PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

MONIQUE D. ALMY, Chapter 7 Trustee for the Bankruptcy Estate of BioniCare Medical Technologies, Incorporated, *Plaintiff-Appellant,* v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, *Defendant-Appellee.*	No. 10-2241

Appeal from the United States District Court
for the District of Maryland, at Baltimore.
Richard D. Bennett, District Judge.
(1:08-cv-01245-RDB)

Argued: January 26, 2012

Decided: April 26, 2012

Before WILKINSON, GREGORY, and KEENAN,
Circuit Judges.

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Gregory and Judge Keenan joined.

COUNSEL

ARGUED: Robert Lloyd Roth, HOOPER, LUNDY & BOOKMAN, PC, Washington, D.C., for Appellant. Michael Raab, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. **ON BRIEF:** Matthew W. Cheney, CROWELL & MORING LLP, Washington, D.C., for Appellant. William B. Schultz, Acting General Counsel, Janice L. Hoffman, Associate General Counsel, Mark D. Polston, Deputy Associate General Counsel for Litigation, Brett Bierer, Janet Freeman, Gerard Keating, DEPARTMENT OF HEALTH & HUMAN SERVICES, Washington, D.C.; Tony West, Assistant Attorney General, Irene M. Solet, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Rod J. Rosenstein, United States Attorney, Larry D. Adams, Assistant United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Baltimore, Maryland, for Appellee.

OPINION

WILKINSON, Circuit Judge:

Medicare Part B is a federal program that, among other things, subsidizes items of durable medical equipment for qualified recipients. Plaintiff Monique D. Almy, the Chapter 7 trustee for the bankruptcy estate of BioniCare Medical Technologies, Inc., contests determinations of the Medicare Appeals Council (MAC) refusing to provide coverage for the BIO-1000, a device to treat osteoarthritis of the knee. Almy alleges that the Secretary of Health and Human Services improperly used the adjudicative process to create a policy of denying coverage for the BIO-1000, that the MAC's decisions were not supported by substantial evidence, and that the MAC's decisions were arbitrary and capricious on account of a variety of procedural errors. We reject those contentions and affirm the judgment of the district court.

I.

A.

Medicare is a federal program providing subsidized health insurance for the aged and disabled. *See* 42 U.S.C. § 1395 *et seq.* The Secretary of Health and Human Services ("the Secretary"), Kathleen Sebelius, is charged by Congress with administering the Medicare statute. *Id.* § 1395ff(a)(1).

Part B of the Medicare Act extends coverage to certain types of durable medical equipment (DME) for qualified recipients. 42 U.S.C. § 1395k(a); *id.* § 1395x(s)(6). Not all DME is guaranteed coverage under Medicare Part B, however. The Medicare statute explicitly provides that "no payment may be made under . . . Part B of this subchapter for any expenses incurred for items . . . [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a)(1)(A).

Acting through her operating components, the Secretary can elect to determine the coverage of DME in one of three ways. First, she can make a "national coverage determination" (NCD) binding throughout the Medicare system and not subject to review by administrative law judges. *Id.* § 1395ff(f)(1)(B). Second, one of the private insurance carriers with whom the Secretary contracts to administer claims under Part B, *see id.* § 1395u(a), can issue a "local coverage determination" (LCD) "respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis." *Id.* § 1395ff(f)(2)(B). Finally, if no NCD or LCD is in place, "contractors may make individual claim determinations," including whether a particular DME meets the statutory requirement of being "reasonable and necessary." 68 Fed. Reg. 63,693.

The Secretary has also developed guidance in the Medicare Program Integrity Manual (MPIM) for Medicare contractors applying the "reasonable and necessary" standard. Rather than create distinct criteria for individual claim determinations and LCDs, the Secretary has directed contractors to apply a uniform set of standards, providing that "[w]hen making individual claim determinations, . . . [a] service may be covered by a contractor if it meets all of the conditions listed in [MPIM] § [1]3.5.1, Reasonable and Necessary Provisions in LCDs below."[1] MPIM § 13.3, Individual Claim Determinations. For a device to be considered "reasonable and necessary," contractors must determine that the item is "safe and effective; not experimental or investigational . . . ; and appropriate" in terms of both "accepted medical practice" and "the patient's medical need." MPIM § 13.5.1, Reasonable and Necessary Provisions in LCDs.

The Secretary has also instructed contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either "published authoritative evidence" such as "definitive randomized clinical trials" or "general acceptance by the medical community," with the caveat that "[a]cceptance by individual health care providers" and "limited case studies distributed by sponsors with a financial interest in the outcome[ ] are not sufficient evidence of general acceptance by the medical community." MPIM § 13.7.1, Evidence Supporting LCDs.

The Medicare statute and accompanying regulations create a five-step appeals process for claimants dissatisfied with the initial determination of the Medicare contractor. First, the party can seek redetermination from the initial contractor. 42 U.S.C. § 1395ff(b)(1)(A). Second, the claimant can seek "re-

[1]MPIM § 13.3, Individual Claim Determinations, erroneously lists the chapter number for "Reasonable and Necessary Provisions in LCDs" as "3.5.1." This appears to be a typographical error; the correct heading for that subsection is "13.5.1."

consideration" of the contractor's determinations by a "qualified independent contractor" (QIC). *Id.* § 1395ff(c). If no applicable NCD or LCD governs claims for a particular device, the QIC is instructed by statute to "make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence." *Id.* § 1395ff(c)(3)(B)(ii)(III). Third, a claimant can request "a hearing on a decision of a qualified independent contractor" before an administrative law judge. *Id.* § 1395ff(d)(1). Fourth, a party's final administrative appeal within the Department of Health and Human Services is to the Medicare Appeals Council (MAC), a part of the Departmental Appeals Board. *Id.* § 1935ff(d)(2). The statute specifically provides that "the Departmental Appeals Board shall review the case de novo." *Id.* § 1395ff(d)(2)(B). Lastly, a party can bring a civil action in federal court to review a final decision of the Secretary (through the Medicare Appeals Council). *Id.* § 1395ff(b)(1)(A); § 405(g). The statute there prescribes that the Secretary's findings, "if supported by substantial evidence, shall be conclusive" in the judicial proceeding. *Id.* § 405(g).

B.

The DME at issue in this case is the BioniCare Stimulator System, Model 1000 (BIO-1000), a medical device used to treat osteoarthritis of the knee by delivering electrical pulses to the joint. The device was originally developed by Murray Electronics, which sought approval from the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act to market the device. The BIO-1000 was originally submitted for "Pre-Market Approval" (PMA), the most stringent review under the Act, which requires sophisticated proof of the safety and effectiveness of the device. *See* 21 U.S.C. § 360c *et seq.* In 1997, however, Murray Electronics notified the FDA of its intent to market the BIO-1000 pursuant to a less-rigorous provision of the statute, known as the "510(k) process." *See* 21 U.S.C. § 360c(f)(1)(A)(ii).

Section 510(k) allows a device to be marketed based not on independent clinical trials of the device itself, but instead because the device is "substantially equivalent to another device" that is already on the market. *Id.* FDA regulations require that for a device to receive 510(k) approval, the device must have "the same intended use as the predicate device" and the sponsor must "demonstrate[ ] that the device is as safe and as effective as a legally marketed device." 21 C.F.R. § 807.100(b)(ii)(B). In July 1997, the FDA issued approval under 510(k) for the BIO-1000 to be marketed, finding that it was substantially equivalent to the Transcutaneous Electric Nerve Stimulator (TENS) device that was already on the market.

Since that time, BioniCare has distributed the BIO-1000 to thousands of patients and submitted numerous Medicare claims. While some contractors have provided Medicare coverage for the BIO-1000, others have frequently refused to cover the device. At issue in this appeal are eight groups of claims denying coverage, which were appealed through the entire administrative process to the MAC. In seven of those cases, the Secretary, through the MAC, determined that the BIO-1000 was not "reasonable and necessary" and was therefore excluded from the statutory coverage of Medicare Part B. All seven cases relied on BioniCare's failure to provide evidence in accordance with MPIM § 13.7.1 that demonstrated that the device was "safe and effective." Appellant's Br. at 21-27 (describing the 535, 310, 208, 891, 852, 259, and 781 Decisions). In the eighth case, BioniCare did not appeal the ALJ's determination that the device was "reasonable and necessary," and so the MAC did not address that question. Instead, the MAC merely affirmed a payment calculation based on a local fee schedule that was unfavorable to BioniCare. Appellant's Br. at 27-28 (describing 191 Decision).

Plaintiff Monique D. Almy, the Chapter 7 trustee for the bankruptcy estate of BioniCare, filed this lawsuit in May 2008, seeking a reversal of the MAC decisions. Both Almy

and the Secretary moved for summary judgment, and on September 3, 2010, the district court granted the Secretary's motion in full. This appeal followed.

II.

A brief discussion of the standard of review of the Secretary's decision is necessary at the outset.

A.

With respect to factual determinations, the Medicare statute specifies that "the findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g). The Supreme Court has defined substantial evidence as "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Our review is therefore necessarily a limited one. "[W]e do not undertake to re-weigh conflicting evidence, make credibility determinations, or substitute our judgment for that of the Secretary. Where conflicting evidence allows reasonable minds to differ . . . , the responsibility for that decision falls on the Secretary." *Craig v. Chater*, 76 F.3d 585, 589 (4th Cir. 1996).

Quite apart from matters of fact, the Secretary's decisions are governed by the Administrative Procedure Act (APA), which requires courts to determine whether the agency's action was "arbitrary, capricious, an abuse of discretion, . . . otherwise not in accordance with law, . . . [or] without observance of procedure required by law." 5 U.S.C. § 706(2). Our court has been clear that "[r]eview under this standard is highly deferential, with a presumption in favor of finding the agency action valid." *Ohio Vall. Envt'l Coalition v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009). In practice, an action will not be considered arbitrary and capricious so long as "the agency has examined the relevant data and provided

an explanation of its decision that includes 'a rational connection between the facts found and the choice made.'" *Id.* at 192-93 (quoting *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983)).

B.

In addition to these statutory directives, a variety of judicial doctrines require that courts not casually overturn the Secretary's decisions. First, it is well recognized that the Secretary's interpretation of what is "reasonable and necessary" under the Medicare Act is entitled to judicial deference pursuant to *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). "[B]ecause the Secretary is charged with administering the Medicare Act, we substantially defer to the Secretary's construction of any ambiguous language in the Act, if the Secretary's construction 'is based on a permissible construction of the statute.'" *MacKenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341, 346 (4th Cir. 2007) (quoting *id.* at 843).

Second, the Secretary is also entitled to deference under *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945), for her interpretation of the regulations that implement the Medicare Act's "reasonable and necessary" standard. This principle requires courts to give an agency's view of its own regulations "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id.* at 414. The Supreme Court has emphasized the importance of careful adherence to this standard in the Medicare context, which deals with "a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns." *Th. Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)

Thus the very nature of the Medicare program suggests that the Secretary's determinations are entitled to deference from

this court. The parties agree that Medicare regulation "is technical and complex" and that the Secretary "has longstanding expertise in the area," circumstances under which "principles of deference have particular force." *Alum. Co. of Amer. v. Cent. Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 390 (1984). Because the determination of what is "reasonable and necessary" also requires a significant degree of medical judgment, we must be mindful that "[w]hen examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential." *Balt. Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983).

With these limitations in mind, we consider in turn BioniCare's three challenges to the MAC decisions affirmed by the district court. First, BioniCare disputes the Secretary's use of the individual adjudication process at all, arguing that she should instead have issued an NCD or LCD for the BIO-1000. Second, even if adjudication was the correct process, BioniCare asserts that the MAC decisions were not supported by substantial evidence. Finally, BioniCare alleges a variety of procedural errors at the various rungs of the administrative ladder that it claims infect the MAC's ultimate decisions.

III.

BioniCare contends that because the MAC decisions were based on the safety and effectiveness of the BIO-1000 generally, rather than the medical necessity of the device for any particular patient, the Secretary erred by proceeding through individual adjudications, and she should instead have issued an NCD or LCD to implement a prospective coverage policy. But BioniCare ignores directly applicable Supreme Court precedent, which makes clear that the Secretary enjoys full discretion to choose to proceed by adjudication rather than by rulemaking.

One of the earliest principles developed in American administrative law was the idea that "the choice made

between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute preserves this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process. Indeed, in *Heckler v. Ringer*, 466 U.S. 602 (1984), the Supreme Court expressly foreclosed the argument that BioniCare now presses, holding that "[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." *Id.* at 617.

Not only does the Secretary have the discretion to choose which route to take in assessing the Part B coverage for a device, but BioniCare's asserted concern that the Secretary is "improperly implement[ing] a coverage policy," Appellant's Br. at 50, is simply illusory. The Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. *See, e.g.*, 42 C.F.R. § 405.1062 ("If an ALJ or MAC declines to follow a policy in a particular case, . . . [the] decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect."). The purported "policy" in this case is nothing more than the accretion of individual decisions finding that the BIO-1000 does not meet the statutory requirements for coverage.

Our court has previously refused to constrict the "flexibility of the Secretary" in implementing the "reasonable and necessary" standard, *MacKenzie Medical Supply*, 506 F.3d at 348, but that is precisely what BioniCare asks us to do. As the district court correctly recognized, the result of BioniCare's theory would be to "effectively requir[e] the Secretary to issue item-specific coverage rules for each and every item of DME

before issuing case adjudications." *Almy v. Sebelius*, 749 F. Supp. 2d 315, 324 n.2 (D. Md. 2010). But Congress has clearly left it to the discretion of the Secretary to decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year. The Medicare Act "has produced a complex and highly technical regulatory program," the administration of which turns on "[t]he identification and classification of medical eligibility criteria [that] necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991). These are the hallmarks of agency discretion, and BioniCare points to no statutory text or other legal basis that would allow the courts to inject themselves into the administration of the Part B claims process. Congress has not seen fit to set mandatory conditions for the use of NCDs or LCDs, and we refuse to craft such requirements out of whole cloth.

The Supreme Court has long warned about the unsuitability of precisely the kind of rule BioniCare urges us to adopt: "To hold that the [Secretary] had no alternative in this proceeding but to approve the proposed transaction, while formulating any general rules it might desire for use in future cases of this nature, would be to stultify the administrative process." *Chenery*, 332 U.S. at 202. And like the Supreme Court, "[t]hat we refuse to do." *Id.*

IV.

BioniCare's next major claim is that the Secretary's decisions were not supported by "substantial evidence" as required by both the Medicare statute and the APA. This allegation comes in three parts. First, BioniCare asserts that the Secretary applied the wrong standard in assessing the relevant evidence. Second, it claims that the Secretary has a heightened burden of proof. BioniCare asserts that it made a prima facie case for coverage, which requires the Secretary to produce affirmative evidence in rebuttal in order for the MAC's

denial of coverage to be supported by substantial evidence. Finally, BioniCare claims that it did in fact produce adequate evidence to justify coverage of the BIO-1000, and that the MAC's critique of that proof is inadequate to support a denial of such coverage. We disagree with BioniCare on all three fronts.

A.

BioniCare first contends that the MAC decisions applied the wrong standard for individual claim determinations, arguing that the MAC erroneously relied on standards only applicable to LCDs. The Secretary has, however, made clear that the same criteria that govern LCDs should also govern individual adjudications. MPIM § 13.3, Individual Claim Determinations, specifically provides that for individual adjudications, contractors should use the standards set out for LCDs in MPIM § 13.5.1. It is that section, entitled "Reasonable and Necessary Provisions in LCDs," that sets out the substantive criteria that a device must meet in order to receive coverage. Specifically, in order to be considered "reasonable and necessary," *see* 42 U.S.C. § 1395y(a)(1)(A), a device must be "safe and effective; not experimental or investigational . . . ; and appropriate," MPIM § 13.5.1, and BioniCare does not dispute that a device must meet those requirements in order to receive Part B coverage.

BioniCare contends, however, that the Secretary erred by using the guidelines of MPIM § 13.7.1, Evidence Supporting LCDs, to evaluate the studies it offered to show that the BIO-1000 was safe and effective. BioniCare argues that these standards apply only to LCDs, and not to individual adjudications. As we have explained, however, the Secretary has adopted a single set of standards that governs both LCDs and individual adjudications. The MPIM section on individual adjudications, § 13.3, indisputably incorporates by reference the substantive criteria applicable to LCDs in § 13.5.1, and MPIM § 13.7.1 does no more than explicate the type of evidence that may

demonstrate a device's compliance with the conjunctive standards of § 13.5.1. Specifically, MPIM § 13.7.1 requires a claimant to show that a device is safe and effective through "published authoritative evidence" such as "definitive randomized clinical trials" or "general acceptance by the medical community," with the qualification that "[a]cceptance by individual health care providers" and "limited case studies distributed by sponsors with a financial interest in the outcome[ ] are not sufficient evidence of general acceptance by the medical community." MPIM § 13.7.1, Evidence Supporting LCDs. Far from being "arbitrary [or] capricious," the Secretary has directed contractors to use uniform criteria in assessing Part B coverage, supported by uniform types of evidence, and it was not erroneous or inconsistent for the MAC to have applied the requirements of MPIM § 13.7.1.

B.

Second, BioniCare disputes the appropriate burden of proof that governs a "reasonable and necessary" determination by the MAC. It claims that, having made a prima facie case, the burden shifts to the Secretary to rebut that evidence with her own offer of proof, and that it is insufficient for the MAC to provide merely a critique of BioniCare's showing. But there is no basis in law for this assertion. It is well established that "a claimant . . . has the burden of proving entitlement to Medicare benefits," *Friedman v. Sec'y of Dept. of Health and Hum. Servs.*, 819 F.2d 42, 45 (2d Cir. 1987).

Even the case BioniCare cites in support of its conclusion, *Dir., Off. of Worker's Comp. Progs. v. Greenwich Collieries*, 512 U.S. 267 (1994), does not point to a different result. While it is doubtful that the standards for formal adjudication at issue in that case even apply to these informal proceedings under the Medicare Act, the most that the *Greenwich Collieries* Court concluded was that "when the party with the burden of persuasion establishes a prima facie case supported by 'credible and credited evidence,' it must either be rebutted or

accepted as true." *Id.* at 280. Here, the MAC's conclusion was that BioniCare had failed to satisfy the critical first step, because it did not provide "credible and credited evidence," as measured against the standards set out in MPIM § 13.7.1.

C.

Using the appropriate standard of review and burden of proof, the Secretary's determination that BioniCare did not establish that the BIO-1000 was "safe and effective" and "not experimental or investigational" was in fact supported by substantial evidence. 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.

The MAC reviewed the studies submitted by BioniCare in support of the BIO-1000 and identified numerous deficiencies that deprived them of persuasive value. BioniCare submitted twenty-one separate studies. Five of these included no analysis and were merely conclusory. Eight did not discuss the type of electrical stimulation treatment for which the BIO-1000 was ostensibly prescribed. One referred to a device other than the BIO-1000. And three tested electrical stimulation treatments in animals.

The MAC identified additional methodological errors in the four remaining studies that did actually address the BIO-1000's safety and effectiveness in humans and that could potentially offer credible evidence. All four studies failed to isolate the effect of concurrent drug therapy. In other words, they failed to exclude the possibility that other drugs or regimens besides the BIO-1000 accounted for any patient improvement. Two studies had small sample sizes, one of only 58 subjects and another with 78 subjects. Two others had experimental design problems -– one study was not random-

ized or double-blind, and the other lacked a proper control group.

In addition, the MAC discounted these four studies because the authors all had financial ties to either BioniCare or the BIO-1000's original developer Murray Electronics. The regulations pertaining to acceptable evidence in the MPIM explicitly provide that "limited case studies distributed by sponsors with a financial interest in the outcome[ ] are not sufficient evidence of general acceptance by the medical community." MPIM § 13.7.1, Evidence Supporting LCDs.

BioniCare asserts that because its studies were independently published, they were not "distributed by sponsors," and therefore not within this rule. Given the substantial deference that we owe the Secretary's reasonable interpretations of her own regulations, however, we cannot conclude that her actions were unreasonable. *See Seminole Rock*, 325 U.S. at 414. It is a maxim of evidence that a party's interest in a potential outcome can affect his objectivity, and the MPIM regulation is clearly directed at ensuring that coverage decisions rest on an objective and disinterested foundation. The financial interest of those conducting studies goes to the credibility of the supporting evidence, and this court has been clear that "absent extraordinary circumstances, we will not disturb an [agency]'s credibility determinations." *N.L.R.B. v. Transpersonnel, Inc.*, 349 F.3d 175, 184 (4th Cir. 2003).[2]

[2]BioniCare seeks to rehabilitate its evidence from this deficiency by claiming that any bias in the studies is outweighed by the fact that the articles are peer-reviewed. The weight to be given peer reviews is again an evidentiary matter best left to the MAC as finder of fact, and not to a reviewing court of appeals. Moreover, it is an argument that courts are particularly ill-equipped to assess. Whether a medical study satisfied the standards of scientific rigor that BioniCare claims is hardly a matter on which the normal judicial deference to the Secretary's determinations can be discarded.

While the record is more than sufficient to justify the Secretary's factual conclusion that BioniCare had not carried its burden of showing that the BIO-1000 was safe and effective, our analysis is not scientifically detailed. Nor would such an assessment be permitted. The Supreme Court has warned time and again that a "technical factual dispute simply underscores the appropriateness of deferring" to agency decisions. *Talk America, Inc. v. Mich. Bell Tel. Co.*, 131 S. Ct. 2254, 2265 n.7 (2011). Properly mindful of this fact, BioniCare's brief does not explore the substance of the science. For "we as a court are confronted with a problem in administrative law, not in chemistry, biology, medicine, or ecology. It is the administrative agency which has been called upon to hear and evaluate testimony . . . relevant to its ultimate question." *Envt'l Def. Fund v. EPA*, 489 F.2d 1247, 1252 (D.C. Cir. 1973). The MAC "has greater expertise and stands in a better position than this Court to make the technical and policy judgments necessary to administer the complex regulatory program at issue." *Talk America*, 131 S. Ct. at 2265 n.7. The court's role is to perform the "narrowly defined duty of holding agencies to certain minimal standards of rationality." *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976). There can be little doubt that the Secretary's decisions surpass that threshold and are supported by "substantial evidence."[3]

[3]BioniCare also argues that the Secretary's acceptance of the BIO-1000's safety and effectiveness is demonstrated by the fact that the Center for Medicare and Medicaid Services assigned a billing code to the device under the Healthcare Common Procedure Coding System (HCPCS) and created a fee schedule for claims for the device. But the fact that the Secretary may have taken steps to facilitate the administration of the thousands of claims for the BIO-1000 cannot dictate the ultimate determination on those claims. The Medicare statute precludes coverage of items that are "not reasonable and necessary" "[n]otwithstanding any other provision of this subchapter." 42 U.S.C. § 1395y(a)(1)(A). Further, the HCPCS code book contains a disclaimer that "[i]nclusion or exclusion of a procedure, supply, product or service does not imply any health insurance coverage or reimbursement policy." *Almy*, 749 F. Supp. 2d at 332.

V.

Even though the Secretary exercised her statutory discretion to proceed through adjudication, and her decisions were supported by substantial evidence, BioniCare nevertheless contends that the Secretary committed a variety of procedural errors that fatally undermine the MAC decisions. These claims are rooted in the familiar standards of the APA, 5 U.S.C. § 706(2)(A), which permits a court to "set aside agency actions, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* This is a demanding burden for BioniCare to carry. As this court has noted, "[w]hen the question before the court is whether an agency has properly interpreted and applied its own regulation, the reviewing court must give the agency's interpretation 'substantial deference.'" *Md. Gen. Hosp., Inc. v. Thompson*, 308 F.3d 340, 343 (4th Cir. 2002) (quoting *Th. Jefferson Univ.*, 512 U.S. at 512). BioniCare has failed to demonstrate that the MAC's application of the relevant standards was "plainly erroneous or inconsistent with" the regulations, *Seminole Rock*, 325 U.S. at 414, and these claims therefore have no merit.

A.

BioniCare contends that the Secretary failed to give adequate consideration to the FDA's clearance of the BIO-1000 for marketing under the 510(k) process. It argues that FDA clearance per se satisfies the requirement of MPIM § 13.5.1 that, in order to be considered "reasonable and necessary," a supplier must establish that a device is safe and effective and not experimental or investigational. This argument misapprehends, however, both the separate statutory allocations of interpretive authority to the Secretary and to the FDA and the relative import of the FDA's 510(k) clearance.

The Medicare statute clearly vests the Secretary with the authority to interpret when a device is "reasonable and neces-

sary," and therefore eligible for coverage under Part B. The statute contemplates no role for the FDA, which is charged with applying the standards of the Federal Food, Drug, and Cosmetic Act, not the Medicare statute. The FDA examines "the labeled use of a device only," concentrating its review on the safety of a device, whereas Medicare review "focus[es] on . . . a device under average conditions of use" to determine whether the device meets the broader requirement of the Medicare statute that a device be "reasonable and necessary." 54 Fed. Reg. 4307. The Secretary has underscored this difference, noting that Medicare "contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority." 68 Fed. Reg. 55,636. The statement proceeds to make clear that while FDA approval has been adopted as a prerequisite to Medicare coverage, "FDA approval/clearance alone does not generally entitle that device to coverage." *Id.* While FDA approval may thus inform the Secretary's decision as to whether a device is "reasonable and necessary," it cannot tie the Secretary's hands.

This holds especially true for a device such as the BIO-1000, which was only cleared by the FDA under the abbreviated 510(k) process. The Secretary has long noted the significance of the type of clearance a device receives: "FDA approval . . . will not necessarily lead to a favorable coverage recommendation, particularly if FDA requirements have been met by means of a notice issued under section 510(k). . . . This is because a section 510(k) notice generally does not involve clinical data showing safety and effectiveness." 54 Fed. Reg. 4307. Section 510(k) approval requires only that a device be "substantially equivalent" to another device that the FDA has already approved for marketing, and not that the device have been clinically examined for safety and effectiveness. The Supreme Court has emphasized this distinction, noting that a device approved under 510(k) "has never been formally reviewed . . . for safety or efficacy." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). In the face of such consis-

tent statements that FDA approval alone is not enough, and that 510(k) clearance is especially deficient, we cannot say that it was arbitrary or capricious of the Secretary to require additional proof of the BIO-1000's safety and effectiveness.

Not only was the BIO-1000 not subject to the more demanding safety review of the Pre-Market Approval (PMA) process, neither was the TENS device that served as the predicate for the 510(k) clearance. Because the TENS device was marketed prior to the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, its market approval was "grandfathered" rather than the result of satisfying the requirements of the PMA regime. In short, the FDA's clearance of the BIO-1000 was based on its equivalence to a device that was never itself tested for safety and effectiveness. It was therefore surely reasonable for the Secretary to require evidence in addition to the mere fact of 510(k) approval to demonstrate the BIO-1000's safety and effectiveness.

BioniCare further undercut the already limited significance of the "substantially equivalent" 510(k) clearance in the Medicare administrative proceedings by highlighting differences between the BIO-1000 and the TENS device. The TENS device seeks to mask pain in nerve tissue by sending high voltage electrical impulses that interrupt pain signals to the brain. The BIO-1000, by contrast, operates on cartilage tissue, using smaller impulses intended to actually improve the condition of knee joints rather than merely hide the discomfort of the underlying condition. BioniCare also charges significantly more for the BIO-1000 than Medicare allows providers to charge for the TENS device. It was reasonable of the Secretary to conclude that BioniCare's representations showed that the BIO-1000's "average conditions of use" were quite different from the uses of the TENS device that served as the predicate to the FDA's 510(k) clearance, and that the FDA's clearance was therefore not adequate proof of the device's safety and effectiveness.

BioniCare attempts to claim credit for having initially submitted the BIO-1000 under the PMA process, under which "[t]he FDA evaluates safety and effectiveness under the conditions of use set forth on the label." *Riegel v. Medtronic*, 552 U.S. 312, 318 (2008). We need not consider here whether PMA approval would per se satisfy the requirements of MPIM § 13.5.1, because although the BIO-1000 was submitted for PMA approval, it only received approval under section 510(k). It is immaterial that the FDA suggested that BioniCare withdraw its request for PMA review and accept a 510(k) approval "as a result of increasing Congressional pressure to clear out its backlog." Appellant's Br. at 46. BioniCare clearly had the choice to remain in the PMA pipeline. Had it done so, it could at least now argue to us the greater significance of the more rigorous approval process. Instead, it opted for the likely more profitable course of getting the device to market faster. BioniCare chose the speedier and less-demanding route of 510(k) clearance, and it cannot now claim the legal benefit of a more exacting review process it ultimately elected not to undertake.

B.

BioniCare next asserts that the intermediate review by a qualified independent contractor (QIC) failed to comply with regulations requiring input from "a panel of physicians or other appropriate health care professionals." 42 C.F.R. § 405.968(a)(1). BioniCare is correct that such input was required, both because "the initial determination involve[d] a finding on whether an item or service is reasonable and necessary," *id.*, and because the "claim pertains to . . . the provision of items or services by a physician," *id.* § 405.968(c)(3). But BioniCare's only evidence that this requirement was not satisfied is its assertion that the record does not document compliant participation by a physician. As the district court properly found, this allegation does not satisfy BioniCare's burden to substantiate its claim. *See Almy*, 749 F. Supp. 2d at 333.

The regulation imposes no obligation on the QIC to document the physician review, and BioniCare does not assert that the decisions failed to adequately explain the scientific or medical basis for the QIC's decision. "The presumption of regularity supports the official acts of public officers, and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties." *United States v. Chem. Found.*, 272 U.S. 1, 14-15 (1926). Respect for an administrative agency's implementation of its own regulations requires clear evidence to surmount the hurdle of arbitrary and capricious review. BioniCare provides no affirmative proof of failure to comply with the regulation, and we have no reason to displace the "presumption of regularity [that] attaches to the actions of government agencies." *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001).

C.

BioniCare last argues that the Secretary's decisions were arbitrary and capricious because the MAC decisions at issue here reach a different result from other decisions at the ALJ and contractor levels of the Medicare review process that allowed coverage for the BIO-1000. Because some ALJs and contractors have covered the device and some have not, BioniCare contends that the Secretary has made inconsistent decisions. As BioniCare admits, however, "some inconsistency related to the patient-specific nature of the determination is, perhaps, inevitable." Appellant's Reply Br. at 2.

Moreover, it is undisputed that these lower-level decisions are not precedential and not binding on the MAC. The Secretary's promulgated regulations make clear that a decision by a contractor or ALJ is only binding on the parties to that particular case, and that a decision is not binding once "a party files a written request for a MAC review that is accepted and processed." 42 C.F.R. § 405.984. Other circuits have considered analogous situations, and they all reach the shared conclusion that "[t]here is no authority for the proposition that a

lower component of a government agency may bind the decision making of the highest level. . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003); *see Almy*, 749 F. Supp. 2d at 326-28 (collecting cases).

Moreover, the MAC is explicitly charged with undertaking *de novo* review, *see* 42 U.S.C. § 1395ff(d)(2)(B); 42 C.F.R. § 405.1100(d), which is incompatible with BioniCare's proffered notion that the MAC is somehow obligated to defer to the outcomes of prior decisions below. Nowhere does any policy or regulation suggest that the MAC owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device.

As the Secretary notes, only MAC decisions constitute the final decision of the Secretary. *See id.* § 405.1130. BioniCare points to no other MAC decision specifically finding that the BIO-1000 was "reasonable and necessary" or "safe and effective." We therefore cannot conclude that "the agency has failed to explain its departure from prior precedent," *Bush-Quayle '92 Primary Comm., Inc. v. FEC*, 104 F.3d 448, 453 (D.C. Cir. 1997), such that the MAC decisions are deprived of deference, because there simply was no contrary precedent from which the agency departed. While BioniCare attempts finally to assert that even the MAC decisions are inconsistent with one another, in every instance in which the question of whether the device was "reasonable and necessary" was before the MAC, it applied the same proper standards from the MPIM and reached the same conclusions about the inadequacy of BioniCare's proffered evidence.

In addition, BioniCare's proposed expansion of what constitutes binding agency precedent would severely constrict the undisputed delegated authority of the Secretary to administer

the Medicare system. The Medicare statute and its accompanying regulations create a "mammoth bureaucracy with seemingly endless layers of internal review." *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987). BioniCare seeks to impose massive resource costs on the Secretary, requiring her to reverse any decision at a lower level of adjudication either through promulgation of an NCD or through MAC review lest that lower decision become precedent that precludes a different considered result in future cases before the MAC. As the Secretary notes, there were 970 million Medicare Part B claims in 2008 alone, and the Secretary rarely participates in the lower level adjudications of those claim determinations. Appellee's Br. at 55 n.19. Exercising her acknowledged discretion to allocate agency resources, the Secretary has promulgated regulations limiting *sua sponte* review to cases that either "contain[ ] an error of law material to the outcome of the case or present[ ] a broad policy or procedural issue that may affect the general public interest." 42 C.F.R. § 405.1110(c)(2). The Secretary has simply not seen fit to invoke her final authority in every case in which there is an argument over whether the evidence adequately supports a finding that a device was "reasonable and necessary."

In so complex an area as Medicare Part B administration, the courts should not casually direct the Secretary as to when she must exercise her authority to make final determinations, especially where, as here, the final determinations that she has made have been consistent in denying coverage for the BIO-1000. Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court. It was therefore not arbitrary and capricious of the MAC to make final determinations that may have been at odds with prior coverage deci-

sions that did not carry the full imprimatur of the Secretary's authority.[4]

VI.

Our court has previously noted that the Medicare statute is "among the most completely impenetrable texts within human experience." *Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). This complexity, however, in no way permits courts to abandon their reviewing role, for the absence of judicial oversight would risk unsupported and unexplained agency decisions. We have thus reviewed the

[4]BioniCare raises two other issues that do not merit extended discussion. First, it disputes the application of a local fee schedule in one of the eight MAC cases under review. The Medicare statute limits reimbursement for DME to 80 percent of the lesser of either the actual charge for the item or the fee schedule amount for the item. 42 U.S.C. § 1395m(a)(1); 42 C.F.R. § 414.210(a). The ALJ and MAC made findings that a fee schedule was properly implemented by a local contractor pursuant to guidance from the Secretary authorizing local "gap-filling" fee arrangements when no national fee schedule exists. *See* Medicare Claims Processing Manual (MCPM) Ch. 23, § 60.3. We agree with the district court's conclusion that the MAC did not act arbitrarily or capriciously in determining that the lower payment authorized by the fee schedule amount was the appropriate reimbursement. *See Almy*, 749 F. Supp. 2d at 333-34.

Second, BioniCare argues that the Secretary erred in rejecting certain "Advance Beneficiary Notices" (ABN) that purported to shift liability for device costs to the recipients of the BIO-1000. A supplier can shift the burden to a beneficiary by providing the beneficiary with advance written notice that a device will probably not be covered by Medicare. MCPM Ch. 30, § 40.1.1. If the notice merely does "no more than state that Medicare denial of payment is possible," *id.* § 40.3.6.1, however, then liability remains with the supplier. In two decisions at issue here, the Secretary ruled invalid ABNs that stated that "it is unclear what criteria Medicare will use when evaluating whether the device was reasonable and medically necessary for you. Medicare will not pay for a device that it does not deem reasonably necessary for you." We similarly affirm the district court's conclusion that the MAC did not act arbitrarily or capriciously in finding that these generic statements failed to offer a "genuine reason that denial by Medicare is expected." *Almy*, 749 F. Supp. 2d at 335 (quoting MCPM Ch. 30 § 40.3.6.1).

claims herein with care, and we are satisfied that the Secretary has proceeded in accordance with law.

To go further would invite unforeseeable consequences in health care costs, public resource allocation, and coverage of dubious medical devices. At the end of the day, we must respect the fact that Congress has chosen to leave the interpretation of the "reasonable and necessary" requirement of Medicare Part B to the informed discretion of the Secretary and the professional panels who exercise her authority. The Secretary has not taken this responsibility lightly, promulgating voluminous regulations, coverage manuals, and notice documents explaining the standards that will guide her determinations. She has created an exhaustive review process ensuring that claimants will have repeated and extensive opportunities to ensure that compliant claims are properly reimbursed.

Yet BioniCare urges us to wade into this area with very little to keep us afloat. It would have us supplant the Secretary's decisions about whether to adjudicate, how to adjudicate, and even how to decide those adjudications without a shred of guidance from Congress to secure our decisions. It is the Secretary, not the courts, who bears the responsibility for the disbursement of billions of dollars of public money under the Medicare system. Appropriations are not our forte, and we shall not redirect the Secretary without a greater showing in law than BioniCare has made here.

The judgment of the district court is

AFFIRMED.