United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 8, 2007 Decided December 21, 2007

No. 06-5371

CHIPPEWA DIALYSIS SERVICES,
APPELLANT

v.

MICHAEL O. LEAVITT, IN HIS OFFICIAL CAPACITY AS
SECRETARY OF HEALTH AND HUMAN SERVICES,
APPELLEE

Consolidated with
06-5372, 06-5373

Appeals from the United States District Court
for the District of Columbia
(No. 04cv00218)
(No. 04cv00219)
(No. 04cv00222)

Jeffrey A. Lovitky argued the cause and filed the briefs for appellants.

Daniel J. Davis, Attorney, U.S. Department of Justice, argued the cause for appellee. With him on the brief were *Peter D. Keisler*, Assistant Attorney General, *Jeffrey A. Taylor*, U.S.

Attorney, and *Thomas M. Bondy*, Attorney. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Before: HENDERSON and TATEL, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* TATEL.

TATEL, *Circuit Judge*: Claiming that their patients require atypically high-cost dialysis services, three Michigan dialysis providers asked the Secretary of Health and Human Services to reimburse them at higher rates than Medicare normally pays for such services. The Secretary denied the requests, the district court granted summary judgment to the Secretary, and the providers now appeal. Among other things, they argue that the standard the Secretary used to assess treatment costs qualifies as an "interpretative rule," "statement of policy," and/or "guideline of general applicability," and therefore should have been published in the Federal Register under the applicable statute. Although we agree, we need not remand two of the providers' cases because independent grounds exist to uphold the Secretary's decision as to them. With regard to the third provider, we reverse and remand for further proceedings.

I.

The Secretary of Health and Human Services reimburses facilities providing dialysis services under the Medicare program based on a "prospective determination of a rate . . . for each mode of care based on a single composite weighted formula." 42 U.S.C. § 1395rr(b)(7). This "composite rate" represents the approximate per treatment cost the Secretary expects dialysis providers to incur for various treatments. *Id.*

In unusual circumstances, providers can request exceptions to the composite rate. *Id.* Under the regulations in effect at the

time of the events at issue here, a facility providing treatment for end stage renal disease (ESRD) could request an exception to the composite rate if it projected it would have higher costs per treatment than the composite rate and showed the higher costs were attributable to certain factors, one of which, central to this case, is "[a]typical service intensity (patient mix)." 42 C.F.R. §§ 413.180(b), 413.182 (2005). To qualify for this exception, "[a] facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services." *Id.* § 413.184(a)(1). According to the Secretary, a facility must show both an atypical patient mix and atypically intense dialysis services, and given that the providers nowhere challenge this interpretation, we accept it as well. The facility bears the burden of proving it has met the criteria and its excessive costs are reasonable. *Id.* § 413.180(g).

Appellants are three Michigan dialysis providers—Alpena Dialysis Services ("Alpena"), Northern Michigan Hospital ("Northern"), and Chippewa Dialysis Services ("Chippewa")—that applied for exceptions to the ESRD composite rate. The Centers for Medicare and Medicaid Services (CMS), at that time known as the Health Care Financing Administration, reviewed their exception requests. All three providers based their exception requests on atypical patient mix, specifically, higher than average percentages of aged and diabetic patients. Consistent with CMS's Provider Reimbursement Manual (PRM), each provider sought to show that its patients, due to their special needs, required more hours of nursing services than did patients in other facilities. *See* PRM § 2725.1.

CMS denied all three requests. As to atypical nursing services, it stated that "[n]ational audited data for 1988 and 1991, the latest available, show that average direct patient care

hours . . . were 3.00 hours per treatment." *Alpena Dialysis Servs.*, No. 2004-D6, Provider Reimbursement Rev. Bd. 4 (Dec. 22, 2003); *N. Mich. Hosp.*, No. 2004-D7, Provider Reimbursement Rev. Bd. 6 (Dec. 22, 2003); *Chippewa Dialysis Servs.*, No. 2004-D5, Provider Reimbursement Rev. Bd. 5 (Dec. 22, 2003). Because the per treatment hours of all three providers fell below that level—2.78 hours for Alpena, 2.66 hours for Northern, and 2.90 hours for Chippewa—CMS concluded they had failed to show atypical nursing services and were thus ineligible for the exception. *Alpena*, No. 2004-D6, at 4; *N. Mich. Hosp.*, No. 2004-D7, at 6; *Chippewa*, No. 2004-D5, at 5.

CMS also found that Northern and Chippewa had failed to substantiate atypical patient mix. As to Northern, it found that although the provider had a higher than average percentage of patients sixty-five or older, its percentage of diabetic patients, properly calculated, virtually matched the national average. *N. Mich. Hosp.*, No. 2004-D7, at 4-5. In addition, Northern's mortality rate and average length of stay both fell below national averages. *Id.* at 5. As to Chippewa, CMS found that although the provider served higher than average percentages of diabetic patients and patients sixty-five or older, its average length of stay, percentage of patients with hypertension, and average age of patients all fell below national averages. *Chippewa*, No. 2004-D5, at 4. CMS made no finding about patient mix regarding Alpena, resting its decision instead on the provider's failure to demonstrate atypical nursing services. *Alpena*, No. 2004-D6, at 3.

Challenging (among other things) CMS's use of the 3.0 hours per treatment standard, all three providers appealed to the Provider Reimbursement Review Board ("Board"). At the hearing before the Board, a CMS Health Insurance Specialist testified as to the source of what the Board referred to as the

"3.0 hours per treatment standard." *Alpena*, No. 2004-D6, at 8; *N. Mich. Hosp.*, No. 2004-D7, at 9; *Chippewa*, No. 2004-D5, at 8. According to the witness, the supporting data was "primarily obtained from audited cost reports of freestanding ESRD facilities for fiscal years 1988 and 1989. The data was selected based upon a stratified random sample that was statistically representative of freestanding facilities in the United States." *Alpena*, No. 2004-D6, at 8; *N. Mich. Hosp.*, No. 2004-D7, at 9; *Chippewa*, No. 2004-D5, at 8. Relying on various government reports, the witness further testified that 3.5 hours was "a more realistic standard, and that the application of the 3.0 hours threshold in denying the Provider[s'] exception request[s] was a very generous and liberal standard." *Alpena*, No. 2004-D6, at 8; *N. Mich. Hosp.*, No. 2004-D7, at 10; *Chippewa*, No. 2004-D5, at 8.

The Board rejected the providers' challenge to the 3.0 hours per treatment standard, noting that "[a]lthough the Provider[s] cited various deficiencies in the data and methodology employed by [CMS] in establishing the 3.0 hours per treatment standard, . . . the Provider[s] did not present alternative data which would support the use of another standard." *Alpena*, No. 2004-D6, at 14; *N. Mich. Hosp.*, No. 2004-D7, at 14; *Chippewa*, No. 2004-D5, at 13. By contrast, CMS demonstrated that "a more realistic contemporary standard for the duration of a dialysis session may have increased to 3.5 hours." *Alpena*, No. 2004-D6, at 13; *N. Mich. Hosp.*, No. 2004-D7, at 14; *Chippewa*, No. 2004-D5, at 13.

The Board also affirmed CMS's conclusion that Northern and Chippewa had failed to show an atypical patient mix, explaining that although the providers' patient populations may have contained higher than average percentages of aged and diabetic patients, "the variations did not reflect a substantial deviation from the national norms." *N. Mich. Hosp.*, No. 2004-

D7, at 13; *Chippewa*, No. 2004-D5, at 12. According to the Board, the providers had also failed to consider other factors CMS addressed in reviewing patient mix, "i.e., mortality rate, length of stay for patients requiring inpatient admission, average age of patient population, and individual patient diagnosis." *N. Mich. Hosp.*, No. 2004-D7, at 13; *Chippewa*, No. 2004-D5, at 12.

Although the Board found that CMS erred by failing to determine whether Alpena had an atypical patient mix, it went on to make that determination for itself. Employing the same language it used in rejecting Northern's and Chippewa's appeals, the Board found that Alpena's higher percentages of aged and diabetic patients "did not reflect a substantial deviation from the national norms" and that the provider had failed to consider other factors, "i.e., mortality rate, length of stay for patients requiring inpatient admission, average age of patient population, and individual patient diagnosis." *Alpena*, No. 2004-D6, at 12. Accordingly, the Board affirmed the denial of Alpena's request.

The three providers sought review in the district court, and both sides moved for summary judgment. The district court granted the Secretary's motion for summary judgment as to Northern and Chippewa, but initially denied it as to Alpena. *Alpena v. Leavitt*, No. 04-218, slip op. at 34 (D.D.C. Sept. 18, 2006). The court found that because CMS had failed to base its Alpena decision on patient atypicality, "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." *Id.* at 24. After the Secretary moved for reconsideration, however, the district court granted his motion for summary judgment, finding that regardless of whether Alpena had an atypical patient mix, it was unqualified for the exception because it had failed to establish atypical

nursing services. *See Alpena v. Leavitt*, No. 04-218, slip op. at 4 (D.D.C. Nov. 15, 2006). "[R]emand would serve no useful purpose," the district court concluded, because "independent, legally sufficient ground[s] for denial of Alpena's exception request" existed. *Id.*

The providers now appeal. All three challenge the Board's use of the 3.0 hours per treatment standard, arguing that the Medicare Act required the Secretary to publish it in the Federal Register. 42 U.S.C. § 1395hh(c)(1). In addition, they argue that the 3.0 hours per treatment standard is unsupported by substantial evidence. Northern and Chippewa also dispute the Board's conclusion that they failed to demonstrate atypical patient mix. Alpena contests the Board's atypical patient mix finding, arguing that it had no notice that the Board would decide the issue itself.

"Because the district court entered a summary judgment, we review its decision de novo and therefore, in effect, review directly the decision of the Secretary." *St. Luke's Hosp. v. Thompson*, 355 F.3d 690, 693 (D.C. Cir. 2004) (quoting *Lozowski v. Mineta*, 292 F.3d 840, 845 (D.C. Cir. 2002)). "[W]e will set aside the [Secretary's] factual findings only if unsupported by substantial evidence on the record as a whole; we will set aside the [Secretary's] legal conclusions only if 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" *Proffitt v. FDIC*, 200 F.3d 855, 860 (D.C. Cir. 2000) (quoting 5 U.S.C. § 706(2)(A), (E)).

II.

We begin with the issue common to all three providers—whether the Secretary should have published the 3.0 hours per treatment standard in the Federal Register. The Medicare Act requires that "[t]he Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability." 42 U.S.C. § 1395hh(c)(1). The statute does not define these terms, nor, as far as we are aware, has any court interpreted them as used in this statute. We have, however, fleshed out two of the phrases—interpretative rules and statements of policy—as used in the Administrative Procedure Act, 5 U.S.C. § 553(b)(A). In *Syncor International Corp. v. Shalala*, 127 F.3d 90 (D.C. Cir. 1997), we explained that an interpretative rule "typically reflects an agency's construction of a statute that has been entrusted to the agency to administer." *Id.* at 94. An interpretative rule, *Syncor* explains, can also "construe an agency's substantive regulation." *Id.* By contrast, a statement of policy "represents an agency position with respect to how it will treat—typically enforce—the governing legal norm. By issuing a policy statement, an agency simply lets the public know its current enforcement or adjudicatory approach." *Id.* Although nothing in the APA requires agencies to publish interpretative rules and statements of policy, we nonetheless think that *Syncor*'s definition of those phrases is helpful in the context we face here. Indeed, we have observed that, "as the Medicare Act was drafted after the APA," the reference to interpretative rules—and by extension policy statements—in the Medicare Act suggests that Congress intended the terms to be "at least *similar* in scope" to identical provisions in the APA. *See Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001).

Issued pursuant to the Medicare Act, the relevant regulation, 42 C.F.R. § 413.184(a)(1) (2005), states that in order

to qualify for the atypical patient mix exception, providers must show "that a substantial proportion of the facility's . . . dialysis treatments involve atypically intense dialysis services." *Id.* The regulation, however, includes no standard for measuring "atypically intense dialysis services." Because the 3.0 hours per treatment standard fills this gap, it looks a lot like an "interpretative rule." To use *Syncor*'s language, the standard reflects the agency's "construction of a statute that has been entrusted to the agency to administer." *Syncor*, 127 F.3d at 94. The 3.0 hours per treatment standard also informs the public of the agency's adjudicatory approach to determining exception requests based on nursing hours. In this sense, it could qualify as a "statement of policy," given that it "represents an agency position with respect to how it will treat . . . the governing legal norm." *Id.*

In the end, however, we need not decide whether the 3.0 hours per treatment standard qualifies as either an interpretative rule or a statement of policy because we believe it most clearly qualifies under the Medicare Act as a guideline of general applicability. According to the record, the Secretary has applied the standard not only to the three cases at issue here, but also to at least three others decided in 1994. Indeed, CMS's own witness testified that the agency had used the 3.0 hours per treatment standard as the threshold in the past and intended to continue using the standard, at least until "legislation is revised." By contrast, the Secretary has identified no case where he applied a different standard. As far as the record here is concerned, then, the 3.0 hours per treatment standard serves as the baseline by which the Secretary measures providers' eligibility for the atypical patient mix exception. Given this, and given that CMS and the Board both repeatedly referred to the 3.0 hours per treatment standard as a "standard," the Medicare Act requires the Secretary to publish it in the Federal Register.

The Secretary's arguments to the contrary are unpersuasive. He insists that the 3.0 hours per treatment standard is merely an "evaluative tool" that evolved from the data as a "reasonable factual finding[]" during the adjudicatory process. Appellee's Br. 36. But guidelines of general applicability can also evolve from data, and mere citation to the data each time the agency applies the guideline hardly converts it into a factual finding. Furthermore, as counsel for the Secretary conceded at oral argument, the Secretary relied on the same data set in all six proceedings in the record—the three providers' requests at issue here and the three 1994 proceedings. The Secretary also points out that the providers challenged the 3.0 hours per treatment standard during the administrative proceedings. This is true, but irrelevant: a guideline does not cease to be a guideline simply because the parties had an opportunity to challenge it. Finally, the Secretary notes that the CMS witness suggested that an even higher 3.5 hour baseline might be appropriate. This too is irrelevant, for as we have said many times, agencies are generally free to change their positions. *See, e.g.*, *Williams Gas Processing-Gulf Coast Co. v. FERC*, 475 F.3d 319, 322 (D.C. Cir. 2006) ("[A]n agency is free to change course in a regulatory regime provided that it offers a reasoned explanation for so doing and is not otherwise constrained by statutory limitations."). That the Secretary might someday choose to alter the 3.0 hours per treatment standard in no way suggests that the standard need not be published in the Federal Register; it simply means that it represents a standard the Secretary might choose to modify.

III.

Given our conclusion that the Secretary should have published the 3.0 hours per treatment standard, and given that the Secretary never responds to Alpena's argument that the provider lacked notice that the Board would address atypical patient mix, we shall remand Alpena's case to the district court for further proceedings consistent with this opinion. For Northern and Chippewa, however, we must still consider the Board's resolution of the atypical patient mix issue because, if correct, it would provide an independent ground for upholding the Board's decision. *See PDK Labs. Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration.").

The Board found that Northern's mortality rate and average length of stay were lower than national averages, and that Chippewa's average length of stay, percentage of patients with hypertension, and average age of patients were also lower than national averages. Applying a "totality of the circumstances" test, the Board concluded that it was "not able to make a clear determination that the [providers] had . . . atypical patient mix[es] which justified the incurrence of additional costs per treatment." *N. Mich. Hosp.*, No. 2004-D7, at 14; *Chippewa*, No. 2004-D5, at 12.

The providers nowhere challenge the Secretary's use of a totality of the circumstances test. Instead, they point out that Chippewa's percentages of aged and diabetic patients exceeded national averages and that Northern's percentage of diabetic patients was also higher. Acknowledging this data, however, the Board concluded that neither provider had shown "*substantial* deviation" from national averages. *N. Mich. Hosp.*, No. 2004-D7, at 13 (emphasis added); *Chippewa*, No. 2004-D5, at 12 (emphasis added). At bottom, the providers' attack on the

Secretary's application of the totality of the circumstances test is woefully incomplete: they do no more than show that some of the many factors tilt in their direction. Given this, we have no basis for concluding that the Secretary's decision was unsupported by substantial evidence. *See, e.g.*, *Ass'n of Data Processing Serv. Orgs. v. Bd. of Governors of the Fed. Reserve Sys.*, 745 F.2d 677, 683-84 (D.C. Cir. 1984) (stating that an agency decision unsupported by substantial evidence is arbitrary and capricious). The Secretary's failure to publish the 3.0 hours per treatment standard was thus harmless error with regard to Northern and Chippewa, leaving us with no need to remand their cases.

IV.

For the foregoing reasons, we affirm the district court's grant of summary judgment to the Secretary with respect to Northern and Chippewa, and reverse and remand with respect to Alpena.

So ordered.