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ELECTRONIC CITATION: 2001 FED App. 0402P (6th Cir.)
File Name: 01a0402p.06

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

MAXIMUM HOME HEALTH
CARE, INC.,
Plaintiff-Appellant,

v.

DONNA E. SHALALA, as
Secretary of the United States
Department of Health and
Human Services,
Defendant-Appellee.

No. 00-6240

Appeal from the United States District Court
for the Middle District of Tennessee at Nashville.
No. 99-00299—William J. Haynes, Jr., District Judge.

Argued: September 24, 2001

Decided and Filed: November 15, 2001

Before: MERRITT, SILER, and DAUGHTREY, Circuit
Judges.

COUNSEL

ARGUED: John P. Konvalinka, GRANT, KONVALINDA & HARRISON, Chattanooga, Tennessee, for Appellant. Howard H. Lewis, DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE GENERAL COUNSEL, Atlanta, Georgia, for Appellee. **ON BRIEF:** John P. Konvalinka, James S. McDearman, GRANT, KONVALINKA & HARRISON, Chattanooga, Tennessee, for Appellant. Michael L. Roden, ASSISTANT UNITED STATES ATTORNEY, for Appellee.

OPINION

MERRITT, Circuit Judge. This case arises under Title XVIII of the Social Security Act (the “Medicare Act”), 42 U.S.C. § 1395 *et seq.*, as a challenge to the denial of reimbursement of costs for providing health care to Medicare patients. Plaintiff Maximum Home Healthcare, Inc. (“Maximum”) appeals the district court’s judgment affirming the denial of Medicare reimbursements by Department of Health and Human Services Secretary Donna Shalala (“Secretary” or “Defendant”), in the amounts of \$58,272 and \$79,354 for the fiscal years 1990 and 1991, respectively. Maximum argues that the denial of reimbursement is arbitrary and capricious, or in the alternative, is not supported by substantial evidence. Because the Secretary has informally imposed on Medicare providers a “competitive bidding” requirement not previously made a part of Medicare regulations, the holding of the district court is REVERSED.

Facts

Maximum is a certified home health care agency that provides management consultant services to companies administering medical care to Medicare patients. In 1988, Maximum entered into a contract with Diversified Health Management Company (“Diversified”) to provide management services. For the fiscal years in question, Maximum charged \$13.00 in 1990, and \$13.60 in 1991, for each visit by Diversified to a Medicare patient. Under the Medicare Act, the Secretary contracts with a fiscal intermediary (the “intermediary”) to process and audit reimbursements to providers such as Maximum. *See* 42 U.S.C. §§ 1395h, 1395oo(a)(1)(A)(i); 42 C.F.R. §§ 413.20, 405.1803(a)(1)(1997). In this case, Blue Cross and Blue Shield of South Carolina was the intermediary. After reviewing Maximum’s fees, the intermediary determined that the average per visit rate was \$9.74 for comparable companies during both 1990 and 1991. As a result, the intermediary found that Maximum’s fees were substantially out-of-line¹ with market values. Because the Medicare Act requires that costs not be substantially out-of-line from costs of comparable institutions, the Secretary denied reimbursement of Maximum’s fees for amounts above \$9.74 per visit. *See* 42 C.F.R. § 413.9(c)(2)(articulating the substantially out-of-line standard).

¹42 C.F.R. § 413.9(c)(2) provides:

The costs of providers’ services vary from one provider to another and the variations generally reflect differences in scope of services and intensity of care. The provision in Medicare for payment of reasonable cost of services is intended to meet actual costs, however widely they may vary from one institution to another. This is subject to a limitation if a particular institution’s costs are found to be *substantially out of line* with other institutions in the same area that are similar in size, scope of services, utilization and other relevant factors (emphasis added).

Pursuant to 42 U.S.C. § 1395oo, Maximum appealed the intermediary's determination to the Provider Reimbursement Review Board (the "review board"). The review board reversed the intermediary and awarded full reimbursement to Maximum. In its reversal of the intermediary, the review board found that the intermediary's study was flawed because the companies to which Maximum was compared had been chosen arbitrarily and there was no evidence that the services offered by Maximum were identical to the other companies. In addition, the review board also found that a study done by the independent accounting firm KPMG Peat Marwick was more persuasive than the intermediary's study based on KPMG's more thorough componentized market analysis. The KPMG study found an average cost of \$11.38 per visit, with a standard deviation of \$2.93. Because Maximum's costs fell within the standard deviation, the review board found that they were reasonable and not substantially out-of-line with the market.

The intermediary then appealed to the Administrator of the Health Care Financing Administration, acting on behalf of the Secretary. The Administrator reversed the review board, and reinstated the decision of the intermediary. In finding that Maximum was not entitled to reimbursement in excess of \$9.74 per visit, the Administrator looked for guidance from the Medicare Provider Reimbursement Manual (the "manual"). Relying on the manual, the Administrator held that Maximum was not a prudent buyer,² and as a result, held

²PRM § 2102.1 states:

Reasonable costs- . . . Implicit in the intention that actual costs be paid to the extent that they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a *prudent and cost conscious buyer* pays for a given service (See § 2103). If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program (emphasis added).

costs so long as they are not substantially out-of-line with comparable companies. Thus, the holding of the district court is REVERSED, and the case is REMANDED to the district court with instructions to return the case to the Administrator to determine whether the Plaintiff's costs were substantially out-of-line with comparable companies.

competitive bidding requirement is a rule that creates a significant new burden on the provider, the rule should be subject to the rulemaking procedures. If the Secretary wants to add a competitive bidding requirement consistent with the Administrator's interpretation, she should do so, absent emergency or other justification, in accordance with the notice and comment rulemaking procedures mandated by 5 U.S.C. § 553. *See State of Ohio Dep't of Human Services v. U.S. Dep't of Health & Human Services*, 862 F.2d 1228, 1233-37(6th Cir. 1988)(holding that the adoption of an additional requirement not compelled by or implicit in existing regulations required notice and comment). Until such an amendment is made, application of the manual provisions to require competitive bidding and as a result disallow costs that are not substantially out-of-line with comparable institutions cannot be sustained. *Id.*

Lastly, it is important to note that although the district court relied on several cases to support the proposition that the prudent buyer principle can be employed to determine reasonable cost, none of the cited cases established that the prudent buyer principle is a legitimate method of disallowing costs independent of the substantially out-of-line test. *See LGH, Ltd. v. Sullivan*, 786 F. Supp. 1047, 1054 (D.D.C. 1992) (acknowledging the prudent buyer principle but neglecting to apply it as an independent standard); *New Jersey Chapter Inc. of the Am. Physical Therapy Assoc. v. Prudent Life Ins. Co.*, 502 F.2d 500 (D.C. Cir.1974)(recognizing the prudent buyer principle as a valid provision but using it to disallow costs that were substantially out-of-line); *New Jersey Speech-Language-Hearing Assoc.*, 551 F. Supp. 1024 (D.N.J. 1982) (recognizing a duty to follow manual provisions but dismissing the case based on lack of standing).

Because the actions of the Administrator in imposing the competitive bidding requirement informally were arbitrary and capricious, we do not reach the question of whether the Administrator's decision was supported by substantial evidence. It is clear that the Plaintiff is entitled to all of its

that its costs were not reasonable. *See* PRM §§ 2102.1, 2103A (articulating the prudent buyer standard). Specifically, the Administrator found fault with Maximum's failure to follow the manual's suggested procedures and solicit competitive bids³ before entering into a contract with Diversified. *See* PRM § 2135.2 (suggesting the solicitation of competitive bids). In addition, the Administrator relied on the survey by the intermediary and discounted the survey by KPMG, noting that the KPMG study did not name the comparable companies used in its survey. Relying on the prudent buyer principle and following the reasoning of the Administrator, the district court affirmed the decision of the Administrator by issuing a judgment on the administrative record. Maximum timely appealed the decision of the district court.

Discussion

The question before the Court is whether the Administrator's denial of reimbursement to Maximum was arbitrary and capricious, contrary to law, or unsupported by substantial evidence. *See* 5 U.S.C. § 706(2); *see e.g., Medical*

PRM § 2103 A states:

A. General - The *prudent and cost conscious* buyer not only refuses to pay more than the going price for an item or service, he/she also seeks to economize by minimizing cost. . . Any alert and cost conscious buyer seeks such advantages, it is expected that Medicare providers of services will also seek them (emphasis added).

³PRM § 2135.2 states that:

Generally, a *provider is prudent to solicit competitive bids*. Therefore, in the absence of competitive bidding which would otherwise be appropriate in the circumstance, the provider must demonstrate the manner in which it searched the marketplace for the most appropriate and effective means of obtaining services (emphasis added).

Rehab. Serv. P.C. v. Shalala, 17 F.3d 828, 831 (6th Cir. 1994). The Medicare Act provides that reimbursements are to be made where the costs claimed are reasonable. *See* 42 U.S.C. §§ 1395d, 1395i, 1395x. The Medicare Act defines reasonable cost as “the costs actually incurred . . . and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs.” 42 U.S.C. § 1395x(v)(1)(A). Both the regulations and the manual provide additional guidance in determining what constitutes reasonable cost. The regulations mandate applying the substantially out-of-line standard, and the manual advocates using the prudent buyer standard. *See supra* n.1 and 2. Neither the regulations nor the manual make clear how these two standards should be reconciled.

The Plaintiff argues that the Administrator’s reliance on the prudent buyer standard is misplaced because it is inconsistent with the substantially out-of-line standard, and a regulation trumps a manual provision. On their face, the substantially out-of-line standard and the prudent buyer provision as articulated in PRM §§ 2102.1, 2103A appear to be reconcilable. The Secretary could reasonably require the Plaintiff to act as a prudent buyer to avoid charging excess fees which are substantially out-of-line with the market valuation of the services.⁴

⁴The Secretary herself has provided support for this interpretation. In 1995, the Secretary stated that the adoption of the prudent buyer principle was not intended to alter or replace the substantially out-of-line test:

Regulations at 42 C.F.R. § 413.9 provide that while Medicare payment based on a provider’s reasonable costs is intended to meet the costs actually incurred, a limit applies where a particular institution’s costs are found to be substantially out of line with other institutions in the same area which are similar in size, scope of services, utilization, and other relevant factors, or the costs are otherwise not reasonable. This limitation has been interpreted in various program manuals and instructions as a

The Administrator, however, reads the prudent buyer concept as including a competitive bidding or similar market survey requirement. *See supra* n.3. Under PRM § 2135.2, the Administrator found that, to act as a prudent buyer, a provider must meet the additional requirement of engaging in a competitive bidding process or otherwise making an undefined search of the marketplace. Insofar as it adds the requirement of competitive bidding or equivalent process, we find that the Administrator’s interpretation of the prudent buyer principle is inconsistent with the substantially out-of-line test.

Because the Administrator relied on a manual provision that was inconsistent with an administrative regulation, we hold that his denial of full reimbursement to Maximum was arbitrary and capricious. The purpose of a regulatory scheme such as Medicare is to provide uniform rules by which all participants may be treated equally. *See generally* 42 U.S.C. § 1395 *et seq.* Where an administrative agency creates manual provisions that are inconsistent with the governing regulations, it creates for itself a kind of open-ended discretion in its administrative investigations, and opens the door to disparate treatment of interested parties. By adding the requirement of competitive bidding in the manual, the Secretary leaves the provider to guess as to what rule will be applied. It undermines the clear congressional purpose underlying the requirement that significant rules be established by regulations.

A fundamental requirement of the Administrative Procedures Act is that interested persons be given notice of proposed “substantive” or “legislative” regulations, and an opportunity to comment. *See* 5 U.S.C. § 553. Because the

“prudent buyer” concept.

Memorandum Distributed by the Deputy Director of the Secretary’s Bureau of Policy Development, 1995, *quoted by Granicare, Inc. v. Shalala*, 93 F. Supp.2d 24, 32 (D.D.C. 2000).