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U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

KGV EASY LEASING CORPORATION,
a corporation,

Plaintiff - Appellant,

v.

MICHAEL O. LEAVITT, Secretary of the
United States Department of Health and
Human Services (“DHHS”),

Defendant - Appellee.

No. 10-55323

D.C. No. 2:08-cv-06281-DSF-RZ

MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Dale S. Fischer, District Judge, Presiding

Submitted February 7, 2011**
Pasadena, California

Before: PREGERSON, WARDLAW, and BEA, Circuit Judges.

KGV Easy Leasing Corporation (“KGV”) is a Medicare designated
Independent Diagnostic Testing Facility (“IDTF”), an entity that performs medical

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

** The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

diagnostic tests. *See* 42 C.F.R. § 410.33(d). KGV appeals the district court’s decision upholding the Secretary of the Department of Health and Human Services’ (the “Secretary”) determination that KGV’s testing services were not reimbursable by Medicare because KGV failed to demonstrate that the tests were medically reasonable and necessary.¹ We have jurisdiction under 28 U.S.C. § 1291 and, for the reasons that follow, we affirm.

We must affirm the findings of the Secretary “if they are supported by ‘substantial evidence’ and if the proper legal standard was applied.” *Mayes v. Massanari*, 276 F.3d 453, 458-59 (9th Cir. 2001) (citing *Aukland v. Massanari*, 257 F.3d 1033,1035 (9th Cir. 2001); *see also* 42 U.S.C. § 405(g) (incorporated by reference in 42 U.S.C. § 1395ff(b)(1)(A)).

1. Medical Necessity

Medicare pays only for medical tests that are reasonable and necessary for the diagnosis or treatment of a patient. *See* 42 U.S.C. § 1395y(a)(1)(A). The Secretary has broad discretion to determine what documentation is required to establish such medical necessity. *See Maximum Comfort, Inc. v. Sec’y of Health and Human Servs.*, 512 F.3d 1081, 1086-88 (9th Cir. 2007). The documentation

¹ Because the parties are familiar with the facts of this case, we repeat them here only as necessary to explain our decision.

requirements for IDTFs, such as KGV, are found at 42 C.F.R. § 410.33.

KGV's preprinted physician order forms, submitted in support of its reimbursement claims, did not conform to the requirements of 42 C.F.R. § 410.33(d), which mandates both that (1) the beneficiary's treating physician order the tests; and (2) the results are used "in the management of the beneficiary's specific medical problem." KGV's order forms merely identified the referring physician and included check boxes which identified symptoms and possible diagnoses. KGV provided no evidence that the referring physician was also the treating physician, or that the test results were later used to help manage the patient's medical conditions.

KGV never presented evidence that supplemented the information contained on its order forms or otherwise established medical necessity, such as medical records or signed declarations from the physicians named on the forms. Therefore, the Secretary properly found that KGV failed to fulfill the IDTF documentation requirements for Medicare reimbursement.² *See* 42 C.F.R. § 410.33.

KGV's contention that various federal laws prohibited it from obtaining the

² The Secretary did not err in failing to consider the opinion of medical expert Dr. Clarke Espy because Dr. Espy's conclusions were based solely on the information contained in the order forms. Dr. Espy possessed no other information regarding the patients' medical conditions, nor did he receive any information from any treating physician.

patient medical information necessary to substantiate its claims is without merit.

The Privacy Act does not apply because it pertains only to records kept by federal agencies, *see* 5 U.S.C. 552a(a)(1), 552(f), and the Health Insurance Portability and Accountability Act of 1996 provides a means for obtaining patient medical information when used for “treatment, payment, or health care operations.” 45 C.F.R. §§ 164.502, 164.504, 164.506.

2. Waiver

Pursuant to the waiver provisions of Section 1879 of the Social Security Act, even when tests are not deemed medically necessary, Medicare may nevertheless reimburse if the provider did not know or could not reasonably have been expected to know that payment for services would be denied. *See* 42 U.S.C. § 1395pp(a).

As a Medicare supplier, however, KGV was charged with knowledge of the Medicare regulations and with the understanding that Medicare would not provide reimbursement for services that are not properly documented. *See, e.g., Fed. Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384-85 (1947) (the publishing of rules and regulations in the Federal Register gives legal notice of their contents); *Maximum Comfort*, 512 F.3d at 1088 (supplier had constructive notice of publications from the Medicare contractor setting forth documentation requirements). The documentation requirements which govern KGV are provided in federal

regulations that took effect more than seven years before the first claims at issue were filed. *See* 62 Fed. Reg. 59048 (October 31, 1997). Thus, the Secretary properly found that KGV knew or should have known that its claims would be denied, and, therefore, KGV was not entitled to a waiver under Section 1879.

CONCLUSION

For the foregoing reasons, the Secretary's final decision in this matter was supported by substantial evidence and the proper legal standards were applied.

AFFIRMED.