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* Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.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

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