

File Name: 04a0397p.06

**UNITED STATES COURTS OF APPEALS**

FOR THE SIXTH CIRCUIT

ANTHONY GUZZO,

*Plaintiff-Appellant,*

v.

THOMAS G. THOMPSON, Secretary of State of the United  
States Department of Health and Human Services,

*Defendant-Appellee.*

No. 03-1346

Appeal from the United States District Court  
for the Eastern District of Michigan at Detroit.  
No. 02-70711—Patrick J. Duggan, District Judge.

Argued: April 28, 2004

Decided and Filed: June 25, 2004\*

Before: COLE and COOK, Circuit Judges; SPIEGEL, Senior District Judge.\*\*

**COUNSEL**

**ARGUED:** Ryan D. Heilman, Joseph K. Grekin, SCHAFFER AND WEINER, Bloomfield Hills, Michigan, for Appellant. Elizabeth Larin, ASSISTANT UNITED STATES ATTORNEY, Detroit, Michigan, for Appellee. Sally Hart, CENTER FOR MEDICARE ADVOCACY, Tucson, Arizona, for Amici Curiae. **ON BRIEF:** Joseph K. Grekin, SCHAFFER AND WEINER, Bloomfield Hills, Michigan, for Appellant. Elizabeth Larin, ASSISTANT UNITED STATES ATTORNEY, Detroit, Michigan, for Appellee. Sally Hart, CENTER FOR MEDICARE ADVOCACY, Tucson, Arizona, Sarah L. Lock, AMERICAN ASSOCIATION OF RETIRED PERSONS, Washington, D.C., for Amici Curiae.

SPIEGEL, D. J., delivered the opinion of the court, in which COLE, J., joined. COOK, J. (p. 5), delivered a separate dissenting opinion.

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\* This decision was originally issued as an “unpublished decision” filed on June 25, 2004. On September 20, 2004, the court designated the opinion as one recommended for full-text publication.

\*\* The Honorable S. Arthur Spiegel, Senior United States District Judge for the Southern District of Ohio, sitting by designation.

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**OPINION**

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SPIEGEL, Senior District Judge. Plaintiff-Appellant, Anthony Guzzo, appeals from the district court's grant of summary judgment in favor of Defendant-Appellee, the Secretary of Health and Human Services (the "Secretary"), upholding the Secretary's decision to deny Guzzo Medicare reimbursement for cryosurgery, a medical treatment he underwent for prostate cancer. For the following reasons, we **REVERSE** the judgment of the district court and **GRANT** summary judgment in favor of Guzzo.

Guzzo is a Medicare beneficiary who was diagnosed with prostate cancer in 1999. His physicians prescribed cryosurgical ablation ("cryosurgery"), which was performed successfully on March 30, 1999. The question before us is whether Guzzo was legally entitled to Medicare reimbursement for his cryosurgery.

The Medicare statute authorizes coverage for numerous medical treatments and health services. *See, e.g.*, 42 U.S.C. §§ 1395d, 1395k-m. However, an exclusion from coverage is carved out "for items and services . . . not 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).

In 1997, the Secretary issued National Coverage Decision 35-96 ("NCD"), which prohibited reimbursement for cryosurgery, stating:

Cryosurgery of the prostate gland . . . destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland. The evidence is not yet sufficient to demonstrate the effectiveness of this procedure. Therefore, cryosurgery of the prostate cannot be considered reasonable and necessary under [the Medicare statute].

In subsequent years, evidence of cryosurgery's safety and effectiveness accumulated, and the Medicare administration recognized the error of the 1997 NCD. Accordingly, on February 1, 1999 – approximately two months before Guzzo underwent his surgery – the Department of Health and Human Services issued a "Decision Memorandum" approving cryosurgery for clinically localized prostate cancer. The Decision Memorandum stated that: "Cryosurgery is safe, effective, as well as medically necessary and appropriate in certain patient populations. . . . It has demonstrated effectiveness through an absolute analysis as well as through a comparative analysis." The memorandum makes clear that its purpose is to "[approve coverage of cryosurgery] as a primary treatment for clinically localized prostate cancer." The memorandum also states that NCD 35-96 "will be modified to reflect this change in policy," meaning that the NCD's prohibition of coverage for cryosurgery is lifted by force of the Decision Memorandum, and the NCD itself would be amended to reflect that.

Guzzo contends that he is entitled to reimbursement for the cryosurgery because the Decision Memorandum, issued two months before his surgery, deemed the procedure "necessary and appropriate" for the treatment of prostate cancer. The Secretary counters that the Decisional Memorandum did not make coverage effective as of February 1, 1999, because the Memorandum stated that various administrative steps – most of them relating to billing and claims processing – would have to be complete before coverage for cryosurgery would be effective. (A short time later, the Secretary announced that cryosurgery coverage would be effective beginning July 1, 1999). As such, the Secretary argues, the 1997 NCD prohibiting cryosurgery coverage was still in effect at the time of Guzzo's surgery in March 1999.

In short, Guzzo underwent cryosurgery approximately two months after the Secretary deemed the procedure "reasonable and necessary" in a Decision Memorandum, but approximately three months before the date specified by the Secretary when an administrative infrastructure would be ready to issue reimbursements.

The statute at issue in this case, 42 U.S.C. § 1395y(a)(1)(A) makes clear that the legal question before us is one of entitlement, and that entitlement to reimbursement is triggered when the Government announces that a medical procedure is “reasonable and necessary.” Here, that event occurred on February 1, 1999, when the secretary issued a decisional memorandum deeming cryosurgery “reasonable and necessary” for the treatment of prostate cancer. The language and very title of the memorandum leave no doubt that the memorandum itself is the Government’s pronouncement that cryosurgery is “reasonable and necessary.” Although the memorandum indicates that an administrative infrastructure designed to handle cryosurgery claims and billing still had to be established, the “reasonable and necessary” determination was effective as of February 1. Accordingly, we hold that because the Secretary had declared cryosurgery “reasonable and necessary” for the treatment of prostate cancer two months before Guzzo’s surgery, Guzzo is entitled to reimbursement. The Secretary might have been entitled to delay reimbursement until the administrative claims-processing system was in place, but the Secretary’s denial of Guzzo’s claim altogether was contrary to the Medicare statute.

We are not unmindful of the Department’s interest in ensuring the efficient processing of claims once a new procedure is approved. But the Department appears to have changed its practices in response to the instant case. At oral argument, the Government stated that it no longer titles these memoranda “decisional,” but rather, refers to them as “analytical” documents. Moreover, whereas the February 1 Decisional Memorandum has the language and force of an enacting document, the Department’s new memoranda make clear that any such pronouncements about changes in the status of a procedure are merely statements of intent, thereby allowing the Department to choose a date on which a formal pronouncement is made about the procedure’s reasonableness or necessity, and to synchronize that with the inauguration of an administrative scheme to process claims that would then flow from the procedure’s new, covered status.

Mr. Guzzo also requests his attorney’s fees for having to litigate the Secretary’s wrongful refusal to deny him his reasonable and necessary medical expenses. As the Secretary points out, under 28 U.S.C. § 2412(d)(1)(A), Plaintiff is only entitled to fees and costs if the Court would find the government’s position was not substantially justified. The Secretary’s position is substantially justified if it is “justified to a degree that could satisfy a reasonable person.” *Jankovich v. Bowen*, 868 F.2d 867, 869 (6<sup>th</sup> Cir. 1989)(quoting *Pierce v. Underwood*, 487 U.S. 552, 565 (1988)). “[A] position can be justified even though it is not correct. . .it can be substantially (i.e., for the most part) justified if a reasonable person could think it correct, that is, if it has a reasonable basis in law and fact.” *Cummings v. Sullivan*, 950 F.2d 492, 497 (7<sup>th</sup> Cir. 1991)(quoting *Pierce*, 487 U.S. at 566 n.2).

The Secretary argues that his position in denying Mr. Guzzo benefits was substantially justified in his reliance on NCD 35-96, and such decision was affirmed by the district court. The Secretary quotes *Heckler v. Ringer*, 466 U.S. 602, 617 (1984), “[t]he Secretary’s decision as to whether a particular medical service is ‘reasonable and necessary’ and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions.” In contrast, Plaintiff argues that the Secretary’s position was not substantially justified, as the Secretary denied payment for coverage which the Secretary himself admits was reasonable and necessary. Plaintiff argues that the Secretary knows full well that he is not entitled to create his own exceptions to mandated coverage, based on administrative convenience.

The Court finds in this instance that the Secretary’s position was not substantially justified, and that Mr. Guzzo is therefore entitled to his attorney’s fees and costs. The Secretary relied on a NCD that he had already announced was no longer correct. The Secretary’s announcement, that predated Mr. Guzzo’s surgery, clearly indicates that such surgery was reasonable and necessary. To deny coverage for a service that is designated reasonable on the basis of an outdated rule is unreasonable. The Secretary’s reliance on *Heckler* is misplaced, as in this case the issue is not whether cryosurgery is reasonable and necessary or whether Plaintiff should not have had the procedure, but rather whether the Secretary can deny a beneficiary

a treatment that has already been determined to be reasonable and necessary. For these reasons, Mr. Guzzo is awarded his reasonable attorney's fees and costs.

Having reviewed this matter, the Court FINDS for the Appellant Mr. Guzzo, DETERMINES that the Secretary's denial of Mr. Guzzo's reimbursement for cryosurgery was contrary to Congressional intent and the Medicare Act, DETERMINES that at the date of Mr. Guzzo's surgery NCD 35-96 was not supported by adequate information, VACATES the judgment and opinion of the district court, and AWARDS Mr. Guzzo attorney's fees for having to litigate the Secretary's refusal to reimburse him for his reasonable and necessary medical expenses.

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**DISSENT**

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COOK, Circuit Judge, dissenting. I would affirm the district court's grant of summary judgment in favor of the Secretary for the reasons stated in that court's opinion. The majority reaches its well-intentioned conclusion in this case without reconciling its departure from the national coverage decision (NCD) that mandated denial of Guzzo's claim, with the governing statutory and regulatory framework of the Medicare Act. The majority's opinion instead accords force of law to a "Decision Memorandum" that forecasted a likely change in the controlling NCD, though Guzzo's ineligibility was fixed by the NCD in effect at the time of his surgery.