

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT
Argued October 21, 1994 Decided January 10, 1995

No. 93-5247

NATIONAL MEDICAL ENTERPRISES, INC.,
A NEVADA CORPORATION, D/B/A
CENTURY CITY HOSPITAL,
APPELLANT

v.

DONNA E. SHALALA, SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
91cv03129

Byron J. Gross argued the cause for appellant. With him on the briefs were *John R. Hellow* and *W. David Allen*.

Stuart M. Langbein, Attorney, United States Department of Health and Human Services, argued the cause for appellee. With him on the briefs were *Eric H. Holder, Jr.*, United States Attorney, *Frank W. Hunger*, Assistant Attorney General, and *Henry R. Goldberg*, *Darrell J. Grinstead* and *Harriet S. Rabb*, Attorneys, United States Department of Health and Human Services. *R. Craig Lawrence*, Assistant United States Attorney, and *Gerard Keating*, Attorney, United States Department of Health and Human Services, entered appearances for appellee.

Before EDWARDS, *Chief Judge*, and SENTELLE and TATEL, *Circuit Judges*.

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

SENTELLE, *Circuit Judge*: National Medical Enterprises, Inc., doing business as Century City Hospital (the "Hospital"), appeals a decision of the district court granting the Secretary of Health and Human Services ("HHS"), Donna Shalala (the "Secretary"), summary judgment on the Hospital's challenge to her decision approving the reclassification of the Hospital's labor costs associated with the administration of intravenous ("IV") therapy to a "routine" care cost center from an "ancillary" cost center. Because the district court properly determined that the Secretary's decision was not arbitrary or capricious, an abuse of discretion, or otherwise not in accordance with law, we affirm.

I. BACKGROUND

The Hospital is a designated provider of hospital services to persons eligible for Medicare coverage under the Medicare Act, 42 U.S.C. § 1395 *et seq.* (1988). As such, it is entitled to reimbursement for the reasonable cost of rendering services to Medicare beneficiaries. *See* 42 U.S.C. § 1395f(b). A fiscal intermediary representing the Medicare program audits the Hospital's cost report to determine its reasonable costs. In its cost reports for 1982 and 1983, the Hospital classified labor costs from the administration of IV therapy in an ancillary cost center it established to keep track of all costs arising from IV therapy, including equipment and supplies. The Hospital had created a separate team of nurses who administered IV therapy and who were also available to perform other duties, such as serving as members of the Cardiac Resuscitation Team. While the fiscal intermediary approved the establishment of the ancillary cost center for IV therapy and the inclusion of costs for IV equipment and supplies, it removed IV labor costs from the ancillary cost center and reclassified them to the routine cost center of the cost report. Under applicable regulations, routine services include "the regular room, dietary, and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made." 42 C.F.R. § 405.452(b) (1983).¹ Ancillary services are those services "for which charges are customarily made in addition to routine services." *Id.* The Hospital states that the result of this reclassification of IV labor costs was a denial of Medicare reimbursement for a total of approximately \$406,000 over the 1982 and 1983 fiscal years.

The Hospital's initial challenge to the reclassification before the Provider Reimbursement Review Board ("Review Board") was successful. The Review Board stated that apportioning IV therapy personnel costs based on the actual charges for IV therapy was the most accurate method for determining the relative costs for such services used by Medicare and non-Medicare patients. The Review Board also noted that other intermediaries had apparently approved this allocation method for two hospitals near Century City Hospital. (In fact, the intermediary for one of the hospitals, St.

¹Since the fiscal years at issue in this appeal, HHS has reorganized its regulations. All references to regulations are to the 1983 C.F.R., unless otherwise noted.

John's Hospital and Health Center, had already reclassified that hospital's IV therapy labor costs as routine.) The Deputy Administrator of the Health Care Financing Administration, acting for the Secretary, reversed the Review Board's decision on the basis that the customary and prevailing practice among hospitals in California is to include IV therapy services, which are not specifically identified as ancillary under the regulations, within routine nursing services and not to bill separately for them.

The Hospital filed a challenge to this decision in district court. After considering the parties' cross-motions for summary judgment, the district court granted the Secretary's motion. *See National Medical Enters. v. Shalala*, 826 F. Supp. 558 (D.D.C. 1993). The issue before the court was whether the Secretary erred in allocating IV therapy costs to a routine rather than an ancillary cost center. The importance of the classification of such costs stems from the way these costs are reimbursed by the Secretary. Routine services are reimbursed on a *per diem* basis, so that if 10% of patients using IV services on a given day are Medicare recipients, the Secretary will reimburse the Hospital for 10% of its routine services on that day. Ancillary services are reimbursed on a utilization basis so that if the same 10% of patients who are Medicare recipients actually account for 20% of the IV charges, the Secretary will reimburse the Hospital for 20% of its IV costs on that day. *Id.* at 559-60.

The Hospital argued that the Secretary's allocation of IV cost was not based on substantial evidence in the record and violated the Medicare Act's prohibition against cost-shifting and that section 2203 of HHS's Provider Reimbursement Manual ("PRM"), which provides a three-part guide for allocating costs to routine or ancillary centers, is inconsistent with governing statutory and regulatory provisions and was improperly promulgated. The district court rejected these theories as well as the Hospital's argument that the Secretary arbitrarily and capriciously treated it differently than another California hospital that had been permitted to put its IV therapy labor costs into an ancillary cost center.

Because the district court decided this case on summary judgment, we review the matter *de novo*. As there are no asserted disputes of material fact our only task is to determine if the district

court properly applied governing law. *Beckett v. Air Line Pilots Ass'n.*, 995 F.2d 280, 284 (D.C. Cir. 1993). For the reasons set forth more fully below we determine that it did.

II. ANALYSIS

A. Classification of Costs as Ancillary or Routine

Insofar as the Secretary's determination of whether the disputed costs are properly allocated to routine, as opposed to ancillary, cost centers is treated as a finding of fact, that finding constitutes agency action which neither the district court nor this court can set aside unless it fails to meet the highly deferential standard set forth in the Administrative Procedure Act, 5 U.S.C. § 706(2) (1988). In this case, the Hospital asserts that the Secretary failed that deferential standard because the decision was "unsupported by substantial evidence" in the record. 5 U.S.C. § 706(2)(E). Like the district court, we reject this contention.

In making the allocation, the Secretary applied section 2202.6 of the PRM which states that routine services include "regular room, dietary and nursing services, minor medical and surgical supplies" and other facilities for which a "separate charge is not customarily made." Section 2202.8 specifies as ancillary laboratory, radiology, drugs, delivery room, operating room, and therapy services, and further provides that ancillary services may also include other special items and services for which separate charges are customarily made. A cost not recognized as an ancillary service under section 2202.8 is a routine service cost unless section 2203 permits ancillary allocation. That section provides:

A separate ancillary charge for a particular item or service other than those listed as ancillary in § 2202.8 is not recognized, and the cost of the item or service is not included in an ancillary cost center, where the common or established practice of providers of the same class ... in the same State is to include the item or service in the routine service charge. Where there is no common or established classification of an item or service as routine or ancillary among providers of the same class in the same State, a provider's customary charging practice is recognized so long as it is consistently followed for all patients and does not result in an inequitable apportionment of cost to the program.

Medicare Provider Reimbursement Manual § 2203. In applying section 2203 to allocate the disputed charges, the Secretary relied on *Loma Linda University v. Schweiker*, Medicare & Medicaid Guide (CCH) ¶ 31,650 at 10,148 (C.D. Cal. 1981), and concluded that the common or established practice

of hospitals in California was not to charge separately for IV therapy labor costs. In *Loma Linda*, which also considered whether IV therapy labor costs were routine or ancillary, the Secretary cited a survey of two fiscal intermediaries that cover approximately 75% of California's acute care hospitals who stated that the vast majority of these hospitals classify IV administration as a routine service. The district court in that case upheld the reclassification of the IV therapy labor costs as routine on the basis that the record established that the customary and prevailing practice among California hospitals is to include IV therapy services as routine nursing services and not to bill separately for them. *Id.* at 10,151.

The Hospital maintains that the Secretary improperly relied on the holding in *Loma Linda* because the survey used in that case was not presented to the Review Board, and thus was not available for review by the Hospital, and because a Medicare procedural regulation, 42 C.F.R. § 405.1875(g)(3) (1991),² requires the decision be confined to the record of the Review Board, materials submitted by the parties, and generally known facts not reasonably in dispute. Without *Loma Linda*, the Hospital maintains that the Secretary's decision was unsupported by substantial evidence, and that the only evidence properly before her was that HHS allowed Brotman Medical Center ("Brotman") to list its IV therapy administration costs as ancillary.

This argument ignores the Secretary's explicit authority under 42 C.F.R. § 405.1875(g)(4) (1991), to "rely on prior decisions of the Board, the Administrator and the courts, and other applicable law, whether or not cited by the parties...." The Hospital was aware of the holding in *Loma Linda*, as evidenced by its citation to the case in its position paper submitted to the Review Board, and it had an opportunity to rebut the *Loma Linda* findings. Its evidence that Brotman was allowed to list these costs as ancillary was not sufficient to refute the statewide IV therapy statistics developed in *Loma Linda*. In short, there was sufficient support for the Secretary's determination that the customary practice in California was not to include IV therapy labor costs as ancillary.

As to the evidence upon which the Hospital relies that Brotman was allowed to allocate its

²The 1991 regulations are the ones pertinent to this issue because the Secretary's decision was rendered in October 1991.

similar costs to an ancillary center, the Secretary tendered in the district court an affidavit by Charles R. Booth, Director of the Office of Payment Policy at HHS's Health Care Financing Administration, to the effect that the placement of Brotman's costs was a mistake on the part of the financial intermediary and HCFA Region IX. The Hospital correctly asserts the general rule that courts review administrative action on the administrative record, without augmentation by supplemental affidavit. *See Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985). It therefore contends the district court improperly considered the affidavit in upholding the Secretary's decision. We disagree. Without considering the possibility of exception to the general rule stated in *Florida Power & Light Co.*, given the comprehensive nature of the Secretary's *Loma Linda* study and the isolated character of the Brotman incident forwarded by the Hospital, to have remanded the matter for resolution would have been a vain thing. There was substantial evidence on the record to support the Secretary's decision and that is all that the district court or this court can require.

Although we conclude that the Secretary's action was supported by substantial evidence in the record, the Hospital also challenges the Secretary's interpretation of applicable law by asserting that because the Secretary's decision rejected the allegedly more accurate allocation of IV therapy labor costs into an ancillary cost center, it violated the Act's fundamental ban on shifting costs attributable to Medicare patients to non-Medicare patients. *See* 42 U.S.C. § 1395x(v)(1)(A) (in prescribing regulations, the Secretary shall take into account the costs of services so that the necessary costs of delivering services to covered individuals will not be borne by individuals not covered by this program); 42 C.F.R. § 405.452(a) (total allowable costs of a provider shall be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries).

The Hospital cites a decision by the Administrator of the Health Care Financing Administration, *Roper Hospital v. Blue Cross*, Medicare & Medicaid Guide (CCH) ¶ 39,428 at 26,862 (1991), which stressed that the object of any cost apportionment is to determine the relative costs incurred by Medicare and non-Medicare patients as accurately as possible. *Id.* at 26,864. The Hospital notes that this principle was also emphasized by the Review Board when it found in the

Hospital's favor. Furthermore, the Hospital points out that in *Sisters of Charity Hospital of Buffalo v. Blue Cross Ass'n*, Medicare and Medicaid Guide (CCH) ¶ 31,454 at 9283 (1981), the Administrator approved allocating to each ancillary department the costs of wages for employees who transported patients to different specialty departments within the hospital and noted that there is little correlation between the use of patient transporters and the number of days a patient spends in the hospital. *Id.* 9286-87. The Hospital maintains that there is likewise little correlation between IV therapy and the number of days a patient spends in the hospital so that IV wage costs should similarly be allocated to ancillary cost centers.

Again, we apply a deferential standard of review. Where, as here, an agency is applying a statute entrusted by Congress to its administration, we employ the familiar analysis set forth in *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984). Under *Chevron*, when Congress has left an ambiguity or silence to a specific issue, we proceed to what is called the second step of *Chevron*, where we "defer to the Agency's interpretation of the statute if it is reasonable and consistent with the statute's purpose." *Chemical Mfrs. Ass'n v. EPA*, 919 F.2d 158, 162-63 (D.C. Cir. 1990). Here, in applying the statutory ban against cross-subsidization of Medicare and non-Medicare patients, Congress has not precisely spoken to the question of allocation between specific and general cost centers and therefore, the district court, and we in turn, must approve the Secretary's methodology provided it is reasonable and consistent with the statutory scheme.

As this court and others have previously noted, the Secretary has resolved this difficult task by adopting an averaging system wherein costs are balanced between Medicare and non-Medicare patients as a whole and not on a per service basis. *See Vista Hill Found. v. Heckler*, 767 F.2d 556, 564-66 (9th Cir. 1985) (overturning Secretary's decision to exclude children's educational costs from routine cost pool, which was based on the fact that few Medicare patients use such services, because she adopted a system of overall routine cost averaging based on all patients' use of facilities). *See also Villa View Community Hosp., Inc. v. Heckler*, 728 F.2d 539 (D.C. Cir. 1984) (per curiam); *Psychiatric Inst. of Washington, D.C., Inc. v. Schweiker*, 669 F.2d 812 (D.C. Cir. 1981) (per curiam).

Medicare patients may be 20% of a hospital's population but generate only 15% of its IV use. Or Medicare patients may, on average, use more of some routine service than do non-Medicare patients. The Secretary's decision to average in the way that she has accommodates the inevitability of specific disparities against the difficulty of exact allocation. Thus, the mere fact that IV labor costs for Medicare patients could be borne by non-Medicare patients in particular circumstances is not a sufficient basis upon which to find the Secretary's methodology unreasonable under the deferential standard of review.

The decisions upon which the Hospital relies are not to the contrary. In *Roper Hospital* the Administrator stressed that the object of any cost apportionment is to determine the relative costs incurred by Medicare and non-Medicare patients as accurately as possible. That case did not involve the distinction between ancillary and routine costs but rather in which ancillary department disputed supply costs should be included. Ancillary costs are reimbursed by Medicare on a relative basis. 42 C.F.R. § 405.452(a)(1). Thus, determining the relative cost of ancillary services to Medicare patients as accurately as possible does not conflict with drawing the line between ancillary and routine costs so that an approximate balance is achieved overall without separate allocation of each individual cost. *Sisters of Charity Hospital* is also distinguishable. There the patient transporters moved patients and performed other services *solely* for the ancillary areas. Medicare and Medicaid Guide (CCH) ¶ 31,454 at 9286. While the case does make the point that it is more accurate to apportion patient transporter costs through ancillary costs centers when there is little correlation between the use of patient transporters and the number of days a patient spends in the hospital, that reasoning does not compel the Secretary to deem IV labor costs ancillary in the instant case where the IV therapy personnel also perform nursing functions in routine cost center areas.

B. Validity of Section 2203

The Hospital further argues that section 2203 of the PRM is invalid, as it is inconsistent with the governing regulations and was improperly promulgated. Appellant reasons that the term "customary" is used in other Medicare regulations to refer to a provider's own usual practice rather than to the common practice of all providers in a state, *see, e.g.*, 42 C.F.R. § 405.503(a) (1993)

("customary charge" refers to uniform amount which the individual physician charges in the majority of cases), and that section 2203's interpretation of the term "customarily" as used in 42 C.F.R. § 405.452(b) is thus inconsistent with the meaning it has been given in other Medicare regulations. Based on the purportedly novel definition of "customarily," the Hospital argues that the provisions of section 2203 are actually substantive in nature, not merely interpretive of the regulations codified in 42 C.F.R., and therefore should have been published in conformance with the rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. § 553. *See Joseph v. United States Civil Serv. Comm'n*, 554 F.2d 1140, 1153-54 (D.C. Cir. 1977) (regulations invalid where notice and comment procedures not followed).

Insofar as the Hospital's challenge calls into question the Secretary's interpretation of her own regulations, we apply a still more deferential standard than that afforded under *Chevron*. "[P]rovided an agency's interpretation of its own regulation does not violate the constitution or a federal statute, it must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Stinson v. United States*, --- U.S. ---, ---, 113 S. Ct. 1913, 1919 (1993) (internal quotations omitted; citations omitted). The PRM provisions challenged by the Hospital reflect the application of the regulation codified at 42 C.F.R. § 405.452(b), which defines ancillary services as those services for which charges are customarily made in addition to routine services. Incorporation of state-wide custom into section 2203 of the PRM is not a plainly erroneous interpretation of section 405.452(b). Indeed, courts have recognized that the common practice of similar providers in the same state is an appropriate basis upon which to classify costs as ancillary or routine. *See, e.g., Creighton Omaha Regional Health Care Corp. v. Bowen*, 822 F.2d 785, 792 (8th Cir. 1987); *Charter Peachford Hosp., Inc. v. Bowen*, 803 F.2d 1541, 1548 (11th Cir. 1986).

Nothing of merit remains of the Hospital's claim that section 2203 is a substantive rule requiring notice and comment promulgation. As discussed in *American Hospital Association v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987), substantive rules are those which grant rights, impose obligations, or effect a change in existing policy. By contrast, interpretive rules are those that merely clarify or explain existing laws or regulations. *Id.* In *American Postal Workers Union v. United*

States Postal Service, 707 F.2d 548, 558-60 (D.C. Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984), we held that the Postal Service's change in the method of annuity computation was an interpretive, rather than a substantive, rule because it solely concerned an agency's interpretation of the term "average pay." Likewise, in this case, section 2203 solely sets forth the agency's interpretation of the term "ancillary" as it relates to hospitals' charging practices. "While the spectrum between a clearly interpretive rule and a clearly substantive one is a hazy continuum," *Bowen*, 834 F.2d at 1045, section 2203 falls well within the interpretive end of the spectrum. Thus it was not subject to the rulemaking requirements of the Administrative Procedure Act. *See* 5 U.S.C. § 553(b) (rulemaking requirements do not apply to "interpretative" rules); *Creighton Omaha Regional Health Care Corp.*, 822 F.2d at 791 (provisions in the PRM are interpretive rules not subject to the rulemaking process of the Administrative Procedure Act).

III. CONCLUSION

The district court properly concluded that the Secretary did not err in applying either the governing statute or her regulation to the classification of the Hospital's IV therapy labor costs as routine rather than ancillary services. Neither did the Secretary act arbitrarily or capriciously in applying the law to the facts of this controversy, nor in the method of adoption of the governing manual. Accordingly, the district court's grant of summary judgment to the Secretary is hereby

Affirmed.