UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALPENA DIALYSIS SERVICES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 04-218 (GK)**
	)	
MICHAEL O. LEAVITT,	)	
	)	
Defendant.	)	
	)	
CHIPPEWA DIALYSIS SERVICES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 04-219 (GK)**
	)	
MICHAEL O. LEAVITT,	)	
	)	
Defendant.	)	
	)	
NORTHERN MICHIGAN HOSPITAL,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 04-222 (GK)**
	)	
MICHAEL O. LEAVITT,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM OPINION

In this consolidated action, three providers of End Stage Renal Disease ("ESRD") treatment bring suit against Defendant Michael O. Leavitt, Secretary of the U.S. Department of Health and

Human Services ("HHS"),[1] pursuant to Title XVII of the Social Security Act, 42 U.S.C. §§ 1395 et seq. ("the Medicare Act"). Plaintiffs—Alpena Dialysis Services ("Alpena"), Chippewa Dialysis Services ("Chippewa"), and Northern Michigan Hospital ("NMH")—seek review of final agency action denying their request for exceptions to the prospective payment rate system used in the federal Medicare program.

This matter is before the Court on Plaintiffs' Motion for Summary Judgment [#13] and Defendant's Cross Motion for Summary Judgment [#15]. Upon consideration of the Motions, Oppositions, and Replies, and the entire record herein, and for the reasons stated below, Plaintiffs' Motion for Summary Judgment is **denied** and Defendant's Motion for Summary Judgment is **granted in part and denied in part**.

I. BACKGROUND

A. Statutory and Regulatory Framework

Congress created the Medicare program in 1965 to pay for certain specified, or "covered," medical services provided to eligible elderly and disabled persons. See 42 U.S.C. §§ 1395 et seq.. Under the program, health care providers are reimbursed for

[1] When Plaintiffs initially brought this action, Tommy M. Thompson was Secretary of Health and Human Services and was named, in his official capacity, as Defendant. On January 26, 2005, however, Michael O. Leavitt succeeded Thompson. Pursuant to Federal Rule of Civil Procedure 25(d)(1), the Court has substituted Leavitt, in his official capacity, as Defendant.

a portion of the costs that they incur treating Medicare beneficiaries pursuant to an extremely "complex statutory and regulatory regime." Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 404 (1993). That regime is administered by the Centers for Medicare & Medicaid Services ("CMS" or "the agency")[2] under the supervision of the Secretary of HHS ("the Secretary") and through a network of fiscal intermediaries, private entities with which the Secretary contracts to review and process Medicare claims in the first instance.

Medicare covers inpatient and outpatient dialysis treatments for ESRD patients. See 42 C.F.R. § 413.180.[3] CMS reimburses outpatient ESRD treatments through a prospectively-determined "composite rate system" that sets a facility's per-treatment reimbursement rate on the basis of its labor costs, patient population, service intensity, and other relevant factors. See 42 U.S.C. § 1395rr. During certain periods of time, called "exception

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[2] Prior to July 1, 2001, CMS was known as the Health Care Financing Administration ("HCFA"). Both names appear in the record in this case. The Court will refer to the agency by its current name, CMS, even when discussing actions taken when it was still known as HCFA.

[3] On January 1, 2006, pursuant to the Medicare Modernization Act of 2003, Pub. L. No. 108-73, 117 Stat. 2066, a comprehensive set of new Medicare regulations went into effect. The new regulations make significant changes to the ESRD exception process. See 70 Fed. Reg. 70,215. All citations herein refer to the Code of Federal Regulations provisions in effect at the time Plaintiffs appealed CMS's denial of their exception requests to the PRRB and filed this case.

windows," the Secretary will entertain a facility's request for an increase in its composite rate, called an "exception." See 42 C.F.R. § 413.180.

To qualify for an exception, the petitioning facility must satisfy a two-prong test "by convincing objective evidence." First, it must demonstrate that its total per-treatment costs are reasonable and allowable. Second, it must establish that one of five enumerated factors causes its actual treatment costs to exceed its composite payment rate. Id. § 413.182. A petitioning facility must satisfy CMS that an exception is appropriate under the applicable regulations and carries the burden of proof at all times. Id. § 413.180.

A facility seeking an exception initiates the process through its fiscal intermediary, which then forwards the request to CMS with a recommendation that it be approved or denied. Id. § 413.94. Taking the intermediary's recommendation into account, CMS must decide whether to grant the exception. All CMS decisions are subject to review by the Provider Reimbursement Review Board ("PRRB" or "the Board"), an administrative appellate body within HHS. Id.; see also 42 U.S.C. § 1395oo(a). The CMS Administrator ("the Administrator"), acting as the Secretary's proxy, may affirm or reverse any decision made by the PRRB. If the Administrator takes no action for 60 days, the PRRB decision becomes final agency action. 42 U.S.C. § 1395oo(f)(1). A party may seek judicial

review of the Administrator's action or, if the Administrator does not act within 60 days, of the PRRB's decision. Id.

B. The Instant Requests for Composite Rate Exceptions[4]

Plaintiffs are Medicare-approved dialysis providers located in northern Michigan. Alpena, Chippewa, and NMH each sought exceptions to their composite rate during an exception window that opened on March 1, 2000. Each Plaintiff claimed it had an atypical patient population or atypical service intensity, both of which are among the permissible grounds for seeking an exception. See 42 C.F.R. § 413.184. All three Plaintiffs are represented by the same counsel and are jointly litigating this consolidated case.

1. Plaintiff Alpena

Alpena is a free-standing facility that provides outpatient dialysis services to residents of Alpena, Michigan and surrounding areas. At all relevant times, the composite rate for Alpena was $123.96 per treatment. Claiming atypical service intensity resulting in unusually high labor costs, it requested an exception of $26.65 per treatment in March 2000. See Alpena Admin. R. at 1623. If approved, the exception would have raised its

[4] Pursuant to Local Civil Rule 7(h), "[i]n determining a motion for summary judgment, the Court may assume that facts identified by the moving party in its statement of material facts are admitted, unless such a fact is controverted in the statement of genuine issues filed in opposition to the motion." Unless otherwise noted, the Court states only uncontroverted facts from the parties' Statements of Material Facts Not in Dispute.

reimbursement rate to $150.61 per treatment. United Government Services, L.L.C. - WI, Alpena's fiscal intermediary, forwarded the request to CMS with a recommendation that it be approved. Id. at 16.

On October 12, 2000, CMS denied the exception. The agency found that Alpena had miscalculated its average labor costs in two ways: by failing to include data about treatments provided to its home dialysis patients; and by including salaries only, instead of salaries and employee benefits, in its calculation. Id. As a result, while Alpena had argued that its labor costs in fiscal year 1999 were $52.16 per treatment compared to a composite rate allowance of $40.00, CMS concluded that its actual labor costs were $44.75 per treatment compared to an allowance of $47.00. Id. at 1623-24. CMS denied the exception on the ground that Alpena's actual labor costs were less than what was allowed under its composite rate and were projected to remain so. See Alpena Admin. R. at 1624.

CMS also rejected Alpena's argument that its patient population required nursing hours that were atypically high. See id. The agency found that its average nursing hours per treatment were 4.19 in fiscal year 1998 and 2.70 in fiscal year 1999 and were projected to be 2.78 in fiscal year 2000. Id. According to CMS, "national audited data for 1988 and 1991, the latest available," showed an average per-treatment duration of 3.0 hours. Id. As a

result, CMS concluded that "even if [Alpena's] patient mix [were] to be found atypical, its nursing hours per treatment were not atypical." Id.

CMS did not decide whether Alpena in fact treated an atypical patient population. The agency argued that because it had found that the facility's per-treatment labor costs did not deviate substantially from national norms, it was not necessary to decide whether its patient population was atypical. Id. at 22.

Alpena appealed to the PRRB on January 8, 2000. It argued, first, that the agency improperly declined to decide whether it served an atypical population. Second, Alpena alleged that CMS failed to give adequate weight to the high percentage of aged and diabetic patients it treats. Third, and finally, Alpena criticized the figure of 3.0 nursing hours per treatment ("the 3.0 hours figure") as improper and deficient and argued that the agency's use of it was reversible error. Id. at 23-25.

By order dated December 22, 2003, the PRRB affirmed CMS's denial of Alpena's exception request.[5] The Board determined that while Alpena based its request on its composition of aged and diabetic patients, a finding of atypicality also requires consideration of factors such as mortality rates, average length of patient stay, and individual patient diagnoses. Id. at 26.

[5] The PRRB held a consolidated hearing on the appeals by all three Plaintiffs but issued separate decisions and orders for each facility.

Considering all these factors, and using Alpena's "own patient analysis," the Board concluded that it was "unable to make a clear determination that [the facility] had an atypical patient mix which justified the incurrence of additional costs per treatment." Accordingly, it held that Alpena had "failed to meet the threshold requirement of patient atypicality" that would justify an exception under 42 C.F.R. § 413.184. Id.

The Board also discussed Alpena's contention that CMS improperly compared its per-treatment nursing hours to a national average of 3.0 hours. The PRRB determined that while Alpena presented some valid criticisms of the 3.0 hours figure, it did not present any data to support an alternative. In contrast, it found that CMS did establish that the average duration of a dialysis session ranged from 3.0 to 3.5 hours. Id. at 27. As a result, it concluded that the 3.0 figure was appropriate "to measure the Provider's atypical service intensity" and that CMS "properly denied [Alpena's] exception request." Id.

The Administrator declined to review the PRRB's order and notified Alpena of that decision on February 17, 2004. Alpena Admin. R. at 1.

2. Plaintiff Chippewa

Like Alpena, Plaintiff Chippewa is a free-standing dialysis facility. It provides ESRD treatment to residents of Sault Ste. Marie, Michigan and surrounding areas, including members of the

Sault Ste. Marie Tribe of Chippewa Indians. In March 2000, Chippewa requested an exception in the amount of $31.85 per treatment to its composite rate of $123.96, which would have yielded a revised reimbursement rate of $155.81. Chippewa made its exception request on grounds similar to Alpena's: namely, that it provided atypically intense ESRD services that drove its labor costs higher than the amount allotted in its composite rate. Chippewa's fiscal intermediary, United Government Services, L.L.C. - WI, forwarded the request to CMS with a recommendation that it be approved.

CMS denied the exception request. The agency found that contrary to Chippewa's representations, the average age of its patients – 61.4 – was close to the national average of 62.4. Chippewa Admin. R. at 18. Furthermore, while Chippewa had argued that its inpatient treatments lasted longer, on average, than those provided by other facilities, CMS found that Chippewa had improperly included the days of admission and discharge in its calculation. When those days were excluded, the average length of stay for Chippewa's patients of 6.64 days was lower than the national average of 8.30. Id.

The agency also rejected Chippewa's argument that its composite rate failed to cover above-average labor costs. Noting that salaries and employee benefits comprise $47.00 of a facility's composite rate, and that Chippewa's costs were $48.73 per

treatment, CMS found that Chippewa did not incur unusually high labor costs. Id. at 21. Finally, as it did in Alpena's case, CMS found that Chippewa's average nursing hours per treatment did not deviate substantially from the national average of 3.0 hours. Id. at 18.[6]

Chippewa appealed the CMS decision on January 8, 2001. Before the PRRB, it renewed its argument that an atypical intensity of ESRD services justified its exception request. Chippewa alleged, inter alia, that it served a high percentage of aged and diabetic patients and that doing so pushed its labor costs above national norms. Like Alpena, Chippewa also attacked the 3.0 hours figure. Id. at 19-20.

In language similar to that used in the Alpena decision, the PRRB upheld CMS's denial of the request. According to the PRRB, Chippewa's percentage of aged and diabetic patients, though high, was not a "substantial deviation from national norms." The Board also found that the facility had failed to consider other relevant factors in determining whether its population was in fact atypical. For this and other reasons, the PRRB concluded that "[Chippewa] failed to meet its burden of proving that it rendered atypical services to its ESRD patients." Id. at 26.

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[6] Chippewa reported an average of 2.29 hours per treatment in fiscal year 1998 and 2.82 in fiscal year 1999. It forecast its fiscal year 2000 average to be 2.90. See Chippewa Admin. R. at 19.

The Board again noted that the 3.0 hours figure was reasonable and that while Chippewa had pointed out some valid statistical concerns about it, the facility had not presented a useful alternative. Id. at 27.

The Administrator did not review the Board's order and it became final agency action on February 22, 2004. Chippewa Admin. R. at 1.

3. Plaintiff NMH

Plaintiff NMH is a hospital-based facility that provides dialysis services on both an inpatient and outpatient basis to residents of Petoskey, Michigan and surrounding areas. NMH is a part owner of both Alpena and Chippewa and serves as a back-up center when either facility experiences high patient volume. During the March 2000 exception window, NMH requested a $23.39 per-treatment exception to its composite rate of $127.82. If approved, the exception would have raised its reimbursement rate to $151.21 per treatment. Like its subsidiaries Alpena and Chippewa, NMH argued that it furnished atypically intense ESRD services and incurred above-average labor costs as a result. See NMH Admin. R. at 14. And as it did in the Alpena and Chippewa cases, United Government Services, L.L.C. – WI forwarded NMH's exception request to CMS with a recommendation that it be approved. Id.

CMS found that none of the evidence presented by NMH justified an exception to its composite rate and rejected its request on

October 12, 2000. Id. Specifically, CMS found that in attempting to establish an above-average percentage of diabetic patients, NMH had improperly excluded from its patient population "transient" patients, which NMH defined as those part-time residents who undergo four or fewer treatments at the facility per year. Id. at 16. Including such patients, the percentage of diabetics within NMH's patient population was 36.3%, nearly identical to the national average of 36.7%. Id. CMS also found that NMH's mortality rate and average length of stay were significantly lower than national norms. Id. at 17. As it did in the other two cases, furthermore, CMS found that the average nursing hours per treatment at NMH were consistent with the national average of 3.0 hours. Id. at 18.[7]

NMH appealed to the PRRB on January 8, 2001. As its affiliated facilities had, NMH sought review of CMS's determination that its percentages of aged and diabetic patients were consistent with national norms and challenged the 3.0 hours figure. Id. at 22-23. NMH also attacked the agency's exclusion of transient patients in its calculation of the facility's percentage of diabetic patients. Id. at 22.

The PRRB, in an order dated December 22, 2003, upheld CMS's decision. It found that NMH had failed to meet its burden of

[7] NMH reported an average of 2.87 hours per treatment in fiscal year 1998 and 2.66 in fiscal year 1999 and forecast its fiscal year 2000 average to be 2.66. See NMH Admin. R. at 18.

demonstrating atypical service intensity. Id. at 25. By focusing exclusively on the composition of aged and diabetic patients at the facility, NMH "did not take into consideration other factors in its patient mix analysis which CMS addressed in reviewing the exception request." Id. And because the facility's own data, even on the limited factors it did consider, failed to "demonstrate a significant deviation from the national averages," the Board could not conclude that it had "an atypical patient mix which justified the incurrence of additional costs per treatment." Id.

The PRRB again took the opportunity to note that CMS did not err in using the 3.0 hours figure. It found that it was a reasonable figure that was, if anything, too generous to ESRD providers. Id. at 26.

The Administrator declined to review the PRRB's order, which became final agency action on February 22, 2004. Id. at 1.

In sum, Defendant (through decisions of the PRRB, as affirmed by the Administrator) decided that all three Plaintiffs had failed to demonstrate by convincing objective evidence one or more of the grounds for an exception (atypical service intensity, atypical patient mix, or excessive labor costs) and that its per-treatment costs in excess of its reimbursement rate were directly attributable to such factors.

C. Procedural History

On February 12, 2004, the Plaintiffs filed three separate actions in this Court. Each Plaintiff seeks review, pursuant to 42 U.S.C. § 1395oo(f)(1), of the respective PRRB order denying its exception request.[8] All Plaintiffs request a declaratory judgment that Defendant improperly denied their exception requests, an order that Defendant approve those requests, and other miscellaneous relief. See Alpena Compl. at 8-9, Chippewa Compl. at 8-9, and NHM Compl. at 8.

Because all Plaintiffs present similar and/or related legal claims and request the same relief, and all are represented by the same counsel, on April 26, 2004 the Court consolidated the three instant cases and ordered them to proceed under the caption Alpena Dialysis Services v. Thompson and case number 04-218. See Minute Order Consolidating Cases, 04-cv-218, (D.D.C. Apr. 26, 2004). On June 28, 2004 Defendant answered and filed the Administrative Record in each case.

Plaintiffs thereafter filed their Motion for Summary Judgment and Defendant filed its Cross Motion for Summary Judgment.

II. STANDARD OF REVIEW

Summary judgment will be granted when the pleadings, depositions, answers to interrogatories and admissions on file,

[8] The individual actions were assigned the following case numbers: 04-218 (Alpena Dialysis Services v. Thompson), 04-219 (Chippewa Dialysis Services v. Thompson), and 04-222 (Northern Michigan Hospital v. Thompson).

together with any affidavits or declarations, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). A fact is "material" if it might affect the outcome of the action under the governing law. Anderson v. Liberty Lobby, Inc. 477 U.S. 242, 248 (1986).

When reviewing actions by an administrative agency, courts are bound by the highly deferential standard embodied in the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A). Under this standard, which is incorporated in the Medicare Act, an agency action may be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); see also 42 U.S.C. § 1395oo(f)(1). If the "agency's reasons and policy choices . . . conform to 'certain minimal standards of rationality'. . . the [agency decision] is reasonable and must be upheld." Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 521 (D.C. Cir. 1983) (citation omitted).

Because of the "'tremendous complexity' of the Medicare program," agency actions concerning it are entitled to even greater deference. Community Care Found. v. Thompson, 318 F.3d 219, 225 (D.C. Cir. 2003) (citation omitted); see also Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (noting that because Medicare is a "complex and highly technical regulatory program"

"broad deference" to the agency is "even more warranted"). Courts are thus compelled to play a "limited role" in reviewing Medicare decisions and to accept the Secretary's actions so long as they have a rational basis and are consistent with the underlying statute. See Villa View Cmty Hosp., Inc. v. Heckler, 728 F.2d 539, 543 (D.C. Cir. 1984).

III. ANALYSIS

Plaintiffs argue that the Secretary's denial of their exception requests was arbitrary, capricious, and unsupported by substantial evidence, and therefore invalid. They allege both procedural and substantive violations of the relevant statutes and highlight what they characterize as fatal flaws in the data underlying the Secretary's determinations.

The Secretary contends that the proceedings below satisfied all the procedural requirements of the Medicare Act and the APA and argues that substantial evidence supported his determinations. On that basis, the Secretary urges the Court to defer to his judgment and uphold the determinations he made.

Bearing in mind the high deference generally due to the Secretary in these matters, the issue for the Court is whether either procedural or substantive deficiencies render his decisions invalid.

A. Plaintiffs' Procedural Challenges to the Secretary's Determinations

Plaintiffs mount two primary procedural attacks. First, they argue that Defendant erred by failing to publish the 3.0 hours figure in the Federal Register before considering it in their exception requests. See Pls.' Mot. for Summ. J. at 11. Second, in the case of Alpena only, they contend that the PRRB improperly determined that the facility's patient population was atypical in the absence of CMS making such a determination in the first instance. See id. at 22.

1. The Secretary was not required to publish the 3.0 hours figure in the Federal Register

There is no dispute that the 3.0 hours figure was never published in the Federal Register. Whether it should have been, however, is an issue on which the parties vigorously disagree. Plaintiffs contend that "there is little doubt that the Secretary considers the 3.0 hours rule to be a guideline of general applicability,"[9] pointing out that it has been applied to "other providers" and was referenced in "at least three other exception requests during the 1994 exception window." Id. at 12. Therefore, Plaintiffs argue, the Secretary was obligated to publish the figure

[9] During the briefing that accompanied the instant Motions, Plaintiffs also characterized the 3.0 hours figure as an interpretive rule. See Pls.' Reply and Opp'n at 7. Because our Court of Appeals has held that an interpretive rule is one in which an agency attempts to clarify provisions of its organic statute, Plaintiffs' characterization is incorrect. See General Motors Corp. v. Ruckelhaus, 742 F.2d 1561, 1565 (D.C. Cir. 1984).

and his failure to do so was a fatal procedural error. See Pls.' Mot. for Summ. J. at 12.

Defendant takes the position that the "3.0 figure is neither an interpretive rule nor a guideline of general applicability." Def.'s Cross Mot. for Summ. J. at 32. Instead, the Secretary describes it as an "evaluative tool" or "merely a piece of evidence CMS looks to in determining if a facility is providing atypical services." Id.

HHS is not required to submit for publication in the Federal Register every figure, piece of evidence, and data point it considers in evaluating exception requests. The Medicare statute requires publication only of final rules, "interpretative rules, statements of policy, and guidelines of general applicability." 42 U.S.C. § 1395hh(c)(1). Thus, unless the 3.0 hours figure falls into one of these categories, the Secretary's failure to publish it is of no consequence.

Because the 3.0 hours figure is neither an interpretive rule nor a statement of substantive policy, Plaintiff must establish that it is a guideline of general applicability. See Ruckelhaus, 742 F.2d at 1565 ("An interpretative rule . . . states what the administrative agency thinks [its organic] statute means, and only 'reminds' affected parties of existing [legal] duties.") (citation omitted); American Mining Congress v. Mine Safety and Health Admin., 995 F.2d 1106, 1109 (D.C. Cir. 1993) ("Substantive rules

[are] . . . issued by an agency pursuant to statutory authority [and] have the force and effect of law.") (citation omitted).

Neither the Medicare Act nor the APA defines the term "guideline of general applicability" and our Court of Appeals has offered no definitive guidance on its meaning. As a purely semantic matter, the term would seem to refer to a figure that is both definitive (a guideline) and widely used (generally applicable). See Webster's Third New International Dictionary (Unabridged) (Phillip Babcock Gove ed., 2002) at 1009 (defining "guideline" as "an indication or outline of future policy or conduct (as of a government)"); id. at 944 (defining "general" as "involving or belonging to every member of a class, kind, or group: applicable to every one in the unit referred to"). The evidence Plaintiffs offer suggests that the 3.0 hours figure is neither.

Defendant has maintained throughout these proceedings that the 3.0 hours figure is merely an estimate of the average duration of dialysis sessions in the United States. See Def.'s Cross Mot. for Summ. J. at 25. The average length of a facility's dialysis sessions is one of many criteria the Medicare Provider Reimbursement Manual ("PRM") allows CMS to use when evaluating whether a facility experiences atypical service intensity. See CMS Publication 15-1: Medicare Provider Reimbursement Manual (hereinafter "PRM") § 2725.1. Other factors that bear on this analysis include whether the facility experiences "higher staff-to-

patient ratios . . . based upon patient acuity" and whether it incurs "higher overhead costs" because of special circumstances, including patients with illnesses such as hepatitis. See id. § 2725.1(B)(2)-(4). The PRM provides that CMS will use "one or more" of these criteria to evaluate an exception request on the basis of atypical service intensity but does not mandate the application of any particular factor in every case. See id. § 2725.1(B). While the term "guideline of general applicability" connotes a uniform rule that must be applied in every case, the 3.0 hours figure functions very differently. It is one of several factors CMS may consider in evaluating exception requests.

Not only is the 3.0 hours figure not a "guideline," it also does not appear to be "generally applicable." According to Plaintiffs' own count, CMS used the figure in, at most, three prior adjudications over a ten year period. See Pls.' Mot. for Summ. J. at 12. A figure used so infrequently can hardly be considered generally applicable.

Since use of the 3.0 hours figure is not mandatory in CMS's evaluation of exception requests and the record demonstrates that its use is relatively rare, it is not a guideline of general applicability. Consequently, the Secretary made no procedural error in failing to publish it in the Federal Register.[10]

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[10] Plaintiffs' claim that they were unaware that the figure might be used in adjudicating their cases is unconvincing. See (continued...)

2. The PRRB erred by determining that Alpena did not serve an atypical patient population in the absence of CMS making such a determination in the first instance

There is no dispute that CMS did not make a finding as to the typicality of Alpena's patient population and instead rejected Alpena's exception request on the sole ground that it had failed to establish excessive labor costs per treatment. CMS explained that

> Normally a finding that a provider treats an atypical patient mix . . . is required . . . In the current appeal . . . such a finding is unnecessary because [a] sufficient basis exists for a denial on other grounds. . . [Alpena] has not shown that it furnishes atypical nursing services.

See Alpena Admin. R. at 1369. Even though CMS expressly declined to address the issue of patient atypicality, the PRRB used it as the principal basis for its decision, explaining that the facility "failed to meet the threshold requirement of atypicality" and could not qualify for an exception as a result. See id. at 26.

Prior to the issuance of the PRRB's decision, Alpena did not have notice that the Board would even consider the issue of patient atypicality, let alone that it would turn out to be dispositive. The Notice of Board Hearing the PRRB issued to Alpena on October 15, 2002, which according to the PRRB's standing order must include "a list of issues that will be heard," informed Alpena that it

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[10](...continued)
Pls.' Opp'n and Reply at 5, 7. The figure is published, and explained, on CMS's website. More importantly, in letters to Plaintiffs' counsel, both CMS and the PRRB referenced it. See Defs.' Opp'n and Reply at 11.

would consider one issue only: "Did CMS incorrectly deny Alpena Dialysis Service['s] request for an exception to the ESRD rate?" See Alpena Admin. R. at 320. As Plaintiffs point out, the Notice "provided no indication that issues not considered by CMS in rendering its prior denial would be considered by the Board," including the issue of patient atypicality. See Pls.' Surreply at 5.

Pursuant to 42 C.F.R. § 413.194, which governs appeals of ESRD reimbursement disputes, the PRRB has "authority to review the action taken by CMS." Plaintiffs claim that the PRRB exceeded its mandate in Alpena's case by deciding its exception request on a rationale different from that on which CMS relied. See Pls.' Mot. for Summ. J. at 23-25. Plaintiffs further contend that the PRRB's failure to notify them that it would consider evidence on the issue of patient atypicality deprived them of a meaningful opportunity to be heard on the issue that would ultimately decide Alpena's fate. See Pls.' Surreply at 6.

In response, Defendant argues that in reviewing exception requests, the PRRB's appellate jurisdiction is virtually unlimited. According to Defendant, the Board may review CMS's "action" in its entirety and may consider "all of the issues that are potentially relevant." See Def.'s Opp'n and Cross Mot. for Summ. J. at 18 (citing 42 C.F.R. § 413.94(b)(1)). The Defendant maintains that the Board is not limited to reviewing the discrete grounds CMS

cited as supporting its ultimate action which, in this case, was the denial of Alpena's request.[11] See id.

The APA provides that "[p]ersons entitled to notice of an agency hearing shall be timely informed of — (1) the time, place, and nature of the hearing; (2) the legal authority and jurisdiction under which the hearing is to be held; and (3) the matters of fact and law asserted." 5 U.S.C. § 554(b). In addition, it requires an agency conducting such a hearing to "give all interested parties opportunity for . . . the submission and consideration of facts [and] arguments . . . [and a] hearing and decision on notice . . . in accordance with sections 556 and 557 of this title." Id. § 554(c). Our Court of Appeals has explained that compliance with these provisions requires an agency to give claimants proper notice of the issues on which a hearing will be held and the theories on which the agency might decide the case. See Rodale Press, Inc. v. F.T.C., 407 F.2d 1252, 1256 (D.C. Cir. 1968) ("[I]t is well settled

[11] Defendant also points to the PRRB's organic statute for support. He argues that 42 U.S.C. § 1395oo(d) ("Section 1395oo"), which allows the Board to consider evidence that is presented to it as well as "such other evidence as may be obtained or received by it," justifies its consideration of factors other than those expressly addressed by CMS. That argument is plainly incorrect. Section 1395oo concerns situations in which a provider directly appeals a "final determination of [a] fiscal intermediary" without having to present its arguments to CMS first. The ESRD exception process does not allow a provider to appeal the intermediary's decision directly; instead, it requires all providers to bring their claim before CMS first. See 42 C.F.R. § 413.80. Accordingly, Section 1395oo is inapplicable to the facts of this case.

that an agency may not change theories in midstream without giving respondents reasonable notice of the change.").

Applying these principles to the instant facts, the Court must conclude that the Board erred by deciding Alpena's case on the issue of patient atypicality without giving the facility an adequate opportunity to present arguments on that issue. The Board notified Alpena that it would hear arguments on the validity of CMS's denial of its exception request. See Alpena Admin. R. at 320. CMS could not have been clearer that it based its decision on the facility's labor costs, and that it did not consider whether its patient population was atypical. See id. at 1369-70. Accordingly, Alpena reasonably concluded that its hearing before the PRRB would be confined to the issue of whether it incurred labor costs that deviated substantially from national norms. Without prior notice that the Board would consider patient atypicality, the facility was not, and could not have been, prepared to present arguments on that issue. Such conduct by the Board violates both the letter and the spirit of the APA.

Consequently, the Court will remand the Alpena case so that the facility can have an opportunity to address the issue on which the Board made its determination: whether Alpena treats an atypical patient population.

B. Plaintiffs' Substantive Challenges to the Secretary's Determinations

In addition to alleging procedural deficiencies, Plaintiffs contend that the Secretary made several substantive errors in adjudicating their cases. First, they challenge the 3.0 hours figure as invalid and prejudicial. See Pls.' Mot. for Summ. J. at 7. Second, they attack the $47.00 median cost per treatment statistic to which the Secretary compared their labor costs. See id. at 14. Third, in the Chippewa and NMH cases only, they argue that the Secretary improperly compared their patient population to national averages rather than to a narrower class of similar facilities. See id. at 22.

As a preliminary matter, three points bear repeating: first, under the governing regulations, it is Plaintiffs who bear the burden of proving that the Secretary unreasonably determined that they did not incur "costs per treatment in excess of [their] payment rate" "directly attributable to atypical service intensity (patient mix)" as a result of one or more of the factors set forth in the regulations. See 42 C.F.R. §§ 413.80 - .84. Second, what is under review is the Secretary's ultimate conclusion that Plaintiffs did not meet their burden, not the validity of the discrete data points on which he relied in reaching that conclusion. See 42 U.S.C. § 1395oo(f)(1). Third, because the Secretary, in his or her institutional capacity, amasses such expertise in administering the tremendously complex Medicare

program, the touchstone of judicial review is the essential rationality of the decisions made.

1. The Secretary's use of the 3.0 hours figure was reasonable

In addition to arguing that Defendant's failure to publish the 3.0 hours figure constituted procedural error, Plaintiffs also attack the substantive validity of the figure. They argue that the data underlying it is too old, too narrow, statistically invalid, and otherwise inaccurate. See Pls.' Mot. for Summ. J. at 6-10. After reminding the Court that the 3.0 hours figure "was not the basis of the Secretary's final decisions," Defendant argues that, in any event, "the record is replete with evidentiary support for" it. See Def.'s Reply and Opp'n at 3, Def.'s Cross Mot. for Summ. J. at 25.

It should be noted at the outset that while Plaintiffs attack the 3.0 hours figure with great vigor, the record is clear that the Board did not decide Plaintiffs' exception requests based on that factor.[12] In each case, the Board found that Plaintiffs had not met

[12] As Plaintiffs note, CMS's own expert, William Cymer, testified before the PRRB that the average length of Plaintiffs' dialysis sessions was the "dispositive factor" in CMS's review of the instant matters. See Alpena Admin. R. at 306. While that testimony would seem to help Plaintiffs, it stands in direct conflict with the Board's conclusion that exceptions were unwarranted in these cases since the providers "failed to meet the threshold requirement of patient atypicality." Id. at 27. Because it is the Board's action that is under review, and the Court is satisfied that the 3.0 hours figure was not dispositive in the Board's analysis, Cymer's statement cannot carry the weight (continued...)

their burden of establishing an atypical patient mix and denied the exception request on that ground.[13] See, e.g., Alpena Admin. R. at 26. In each case, however, the Board also noted that "despite [its] finding that the Provider failed to meet the threshold requirement of patient atypicality, the Board nevertheless analyzed the Provider's cost data . . . and determined that the Provider's average number of direct patient care hours per treatment was less than the national average of 3.0 hours." Id. at 27. Accordingly, the Board explained that Plaintiffs' exception requests were denied for failure to establish an atypical patient mix but "nevertheless" addressed the 3.0 hours figure "despite [that] finding." Id. The Board's discussion of the 3.0 hours figure, which bears on a facility's service intensity rather than patient population, was pure dicta and not the rationale for its disposition of Plaintiffs' cases.[14]

To the extent that the validity of the 3.0 hours figure is relevant, however, the Court concludes that it meets the applicable legal standards. Where, as here, the validity of an agency's action depends on a "battle of the experts," courts are instructed

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[12](...continued)
Plaintiffs assign to it.

[13] For the reasons explained above, the Board erred by basing its decision in the Alpena case on that finding.

[14] It follows that because the Board's decisions did not turn on the application of the 3.0 hours figure, Plaintiffs could not have been prejudiced by the discussion of it.

not to substitute their own judgment for that of the agency and to give due deference to its substantive decisions. See Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (noting that courts must ask whether an agency's decision was based on "a consideration of the relevant factors and whether there has been a clear error of judgment" but that a court may not "substitute its judgment for that of the agency"). Unless the 3.0 hours figure fails to meet "minimal standards of rationality," the Secretary's use of it must be upheld. See Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d at 521.

Defendant's pleadings and the record illustrate that the figure was based on a reasonably thorough examination of data about the country-wide average duration of dialysis sessions. See, e.g., Def.'s Cross Mot. for Summ. J. at 25-31; Alpena Admin. R. at 278-90. The 3.0 hours figure was derived from a study that included at least 63 dialysis units from across the country, including both urban and rural areas. Defendant's expert testified at length before the PRRB about the appropriateness of the sample and the validity of the study's conclusions. See Def.'s Cross Mot. for Summ. J. at 28-29; Alpena Admin. R. at 278-90.[15]

[15] Defendant's expert, William E. Cymer, admitted that he had not conducted the survey and that the underlying data was at least 10 years old. See Alpena Admin. R. at 276-285. However, neither fact calls into question his conclusion that the study validly estimates the average duration of contemporary dialysis treatments. At a minimum, there is nothing in the record to suggest that the (continued...)

Plaintiffs argue that the study's sample was flawed and challenge its statistical validity. But the Court's function is not to decide whether CMS used the best possible sample or the most accurate statistical methodology in arriving at the 3.0 hours figure. The inquiry here is limited to whether the Secretary considered the relevant data and made a reasonable determination that the figure is a useful tool for evaluating whether an ESRD facility's service intensity is typical. The Court is satisfied that he did.

2. The Board did not consider the $47.00 national median per-treatment labor cost contained in the Medicare Provider Reimbursement Manual; as a result, the sufficiency of those figures is not before the Court.

The PRM instructs intermediaries to consider the reasonableness of several components of an ESRD facility's per-treatment costs when reviewing an exception request. See PRM § 2723.3(D). Salaries and employee benefits are among the components to be considered. See id. Accordingly, United Government Services, L.L.C. - WI reviewed the Plaintiffs' expenditures for salaries and benefits and reported its findings to CMS. In adjudicating their exception requests, the agency determined that two of the Plaintiffs, Alpena and Chippewa, incurred labor costs that were consistent with the national average of $47.00 per

[15](...continued)
average duration of treatments has increased rather than decreased. Only the former would benefit Plaintiffs.

treatment. See Alpena Admin. R. at 1623-24; Chippewa Admin. R. at 21.

Plaintiffs argue that the PRM contains invalid data concerning national median labor costs and that CMS erroneously used that data in its consideration of the Alpena and Chippewa cases. See Pls.' Mot. for Summ. J. at 13. They challenge the $47.00 per treatment figure on many of the same grounds they raise in opposition to the 3.0 hours figure: that the $47.00 figure relies on invalid and obsolete data, and that the sample from which it was derived is both too small, and too narrow, to yield reliable results. See id. at 14-18.

In addition to defending the substantive merits of the PRM figure, the Secretary argues that this issue is not properly before the Court. In the Alpena and Chippewa cases, the PRRB found that because the facilities had not demonstrated atypical patient populations,[16] it need not address the issue of their labor costs. See Def.'s Cross Mot. for Summ. J. at 14; Alpena Admin. R. at 26; Chippewa Admin. R. at 27. Because the Board did not consider whether Plaintiffs' labor costs were unusually high, but made its determination on other grounds, the Secretary contends that the Court cannot review the PRM figures in those two cases. The issue did not arise in NMH's case.

[16] Again, for the reasons discussed above, the PRRB erred in making that finding as to Alpena.

The judicial review section of the Medicare Act authorizes civil actions to review "any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary." 42 U.S.C. § 1395oo(f)(1). Accordingly, the Court is limited to reviewing final agency action. In these cases, it was the Board's decision that constituted final agency action, not CMS's. The Board decided, based on a variety of factors—including the percentage of aged and diabetic patients Plaintiffs served, the mortality rate of their patients, and the average length of stay at their facilities—that Plaintiffs had not established an atypical patient population justifying an exception to their reimbursement rate. See Alpena Admin. R. at 26-27; Chippewa Admin. R. at 26-27; NMH Admin. R. at 25-26. While CMS considered the PRM data Plaintiff now challenges, there is no evidence that that data was factored into the Board's decisions.

Plaintiffs are unable to cite any authority suggesting that the Court may properly review the validity of the CMS decisions rather than those of the Board.[17] Because the Medicare Act limits

[17] Plaintiffs rely chiefly on an unpublished 1995 decision from this Court: Assinboine and Sioux Tribes of Fort Peck Indian Reservation v. Shalala, No. 93-cv-2419 (D.D.C. Mar. 30, 1995). See Pls.' Mot. for Summ. J. at 16. In Assinboine, the court determined that the Secretary had used faulty data in rejecting plaintiff's ESRD exception request and remanded the case to CMS. Unlike here, however, the Secretary had adjudicated plaintiff's request relying exclusively on the data later challenged in court. As a result, the court was clearly authorized to review that data. Here, by contrast, the data Plaintiffs are challenging was not the basis for (continued...)

the Court's review to the final agency action taken by HHS, Plaintiffs' challenges to the data underlying CMS's decision must be rejected.

3. While Chippewa and NMH cannot challenge the validity of the Board's national ESRD patient profiles at this late date, the case must be remanded so that Alpena can have an opportunity to do so

In each of the cases under review, the Secretary determined that Plaintiffs' patient populations were not atypical. To reach that conclusion, the Secretary used national ESRD patient profiles as a point of reference for evaluating whether Plaintiffs served disproportionate numbers of aged, diabetic, or otherwise unusual patients.

Plaintiffs now attack the ESRD patient profiles as substantively inaccurate. They argue that because the tables rely on data sets that include both inpatients and outpatients, and because "inpatients tend to be sicker than outpatients," they should not have been used by the Secretary to adjudicate their exception requests. See Pls.' Mot. for Summ. J. at 22. The only proper inquiry, Plaintiffs contend, was whether their outpatients were comparable to the outpatient populations at other facilities. By evaluating Plaintiffs' patients against profiles that include both inpatients and outpatients, the Secretary made it

[17](...continued)
the Board's final agency action on their requests. Therefore, Assiniboine is totally distinguishable.

"unreasonably difficult for an outpatient facility to demonstrate" that it serves an atypical population. Id.

Defendant responds that Plaintiffs merely assert that inpatients tend to be sicker than outpatients without providing any evidence to support that conclusion. See Def.'s Cross Mot. for Summ. J. at 25. In fact, they argue, the distinction between the health of inpatients and outpatients is negligible because ESRD patients can be hospitalized at any time and most spend at least some time undergoing inpatient treatment. See Def.'s Reply and Opp'n at 16. Furthermore, Defendant argues that Plaintiffs failed to present this issue during their administrative appeals and therefore are precluded from raising it here. See id. at 15.

It is well-settled that judicial review of agency action is limited to the issues presented to the agency itself. See United States v. L. A. Tucker Truck Lines, Inc., 344 U.S. 33, 37 (1952) ("Simple fairness . . . requires . . . that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice."); Federal Maritime Comm'n v. South Carolina, 535 U.S. 743, 763 (2002) (same); Nuclear Energy Inst. v. Environmental Protection Agency, 373 F.3d 1251, 1297 (D.C. Cir. 2004) ("It is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review.").

These principles preclude Chippewa and NMH from challenging the validity of the ESRD national patient profiles at this late date. Both facilities had prior notice that the Board would consider whether their patient population was atypical and would use its well-publicized national patient profiles to do so. See Def.'s Reply and Opp'n at 15. Neither facility challenged those profiles at the administrative agency level and, accordingly, they cannot do so here. See Nuclear Energy Inst., 373 F.3d at 1297.

In contrast, as explained in great detail above, the Board failed to inform Alpena that it would consider the issue of its patients' typicality.[18] That facility was thus prevented not only from arguing that its patients are atypical but also from mounting a substantive challenge to the yardstick by which the PRRB evaluates patient typicality—the national ESRD patient profiles. As a result, the substantive validity of those profiles is not properly before the Court at this time. Only after Alpena has been given an opportunity, on remand, to challenge the Board's patient

[18] Defendant is incorrect that because the PRRB heard argument on all three cases simultaneously, and neither Chippewa nor NMH challenged the national ESRD patient profiles, Alpena should be deemed to have also waived its right to challenge them. See Def.'s Reply and Opp'n at 15. As Plaintiffs point out, the cases were never formally consolidated before the Board, each individual facility submitted its own briefs both before and after the hearing, the PRRB rendered three separate decisions, and the facilities made three separate requests for review by the Administrator. The failure of Chippewa and NMH to raise this issue cannot, therefore, be imputed to Alpena as well.

profiles will the Court be in a position to make a finding as to their validity.

IV. CONCLUSION

Accordingly, for the foregoing reasons, Plaintiffs' Motion for Summary Judgment [#13] is **denied** and Defendant's Cross Motion for Summary Judgment [#15] is **granted in part and denied in part.**

An Order will issue with this Memorandum Opinion.

September 18, 2006

__/s/_____
Gladys Kessler
U.S. District Judge

Copies to: attorneys on record via ECF