inflation-based bump for events beyond a hospital's control, the hospital must show that the increase is "reasonable, attributable to the circumstances specified separately, identified by the hospital, and verified by" an intermediary. 42 C.F.R. § 413.40(g)(1)(ii).

B

The University of Texas operates a cancer hospital, the M.D. Anderson Cancer Center in Houston, Texas. For 2000 and 2001, the Hospital requested an adjustment to its inpatient target amount to cover the costs of using new cancer drugs. It requested an extra $4.8 million for 2000 and an additional $4.18 million for 2001.

The Hospital submitted its request to a component of HHS called the Provider Reimbursement Review Board, which issued the final HHS decision in this case. After holding an administrative hearing, the Board issued an opinion rejecting the Hospital's request. In that opinion, the Board said that the Hospital had failed to show the *net* financial impact of the new drugs, but rather had shown only the *gross* cost of the new drugs.

Although neither the statute nor the HHS regulation explicitly requires the Hospital to prove the net financial impact of using a new cancer drug, we agree with HHS that such a requirement is a reasonable application of the statute and regulation. If a new drug costs $1000, but saves $1000 that the hospital would have spent on the old cancer

treatment, then the net financial impact for the hospital – that is, the increase that is attributable to the new drug – is $0. Of course, the analysis is rarely so straightforward. And the problem in this particular case is that the Board held its administrative hearing with regard to M.D. Anderson *before* the Board announced (in its later opinion in this case) that a hospital must show the net financial impact of new drugs in order to raise the target amount. In prior proceedings with other hospitals, moreover, the Board had not required an express showing of the net financial impact of the different drugs. *See Belmont Hills Hospital v. Blue Cross & Blue Shield Ass'n/Blue Cross of California*, PRRB Dec. No. 99-D39 (Apr. 21, 1999). In essence, therefore, the Board sprung this requirement on the Hospital *after the hearing* – when it was too late for the Hospital to put forward evidence to satisfy the requirement.

That won't do. To use the terms of our precedents, the "regulated party" here was "not on notice of the agency's ultimate interpretation." *General Electric Co. v. EPA*, 53 F.3d 1324, 1334 (D.C. Cir. 1995) (internal quotation marks omitted). The Hospital did not have notice that it had to show the net financial impact of the new cancer drugs.

We thus reverse the District Court's decision with regard to the Hospital's inpatient costs. The District Court should remand the case to HHS, and HHS in turn should provide the Hospital an opportunity to show the net financial impact of the new cancer drugs it used in 2000 and 2001.

II

We next address the Hospital's Medicare reimbursements for 2000 and 2001 outpatient costs. We review the statutory and regulatory framework, and we then address the merits of

the Hospital's challenge to its Medicare reimbursement for outpatient services.

A

As with Medicare inpatient costs, Congress has repeatedly attempted to slow the rapid increases in Medicare outpatient costs. Under the old system, hospitals treated outpatients, and then informed Medicare of the cost of the treatment, and then received money to cover costs that were "reasonable." Not surprisingly, costs exploded under this system because there was little check on the services and costs for which hospitals received reimbursement. In 1990, Congress instructed HHS to implement a new system for reimbursing those outpatient costs. Under this new approach, Medicare would pay hospitals fixed amounts set in advance of the patients' treatment. The new system – designed "to encourage health care providers to improve efficiency and reduce operating costs" – is called the Prospective Payment System. *Methodist Hospital of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994).

Recognizing that the Prospective Payment System would be implemented slowly, Congress in 1990 instituted an interim policy to lower Medicare payments immediately. That interim policy took effect in 1991. *See* Pub. L. No. 101-508, § 4151, 104 Stat. 1388-71, 71-72 (1990). The interim policy reduced payments to hospitals for their outpatient costs. It did so by imposing various cost reduction factors. For example, if a hospital had $10 million in reasonable outpatient costs, and if the applicable cost reduction factor

was 10%, the hospital would receive $9 million in payments from Medicare.[1]

In 1997, with the Prospective Payment System for outpatients still not implemented by HHS, Congress passed and President Clinton signed the Balanced Budget Act of 1997. Pub. L. No. 105-33, 111 Stat. 251. That law set January 1999 as the initial date by which HHS was required to implement the Prospective Payment System for outpatients. But HHS missed the deadline.

In 1999, Congress then passed and President Clinton signed the Balanced Budget Refinement Act of 1999. Pub. L. No. 106-113, 113 Stat. 1501. Under the 1999 Act, two things relevant to this case were to happen after HHS implemented the Prospective Payment System for outpatients. First, the interim cost reduction factors that had existed since 1991 would expire. Second, a "transitional adjustment to limit decline in payment" for hospitals would begin. 42 U.S.C. § 1395*l*(t)(7) (capitalization altered).

Congress created the "transitional adjustment" because some hospitals would receive significantly less money under the new Prospective Payment System than they had previously been receiving. To ease those hospitals into the new system, they were allowed for the first few years to obtain the amount they would have received before the Balanced Budget Act of 1997 – referred to in the statute as the "pre-BBA amount" – rather than the lower amount they would receive under the Prospective Payment System.

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[1] The cost reduction factor for capital-related costs began at 15% in 1991 and declined to 10% for the years after that. Pub. L. No. 101-508, § 4151, 104 Stat. 1388-71, 71-72 (1990). The cost reduction factor for non-capital-related costs began at 5.8% in 1991 and remained at that level. *Id.*

Of importance here, the transitional adjustment also *permanently* guaranteed cancer hospitals – such as M.D. Anderson – at least their "pre-BBA amount."

The "pre-BBA amount" is defined by the statute as "the reasonable cost of the hospital" for the current year multiplied by a fraction. *Id.* § 1395*l*(t)(7)(F). The fraction's numerator is the Medicare payment that the Hospital received for outpatient "services furnished during the cost reporting period ending in 1996." *Id.* The fraction's denominator is "the reasonable cost of such services for such period." *Id.* Thus, the "pre-BBA amount" equals:

$$\text{(Current Year Reasonable Cost)} \times \frac{\text{(1996 Medicare Payment)}}{\text{(1996 Reasonable Cost)}}$$

It may help to put aside those somewhat confusing details of the formula and focus momentarily on the big picture. A key point of this statutory formula was to ensure that cancer hospitals would generally receive reimbursement for at least the same percentage of their actual costs that they had received in 1996. For example, suppose a hospital's outpatient costs in 1996 were $10 million and it received $9 million from Medicare. If the hospital in 2000 again had the same outpatient costs of $10 million, it again would receive $9 million in reimbursement. In other words, a cancer hospital that had the same outpatient costs in 2000 that it had in 1996 would receive the same reimbursement in 2000 that it had received in 1996.

B

HHS has interpreted the statute in exactly that commonsense fashion. But the Hospital objects, arguing that the statutory text doesn't actually support that seemingly commonsense result. The Hospital focuses on the denominator of the fraction used in the pre-BBA definition – the "reasonable cost" for 1996. The Hospital argues that this term does not mean the reasonable costs actually incurred by the Hospital in 1996, but rather means the reasonable costs as discounted by the statutory cost reduction factors that reduced the Hospital's actual reimbursement in 1996. *See* M.D. Anderson Opening Br. at 35-55; M.D. Anderson Reply Br. at 2-24.

Importantly, by plugging the Hospital's interpretation into the statutory formula, cancer hospitals would be entitled to receive *more* in 2000 than they received in 1996 even if their actual costs in 2000 were exactly the same as in 1996. Needless to say, if you have followed along this far, it seems extremely unlikely that Congress enacted such a windfall provision.

Keep in mind that the Hospital's burden is to show that the statute *unambiguously* supports its interpretation. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984). It cannot do so. The Hospital's interpretation runs into several textual and contextual roadblocks. To begin with, the premise of the Hospital's argument is that the cost reduction factors in 1996 actually reduced a hospital's *costs*, not just its Medicare *payments*. But the statute at least in some places refers to reduction in "payments" to hospitals when describing the effect of the 1996 cost reduction factors. *See* 42 U.S.C. §§ 1395x(v)(1)(S)(ii)(I)-(II). That alone makes

it near impossible for the Hospital to say that the statute *unambiguously* supports its interpretation.

As a matter of common parlance, moreover, the interim outpatient cost reduction factors that began in 1991 caused reductions in the reimbursements or payments to the Hospital, not reductions in the Hospital's actual costs. The fact that a cost-reduction statute that took effect in 1991 lowered Medicare's reimbursements to the Hospital in 1996 obviously does not mean that the Hospital's actual *costs* were somehow magically lower in 1996.

In addition, to reiterate a point made above, the effect of the Hospital's interpretation would be rather bizarre. The Hospital's interpretation of the key statutory term "pre-BBA amount" would give the Hospital *higher* payments in 2000 than it received pre-BBA in 1996 – even if the Hospital's actual costs were exactly the same in 2000 as in 1996. In light of the statutory text, context, and purpose, that result makes no sense at all and highlights the serious flaw in the Hospital's suggested approach.

The Hospital's interpretation would not give hospitals just a "pre-BBA amount," which is what the statutory text requires. Its interpretation would give hospitals a pre-1991 amount – meaning the amount hospitals received back before Congress initially imposed any cost reduction factors on reimbursements to hospitals for outpatient costs. The Hospital's interpretation, in other words, would give cancer hospitals a tremendous windfall that Congress in 1999 plainly did not intend – and did not write into the statute's text.

We need not decide whether the statute unambiguously supports HHS's interpretation. All we need to decide – and do decide – is that the statute does not unambiguously support

the Hospital's interpretation and that HHS's contrary interpretation is reasonable. *See Chevron*, 467 U.S. 837.

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We reverse the judgment of the District Court with respect to the Hospital's inpatient costs. The District Court should remand the case to HHS, and HHS should give the Hospital an opportunity to show the net financial impact of the new cancer drugs it used in 2000 and 2001. We affirm the judgment of the District Court with respect to the Hospital's outpatient costs.

So ordered.