FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

INTERNATIONAL REHABILITATIVE SCIENCES INC, a Washington corporation, DBA RS Medical, *Plaintiff-Appellee,* v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants-Appellants.*	No. 11-35254 D.C. No. 3:08-cv-05442-RBL OPINION

Appeal from the United States District Court
for the Western District of Washington
Ronald B. Leighton, District Judge, Presiding

Argued and submitted
June 7, 2012—Seattle, Washington

Filed July 30, 2012

Before: Barry G. Silverman and Mary H. Murguia,
Circuit Judges, and Leslie E. Kobayashi, District Judge.*

Opinion by Judge Silverman

*The Honorable Leslie E. Kobayashi, United States District Judge for the District of Hawaii, sitting by designation.

COUNSEL

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Irene M. Solet (argued), Tony West, Jenny A. Durkan, Kerry Keefe, and Michael S. Raab, United States Department of Justice, Washington, D.C., and William B. Schultz, Pamela Parker, Janice L. Hoffman, Mark D. Polston, Janet Freeman, Brett Bierer, and Gerard Keating, United States Department of Health and Human Services, Washington, D.C., for the defendants-appellants.

OPINION

SILVERMAN, Circuit Judge:

The Department of Health and Human Services, the agency that administers Medicare, denied Medicare coverage for the BIO-1000, a piece of durable medical equipment used to treat osteoarthritis of the knee. In four decisions, the Medicare Appeals Council, which is the highest level of agency adjudication, ruled that the BIO-1000 had not been shown to be "reasonable and necessary" for the treatment at issue. The

supplier of the device challenges those decisions as arbitrary, capricious, and not supported by substantial evidence.

Today we join the Fourth Circuit in holding that the Medicare Appeals Council's coverage denials for the BIO-1000 were not arbitrary, capricious, or unsupported by substantial evidence. *See Almy v. Sebelius*, 679 F.3d 297, 305 (4th Cir. 2012).

We hold that, although various ALJs in other cases had granted coverage for the BIO-1000, those cases were at low levels of the agency adjudication process and thus were not binding on the Medicare Appeals Council. The Medicare Appeals Council adequately explained its reasons for denying coverage here.

Furthermore, the coverage denials were supported by substantial evidence. After reviewing the scientific studies submitted by the BIO-1000's supplier, the Medicare Appeals Council reasonably concluded that those studies failed to show the device was more effective at alleviating knee pain (the device's primary asserted purpose) than a TENS device costing 80% less. And the Medicare Appeals Council reasonably concluded that the studies failed to show that the device was effective at regenerating cartilage (its secondary asserted purpose) in humans.

We reverse the district court's grant of summary judgment for the BIO-1000's supplier and remand the case to the district court to determine in the first instance whether the supplier of the device is entitled to the benefit of any of Medicare's "limited liability" provisions.

THE MEDICARE STATUTORY AND ADMINISTRATIVE REGIME

Medicare is the federal health insurance program for the elderly and disabled. Part B — the part of the Medicare pro-

gram at issue here — is voluntary supplemental medical insurance covering doctors' services, outpatient care, and durable medical equipment. 42 U.S.C. §§ 1395j, 1395k(a)(2), 1395m. It operates much like private medical insurance: Medicare beneficiaries receive medical treatment and the providers submit claims for government reimbursement. 42 U.S.C. § 1395n.

The government controls Medicare costs, among other ways, by denying coverage claims for items or services that are not "reasonable and necessary" for treatment. 42 U.S.C. § 1395y(a)(1)(A). A device is not "reasonable and necessary" — and thus is not eligible for Medicare coverage — if it is:

- Not "safe" and "effective" — that is, if the device has not "been proven safe and effective based on authoritative evidence" or is not "generally accepted in the medical community as safe and effective for the condition for which it is used";
- "[E]xperimental" — that is, "investigational";
- Not "[a]ppropriate" for the individual beneficiary's needs; or
- "[S]ubstantially more costly than a medically appropriate and realistically feasible alternative pattern of care."

54 Fed. Reg. 4302, 4303-04 (Jan. 30, 1989); 60 Fed. Reg. 48417, 48418 (Sept. 19, 1995); Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., *Medicare Benefit Policy Manual*, ch. 15, § 110.1[C][2], available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads//bp102c15.pdf>.

The burden is on the claimant to show that the device is reasonable and necessary. *See, e.g.*, *Almy v. Sebelius*, 679

F.3d 297, 305 (4th Cir. 2012); *Friedman v. Sec'y of Dep't of Health & Human Servs.*, 819 F.2d 42, 45 (2d Cir. 1987).

Medicare contracts with private insurance carriers to determine coverage claims in the first instance. 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.920. If a contractor denies a claim, the supplier may have another contractor redetermine the claim. 42 C.F.R. § 405.940; 42 U.S.C. § 1395ff(a)(3)(A)-(B). If the supplier is dissatisfied with the redetermination, it may have a qualified independent contractor reconsider the claim. 42 C.F.R § 405.960; 42 U.S.C. § 1395ff(b)(1)(A), (c)(3)(B). If the supplier is dissatisfied with the qualified independent contractor's reconsideration decision, it may have its claim heard before an ALJ. 42 C.F.R. §§ 405.1000 & 405.1002; 42 U.S.C. § 1395ff(d)(1)(A). If the supplier is dissatisfied with the ALJ's decision, it may appeal the decision to the Medicare Appeals Council, a division of the Department of Health and Human Services. 42 C.F.R. § 405.1100; 42 U.S.C. § 1395ff(d)(2). Alternatively, the Medicare Appeals Council may on its own motion review the ALJ's decision. 42 C.F.R. § 405.1110. Each of these administrative appeals applies de novo review. 42 C.F.R. § 405.1000(d); 42 C.F.R. § 405.1100(c). The Medicare Appeals Council's decision is the agency's final decision. 42 C.F.R. § 405.1130.

If the supplier is dissatisfied with the Medicare Appeals Council's decision, it may challenge that decision in federal court. 42 U.S.C. § 1395ff(b)(1)(A).

Even if a coverage claim is denied on the ground that the items or services were not "reasonable or necessary," Medicare will nevertheless pay for the items or services if the supplier and the beneficiary "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services." 42 U.S.C. § 1395pp(a). However, once Medicare indemnifies a supplier for an unforseen claim denial under this "limited liability"

provision, the supplier is deemed to know that Medicare will not pay any future claims for the same or similar items or services. 42 U.S.C. § 1395pp(b).

A supplier can shift the risk of coverage denial to the Medicare beneficiary by notifying the beneficiary in writing that Medicare will likely deny coverage. 42 C.F.R. § 411.404. These advance beneficiary notices "allow beneficiaries to make an informed consumer decision about receiving items or services for which they may have to pay out-of-pocket." *Medicare Benefit Policy Manual*, ch. 15, § 110.1[C].

However, for the supplier to shift liability to the beneficiary, the supplier's notice must be sufficiently specific in explaining why Medicare will likely deny the claim. Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., *Medicare Claims Processing Manual*, ch. 30, § 40.3.6.1. The supplier's notice must also explain that denial is probable, not merely possible. *Id.*

FACTS AND PROCEDURAL HISTORY

Plaintiff International Rehabilitative Sciences, Inc., doing business under the name RS Medical, supplies the BIO-1000, a piece of medical equipment that delivers electrical impulses to the knee to treat osteoarthritis of the knee.

RS Medical charges more than $4,000 for a single-knee BIO-1000 and more than $5,000 for a dual-knee BIO-1000. By comparison, similar devices called "transcutaneous electric nerve stimulators," also known as TENS units, cost less than $800. *See* Centers for Medicare & Medicaid Services Durable Medical Equipment Fee Schedule (Jan. 2012), available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule-Items/CMS1254095.html>.

RS Medical began filing Medicare coverage claims for the BIO-1000 in 2004. At first, those claims were largely denied.

Over the next few years, RS Medical started to receive more coverage approvals from initial contractors, qualified independent contractors, and ALJs. In fact, coverage of the device was approved many times at these lower levels of the process. However, none of those coverage decisions reached the Medicare Appeals Council until now.

This case arises from more than 1000 separate claims for Medicare coverage of the BIO-1000 made by RS Medical on behalf of more than 400 individual beneficiaries. Each claim was denied by a Medicare contractor upon the initial determination and redetermination, then by a qualified independent contractor, then by an ALJ, and finally, when the claims were consolidated, by the Medicare Appeals Council in four separate decisions.

In each of the four decisions, the Medicare Appeals Council concluded that RS Medical had not met its burden of establishing that the BIO-1000 was "reasonable and necessary" for treatment. RS Medical had claimed the BIO-1000 was reasonable and necessary for two purposes: (1) to alleviate pain from osteoarthritis of the knee; and (2) to regenerate knee cartilage. With respect to the first purpose, the Medicare Appeals Council found that RS Medical had not offered reliable evidence to establish that the BIO-1000 was more effective at alleviating pain than TENS units costing 80% less than the BIO-1000. Although RS Medical submitted several studies purporting to show the BIO-1000's effectiveness at alleviating pain, the Medicare Appeals Council discounted those studies because, among other methodological flaws, they had been authored or sponsored by the BIO-1000 manufacturer. And with respect to the second purpose, the Medicare Appeals Council found that although some evidence showed that the BIO-1000 could regenerate cartilage in rabbits and cows, no evidence showed that it was effective at regenerating cartilage in humans. In sum, the Medicare Appeals Council concluded that the medical literature did not show that the BIO-1000 was generally accepted by the medi-

cal community. It denied Medicare coverage for the BIO-1000.

Further, with respect to the limited liability provisions, the Medicare Appeals Council declined to indemnify RS Medical for the coverage denials. It found that RS Medical "knew or had reason to know that Medicare would not cover the device" because "its efficacy had not been established in the requisite peer-reviewed literature" and because "the record does not indicate general acceptance of the device by the medical community."

Finally, the Medicare Appeals Council declined to shift liability from RS Medical to most of the individual Medicare beneficiaries, with some exceptions. It found that most of the advance beneficiary notices provided by RS Medical were generic and thus insufficient to shift liability to the beneficiaries.

After the Medicare Appeals Council denied its coverage claims, RS Medical filed this action challenging the denials as arbitrary, capricious, and not supported by substantial evidence. *See* 5 U.S.C. § 706.

Both parties moved for summary judgment. The district court granted RS Medical's motion and denied the Secretary's motion. *Int'l Rehabilitative Scis., Inc. v. Sebelius*, 737 F. Supp. 2d 1281, 1284 (W.D. Wash. 2010). It first concluded that the Medicare Appeals Council's decisions were not entitled to deference because they were inconsistent with many ALJ decisions in individual cases granting Medicare coverage for the BIO-1000 — even though those grants were at lower levels of the adjudication process, not by the Medicare Appeals Council. *Id.* at 1288-90.

The district court, explicitly proceeding de novo and without any deference to the agency, compared the strength of the evidence supporting the Medicare Appeals Council's four

coverage denials with the strength of the evidence supporting a number of ALJ coverage grants not at issue in this case. First, the district court concluded that the Medicare Appeals Council coverage denials gave no weight to the fact that the FDA had cleared the BIO-1000 as safe and effective. *Id.* at 1291-92. Second, in the district court's view, the evidence as a whole showed the medical community's widespread acceptance of the BIO-1000 for alleviating pain. *Id.* at 1292-93. The district court held that the ALJ coverage grants not at issue here were "more based on substantial evidence than the [Medicare Appeals Council] denials at issue here." *Id.* at 1293.

Having reversed the Medicare Appeals Council's coverage denials, the district court did not reach the limited liability issues of whether Medicare should indemnify RS Medical on the ground that the coverage denials were unforeseeable and whether RS Medical's advance beneficiary notices were sufficiently specific to shift liability for the BIO-1000's cost to the individual Medicare beneficiaries. *Id.* at 1293. The district court remanded the claims to the Medicare Appeals Council to determine the appropriate payment amounts. *Id.* at 1294.

The Secretary moved to amend the district court's judgment under Federal Rule of Civil Procedure 59(e). She argued that the district court's opinion was wrong and that newly discovered evidence showed that the Medicare Appeals Council's coverage denials were consistent with coverage decisions at other levels of agency adjudication. In support of her motion, the Secretary submitted BIO-1000 coverage decisions from lower levels of agency adjudication over the past three years consistently denying coverage for the BIO-1000 — including by some of the same ALJs who had granted coverage for the BIO-1000 in its early years.

The district court denied the Secretary's motion to amend the judgment. It again found that the agency's coverage deci-

sions were inconsistent, and thus the Medicare Appeals Council's coverage denials were arbitrary.

The agency appeals.

While this appeal was pending, the Fourth Circuit decided an almost identical case, *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012), involving the exact same device, brought by the device's manufacturer. BioniCare, the BIO-1000's manufacturer, brought a district court action challenging a number of Medicare Appeals Council decisions denying coverage for the BIO-1000 — including some of the same Medicare Appeals Council decisions at issue here — as arbitrary, capricious, and not supported by substantial evidence.

In *Almy*, the Fourth Circuit upheld the coverage denials. It held that substantial evidence supported the coverage denials because, as the Medicare Appeals Council explained, the studies submitted by the BIO-1000 manufacturer suffered from methodological flaws that weakened their persuasiveness, objectivity, and relevance. 679 F.3d at 305-07. The Fourth Circuit further held that the Medicare Appeals Council coverage denials were not impermissibly arbitrary, even though the agency had previously granted some coverage claims for the BIO-1000 at lower levels in the agency adjudication process, because the Medicare Appeals Council had consistently denied coverage. *Id.* at 310-11.

JURISDICTION

The district court had jurisdiction under 42 U.S.C. § 1395ff(b)(1)(A) and 42 U.S.C. § 405(g). We have jurisdiction under 28 U.S.C. § 1291.

STANDARD OF REVIEW

We review a district court's grant of summary judgment de novo and denial of a Rule 59(e) motion to amend judgment

for abuse of discretion. *Lopez v. Smith*, 203 F.3d 1122, 1131 (9th Cir. 2000) (en banc); *Floyd v. Laws*, 929 F.2d 1390, 1400 (9th Cir. 1991).

The Secretary's denial of coverage will be affirmed unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. The Secretary's factual findings are conclusive if they are supported by "substantial evidence." 42 U.S.C. § 405(g); *see also* 42 U.S.C. § 1395ff(b)(1)(A). "Substantial evidence" means " 'more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.' " *Sandgathe v. Chater*, 108 F.3d 978, 980 (9th Cir. 1997) (quoting *Andrews v. Shalala*, 53 F.3d 1035, 1039 (9th Cir. 1995)).

ANALYSIS

I. THE AGENCY'S COVERAGE DENIALS FOR THE BIO-1000

The district court reversed the Medicare Appeals Council's coverage denials on two independent grounds. We disagree on both.

[1] First, the district court held that the thousands of coverage grants by initial contractors, qualified independent contractors, and ALJs rendered the Medicare Appeals Council's coverage denials here "arbitrary and capricious" under § 706 of the Administrative Procedure Act. But not all agency inconsistency is impermissibly arbitrary — only "*[u]nexplained* inconsistency." *Marmolejo-Campos v. Holder*, 558 F.3d 903, 914 (9th Cir. 2009) (en banc) (alteration in original) (emphasis added). "[Agency] inconsistency provides a basis for rejecting an agency's interpretation only in 'rare instances, such as when an agency *provides no explanation at all for a change in policy*, or when its explanation is so unclear or contradictory that we are left in doubt as to

the reason for the change in direction.' " *Id.* (emphasis added) (citation omitted). Here, the Medicare Appeals Council explained why it disagreed with the lower agency adjudicatory decisions granting coverage: the studies that those decisions relied on purporting to show the BIO-1000's effectiveness at alleviating pain had been authored or sponsored by the BIO-1000 manufacturer, and the studies purporting to show the BIO-1000's effectiveness at regenerating cartilage had been conducted on animals, not humans. Because they explained the reasons for their disagreement, the Medicare Appeals Council's coverage denials were not impermissibly arbitrary.

[2] Moreover, the district court incorrectly measured agency inconsistency across different levels of agency adjudication. No Medicare Appeals Council decision has granted coverage for the BIO-1000; the only coverage grants were by contractors, qualified independent contractors, and ALJs. As the Fourth Circuit held in this exact situation, " '[e]ven if these [decisions from lower levels of agency adjudication] were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently.' " *Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (third alteration in original) (quoting *Cmty. Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003) (holding that Secretary's denial of Medicare Part A payments was not arbitrary and capricious even though it was inconsistent with prior lower-level agency adjudicatory decisions)). The Fourth Circuit illustrated the district court's error by analogy: "The decisions of local contractors cannot deprive [the Secretary] of that discretion [to determine when a device is reasonable and necessary], any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court." *Id.* at 311.

RS Medical argues that the agency has regulatory tools that could remedy these inconsistencies — in particular, it can issue local or national coverage determinations (i.e., up-front

rules about whether a particular item is covered). *See* 42 U.S.C. § 1395ff(f)(1)(B), (2)(B). But while the agency *may* make coverage determinations via up-front rules, it is not *required* to do so; rather, the agency has discretion in whether to make coverage determinations by up-front rulemaking or by case-by-case adjudication. *See Almy*, 679 F.3d at 303-04; *see also Heckler v. Ringer*, 466 U.S. 602, 617 (1984) ("The 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."). As the Fourth Circuit noted in *Almy*, "directly applicable Supreme Court precedent . . . makes clear that the Secretary enjoys full discretion to choose to proceed by adjudication rather than by rulemaking." 679 F.3d at 303.

[3] We hold that the Medicare Appeals Council's coverage denials were not arbitrary.

Second, the district court, having found that the Medicare Appeals Council decisions denying coverage were arbitrary, then compared those decisions side-by-side against the lower-level agency decisions granting coverage and concluded that the coverage grants were "more based on substantial evidence than the [Medicare Appeals Council] denials at issue here." 737 F. Supp. 2d at 1293; *see also id.* at 1291.

[4] As a preliminary matter, the district court misapplied the "substantial evidence" standard of review. That standard requires the district court to determine whether the agency decision *on direct review* is supported by substantial evidence. It does not give the district court license to compare the agency decision on direct review with other agency decisions not on review and determine which is supported by more substantial evidence. That would be tantamount to de novo review, which is not the standard. *See* 42 U.S.C.

§ 405(g); *Sandgathe v. Chater*, 108 F.3d 978, 980 (9th Cir. 1997).

The Medicare Appeals Council held that RS Medical had not met its burden of showing that the BIO-1000 was "reasonable and necessary" because the studies it submitted purporting to show the BIO-1000's effectiveness suffered from methodological flaws. Among other flaws, the studies RS Medical submitted allegedly showing the BIO-1000's effectiveness *at alleviating pain* had been authored or sponsored by the BIO-1000 manufacturer, thus bringing their objectivity into question. And the studies RS Medical submitted purporting to show the BIO-1000's effectiveness at *regenerating cartilage* had been conducted on rabbits and cows, not humans, thus lessening their relevance.

[5] The district court held that the Medicare Appeals Council's decisions "gave no weight to the FDA's clearance of the BIO-1000 for the purpose of treating symptoms of osteoarthritis." 737 F. Supp. 2d at 1291. FDA clearance, however, is *necessary*, but not *sufficient*, for Medicare coverage. 68 Fed. Reg. 55,634, 55,636 (Sept. 26, 2003). FDA review and Medicare coverage review have different purposes. *Id.* FDA review seeks to determine whether a device is "safe and effective" such that it can be marketed to the general public. By contrast, Medicare coverage review seeks to determine whether the device is "reasonable and necessary" for treatment such that the device is worth the government's money. *Medicare Benefit Policy Manual*, ch. 15, § 110.1[C][2]. To be "reasonable and necessary" for treatment, a device must be "safe and effective," but other considerations are also relevant — like whether there are less costly but equally effective devices available. *Id.* As the Fourth Circuit held in *Almy*, "[w]hile FDA approval may . . . inform the Secretary's decision as to whether a device is 'reasonable and necessary,' it cannot tie the Secretary's hands." 679 F.3d at 308.

[6] Additionally, the *type* of FDA clearance is relevant to whether Medicare will cover a device. Section 510(k) clear-

ance — the type of clearance given to the BIO-1000 — is a less rigorous type of FDA review. *See* 21 U.S.C. § 360c(f)(1)(A). It requires the provider to show only that the device is "substantially equivalent" to (that is, as safe and as effective as) a device legally on the market before 1976, when the FDA began regulating medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). In effect, Section 510(k) clearance allows a new device to piggy-back off the approval of a grandfathered device — here, a TENS unit. By contrast, Section 515 premarket approval is a much more rigorous safety review in which the FDA examines all studies and investigations of the device's safety and effectiveness. *Id.* at 317-18. Thus, the fact that the BIO-1000 received only the less rigorous 510(k) FDA clearance further undercuts the district court's holding that the Medicare Appeals Council gave it insufficient weight.

The district court also held that the Medicare Appeals Council's coverage denials were not supported by substantial evidence because they overlooked evidence showing "the medical community's widespread acceptance of the BIO-1000 as a reasonable treatment for osteoarthritis." 737 F. Supp. 2d at 1292-93. In particular, the district court concluded that the Medicare Appeals Council improperly discounted the studies published in peer-reviewed journals purporting to show the BIO-1000's effectiveness at alleviating knee pain on the ground that those studies had been authored or sponsored by the BIO-1000 manufacturer and failed to consider that many other insurers cover the BIO-1000. *Id.* at 1293.

[7] With respect to the studies published in peer-reviewed journals, Medicare's own guidance manual explains — as the Medicare Appeals Council held here — that "limited case studies distributed by sponsors with financial interest in the outcome[ ] are not sufficient evidence of general acceptance by the medical community."[1] Centers for Medicare & Medi-

[1]RS Medical argues that this regulation does not apply because the studies it submitted were merely "authored" — not "distributed" — by the

caid Servs., Dep't of Health and Human Servs., *Medicare Program Integrity Manual* § 13.7.1. Additionally, the Medicare Appeals Council decisions adopted or approved the reasoning of the underlying ALJ decisions denying coverage, each of which detailed additional methodological flaws in the studies — i.e., the studies were not double-blind or random. Thus, the Medicare Appeals Council provided adequate reasons for discounting the studies authored or sponsored by the BIO-1000 manufacturer. As the Fourth Circuit explained in *Almy*: "It is not our office to tender an independent judgment on the value and validity of the various scientific studies submitted. We ask only whether the Secretary's assessment was a reasonable one, and we are satisfied that it was." 679 F.3d at 305-06.

[8] With respect to other insurers' coverage of the BIO-1000, the district court erred in holding that that fact alone established the medical community's general acceptance of the BIO-1000. The Medicare guidance manual explains that "[a]cceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community." *Medicare Program Integrity Manual* § 13.7.1. Rather, whether a device is generally accepted by the medical community depends on, in decreasing order of importance, "[s]cientific data or research studies published in peer-reviewed medical journals," "[c]onsensus of expert medical opinion (i.e., recognized authorities in the field)," and "[m]edical opinion derived from consultations with medical associations or other health care experts." *Id.* Consistent with those standards, the

BIO-1000's sponsors. But as the Fourth Circuit explained in *Almy*: "Given the substantial deference that we owe the Secretary's reasonable interpretations of her own regulations . . . we cannot conclude that her actions were unreasonable. It is a maxim of evidence that a party's interest in a potential outcome can affect his objectivity, and the [guidance manual] regulation is clearly directed at ensuring that coverage decisions rest on an objective and disinterested foundation." 679 F.3d at 306 (citation omitted).

Medicare Appeals Council reasonably concluded that neither research studies nor expert medical consensus established the medical community's general acceptance of the BIO-1000.

RS Medical argues that the fact that the agency had assigned a Healthcare Common Procedure Coding System billing code and fee schedule for the BIO-1000 showed that the agency had determined that the device was covered by Medicare. But the fact that an item receives a billing code or fee schedule does not mean it is covered by Medicare, as the billing code and fee schedule manuals caution. Rather, the purpose of those codes and schedules is to promote uniform reporting and statistical data collection. They are used not only by Medicare, but also by private insurers and state Medicaid programs. As the Fourth Circuit held in *Almy*, the fact that the BIO-1000 had received a billing code and fee schedule does not undermine the substantial evidence supporting the Medicare Appeals Council's coverage denials. 679 F.3d at 307 n.3.

[9] In sum, we hold that the district court erred in finding that there was not substantial evidence supporting the Medicare Appeals Council's coverage denials for the BIO-1000 on the ground that the medical literature did not establish the medical community's general acceptance of the device. We agree with the Fourth Circuit:

> Using the appropriate standard of review and burden of proof, the Secretary's determination that [the BIO-1000's supplier] did not establish that the BIO-1000 was "safe and effective" and "not experimental or investigational" was in fact supported by substantial evidence. . . . The [Medicare Appeals Council] reviewed the studies submitted by [the BIO-1000's supplier] in support of the BIO-1000 and identified numerous deficiencies that deprived them of persuasive value.

Almy, 679 F.3d at 305-06. Thus, we reverse the district court's grant of summary judgment in favor of RS Medical.

II. INDEMNIFICATION AND SHIFTING LIABILITY TO BENEFICIARIES

[10] Because the district court reversed the Medicare Appeals Council's coverage denials, it did not reach the issues of whether substantial evidence supported the Medicare Appeals Council's decision not to indemnify RS Medical for the coverage denials under the "limited liability" provision on the ground that the denials were foreseeable and whether substantial evidence supported the Medicare Appeals Council's conclusions about which of the panoply of advance beneficiary notices in the record were sufficiently specific to shift liability to individual beneficiaries and which were too generic. 737 F. Supp. 2d at 1293-94; 42 U.S.C. § 1395pp. The district court should determine these issues in the first instance on remand.

REVERSED AND REMANDED.