Exhibit 1

918 F.3d 571
United States Court of Appeals, Eighth Circuit.

UNITY HEALTHCARE, Plaintiff - Appellant
v.
Alex M. AZAR, II, Secretary, U.S. Department of Health and Human Services, Defendant - Appellee
St. Anthony Regional Hospital, Plaintiff - Appellant
v.
Alex M. Azar, II, Secretary, U.S. Department of Health and Human Services, Defendant - Appellee
Lakes Regional Healthcare, Plaintiff - Appellant
v.
Alex M. Azar, II, Secretary of the Department of Health and Human Services, Defendant - Appellee

No. 18-1316, No. 18-1703, No. 18-1704
|
Submitted: November 13, 2018
|
Filed: March 12, 2019

Synopsis

Background: Qualifying rural hospitals brought actions challenging decisions of Secretary of Health and Human Services to deny their requested volume-decrease adjustment (VDA) payments under Medicare. The United States District Court for the Southern District of Iowa, Helen C. Adams, Chief United States Magistrate Judge, 289 F.Supp.3d 985, and the United States District Court for the Northern District of Iowa, Leonard T. Strand, Chief Judge, 294 F.Supp.3d 768, affirmed Secretary's decisions. Hospitals appealed, and appeals were consolidated.

Holdings: The Court of Appeals, Erickson, Circuit Judge, held that:

[1] method used by Secretary to calculate hospitals' VDA payments under Medicare was reasonable;

[2] Secretary's interpretation of regulations related to VDA payments was reasonable; and

[3] Secretary did not act arbitrarily and capriciously in reclassifying costs as variable.

Affirmed.

Procedural Posture(s): On Appeal; Review of Administrative Decision.

West Headnotes (9)

[1] **Administrative Law and Procedure**
⇐ Relationship of agency with rule or statute in general

15A Administrative Law and Procedure
15AVIII Administrative Construction of Rules and Regulations
15Ak2404 Deference to Agency in General
15Ak2406 Relationship of agency with rule or statute in general

Court should afford substantial deference to agency's interpretation of its own regulations.

Cases that cite this headnote

[2] **Health**
⇐ Scope of Review

198H Health
198HIII Government Assistance
198HIII(C) Federal Medical Assistance to the Elderly (Medicare)
198Hk554 Judicial Review;Actions
198Hk557 Scope of Review
198Hk557(1) In general

Whether district court erred in affirming decision of Administrator of Centers for Medicare & Medicaid Services regarding participating provider hospital's Medicare reimbursement rates is question of law that Court of Appeals reviews de novo. Social Security Act § 1886, 42 U.S.C.A. § 1395ww(d)(5)(D)(ii).

Cases that cite this headnote

[3] **Administrative Law and Procedure**
⇐ Erroneous or unreasonable construction; conflict with statute

15A Administrative Law and Procedure
15AVII Administrative Construction of Statutes

15AVII(A) In General
15Ak2212 Erroneous or unreasonable construction; conflict with statute

When statutory gap is filled by formal agency adjudication, court will hold such construction impermissible only if agency acted unreasonably.

Cases that cite this headnote

[4] **Health**
Costs incurred
198H Health
198HIII Government Assistance
198HIII(C) Federal Medical Assistance to the Elderly (Medicare)
198Hk532 Providers
198Hk535 Reimbursement
198Hk535(4) Costs incurred

Method used by Secretary of Health and Human Services to calculate qualifying rural hospitals' volume-decrease adjustment (VDA) payments under Medicare—pursuant to which total diagnosis-related group (DRG) payments were separated into "fixed" and "variable" estimates, and variable costs were excluded in allocating DRG payments against actual fixed costs hospitals incurred—was reasonable interpretation of statute, even though Secretary subsequently adopted new interpretation. Social Security Act § 1886, 42 U.S.C.A. § 1395ww(d)(5)(D)(ii).

Cases that cite this headnote

[5] **Administrative Law and Procedure**
Erroneous or unreasonable construction; conflict with statute
15A Administrative Law and Procedure
15AVII Administrative Construction of Statutes
15AVII(A) In General
15Ak2212 Erroneous or unreasonable construction; conflict with statute

Fact that agency has prospectively adopted new interpretation of statute is not sufficient reason to find its prior interpretation arbitrary or capricious.

Cases that cite this headnote

[6] **Administrative Law and Procedure**
Relationship of agency with rule or statute in general
Administrative Law and Procedure
Erroneous or unreasonable construction; conflict with rule or statute
15A Administrative Law and Procedure
15AVIII Administrative Construction of Rules and Regulations
15Ak2404 Deference to Agency in General
15Ak2406 Relationship of agency with rule or statute in general
15A Administrative Law and Procedure
15AVIII Administrative Construction of Rules and Regulations
15Ak2412 Erroneous or unreasonable construction; conflict with rule or statute

Where regulation's plain language does not control issue, court must uphold agency's interpretation of its own regulation unless that interpretation is plainly erroneous or inconsistent with regulation.

Cases that cite this headnote

[7] **Health**
Costs incurred
198H Health
198HIII Government Assistance
198HIII(C) Federal Medical Assistance to the Elderly (Medicare)
198Hk532 Providers
198Hk535 Reimbursement
198Hk535(4) Costs incurred

Secretary of Health and Human Services' interpretation of regulations related to volume-decrease adjustment (VDA) payments to qualifying rural hospitals under Medicare—pursuant to which hospitals' variable costs were excluded in allocating diagnosis-related group (DRG) payments against their actual fixed costs—was not arbitrary and capricious, despite hospitals' contention that sample calculations in Provider Reimbursement Manual conflicted with Secretary's interpretation, where examples were intended to demonstrate how

to calculate adjustment limit as opposed to determining which costs should be included in adjustment. Social Security Act § 1886, 42 U.S.C.A. § 1395ww(d)(5)(D)(ii); 42 C.F.R. § 412.92(e)(3).

Cases that cite this headnote

[8] **Health**
Costs incurred
198H Health
198HIII Government Assistance
198HIII(C) Federal Medical Assistance to the Elderly (Medicare)
198Hk532 Providers
198Hk535 Reimbursement
198Hk535(4) Costs incurred
While fiscal intermediary is Secretary of Health and Human Services' agent for purposes of reviewing cost reports and making final determinations with respect to total reimbursement due to provider absent appeal to Provider Reimbursement Review Board, intermediary interpretations are not binding on Secretary, who alone makes policy.

Cases that cite this headnote

[9] **Health**
Costs incurred
198H Health
198HIII Government Assistance
198HIII(C) Federal Medical Assistance to the Elderly (Medicare)
198Hk532 Providers
198Hk535 Reimbursement
198Hk535(4) Costs incurred
Secretary of Health and Human Services did not act arbitrarily and capriciously in reclassifying costs of billable medical supplies, billable drugs and intravenous solutions, professional services and supplies obtained from outside providers for physical therapy, reference laboratory, blood bank, and radiology, and dietary and linen services and supplies as variable, for purposes of calculating qualifying rural hospitals' volume-decrease adjustment (VDA) payments under Medicare, where each identified cost varied with patient volume. Social Security Act § 1886, 42 U.S.C.A. § 1395ww(d)(5)(D)(ii); 42 C.F.R. § 412.92(e)(3)(i).

Cases that cite this headnote

*573 Appeals from United States District Court for the Northern District of Iowa - Sioux City

Attorneys and Law Firms

Counsel who presented argument on behalf of appellant Unity HealthCare was Leslie Demaree Goldsmith, of Baltimore, MD. The following attorney(s) appeared on the appellant brief of Unity HealthCare; Adam Daniel Zenor, of Des Moines, IA.

Counsel who presented argument on behalf of appellants St. Anthony Regional Hospital and Lakes Regional Healthcare was Angela E. Dralle of Des Moines, IA. Also appearing on the brief of St. Anthony and Lakes Regional was Edwin N. McIntosh of Des Moines, IA.

Counsel who presented argument on behalf of the appellee was Karen Schoen, Appellate, USDOJ, Civil Division, of Washington, DC. The following attorney(s) appeared on the appellee brief; Chad A. Readler, Acting Assistant Attorney General, Michael Raab, Department of Justice, Civil Division, Appellate, Peter E. Deegan, Jr. and Marc Krickbaum, United States Attorneys, Timothy L. Vavricek, Assistant United States Attorney, Jonathan C. Brumer and Nancy K. Achord, U. S. Department of Health and Human Services.

Before BENTON, BEAM, and ERICKSON, Circuit Judges.

Opinion

ERICKSON, Circuit Judge.

The Medicare statute directs the Secretary of Health and Human Services to adjust payment amounts to qualifying sole community and rural hospitals through a "volume-decrease adjustment" ("VDA") when a hospital experiences a significant decrease in the number of its inpatients because of circumstances beyond its control. 42 U.S.C. § 1395ww(d)(5)(D)(ii). Appellants Unity HealthCare, Lakes Regional Healthcare, and St. Anthony Regional Hospital are three qualifying rural hospitals.

The hospitals challenge the method the Secretary, acting through the Administrator of the Centers for Medicare & Medicaid Services, used to calculate the VDA for certain fiscal years during the mid-2000s. They also challenge the Administrator's classification of certain costs as variable costs when calculating the adjustment. On January 30, 2018, the district court upheld the actions of the Secretary in Unity HealthCare's and Lakes Regional's cases.[1] On February 6, 2018, the district *574 court upheld the actions of the Secretary in St. Anthony's case.[2] We consolidated the cases for argument, and affirm.

1 The Honorable Helen C. Adams, Chief United States Magistrate Judge for the Southern District of Iowa.

2 The Honorable Leonard T. Strand, Chief Judge, United States District Court for the Northern District of Iowa, adopting the report and recommendations of the Honorable Kelly K.E. Mahoney, United States Magistrate Judge for the Northern District of Iowa.

I. Background

Before 1983, when a participating provider hospital incurred Medicare-eligible costs the hospital's actual costs incurred were fully reimbursed on a dollar-for-dollar basis so long as the claimed costs were found by the Secretary to be reasonable. Baptist Health v. Thompson, 458 F.3d 768, 771 (8th Cir. 2006). In 1983, Congress responded to concerns that hospitals had "little incentive ... to keep costs down," and implemented an inpatient prospective payment system. Cty. of Los Angeles v. Shalala, 192 F.3d 1005, 1008 (D.C. Cir. 1999) (quoting Tucson Med. Ctr. v. Sullivan, 947 F.2d 971, 974 (D.C. Cir. 1991)). Under the prospective payment system, a treating hospital receives a predetermined fixed payment based on a given patient's "diagnosis-related group," or DRG. See42 U.S.C. § 1395ww(d)(1)(A)(iii), (d)(4). The DRG-adjusted amount "is theoretically equal to the 'average' cost per patient" for a cost-effective hospital in a given location, but does not represent the actual costs of treatment. Cmty. Hosp. of Chandler, Inc. v. Sullivan, 963 F.2d 1206, 1207–08 (9th Cir. 1992), as amended (July 10, 1992). Hospitals are incentivized to minimize actual costs because they may pocket any excess balance between their costs and the DRG-adjusted amount. Seeid.

Certain sole community hospitals and Medicare-dependent, small rural hospitals fall under a modified reimbursement scheme. Those hospitals are paid either based off of the standard DRG "or a hospital-specific rate derived from its actual costs of treatment in one of the base years specified in the statute, whichever is higher." Adirondack Med. Ctr. v. Burwell, 782 F.3d 707, 709 (D.C. Cir. 2015) (citing 42 U.S.C. § 1395ww(d)(5)(D, G); 42 C.F.R. §§ 412.92, 412.108). Such hospital is also able to request a VDA if it experiences "a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control." 42 U.S.C. § 1395ww(d)(5)(D)(ii), (d)(5)(G)(iii). The VDA is offered as "necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services." 42 U.S.C. § 1395ww(d)(5)(D)(ii). Eligible fixed costs, such as "rent, interest, and depreciation," were "those over which management has no control." 48 Fed. Reg. 39,752, 39,781 (Sept. 1, 1983). "Variable costs," such as "food and laundry services," would not be reimbursed because they "vary directly with utilization." Id. at 39,781–82. The Secretary recognized that certain costs were "essential for the hospital to maintain operation but [would] vary with volume." Id. at 39,781. Those "semi-fixed" costs would be "considered as fixed on a case by case basis." Id. at 39,782. This advice was repeated in § 2810.1(B) of the Provider Reimbursement Manual (the "Manual").

In 1987, the agency amended its regulations after observing hospitals claiming eligibility for VDAs after experiencing a downturn in patients even though their DRG payments actually exceeded their inpatient operating costs. Recognizing that granting a VDA in those circumstances would conflict with the general purpose behind adopting the prospective payment system, the agency made clear "that any adjustment amounts granted to [sole community *575 hospitals] for a volume decrease may not exceed the difference between the hospital's Medicare inpatient operating costs and total payments made under the prospective payment system." 52 Fed. Reg. 33,034, 33,049 (Sept. 1, 1987).

To receive a VDA, qualifying hospitals must submit an annual cost report to fiscal intermediaries or Medicare Administrative Contractors. The Centers for Medicare and Medicaid Services contract with those entities to determine payment amounts due providers. 42 U.S.C. § 1395h, 42 C.F.R. §§ 413.20(b) and .24(a-b). The contractor then audits the report and notifies the hospital of its total Medicare reimbursement for that fiscal year. 42

C.F.R. § 405.1803. If a hospital disputes the amount of reimbursement, it may appeal the determination "to the Provider Reimbursement Review Board and, under certain circumstances, may obtain a hearing from the Board." Bethesda Hosp. Ass'n v. Bowen, 485 U.S. 399, 401, 108 S.Ct. 1255, 99 L.Ed.2d 460 (1988). Decisions by the Board are subject to review by the Administrator or the Centers for Medicare and Medicaid Services. 42 C.F.R. § 405.1834. A final decision by the Board or by the Administrator is subject to judicial review. 42 U.S.C. § 1395*oo*(f); 42 C.F.R. § 405.1877.

During the time period in question, no regulation provided for a specific method of calculating a VDA payment. Instead, the contractors were directed to consider: "(A) [t]he individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies; (B) [t]he hospital's fixed (and semi-fixed) costs, other than those costs paid ... under [other provisions]; and (C) [t]he length of time the hospital has experienced a decrease in utilization." 42 C.F.R. § 412.92(e)(3). The amount of the adjustment was capped at the "ceiling" of "the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs." Id.

This consolidated appeal arises from contested decisions by the Administrator concerning the VDA amounts due to each hospital. Unity requested $ 741,308 for fiscal year 2006, the difference between its Medicare inpatient operating costs ($ 5,698,829) and its DRG payments ($ 4,957,521) in that year. The contractor reclassified $ 664,994 in costs as "variable" for: (i) billable medical supplies; (ii) billable drugs and intravenous solutions; (iii) professional services and supplies obtained from outside providers for physical therapy, reference laboratory, blood bank, and radiology; and (iv) dietary and linen services and supplies. The contractor calculated the net VDA payment as $ 76,314. Unity appealed the decision to the Board.

Lakes Regional requested $ 1,184,574 for fiscal year 2006, the difference between its Medicare inpatient costs ($ 4,923,186) and its DRG payments ($ 3,738,612) for that year. The contractor reclassified $ 1,360,118 in costs as "variable" for: (i) billable medical supplies associated with anesthesia, laboratory, oncology and emergency departments and respiratory therapy services; (ii) billable drugs and intravenous solutions; (iii) professional services and supplies obtained from outside providers for physical therapy, speech therapy, blood bank, and radiology; and (iv) dietary and linen services and supplies. Because Lakes Regional's decreased total costs were now lower than the DRG payments Lakes Regional had received for that year, the contractor denied a VDA. Lakes Regional appealed that decision to the Board.

St. Anthony requested $ 1,954,257 for fiscal year 2009, the difference between its total inpatient operating costs ($ 8,333,903) and its total Pay Per Service payments ***576** for that year. The contractor excluded $ 1,619,594 attributed to services and supplies similar to those excluded for Unity and Lakes Regional, corrected the subtracted payment total to equal total DRG payments ($ 6,273,905) and calculated the VDA payment as $ 440,404. St. Anthony appealed that decision to the Board.

The Board upheld the contractor's classification of certain costs as variable in all three cases. However, the Board disagreed with the contractor's method for calculating the VDA. In its decisions in the Unity and Lakes Regional cases, the Board proposed a formula under which a contractor would first ask if the precondition was satisfied that a VDA was warranted. If so, then the VDA amount would be the hospital's total fixed costs, but capped at the regulatory "ceiling" that the payment would not exceed the difference between the hospital's total Medicare inpatient operating costs (including variable costs) and its DRG payments. Since Unity's and Lakes Regional's total fixed costs were far in excess of that ceiling, the Board ruled that each was entitled to a payment equal to the difference its total Medicare inpatient operating costs and its DRG payments, which was the amount the hospitals originally requested.

The Board used a different formula to calculate St. Anthony's VDA. The Board used a proportional method in which it used the ratio of the hospital's fixed costs to total costs to apportion some of the DRG payments to the hospital's fixed costs. The Board then subtracted the "fixed portion" of the DRG payments from the hospital's fixed costs to determine the VDA (concluding it would equal $ 1,690,823).

The Administrator reversed the Board's VDA calculation methodology in all three cases, holding that the

contractor's initial methodology was correct. The Administrator affirmed, however, the Board's rulings that the contractors had properly classified certain costs as variable.

Each hospital sought judicial review, claiming that the Secretary's decision was arbitrary, capricious, and contrary to the statute. In support of their calculation methodology, the hospitals relied heavily on sample calculations contained within § 2810.1(B) of the Manual that subtracted total DRG payments from "Program Inpatient Operating Costs." The hospitals also focused on evidence suggesting that more generous formulas had occasionally been used to calculate the VDA before 2006. The hospitals asserted that in the absence of any formal rule change, the Secretary could not adopt the different formula.

While the hospitals' cases were pending, the agency issued a notice of proposed rulemaking to modify the method used to calculate the VDA. See82 Fed. Reg. 19,796, 19,933–35 (Apr. 28, 2017). The substance of the new proposed rule largely tracked the proportional method the Board had used in the St. Anthony case. Under the new rule, contractors would estimate the "fixed portion" of a hospital's DRG payments by using the ratio of the hospital's fixed costs to total costs. They would then calculate the VDA as the difference between the hospital's fixed costs and the "fixed portion" of its DRG payments. The proposed rulemaking made clear, however, that the agency "continue[d] to believe that [its] current approach in calculating volume decrease adjustments is reasonable and consistent with the statute." Id. at 19,934. When the agency adopted the new rule, it did not apply it retroactively. See82 Fed. Reg. 37,990, 38,179–83 (Aug. 14, 2017).

The district court upheld the Secretary's actions in the Unity and Lakes Regional cases in a single opinion. The district court ***577** referred St. Anthony's case to a magistrate judge, who recommended ruling in favor of the agency. The district court issued an opinion overruling St. Anthony's objections to the recommendation and accepted the recommendation. The hospitals timely appealed, and we consolidated for argument.

II. Discussion

[1] **[2]** Medicare reimbursement decisions are given deference under the Administrative Procedure Act. See42 U.S.C. § 1395*oo*(f)(1). "Under the APA, the Secretary's decision is 'set aside [only] if it is arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or contrary to law.' " Baptist Health, 458 F.3d at 773 (quoting St. Luke's Methodist Hosp. v. Thompson, 315 F.3d 984, 987 (8th Cir. 2003)). "We afford substantial deference to an agency's interpretation of its own regulations." Kindred Hosps. E., LLC v. Sebelius, 694 F.3d 924, 928 (8th Cir. 2012) (citing Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994)). This is particularly true when the case involves "a complex and highly technical regulatory program" such as Medicare, which demands "the exercise of judgment grounded in policy concerns."Thomas Jefferson Univ., 512 U.S. at 512, 114 S.Ct. 2381 (quoting Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 697, 111 S.Ct. 2524, 115 L.Ed.2d 604 (1991)). Whether the district court erred in affirming the Administrator's decision is a question of law we review *de novo*. See, e.g., Baptist Health, 458 F.3d at 773 (quoting Shalala v. St. Paul-Ramsey Med. Ctr., 50 F.3d 522, 527 (8th Cir. 1995)).

A. The Secretary's Interpretation of the Statute

[3] The statute's command that a hospital should be "fully compensated" for its "fixed costs" does not give the Secretary a formula or method for determining what amounts to full compensation. This is an instance where "the Secretary was left with little or no statutory guidance." St. Mary's Hosp. of Rochester, Minn. v. Leavitt, 416 F.3d 906, 914 (8th Cir. 2005). When such a statutory gap "is filled by ... formal agency adjudication, we will hold such a construction impermissible only if the agency acted unreasonably." Id. (citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843–44, 104 S.Ct. 2778, 81 L.Ed.2d 694 ("Chevron") (1984)).

[4] The Secretary's interpretation is a reasonable interpretation of the plain language of the statute. The precise language at issue says that the VDA should be given "as may be necessary to fully compensate" a qualified hospital "for the fixed costs it incurs ... in providing inpatient hospital services." 42 U.S.C. § 1395ww(d)(5)(D)(ii). The Secretary's interpretation ensures that the total amount of a hospital's fixed costs in a given cost year are paid out through a combination of DRG payments and the VDA. As the Secretary

points out, the prospective nature of DRG payments makes it difficult to determine how best to allocate those payments against the actual fixed costs a hospital incurs. Given the lack of guidance in the statute and the substantial deference we afford to the agency in this case, the Secretary's decision reasonably complied with the mandate to provide full compensation.

[5] That the Secretary has prospectively adopted a new interpretation (the proportional approach) is not a sufficient reason to find the Secretary's prior interpretation arbitrary or capricious. "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency ... must consider varying interpretations and the wisdom of its policy on a ***578** continuing basis." Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs., 545 U.S. 967, 981, 125 S.Ct. 2688, 162 L.Ed.2d 820 (2005) (quoting Chevron, 467 U.S. at 863–64, 104 S.Ct. 2778); see alsoLaRouche v. FEC, 28 F.3d 137, 141 (D.C. Cir. 1994) ("The mere fact that regulations were modified, without more, is simply not enough to demonstrate that the prior regulations were invalid."). The agency received substantial feedback from hospitals that separating total DRG payments into "fixed" and "variable" estimates before calculating the VDA would better fulfill the statutory command to ensure "full" compensation. On the basis of that feedback, the agency re-evaluated the "wisdom of its policy" through a formal rulemaking. But that re-evaluation does not require us to conclude that the prior interpretation was unreasonable. A statute can have more than one reasonable interpretation, as in this case. SeeSmiley v. Citibank (S.D.), N.A., 517 U.S. 735, 744–45, 116 S.Ct. 1730, 135 L.Ed.2d 25 (1996) (stating that "the question before us is not whether [an agency interpretation] represents the best interpretation of the statute, but whether it represents a reasonable one").

B. The Secretary's Interpretation of VDA-Related Regulations

[6] "Where a regulation's plain language does not control the issue, we must uphold an agency's interpretation of its own regulation unless that interpretation is plainly erroneous or inconsistent with the regulation." St. Luke's Methodist Hosp., 315 F.3d at 987 (citations omitted) (internal quotation marks omitted). At first glance, the Secretary's interpretation of the relevant regulations in these cases is clearly consistent with their text. See42 C.F.R. § 412.92(e)(3). The formula adopted by the Secretary ensures that any given VDA will not exceed "the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs." Id. And in all three cases, the Secretary considered individual characteristics of each hospital alongside the fixed or non-fixed nature of their costs. Seeid.

[7] **[8]** The hospitals' main argument to the contrary relies on the premise that the Manual's sample calculations unambiguously conflict with the Secretary's interpretation and that the Secretary is bound by the Manual as incorporated via later regulations. The hospitals point out that the Secretary has previously stated that § 2810.1(B) of the Manual, where the examples are located, contains "the process for determining the amount of the volume decrease adjustment." See71 Fed. Reg. 47,870, 48,056 (Aug. 19, 2006). However, the examples are not presented in isolation. The same section of the Manual reiterates that the volume-decrease adjustment is "not to exceed the difference between the hospital's Medicare inpatient operating cost and the hospital's total DRG revenue." In a decision interpreting § 2810.1(B) immediately following the Secretary's guidance, the Board found "that the examples are intended to demonstrate how to calculate the adjustment limit as opposed to determining which costs should be included in the adjustment." SeeGreenwood Cty. Hosp. v. BlueCross BlueShield Ass'n, No. 2006-D43, 2006 WL 3050893, at *9 n.19 (P.R.R.B. Aug. 29, 2006). That decision was not reviewed by the Secretary and therefore became a final agency action. The agency's conclusion that the examples are meant to display the ceiling for a VDA, rather than its total amount, is a reasonable interpretation of the regulation's use of "not to exceed," rather than ***579** "equal to," when describing the formula. [3] We conclude that the Secretary's interpretation was not arbitrary or capricious and was consistent with the regulation. [4]

3 The hospitals' argument that some fiscal intermediaries may have used a more generous formula in previous years does not alter our conclusion that the Secretary's interpretation in these cases was not arbitrary or capricious. "While a fiscal intermediary is the Secretary's agent for purposes of reviewing cost reports and making final determinations with respect to the total

reimbursement due to a provider absent an appeal to the [Board], intermediary interpretations are not binding on the Secretary, who alone makes policy." Cty. of Los Angeles v. Leavitt, 521 F.3d 1073, 1079 (9th Cir. 2008) (citation omitted). To the extent that the Secretary may have discovered that certain intermediaries were incorrectly using a more generous formula, it was not foreclosed from correcting the formula to better comply with its understanding of the statute and regulations.

4 We note that the Manual contains interpretative rules. SeeIn Home Health, Inc. v. Shalala, 188 F.3d 1043, 1047 (8th Cir. 1999) (citing St. Paul-Ramsey Med. Ctr., 50 F.3d at 527–28 n.4). An agency may change its interpretation of a regulation "if the revised interpretation is consistent with the underlying regulations," as in this case. Perez v. Mortg. Bankers Ass'n, —— U.S. ——, 135 S.Ct. 1199, 1209, 191 L.Ed.2d 186 (2015) (citation omitted).

C. The Secretary's Classification of Certain Costs as Variable

[9] The costs at issue in this case are reasonably classified as variable costs. The agency emphasizes that its overriding principle for classifying costs as variable is whether costs vary with patient volume. Each of the identified costs varies with patient volume. The hospitals are correct that some costs that the agency classified as semi-fixed may also, over time, vary with volume. However, that only serves to demonstrate the sound judgment behind considering some "semi-fixed costs, such as personnel-related costs ... as fixed on a case-by-case basis." Manual § 2810.1(B); seealso42 C.F.R. § 412.92(e)(3)(i) (requiring intermediaries to "consider" semi-fixed costs in determining the VDA, without specifying a particular method of incorporating them into the VDA).

The agency's decision to classify certain costs that are directly tied to patient volume as variable was neither arbitrary nor capricious. To the extent any of the hospitals now claims that some portion of its variable costs were in fact semi-fixed, each has failed to meet its burden of demonstrating entitlement to a payment adjustment. See42 U.S.C. § 1395g(a).

III. Conclusion

We affirm.

All Citations

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