United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
April 5, 2021
Lyle W. Cayce
Clerk

No. 20-60213

LOUISIANA DEPARTMENT OF HEALTH,

Petitioner,

versus

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondents.

Petition for Review of the Final Determination of the United States Department of Health & Human Services
Agency No. 15-02

Before OWEN, *Chief Judge*, and GRAVES and HO, *Circuit Judges*.

PER CURIAM:*

The Louisiana Department of Health petitions for review of a final decision from the Secretary of the Department of Health and Human

* Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.

Services, via the Administrator for the Centers for Medicare and Medicaid Services ("CMS"), denying a proposed state plan amendment for reimbursing pharmacists' Medicaid costs. We DENY the petition for review.

I.

The Medicaid program, enacted as Title XIX of the Social Security Act, is a cooperative federal-state program that provides medical assistance to low-income individuals. *See* 42 U.S.C. § 1396; *Atkins v. Rivera*, 477 U.S. 154 (1986). The federal government and the states together finance the program, while the states administer it. "In theory, this arrangement incentivizes states to keep rates at efficient levels, because they share financial responsibility for Medicaid costs with the federal government." *Alaska Dep't of Health & Soc. Servs. v. Ctrs. for Medicare & Medicaid Servs.*, 424 F.3d 931, 935 (9th Cir. 2005). The program is voluntary but, to be eligible for federal funds, participating states must submit a "state plan" satisfying the Medicaid statute and rules from the Secretary of the Department of Health and Human Services. 42 U.S.C. § 1396a.

Under the Medicaid statute, the Secretary is responsible for ensuring that state plans meet federal requirements. *See Id.*; *Louisiana v. U.S. Dep't of Health & Human Servs.*, 905 F.2d 877, 878 (5th Cir. 1990). The Secretary has delegated authority to carry out federal duties under the statute to the Administrator of CMS, an agency within the Department. § 1396a. When the Secretary, through CMS' Administrator, approves a state's plan, the federal government reimburses a percentage of the state's Medicaid expenses. 42 U.S.C. § 1396b(a)(1). "As long as the plans meet federal requirements, the states have considerable discretion to design and operate their individual programs." *Louisiana*, 905 F.2d at 878 (citing *Lewis v. Hegstrom*, 767 F.2d 1371 (9th Cir. 1985)). Accordingly, CMS, "on behalf of the Secretary, is required to approve a state plan amendment that complies with all applicable

statutes and regulations." *La. Dep't of Health & Hosps. v. Ctr. for Medicare & Medicaid Servs.*, 346 F.3d 571, 572 (5th Cir. 2003). If the Administrator determines that a state's plan or amendment does not meet the federal requirements, he or she issues a disapproval determination under 42 C.F.R. § 430.15(c). The state may seek administrative and judicial review of these determinations, as Louisiana has done here. *See* 42 U.S.C. § 1316(a)(2), (c); 42 C.F.R. §§ 430.18, 430.60.

The regulations at issue in 2012, when Louisiana sought CMS' approval for the state plan amendment at issue in this case, referred to two components for reimbursements paid to pharmacies for prescription drugs: a drug's ingredient cost and its dispensing fee. 42 C.F.R. § 447.512(b) (2012). Section 447.512(b) addressed how states should determine payment methodology for certain drugs. The provision stated, in pertinent part, that:

> The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established must not exceed, in the aggregate, payments levels that the agency has determined by applying the lower of the—
>
> > (1) [Estimated Acquisition Cost ("EAC")] plus reasonable dispensing fees established by the agency; or
> >
> > (2) Providers' usual and customary charges to the general public.

42 C.F.R. § 447.512(b) (2012). So under the 2012 regulations, payments for prescription drugs could not exceed a drug's EAC plus the provider's dispensing fee. 42 C.F.R. § 447.512(b)(1) (2012). The regulations defined the EAC as the state's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." *Id.* § 447.502 (2012). A state therefore must "determine the closest estimate

possible of the actual acquisition cost," *Louisiana*, 905 F.2d at 881,[1] although the regulations did not prohibit states from relying on an average wholesale price ("AWP") or an average acquisition price index in making this estimate, *see* 42 C.F.R. § 502.

The regulations also establish states' burden in persuading the Administrator that a plan meets federal requirements. The regulations provide that the state must "maintain and make available to [CMS], upon request, documentary evidence to support the findings." 42 C.F.R. § 447.518(c). The "documentary evidence must include data, mathematical and statistical computations, comparisons, and any other pertinent records." *Id.* Given this burden of proof, this court has stated that a state's compliance with § 447.512(b)'s upper-limit categories does not necessarily amount to compliance with the state's burden, which is to assure CMS that its reimbursement methodology is its best estimate of costs that pharmacists generally and currently pay. *See Louisiana*, 905 F.2d at 882 ("But we do not think, given the history of the rulemaking proceeding, that a state complies with federal requirements merely by proving its reimbursements in a particular category do not exceed the aggregate upper limit.").[2]

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[1] Shortly before Louisiana submitted its state plan amendment in 2012, CMS issued a notice of proposed rulemaking that contemplated replacing EAC with "actual acquisition cost," which it defined as a state's "determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers." Medicaid Program: Covered Outpatient Drugs, 77 Fed. Reg. 5320 (proposed Feb. 2, 2012) (to be codified at 42 C.F.R. § 447.502). CMS stated that this change would render Medicaid reimbursements more reflective of the actual prices paid.

[2] The 1987 regulations at issue in *Louisiana* are, in relevant part, identical to the 2012 regulations at issue in this case. *Compare* 42 C.F.R. § 447.301 (1987) (defining "estimated acquisition cost" as "the [state] agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers"), *with* 42 C.F.R. § 447.502 (2012) (defining "estimated acquisition cost" as "the [state] agency's best estimate of the price generally and currently paid by providers for a drug marketed or

II.

Before 2012, Louisiana calculated the EAC of many Medicaid-covered drugs as a percentage of the drug's AWP. Louisiana reimbursed the acquisition cost of most brand-name drugs at either AWP minus 13.5% or AWP minus 15%, depending on the status of the pharmacist. The discount reflects the fact that pharmacies typically can purchase drugs below the wholesale price. Louisiana reimbursed pharmacies for generic drugs at the lowest of various metrics, chiefly the provider's "usual and customary charge" to the public.

In 2010, Louisiana began transitioning to a different reimbursement calculation that it said would more accurately reflect Louisiana-specific costs. Louisiana State Plan Amendment ("SPA") 10-13 restricted maximum compensation for multiple source drugs to 135% of a drug's "average acquisition cost." CMS approved SPA 10-13, effective February 1, 2010. Louisiana then signaled to pharmacies that more changes were on the way.

On September 28, 2012, Louisiana submitted for CMS' approval SPA 12-55, which defined a drug's EAC as its "average acquisition cost," measured by pharmacists' actual invoices, and without any multiplier or percentage increase. SPA 12-55 reflected the State's analysis of several years of data and the advice of a private consultant. The State said that the new reimbursement methodology was "intended to establish an accurate pharmacy reimbursement system based on actual acquisition cost (invoice) data and a statistically validated cost of dispensing survey." The State acknowledged that because SPA 12-55 set prices at the average of actual invoices, some providers would necessarily be underpaid. But SPA 12-55

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sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers").

provided for a review method whereby pharmacists could ask a helpdesk for specific variations. CMS approved SPA 12-55, effective September 5, 2012.

Consistent with this expectation, "[a]lmost immediately," some participating pharmacies complained to the State that the new metric would not adequately cover their costs, and Louisiana faced political pressure to provide a more generous reimbursement rate. The State then convened a workgroup of "more than a dozen independent and chain pharmacists."

On November 1, the State implemented an amended plan (SPA 12-66), based on input from the working group, that would result in higher payments to pharmacists. SPA 12-66 proposed an adjustment to its prescription drug payment methodology by applying multipliers or markups to the average acquisition cost. Specifically, the State revised its definition of EAC as follows:

> Estimated Acquisition Cost (EAC)-- the Average Acquisition Cost (AAC) of the drug dispensed adjusted by a multiplier of 1.1 for multiple source drugs and a multiplier of 1.01 for single-source drugs. If there is not an AAC available, the EAC is equal to the Wholesale Acquisition Cost (WAC), as reported in the drug pricing compendia utilized by the Department's fiscal intermediary. For Department defined specialty therapeutic classes, the EAC is the Wholesale Acquisition Cost adjusted by a multiplier of 1.05.

The State explained in the press release that it would soon provide "a markup of 10 percent" above the average acquisition cost for generic drugs and a markup of 1 percent for brand-name drugs, and that it would reimburse certain classes of "specialty drugs" at their "Wholesale Average Cost (a more generous price index) plus 5 percent." The State also amended the dispensing fee reimbursement for all drugs from $10.13 to $10.51.

Louisiana submitted SPA 12-66 to CMS on December 21, 2012, with a requested effective date of November 1, 2012.[3] The State told CMS that it had "received numerous concerns from community pharmacists, legislators and other stakeholders" about SPA 12-55's methodology, and that the State had conducted a "detailed review of the cost and reimbursement data through the information submitted by community pharmacists."

On March 19, 2013, CMS requested additional information supporting SPA 12-66. Specifically, CMS asked the State why it reverted from a baseline average based on actual invoices, and how it arrived at the specific markups. The State says that it "provided CMS with some but not all of the analyses that it had conducted." That data consisted of a survey of four independent pharmacies, and an accountant's estimate that SPA 12-66 would save $30 million compared to the AWP-based methodology in place a few years earlier. There are over 1,000 independent and chain pharmacies operating in Louisiana. CMS followed up with several questions further asking the State to "explain" its arrival at the multipliers. The State responded that the figures are "[b]ased on discussions, research, and analysis of information submitted by providers," but the State did not provide that underlying data. The State also responded that it implemented SPA 12-66 in response to legislators and participating pharmacists' criticisms of SPA 12-55.

In September 2014, CMS communicated to the State that it would approve SPA 12-66's dispensing fee reimbursements but would disapprove SPA 12-66's reimbursement rates for ingredient costs. In response, the State divided SPA 12-66 into two components: SPA 12-66A referred to dispensing

[3] The regulations allow states to implement their plans before CMS' approval, although doing so risks going without federal reimbursement if the plan is later disapproved, as happened here. *See* 42 C.F.R. §§ 430.20(b); 447.256(c).

fees while SPA 12-66B referred to ingredient costs. The State then returned to reimbursing all drugs based on average acquisition cost without any markup.

CMS issued its decision on December 11, 2014. The CMS Administrator concluded that the State had not shown that SPA 12-66B met 42 C.F.R. § 447.502's EAC definition. Specifically, the Administrator concluded that the State did not sufficiently demonstrate how it arrived at the specific multipliers, and why it reverted to the more generous wholesale acquisition price for specialty drugs. The Administrator thus found that SPA 12-66B did not comply with § 1902(a)(30)(A), which requires that states have methods and procedures to assure that payment rates are consistent with efficiency, economy, and quality of care, or with the implementing regulations at 42 C.F.R. §§447.502 and 447.512. The Administrator accordingly disallowed Federal Financial Participation for payments to pharmacists based on SPA 12-66B. Those payments amounted to $26 million over the two-year period. Had CMS approved SPA 12-66B, the federal government would have paid 61% percent of the total, or about $16 million.

The State timely requested reconsideration of CMS' disapproval of SPA 12-66B. The State then submitted additional data—two declarations and thirty-one exhibits consisting mostly of spreadsheets of pharmacist surveys—that it had not presented to CMS in its initial petition or in its responses to CMS' follow-up questions.

CMS' presiding officer first held that CMS properly disapproved SPA 12-66B. He declined to review CMS' decision de novo, and so refused to consider the State's supplementary evidence as untimely. The State had cited regulations allowing discovery in the review process, and it argued that it had the "absolute right" to introduce new evidence on reconsideration. The presiding officer, however, concluded that the State's cited regulations "must be read in the context of the overall" SPA review framework, and, in

that light, "the regulations in 430 Subpart D discuss gathering and submitting evidence that has previously been timely submitted for CMS to consider in its initial review of the SPA." Accordingly, the presiding officer considered only the evidence that the State had initially supplied regarding the four surveyed pharmacies.

On the merits, the presiding officer mainly concluded that the State did not satisfy 42 C.F.R. § 447.512 (2012), because the State had submitted insufficient data explaining how it arrived at the across-the-board multipliers. He also concluded that the State's proposed markup impermissibly combined the ingredient costs and dispensing fee, because the State had acknowledged that it used the multipliers to reflect both ingredient costs and "other costs associated with dispensing" drugs. Accordingly, the presiding officer concluded that the State had not assured that SPA 12-66's ingredient reimbursement methodology represented the State's best estimate of prices that pharmacists generally paid in 2012.

The State timely asked the Administrator to reverse the presiding officer's conclusions. The Administrator agreed with the presiding officer that the additional data should not be considered, but the Administrator also concluded that the additional data did not merit reversal even if considered. The Administrator decided that, on the record before CMS, the State had not demonstrated that the proposed payment increases were consistent with the aggregate upper payment limitations set forth in 42 C.F.R. § 447.512. He further concluded that the State's proposed EAC calculation did not represent the State's "'best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of a drug most frequently purchased by providers.'" *See* 42 C.F.R. § 447.502 (2012). The Administrator did not endorse the presiding officer's conclusions regarding ingredient-dispensing cost conflation, holding instead that this rationale "was not included as a

reason in the original disapproval" and that the presiding officer's finding was "not pertinent to upholding the disapproval." Last, the Administrator concluded that, even considering the supplementary evidence, that evidence shows that SPA 12-66B reimbursement rate would overpay more than sixty percent of pharmacies in excess of their actual costs for multiple and single source drugs. Accordingly, the Administrator upheld CMS' initial decision that SPA 12-66B does not represent the State's best estimate of costs that Louisiana pharmacists generally paid in 2012. Louisiana timely petitioned for review in this court.

III.

We review the Administrator's decision disapproving a state plan amendment under the Administrative Procedure Act, 5 U.S.C. §§ 701–706 (2003), to ensure that the decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706; *La. Dep't of Health & Hosps.*, 346 F.3d at 576. We also must "defer to the Secretary's interpretation of Medicare legislation and its attendant regulations—the Secretary's interpretation of Medicare regulations is given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" *Id.* (quoting *Harris Cty. Hosp. Dist. v. Shalala*, 64 F.3d 220, 221 (5th Cir. 1995)). "If the agency's ruling meets these standards, our belief that an alternate interpretation is more appropriate is irrelevant." *Louisiana*, 905 F.2d at 881 (citing *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201 (5th Cir. 1980)).

IV.

The Administrator eventually reviewed the State's supplementary data, so we do so as well and we need not determine whether CMS correctly refused initially to credit this later-submitted data. The supplementary evidence consists primarily of spreadsheets of survey data that an accountant prepared for Louisiana in December 2012. The State also submitted the

accountant's narrative declaration that, for certain brand-name drug groups, 34% of the surveyed pharmacies had ingredient costs that exceeded SPA 12-66B's reimbursement rate (average acquisition cost plus 1%). The accountant further explained that, for generic drug groups, about 37% of the pharmacies had ingredient costs that exceeded SPA 12-66's reimbursement rate (average acquisition cost plus 10%).

But as the Administrator noted, these figures do "not disrupt or counter the original supposition when implementing SPA 12-55, which never had an expectation that all pharmacies would have their costs reimbursed, based on average acquisition cost and that a process was provided for that scenario in SPA 12-55."[4] The additional data also undercuts the State's argument: while that data showed that SPA 12-66B's methodology would underpay almost forty percent of pharmacists, the Administrator noted conversely that SPA 12-66B overpaid "*more* than 60 percent of pharmacies in *excess* of their actual costs for" for both generic and brand-name drugs. While an average-based metric will necessarily result in a methodology that underpays some pharmacists, the Administrator reasonably could conclude that SPA 12-66B overpaid most pharmacists. Finally, none of the supplemental data addressed specialty drugs, which SPA 12-66B reimbursed at "Wholesale Average Cost (a more generous price index) plus 5 percent."

The Administrator could also reasonably conclude that the State had not carried its evidentiary burden, even with the additional data. The regulation at 42 C.F.R. § 477.518(b)(2), consistent with § 1902(a)(30)(a) of the Social Security Act, provides that each state must "make assurances

[4] The State told CMS when it proposed SPA 12-55 that, because its methodology represents an average cost, "prices for individual drugs may sometimes be below the cost as experienced by individual providers," and so "[a]djustments will be made to the [general reimbursement rate] when the overall average has increased, which can be reported to [the State's accountant-consultant]."

satisfactory to CMS" that the economy, efficiency, and quality of care requirements are met, and these assurances must be supported, on CMS' request, by "data, mathematical and statistical computations, comparisons, and any other pertinent records." 42 C.F.R. § 447.518(c). While a "a state's EAC formula may overestimate the cost of some specific drugs," the formula must produce "the closest, best estimate of the price pharmacists generally and currently pay for this category as a whole." *Louisiana*, 905 F.2d at 879. None of the data show why the State retreated from the use of actual invoices to using an inflated multiplier. CMS reasonably could be skeptical of Louisiana's disclaimer of reliance on actual invoices less than two months after the State represented that actual invoices provided the most accurate figures. On this record, CMS' decision is not "so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. The Administrator's decision thus withstands our limited appellate review.

V.

Louisiana's remaining arguments fare no better. It contends that, in denying SPA 12-66B, CMS held it to the more onerous but not-yet-enacted rule requiring states' reimbursement methodologies represent their best estimate of pharmacists' actual costs. But as in *Louisiana*, there is nothing in the record suggesting that the State was precluded from relying on average acquisition costs, only that CMS concluded that SPA 12-66B's across-the-board multipliers did not represent the state's best estimate of prices that pharmacists generally paid in 2012. *See Louisiana*, 905 F.2d at 882 ("But there is nothing in the Administrator's decision here that indicates that Louisiana would not have prevailed had it been able to prove that AWP did provide the closest price estimate.").

Louisiana also argues that CMS' decision is arbitrary when compared to its treatment of other states. The State asserts Colorado as a comparator,

because there CMS approved a similar EAC model. The State acknowledges, however, that, contrary to Colorado's CMS-approved rates, Louisiana previously had said that an average acquisition cost, without any multiplier or markup, is the State's best estimate of costs. And Colorado's approved methodology applied only to rural pharmacies, and thus was more targeted than Louisiana's across-the-board multipliers. Further, CMS approved the Colorado plan with the caveat that it would be phased out over a one-year period.

Louisiana also cites CMS' determinations from 1991 involving Arkansas and Oklahoma which it says demonstrate that it carried its burden. Those cases involved CMS' disapproval of state's plan amendments after the states' failure to produce any evidence supporting their proposals. *See Ark. Dep't of Human Servs.*, No. 90-119, 1991 WL 634857 (DAB Aug. 22, 1991); *Okla. Dep't of Human Servs.*, No. 90-164, 1991 WL 634860 (DAB Aug. 13, 1991). While Louisiana's evidence certainly surpasses Oklahoma's and Arkansas's from those cases, Louisiana points to no rule that those cases set a minimum evidentiary benchmark above which CMS is obligated to approve a state's plan. Such a rule would contravene states' obligation to ensure that their plans represent their best estimates of pharmacists' actual costs. CMS' conclusion that Louisiana did not meet this obligation with respect to SPA 12-66 is reasonable.

The petition for review is DENIED.