

UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

RHODE ISLAND HOSPITAL,)
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 Plaintiff,)
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 v.) Civ. Action No. 06-05 S
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 KATHLEEN SEBELIUS, et al.,)
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 Defendants.)
)

OPINION AND ORDER

WILLIAM E. SMITH, United States District Judge

Up until 1996, the Medicare program paid for medical research performed by residents at Rhode Island Hospital ("Plaintiff" or "RIH"). That year, however, the Secretary of Health and Human Services (the "Secretary") decided that only research related to patient care qualified for reimbursement under Medicare regulations. In an earlier phase of this case, the First Circuit upheld the Secretary's view. See R.I. Hosp. v. Leavitt, 548 F.3d 29 (1st Cir. 2008). The immediate dispute concerns Plaintiff's claim that some resident research activities in 1996 actually involved caring for patients. Plaintiff pressed this argument at a hearing before the agency. In a single paragraph, the Secretary found that Plaintiff failed to document any research related to patient care in 1996, and therefore that Medicare covered none.

Plaintiff challenges the Secretary's ruling as arbitrary and capricious under the Administrative Procedure Act ("APA"), see 5

U.S.C. § 706 (2009), and seeks summary judgment reversing the decision. The Secretary and the Department of Health and Human Services ("Defendants") cross-move for summary judgment affirming the Secretary's determination as reasonable based on the evidence in the record. As fully explained below, the decision does not survive review under the APA because the Secretary failed to set forth adequate reasons for denying Plaintiff's claim. The decision fell short in two respects: (i) it failed clearly to explain the criteria by which the evidence was judged, and (ii) it appeared to rely on a 2001 regulation that cannot determine Plaintiff's Medicare payments for 1996. The Secretary's decision is therefore vacated and this case is remanded to the agency for further proceedings.

I. Background

A. Indirect Medical Education Reimbursement Under Medicare

Before turning to the facts of this case, a very brief summary of Medicare funding for teaching hospitals is necessary.¹ Part A of the Medicare program allows hospitals to be reimbursed for the operating costs of providing inpatient services. Under the program, teaching hospitals may recover "indirect medical education" ("IME") expenses of patient care arising from the education and training of residents. The key variable in

¹ For more detail, see R.I. Hosp. v. Leavitt, 548 F.3d 29, 31-32 (1st Cir. 2008).

calculating the amount of IME reimbursement is the number of full-time equivalent residents ("FTEs") at a hospital. FTEs are defined by reference to the hours residents work. Only qualified activities under Medicare regulations count towards a hospital's FTE tally. See 42 C.F.R. § 412.105(f) (2009) (establishing rules for determining the number of FTEs).

B. Procedural History

For fiscal year 1996, Plaintiff sought IME payments for resident training expenses. The fiscal intermediary ("FI"), an insurance company used by Medicare to manage reimbursement, reduced Plaintiff's IME request by 12.06 FTEs attributable to educational research performed by residents. This resulted in a reimbursement disallowance of approximately \$1 million. Because the residents' research did not relate to patient care, the FI found, it did not count towards FTEs under the 1996 version of 42 C.F.R. § 412.105(g) (the "1996 Regulation"), which governed FTE calculations. However, prior to 1996, Medicare had not excluded resident research activities from Plaintiff's IME reimbursement. Believing Medicare covered all resident research, Plaintiff appealed the FI's decision to the Provider Reimbursement Review Board ("PRRB") in 1998.

Plaintiff developed two arguments before the PRRB. Broadly, Plaintiff contended that the 1996 Regulation required reimbursement of pure educational research activities, regardless of whether they related to patient care. In the alternative, Plaintiff claimed

that 7.49 of the disputed FTEs did, in fact, involve caring for patients. In that case, those FTEs should be approved even under the FI's view of the 1996 regulation.

Plaintiff gathered evidence to support its narrow argument during the discovery phase of PRRB proceedings. The evidence included statements from the program directors of departments affected by the FTE reduction (the "Directors") describing residents' research activities, and rotation schedules for the affected residents from 1996. In response to discovery requests from the FI, in December 2001 Plaintiff also asked Directors to complete questionnaires setting forth the percentage of resident research time directly related to patient care. (See Administrative Record, certified Feb. 15, 2006 ("A.R."), at 197.)

In the midst of discovery, in August, 2001 the Secretary issued an amendment to the Medicare regulations governing the calculation of FTEs (the "2001 Amendment"). The 2001 Amendment provides, "The time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. § 412.105(f)(1)(iii)(B) (2001). Upon releasing the 2001 Amendment, the Secretary claimed it simply clarified "longstanding policy." Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education, 66 Fed. Reg. 39,828, 39,896-97 (Aug. 1, 2001). As discussed in detail below, a key issue in this case is what impact,

if any, the 2001 Amendment had on the agency's decision about Plaintiff's 1996 FTE application.²

In September, 2005, the PRRB issued a decision accepting Plaintiff's broad argument that Medicare covered all resident research. On that basis alone it ruled in Plaintiff's favor. However, the Secretary reviewed the PRRB's ruling, and reversed it in November 2005. The Secretary found that under the 1996 Regulation, "Medicare . . . only paid for costs related to patient care." (A.R. at 9.)

The Secretary went on to address Plaintiff's narrower argument:

[Plaintiff] has also argued that 7.49 FTEs of the total of 12.06 FTEs time was spent by residents in research related to the treatment or diagnosis of particular patients. The [Secretary] finds that a review of the record shows that [Plaintiff] did not demonstrate that these residents were involved in research activities related to patient care. To the extent the research times [are] alleged to be patient care related, the record does not show the percentage of time residents saw patients during a monthly research rotation and the research, if any, they may have engaged in that was related to patient care. This is in contrast to other

² Both sides incorporated the 2001 Amendment into their arguments to the PRRB. The FI asserted that the 2001 Amendment codified a longstanding rule precluding payment for research "not directly related to the diagnosis and treatment of an individual hospital patient." (A.R. at 257 (emphasis added).) In response, Plaintiff argued that the 2001 Amendment could not apply retroactively, and therefore did not govern its 1996 FTE application. In the alternative, to the extent the PRRB found the 2001 Amendment to be retroactive, Plaintiff contended that some of the disputed FTEs were attributable to "research that was associated with the treatment or diagnosis of particular hospital patients." (Id. at 1222 (emphasis added).)

evidence in [Plaintiff's] exhibits that these residents were involved in research activities using animals and other laboratory research conducted outside patient care areas. Accordingly, the [Secretary] finds that [Plaintiff] failed to provide sufficient contemporaneous documentation to support its claim that the time spent by residents in research was related to patient care.

(Id. at 10-11.) The Secretary also quoted a reference to animal research in one of the Director's questionnaires, and noted a discrepancy in the evidence about the number of hours residents worked per week. (See id. at 10-11 nn.18-19.)

Plaintiff commenced this action to challenge the Secretary's ruling in January 2006.³ The parties cross-moved for summary judgment, and the District Court (Torres, J.) issued a decision in favor of Plaintiff in August 2007. The sole basis for that ruling was the District Court's determination that the 1996 Regulation did not exclude pure research time from the FTE count. The Secretary appealed the decision to the First Circuit.

The only question presented on appeal was whether the District Court correctly held that the Secretary could not impose a patient care requirement under the 1996 Regulation. The First Circuit reversed the District Court. See R.I. Hosp., 548 F.3d at 44. It approved the Secretary's interpretation of the 1996 Regulation "to exclude time that residents spend performing research unrelated to

³ On the basis of its narrow argument, Plaintiff sought an adjustment to its 1996 IME payment by adding 6.94 FTEs attributable to research related to patient care. This reflects a reduction of .55 FTEs from the demand presented to the PRRB.

patient care.” Id. at 32. The decision did not address the 2001 Amendment. Rather, the analysis focused on the language of the 1996 Regulation, and the Medicare statute. Because the Secretary’s construction of the 1996 Regulation was reasonable, and not at odds with statutory commands, the First Circuit ratified the Secretary’s view. As for Plaintiff’s narrower argument that some research did involve patient care, the First Circuit “express[ed] no opinion.” Id. at 44 n.23. It then remanded the case to resolve Plaintiff’s outstanding challenge to the Secretary’s ruling on that argument.

II. Discussion

In broad strokes, Plaintiff attacks the Secretary’s decision on two grounds: (i) it was arbitrary and capricious for the Secretary to provide no guidance about documenting research prior to 1996, and then to reject the proof Plaintiff offered after the fact, and (ii) the Secretary unreasonably determined that the research in dispute did not involve patient care. While Plaintiff’s first argument goes too far, the Court nevertheless concludes that the Secretary’s decision at a minimum requires clarification on the criteria used to judge the evidence. The Secretary’s failure to adequately explain her decision necessitates a remand to the agency for further proceedings. The Court therefore need not reach the merits of Plaintiff’s second argument.

A. Standard of Review

42 U.S.C. § 1395oo(f) authorizes judicial review of the Secretary's reimbursement decisions pursuant to the standards of the APA. See Visiting Nurse Ass'n Gregoria Auffant, Inc. v. Thompson, 447 F.3d 68, 72 (1st Cir. 2006). "Under the APA, agency action is presumptively valid." R.I. Hosp., 548 F.3d at 33. An agency decision may be overturned only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2) (A). The "arbitrary and capricious" standard merely obligates the administrative body to engage in a rational decision-making process. See NVE Inc. v. Dep't of Health & Human Servs., 436 F.3d 182, 190 (3d Cir. 2006) (explaining that the standard focuses "on the agency's process of reasoning"). For findings of fact, a court must affirm an agency's ruling unless it was "unsupported by substantial evidence." 5 U.S.C. § 706(2) (E). "Generally speaking, substantial evidence comprises proof that a reasonable mind might find adequate, in light of the record as a whole, to support a particular conclusion." South Shore Hosp., Inc. v. Thompson, 308 F.3d 91, 104 (1st Cir. 2002).

While administrative rulings enjoy deference, agencies must explain their decisions. See Kurzon v. United States Postal Service, 539 F.2d 788, 792-93 (1st Cir. 1976) (observing that agencies must not leave the reasons for a conclusion to speculation). The "reasoned decisionmaking" requirement is not

onerous; in most circumstances, “a stated connection between the facts found and the choice made” suffices. Knott v. F.E.R.C., 386 F.3d 368, 371-72 (1st Cir. 2004) (quotation marks and citation omitted). However, where an agency reverses an earlier policy, or applies a rule inconsistently, it must “adequately explain[] the reasons” for doing so. Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs., 545 U.S. 967, 981 (2005); see Cheshire Hosp. v. N.H.-Vt. Hospitalization Serv., Inc., 689 F.2d 1112, 1126 (1st Cir. 1982) (observing that agencies must explain inconsistencies and departures from past precedents) (citing Hatch v. F.E.R.C., 654 F.2d 825, 834 (D.C. Cir. 1981)).

Furthermore, “[p]ure’ legal errors require no deference to agency expertise, and are reviewed de novo.” Knott, 386 F.3d at 372 (quoting Northeast Utils. Serv. Co. v. F.E.R.C., 993 F.2d 937, 944 (1st Cir. 1993)).

B. The Secretary’s Explanation for Rejecting Plaintiff’s Evidence

Under the 1996 Regulation, the Secretary may “exclude time that residents spend performing research unrelated to patient care” from the FTE count. R.I. Hosp., 548 F.3d at 32. Part of the task in deciding Plaintiff’s narrow claim was translating that standard into criteria for reviewing the evidence. In this respect, the Secretary’s decision suffers from two flaws. First, the decision fails to explain clearly why Plaintiff’s proof fell short. Second, it appears to rely on criteria drawn from the 2001 Amendment, which

cannot govern Plaintiff's 1996 IME application. For the reasons more fully explained below, these errors require remand to the agency.

1. **Lack of preexisting guidance on substantiating the patient care requirement**

Plaintiff accuses the Secretary of a "bait and switch" on the requirement of proving that research involved patient care. There were no standards requiring such a showing in 1996, Plaintiff submits, nor any other "rules, guidance, or instruction . . . regarding how and in what manner a provider must document resident research activities." (Rhode Island Hospital's Memorandum of Law in Support of its Motion for Summary Judgment, dated July 24, 2009 ("Pl.'s Mem."), at 20.) Notwithstanding the vacuum of guidance on how to meet the new standard, during PRRB proceedings, Plaintiff undertook to substantiate that some research involved patient care. It then complied fully with the FI's discovery requests. Yet, the Secretary ultimately found that Plaintiff "failed to provide sufficient contemporaneous documentation to support its claim." (A.R. at 11 (emphasis added).)

This decision, Plaintiff says, was arbitrary and capricious. From Plaintiff's perspective, the agency created a moving target, and one that was nearly impossible to hit. Because there was no documentation standard to begin with in 1996, contemporaneous documents on the issue of how research involved patient care would be unlikely to exist. The agency's demands thus forced Plaintiff

to make an educated guess about what evidence would suffice. In 2001, the FI asked for certain materials; in 2005, the Secretary penalized Plaintiff for not providing something other than what the FI had requested.

The Court agrees that this seems unfair. But the problem with Plaintiff's argument as articulated is that the Secretary is not obligated to provide "guidance" about all aspects of Medicare reimbursement. "The APA does not require that all the specific applications of a rule evolve by further, more precise rules rather than by adjudication." Shalala v. Guernsey Memorial Hosp., 514 U.S. 87, 96 (1995). Put differently, the Secretary need not spell out every possible application of the FTE rules in advance. She is free to set reimbursement limits by applying the rules to individual cases.⁴ See id. (explaining that, under the old "reasonable cost" Medicare system, the Secretary had no "duty to promulgate regulations that . . . address[ed] every conceivable question" about reimbursement); Cnty. Hosp. of Monterey Peninsula v. Thompson, 323 F.3d 782, 793 (9th Cir. 2003) ("[I]t is not necessary for the Secretary to resolve all issues by regulation."); Select Specialty Hosp. of Atlanta v. Thompson, 292 F. Supp. 2d 57,

⁴ Defendants points to general documentation standards in place in 1996. See 42 C.F.R. § 413.20(a) (1996) (obligating providers to maintain "sufficient financial records and statistical data for proper determination of costs payable under the program"). They do not specify how a provider should show that resident research involved patient care, but, as explained above, this level of specificity is not required.

70 (D.D.C. 2003) (concluding that “the Secretary was authorized to determine whether” a Part A reimbursement rule applied “via adjudication”).

Thus, the Secretary was empowered to make the determination of “what supporting documentation would be required” to prove that research related to patient care “through [the] adjudication” of Plaintiff’s case. Cnty. Hosp. of Monterey Peninsula, 323 F.3d at 793 (reviewing a dispute over Medicare Part A reimbursement). The mere absence of pre-existing rules for documenting that research involved patient care, on its own, did not render the Secretary’s decision arbitrary and capricious.

2. The Secretary’s change in course and the “reasoned explanation” requirement

While Plaintiff’s “bait and switch” argument is overbroad, the circumstances of this case nevertheless call for a close look at exactly how the Secretary weighed Plaintiff’s evidence. The reason is that the Secretary changed course: before 1996, there was no patient care requirement. This is undisputed. The Secretary does not contest that Plaintiff was previously reimbursed for research irrespective of whether it involved patient care. (See Hr’g Tr. (“Tr.”) 47:13-48:12, Sept. 17, 2009.)⁵ Then, reviewing Plaintiff’s

⁵ Plaintiff confirmed that 1996 was the first time the FI excluded research unrelated to patient care. The Court stated, “I just want to be clear that there had been a history of submission and payment, and then there was a change.” (Tr. at 48:9-11.) The Secretary did not make any contrary representation. Nor do any of the Secretary’s briefs question the premise that the patient care

IME application for 1996 on behalf of the Secretary, the FI informed Plaintiff that Medicare did not cover research unrelated to patient care.⁶

Without question, the Secretary was entitled to make this switch. “[A]n administrative agency is not disqualified from changing its mind.” Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) (quotation marks, alteration, and citation omitted); see Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983) (“[A]n agency must be given ample latitude to adapt [its] rules and policies to the demands of changing circumstances.”) (citation and internal quotation marks omitted). Indeed, although the First Circuit’s opinion in this case did not analyze the patient care requirement as a policy shift, it did ratify the new policy.

The issue here, however, is not whether that policy is permissible, but whether the Secretary applied it reasonably. What evidentiary benchmarks could the Secretary reasonably use in enforcing the patient care requirement? The First Circuit did not

requirement was first applied to Plaintiff’s IME request in 1996.

⁶ The regulatory basis for the patient care limitation has existed in substantially identical form since 1985. The authority for the restriction in the 1996 Regulation is that FTE hours are limited to work performed by residents assigned to “[t]he portion of the hospital subject to the prospective payment system.” 42 C.F.R. 412.105(f) (ii) (1996); see R.I. Hosp., 548 F.3d at 35-36. As of 1985, 42 C.F.R. 412.118(f) restricted FTE hours to “time [that] interns and residents spend in the portion of the hospital subject to the prospective payment system.” 42 C.F.R. 412.118(f) (1985).

address this question. Moreover, the decision on Plaintiff's narrow claim was an equally important aspect of the Secretary's change in course. Making Plaintiff document that research involved patient care abandoned the agency's prior reimbursement practice.

An administrative action that parts with established policy may be "entitled to considerably less deference than a consistently held agency view." INS v. Cardoza-Fonseca, 480 U.S. 421, 446 n.30 (1987) (citation and internal quotation marks omitted); accord Good Samaritan Hosp., 508 U.S. at 417; see Mercy Catholic Med. Center v. Thompson, 380 F.3d 142, 155 (3d Cir. 2004) ("[I]nconsistency can affect the level of deference afforded an agency's interpretation."). This check on agency discretion applies to both formal rulemaking and the application of rules to individual cases. See Succar v. Ashcroft, 394 F.3d 8, 36 (1st Cir. 2005) (noting that the Attorney General's position was "inconsistent with the agency's long-standing previous practice" in applying citizenship status rules during removal proceedings, and citing the principle that inconsistent interpretations reduce deference to the agency). At a minimum, "an agency must provide a 'reasoned analysis' for its change in course." Nat'l Home Equity Mortg. Ass'n v. Office of Thrift Supervision, 373 F.3d 1355, 1360 (D.C. Cir. 2004) (quoting Motor Vehicle Mfrs. Ass'n, 463 U.S. at 57); see Nat'l Cable & Telecomms. Ass'n, 545 U.S. at 981 (citing need to explain

inconsistency); Cheshire Hosp., 689 F.2d at 1126 (1st Cir. 1982) (same).

"[W]hen the action involves a change in a settled course of agency behavior, 'the court should be satisfied both that the agency was aware it was changing its views and has articulated permissible reasons for that change, and also that the new position is consistent with the law.'" Public Citizen v. Steed, 733 F.2d 93, 99 (D.C. Cir. 1984) (quoting NAACP v. F.C.C., 682 F.2d 993, 998 (D.C. Cir. 1982)).

3. **The Secretary's analysis**

The Secretary has failed to "articulate[] permissible reasons" for how the patient care requirement applied to Plaintiff's IME application in two respects. First, the Secretary's decision employs inconsistent and confusing criteria for assessing the patient care requirement. Specifically, the Secretary begins the analysis by noting that Plaintiff claimed some FTEs "related to the treatment or diagnosis of particular patients." (A.R. at 10.) The Secretary goes on to declare, in two other places, that Plaintiff failed to demonstrate that research "related to patient care." (Id.) The Secretary also takes note of the fact that "the record d[id] not show the percentage of time residents saw patients during a monthly research rotation." (Id. (emphasis added).)

These excerpts arguably do no more than restate the same standard each time in slightly different language. However, the

terminology conveys substantive, if subtle, variations that create confusion. The introduction to the Secretary's decision implies that the question to be answered was whether the evidence adequately illustrated the "treatment or diagnosis of particular patients." This arguably creates a more onerous burden than showing research "related to patient care," a phrase the Secretary also uses. For instance, while the latter phrase does not necessarily imply the need to identify individual patients, the Secretary's reference to "particular patients" could very well be interpreted to do so. Similarly, the "percentage of time residents saw patients" appears to exclude activities that might easily qualify as research "related to patient care." For example, performing laboratory tests on patients' blood samples could both serve as a basis for diagnosis and provide data for academic study. That patients were not physically present would not mean the residents were not involved in caring for them. Taken together, these dissonant criteria, crowded into a single paragraph of explanation, cloud the precise reasons relied upon by the Secretary in holding that Plaintiff's proof was insufficient.

Second, some of the criteria appear to draw from the 2001 Amendment, which limited reimbursement to research "associated with the treatment or diagnosis of a particular patient." In fact, the Secretary parroted this language to frame the inquiry for

Plaintiff's narrow argument.⁷ The 2001 Amendment, however, cannot govern Plaintiff's 1996 IME application. Without express statutory authority, "the retroactive application of an agency rule is disfavored." Pine Tree Med. Ass'n v. Sec'y of Health & Human Servs., 127 F.3d 118, 121 (1st Cir. 1997); Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208-09 (1988) (reviewing the Medicare Act and determining that it did not grant the Secretary "authority to promulgate retroactive cost-limit rules" on healthcare provider reimbursements). Indeed, the Secretary does not now contend that the 2001 Amendment can be applied retroactively.⁸ See Univ. of Chicago Med. Ctr. v. Sebelius, No. 07 CV 7016, --- F. Supp. 2d ----, 2009 WL 2382514, at *5 (N.D. Ill. Aug. 3, 2009) (concluding that the 2001 Amendment requiring research to be "associated with the treatment or diagnosis of a particular patient" would "not apply retroactively").

The Secretary proposes that the 2001 Amendment merely reiterated pre-existing policy. This is clearly debatable. A

⁷ As indicated above, Plaintiff incorporated the language of the 2001 Amendment into its arguments to the PRRB, in response to the FI's reliance on that provision. Yet, Plaintiff has always maintained that the 2001 Amendment cannot be retroactive.

⁸ The statute authorizing the Secretary to implement rules for calculating FTEs is 42 U.S.C. § 1395ww(d)(5)(B). Although the statute itself clearly affects Medicare reimbursement for years prior to its enactment, the Court discerns in it no permission for the Secretary to set retroactive limits on FTEs. Such authority would have to be "conveyed by Congress in express terms." Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988).

regulation that "creates a new obligation [or] imposes a new duty" may be improperly retroactive without permission from Congress. Mejia v. Gonzales, 499 F.3d 991, 997 (9th Cir. 2007); see Goncalves v. Reno, 144 F.3d 110, 130 (1st Cir. 1998) (discussing the standard for judging whether a statute has an improper retroactive effect); Ponce Paramedical Coll., Inc. v. U.S. Dep't of Educ., 858 F. Supp. 303, 311 (D.P.R. 1994) (considering whether an agency regulation was improperly retroactive using the "new obligation or duty" test). As noted, under the 1996 Regulation, the Secretary can exclude research "unrelated to patient care" from FTEs. R.I. Hosp., 548 F.3d at 32. This is the extent of the authority that the Secretary asserted on appeal, and that the First Circuit approved.⁹ No one would dispute that treatment and diagnosis are basic components of

⁹ The Secretary unsuccessfully argues that the First Circuit "effectively held that [the 1996 Regulation] was reasonably interpreted by the Secretary to contain a requirement that resident research must be related to the care of particular patients." (Defendants' Post-Argument Supplemental Memorandum, Oct. 5, 2009 ("Defs.' Supp."), at 4.) In other words, the Secretary suggests that the First Circuit confirmed the view that the 2001 Amendment merely clarified the standard existing under the 1996 Regulation. The Secretary's decision does use varying, and confusing, terminology to describe the patient care standard. However, in concluding the analysis of the 1996 Regulation, the Secretary states, "to the extent that the residents' time at issue in this case is spent exclusively in research activities (not related to patient care), the time must be excluded from the IME FTE count." (A.R. at 10.) It is evident that this is what the First Circuit understood the Secretary's position to be: the 1996 Regulation allowed the Secretary "to exclude time that residents spend performing research unrelated to patient care." R.I. Hosp., 548 F.3d at 32. Nowhere did the First Circuit mention that the Secretary believed the 1996 Regulation contained a "particular patients" requirement.

patient care. Thus, under the 1996 Regulation, it would be natural to require Plaintiff to detail how research aided the treatment and diagnosis of patients at RIH. But the phrase, "research that is not associated with the treatment or diagnosis of a particular patient is not countable" arguably goes further. Taking its ordinary meaning, it may reasonably be interpreted to require providers to identify "particular patients" in IME applications. See Wojciechowicz v. United States, 582 F.3d 57, 74 (1st Cir. 2009) (explaining that, as with statutes, when interpreting regulations courts first look to the "plain and ordinary meaning" of the language) (quoting United States v. Lachman, 387 F.3d 42, 50 (1st Cir. 2004)). As the Secretary's decision suggests, it could also be read to require providers to specify when "residents saw" particular patients. To the extent that the Secretary's decision reflects either interpretation, it wielded the 2001 Amendment improperly.

Of course, because the Secretary also discussed whether the evidence "related to patient care," the impact of the 2001 Amendment on the Secretary's decision is not clear. Under the APA, agency decisions of "less than ideal clarity" may pass muster. Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 658 (2007) (quotation marks and citation omitted). Here, however, the Secretary's policy shift shrinks the deference an agency would normally receive. Likewise, the possibility of "legal error" in an

unauthorized retroactive requirement – even if it is not definite that the agency committed such an error – exposes the Secretary's decision to judicial second-guessing. See Knott, 386 F.3d at 372; Lovely v. F.E.C., 307 F. Supp. 2d 294, 301 (D. Mass. 2004) (“This lack of clarity in the administrative decisions and possible error of law compel a reversal and remand.”) (emphasis added). In this case, the Secretary's explanation does not survive scrutiny.

In sum, the Secretary's reasoning was inadequate. The resulting confusion about how Plaintiff's evidence was measured requires remanding the case to the agency for clarification. A remand will give the Secretary “an opportunity to better explain her position.” Harrington v. Chao, 280 F.3d 50, 59-60 (1st Cir. 2002) (finding that an agency's decision “fail[ed] to explain whether [it was] departing from [its] prior course and, if so, the reasons for the change,” and remanding the case for a more detailed explanation); see Lovely, 307 F. Supp. 2d at 301.

On remand, the Secretary is instructed to fulfill the “reasoned explanation” requirement by taking the following steps:

1. Clearly set forth the evidentiary criteria applicable under the 1996 Regulation for documenting that resident research relates to patient care. The criteria cannot have the effect of replicating the substantive standard embodied in the 2001 Regulation.

2. Review the record and explain the extent to which the documentation Plaintiff provided does or does not meet the criteria, and state why or why not.
3. Based on that analysis, state, for each department at RIH where research is at issue, how many of the contested FTEs qualify for reimbursement and how many do not.

It is up to the agency to develop the criteria that will guide the review of Plaintiff's evidence. For that reason, it would be premature to rule on whether substantial evidence supports the determination that zero FTEs for 1996 related to patient care.

Nevertheless, without taking a stance on that issue, it appears to the Court that the evidence is reasonably likely to establish that some of the research at issue falls under the ambit of "related to patient care" under the 1996 Regulation. For instance, according to the Director for Cardiology, one resident "worked on a project in the Nuclear Cardiology laboratory that involved 81 sequential patients who underwent a two-day diagnostic imaging protocol." (A.R. at 2098.) It would appear to be a reasonable conclusion that a research project "involv[ing]" diagnostic procedures for patients involved patient care. Similarly, the Critical Care Medical Director wrote that residents "have applied medications and technology tools in clinical medicine to study a variety of clinical conditions." (Id. at 2121.) Although the parties debate the meaning of the term "clinical," it would again appear to be

reasonable to conclude that “appl[ying] medication[]” in “clinical medicine” means treating a patient.¹⁰

On the other hand, the evidence may also show that other research projects did not relate to patient care. For instance, the Secretary cites references by Directors to animal research, academic publication, and studies of data from overseas. (See, e.g., id. at 2097, 2198, 2607.) In addition, some inconsistencies in Directors’ representations about the percentage of time devoted to research, as well as uncertainty about the length of the resident work-week, might also lead to a reduction in Plaintiff’s FTE demand.

¹⁰ Other examples include the Internal Medicine Director’s explanation that research “involv[ed] human subjects cared for by residents involved in research” (id. at 2372), the Director for Plastic Surgery’s statement that research was “done on patients in the course of delivery of patient care” (id. at 2605), and the declaration by the director for Emergency Medicine/Pediatrics that “[a] majority of projects developed by fellows are clinical and directly related to patient care,” including “central nervous system monitoring in sedation.” (id. at 2253).

III. Conclusion

For the foregoing reasons, Plaintiff's Motion for Summary Judgment is GRANTED in part and DENIED in part. Defendants' Motion for Summary Judgment is DENIED. The Court vacates the Secretary's decision and remands this case to the Secretary for further proceedings consistent with this opinion.

IT IS SO ORDERED.

William E. Smith
United States District Judge
Date: