

FILED

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U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

INTERNATIONAL REHABILITATIVE  
SCIENCES INC, DBA RS Medical, a  
Washington corporation,

Plaintiff-Appellant,

v.

THOMAS E. PRICE, M.D., in his official  
capacity as Secretary, United States  
Department of Health and Human Services;  
UNITED STATES ATTORNEY'S OFFICE;  
UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES;  
UNITED STATES ATTORNEY; UNITED  
STATES ATTORNEY GENERAL,

Defendants-Appellees.

No. 15-35196

D.C. No. 3:08-cv-05442-BJR

MEMORANDUM\*

Appeal from the United States District Court  
for the Western District of Washington  
Barbara Jacobs Rothstein, District Judge, Presiding

Argued and Submitted July 13, 2017\*\*  
Seattle, Washington

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\* This disposition is not appropriate for publication and is not precedent  
except as provided by Ninth Circuit Rule 36-3.

Before: TASHIMA, McKEOWN, and NGUYEN, Circuit Judges.

International Rehabilitative Sciences, Inc. d/b/a RS Medical (“RS Medical”) appeals the grant of partial summary judgment to the Secretary of Health and Human Services (the “Secretary”) regarding RS Medical’s challenge to decisions by the Medicare Appeals Council concerning a knee device, the BIO-1000, that RS Medical supplied to Medicare beneficiaries. 28 U.S.C. § 1291. We affirm.

### **I. Limitation of Liability**

Substantial evidence supports each of the three independent grounds for the Medicare Appeals Council’s conclusion that RS Medical failed to establish that it “did not know, and could not reasonably have been expected to know,” that the BIO-1000 was not covered. 42 U.S.C. § 1395pp(a)(2); *see* 42 C.F.R. § 411.400(a)(2).

First, RS Medical’s knowledge is established by the Advance Beneficiary Notices sent to beneficiaries stating that Medicare probably would not pay for the BIO-1000. *See* 42 C.F.R. § 411.406(d)(1); Centers for Medicare & Medicaid Servs., Dep’t of Health & Human Servs., Medicare Claims Processing Manual, ch. 30, § 40.1.1. RS Medical now contends that it did not know that payment would be denied when it sent the Advance Beneficiary Notices and that it did so simply to protect itself from erratic coverage decisions. But the Secretary’s Medicare Claims Processing Manual warns that “[n]otifiers should not give [Advance Beneficiary

Notices] to beneficiaries unless the notifier has some genuine doubt that Medicare will make payment as evidenced by their stated reasons.” Medicare Claims Processing Manual, ch. 30, § 40.3.6. Nor is it persuasive that RS Medical’s subjective expectations for payment increased when a new billing code went into effect in January 2006. Despite this change, RS Medical continued to provide Advance Beneficiary Notices to beneficiaries stating that Medicare likely would not cover the BIO-1000.

Second, the Secretary’s regulations and manuals laying out the standards for coverage gave RS Medical constructive notice that the BIO-1000 was not covered due to its lack of peer-reviewed studies and general acceptance in the medical community. *See* 42 C.F.R. § 411.406(e)(1) & (3); Medicare Program Integrity Manual, ch. 13, § 13.7.1; Medicare Claims Processing Manual, ch. 30, § 40.1.3. RS Medical should have known that it could not meet these requirements because, as the Medicare Appeals Council properly found in an earlier appeal, “the record does not indicate general acceptance of the device by the medical community” and the BIO–1000’s “efficacy had not been established in the requisite peer-reviewed literature.” *Int’l Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 999, 1003 (9th Cir. 2012).

Third, RS Medical should have known that the BIO-1000 was not covered when it filed the claims at issue because Medicare contractors had rejected nearly

all claims in 2004 and 2005 and continued to reject some in 2006. *See* 42 C.F.R. § 411.406(a), (b). While RS Medical asserts that the denials in 2004 and 2005 were based on the use of a miscellaneous billing code (E1399) that resulted in claims being “systematically denied,” the websites cited do not support this assertion. Furthermore, RS Medical received contractor denials of coverage as late as December 2006, including on the grounds that published studies did not clearly document the effectiveness of the BIO-1000.

Nor do events in 2006 and later—a change in billing code, clinician’s increasing willingness to prescribe the BIO-1000, and more claims being covered by low level administrators—outweigh the above three independent bases for establishing RS Medical’s knowledge that the BIO-1000 was not covered. In an earlier appeal, this court rejected RS Medical’s argument that these subsequent events showed that the BIO-1000 should be covered by Medicare. *Int’l Rehab. Scis.*, 688 F.3d at 1001–04.

## **II. Advance Beneficiary Notices**

Substantial evidence also supports the Medicare Appeals Council’s conclusion that certain Advance Beneficiary Notices were generic, and therefore did not shift liability to the beneficiaries. Unlike another of RS Medical’s Advance Beneficiary Notices, which the Medicare Appeals Council has deemed effective, the Notices at issue here fail to offer a specific reason for a likely denial. Medicare

Claims Processing Manual, ch. 30, § 40.3.6.1.

**AFFIRMED.**