United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 08-3284

Iowa Department of Human Services,	*	
	*	
Petitioner,	*	
	*	On Petition for Review of an
v.	*	Order of the Secretary of
	*	Health and Human Services.
Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services,	*	
	*	
	*	
Respondent.	*	

Submitted: June 11, 2009
Filed: August 19, 2009 (Corrected: 08/21/2009)
(Corrected: 08/31/2009)

Before SMITH, ARNOLD, and SHEPHERD, Circuit Judges.

SHEPHERD, Circuit Judge.

Iowa submitted a state plan amendment ("Plan") to the Centers for Medicare and Medicaid Services ("CMS") in March 2005. The Plan proposed changes to the state's Medicaid program relating to multiple source drugs. CMS disapproved the Plan in November 2005. Iowa requested administrative reconsideration, and the matter was referred to a hearing officer in June 2007. The hearing officer issued a proposed decision in January 2008 denying the state's request. Iowa submitted exceptions to the proposed decision, and, in August 2008, the CMS Administrator issued a final decision on behalf of the Secretary of Health and Human Services

("Secretary") affirming the agency's disapproval of the Plan. Iowa petitions this court to review and reject the Secretary's final decision. We deny the state's petition.

I.

The Medicaid statute, 42 U.S.C. § 1396 et seq., establishes a cooperative federal-state program in which the federal government provides funding to state programs that give medical assistance to people whose income and resources are insufficient to meet the costs of necessary medical services. States that choose to participate in the Medicaid program must submit plans for medical assistance that conform to federal regulations. Minnesota v. CMS, 495 F.3d 991, 993 (8th Cir. 2007); see also 42 U.S.C. § 1396a. To help control rising Medicaid expenses, the Secretary has issued regulations establishing two federal upper limits ("FULs"), which cap the aggregate amount states can pay to purchase prescription drugs for Medicaid patients. See 42 C.F.R. § 447.512. The first FUL applies to "multiple source drugs"[1] that CMS has specifically listed, and it is based on the price of the least costly therapeutic equivalent drug. Id. §§ 447.512(a), 514(a)-(b). The second FUL applies to "other drugs"[2] and is based on the pharmacy's estimated acquisition cost or the usual and customary charge the general public would pay, whichever is lower. Id. § 447.512(b). The FUL for "other drugs" also applies to listed, multiple source drugs but only when they are dispensed after a physician certifies that a specific brand name drug is medically necessary for a particular patient. Id. § 447.512(c).

[1]"Multiple source drug" means a covered outpatient drug with at least one competitor drug for sale in the same state that is pharmaceutically equivalent, therapeutically equivalent, and bioequivalent. 42 C.F.R. § 447.502. In layman's terms, this means a brand name drug that is also available in generic form or under a different brand name.

[2]"Other drugs" include single source drugs and non-listed multiple source drugs. See 42 C.F.R. § 447.512(b).

Congress established the Medicaid Drug Rebate Program to further reduce Medicaid spending. See Pub. L. No. 101-508, § 4401 (1990) (codified at 42 U.S.C. §§ 1396a, 1396b, and 1396r-8). The program requires drug manufacturers to enter into rebate agreements with the Secretary in order for their drugs to be eligible for Medicaid reimbursement. See 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(1). Pursuant to these federal agreements, drug manufacturers must provide rebates to states for covered outpatient drugs for which payment was made under state Medicaid plans. Id. § 1396r-8(b)(1)(A). In addition, an individual state can negotiate supplemental rebate agreements with drug manufacturers. Many manufacturers provide these supplemental rebates in return for placement on a state's list of "preferred drugs," which doctors may prescribe to Medicaid patients without having to obtain prior authorization from the state.

Iowa has entered into supplement rebate agreements with multiple drug manufacturers, and the state maintains a preferred drug list. For drugs under its current Medicaid plan, the state will pay the lesser of: (1) the drug's estimated acquisition cost, (2) the multiple-source-drug FUL, (3) a state-set upper limit, or (4) the usual and customary charge for the drug. The current plan also provides that, if a physician certifies that a specific brand is medically necessary, Iowa will pay the lesser of options (1) and (4). By including options (1), (2), and (4), as well as the physician certification requirement, Iowa's current plan complies with the federal Medicaid regulations governing payments for prescription drugs.

In 2005, Iowa submitted the Plan, which proposed two amendments to its Medicaid program regarding multiple source drugs. First, the Plan abolishes the physician certification requirement. Second, the Plan deletes all references to the FUL for multiple source drugs. Instead, for all brand name drugs, the Plan requires Iowa to pay the lesser of (1) the drug's estimated acquisition cost or (2) the provider's usual and customary charge for the drug. After Iowa submitted the Plan, CMS requested additional information from the state pursuant to 42 U.S.C. § 1396n(f)(2). CMS asked

Iowa whether it was contending it could "dispense brand name prescription drugs cheaper than [] generic drugs after consideration of the rebates?" (Pet'r App. 10.) CMS advised the state that "[t]he Federal Upper Limit (FUL) under Federal statute applies to the agency's payment to the pharmacy" and instructed Iowa to "explain how [it] can reconcile using the price after rebate rather than the price paid to the pharmacy." (Id.) In its response, Iowa asserted that it could provide brand name drugs more cheaply than generic equivalents (and thus below the multiple-source-drug FUL) *after accounting for federal and state rebates*. In other words, Iowa's payments to pharmacies for brand name drugs would exceed the FUL for multiple source drugs, but Iowa's eventual receipt of both federal and state rebates would reduce its net costs for brand name drugs below the FUL. Iowa also argued that, in light of its preferred drug list, the physician certification requirement was obsolete because the state had already granted prior authorization for dispensing covered brand name drugs.

After reviewing Iowa's response, CMS disapproved the state's Plan. CMS noted that the Plan did not conform to regulations requiring that a physician certify a brand name drug as medically necessary in order for it to be excluded from the multiple-source-drug FUL. CMS further noted that the multiple-source-drug FUL applied to Iowa's payments to the pharmacy, not to its net costs after taking into account federal and state rebates. After Iowa sought reconsideration, a hearing officer issued a proposed decision affirming the agency's initial disapproval of the Plan. After reviewing the record and the hearing officer's proposed decision, the CMS Administrator issued the agency's final decision affirming disapproval of the Plan. The Administrator stated, "the law and regulations require that the FUL is to be applied to the State's payments, or expenditures, to the pharmacies, and not calculated to include rebates." (Id. at 140.) The Administrator explained that "[i]n order for the term 'payment' (or similarly expenditures) to be used throughout the Medicaid statute and regulations in a consistent manner, the State's payments for purposes of the FUL regulation must be interpreted to mean payments *before* rebates." (Id. at 141.)

Finally, the Administrator observed that, when the agency promulgated new FUL regulations in 2007, the Secretary expressly rejected the same argument Iowa advanced in support of its Plan:

> Comment: A few commenters said that FULs should be compared to net payments after rebates, since that will allow the State to take advantage of higher rebates on brand name drugs.
>
> Response: We disagree. In accordance with provisions of the [Deficit Reduction Act of 2005] which amended section 1927(e) of the [Medicaid Statute], the FUL is based on 250 percent of the AMP [Average Manufacturer Price]. Thus, we have based the FULs on AMP, as opposed to any payments by States net of rebates.

Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,214 (July 17, 2007). Moreover, "neither CMS, nor the commenters, suggested that the inclusion of the rebates was a prior practice in the application of the FUL."[3] (Pet'r App. 143.) Because Iowa could not "give assurances that the [Plan] is in conformity with" the relevant federal statutes and regulations, the Administrator decided that "CMS properly disapproved" the Plan. (Id.) Iowa petitions this court for review and requests that we overturn the agency's final decision.

[3]Iowa alleges that CMS has approved state plan amendments proposed by Arkansas and Pennsylvania that, according to Iowa, are similar to the Plan. (See Pet'r Br. 39-40.) We express no opinion as to the accuracy of this allegation because Arkansas's and Pennsylvania's plan amendments were approved prior to 2007 and, thus, prior to the new FUL regulations, which were issued in 2007 via notice-and-comment rulemaking and which rejected Iowa's proposed method of calculating aggregate payments for multiple source drugs. This intervening regulatory change blunts any argument that CMS's disapproval of Iowa's Plan in August 2008 was somehow inconsistent with prior agency practice.

II.

We review CMS's final disapproval of the Plan under the Administrative Procedure Act's ("APA's") "requirements for an individual adjudication. Under the APA, the Secretary's decision is set aside if it is arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or contrary to law." Minnesota v. CMS, 495 F.3d at 996 (quotations omitted); see also PhRMA v. Walsh, 538 U.S. 644, 661 (2003) (the agency's final disapproval, after a hearing, of a proposed state Medicaid plan amendment is "presumptively valid"). In addition, "[w]e must give substantial deference to an agency's interpretation of its own regulations." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994). "Our task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." Id. (quotation omitted). "This broad deference is all the more warranted when, as here, the regulation concerns a complex and highly technical regulatory program . . . ." Id. (quotation omitted).

Medicaid regulations state that Iowa's "*payments* for multiple source drugs identified and listed . . . by CMS . . . must not exceed, in the aggregate," the FUL. 42 C.F.R. § 447.514(b) (emphasis added); accord id. § 447.512(a) ("the [state] agency *payment* for multiple source drugs must not exceed, in the aggregate . . . the specific limits established in accordance with § 447.514" (emphasis added)). The Medicaid regulations also direct CMS to set the FUL by calculating "250 percent of the AMP [Average Manufacturer Price] . . . for the least costly therapeutic equivalent" drug. Id. § 447.514(b). CMS determined that the state's Plan would permit Iowa to pay pharmacies amounts that *exceed* the FUL for multiple source drugs, with the expectation that Iowa would eventually receive supplemental rebates from drug manufacturers to bring its net costs below the FUL. Iowa does not dispute this determination and agrees that "preferring the drug with the lowest net cost, after

rebates, sometimes requires an initial payment for a multiple source brand name drug that exceeds the specific FUL . . . ." (Pet'r Br. 5-6.)

Iowa argues that, for purposes of meeting the multiple-source-drug FUL, the term "payment" in the Medicaid regulations is ambiguous and that, in this context, any ambiguity in the regulations should be resolved in favor of the state. Iowa contends that "payment" should be interpreted as referring to the net cost, after rebates, that the state pays for prescription drugs, in order "to assure that payments [for prescription drugs] are consistent with efficiency [and] economy." (Id. at 20 (citing 42 U.S.C. § 1396a(a)(30)(A)).) Under this reading, Iowa's Plan would comply with the FUL for multiple source drugs, and the state would save money. CMS contends that "payment" is not ambiguous, noting that the Medicaid statute differentiates between "payments" made initially to pharmacies and "rebates" received subsequently from manufacturers. CMS further argues that, even if the terms were ambiguous, its interpretation of its regulations would be entitled to deference unless it is plainly erroneous or inconsistent with the regulation. Finally, CMS contends that its interpretation will further the agency's goal of promoting the use of generic drugs in the national market and will make the Medicaid rebate program easier to administer.

We find that CMS's interpretation of its own regulations is not "plain[ly] erroneous or inconsistent with the regulation[s]." Thomas Jefferson Univ., 512 U.S. at 512. Specifically, we find reasonable the agency's interpretation of the term "payment" in 42 C.F.R. §§ 447.512 and 447.514. As CMS notes, the drug rebate provisions in the Medicaid statute use the terms "payment" and "rebate" to describe different concepts. See, e.g., 42 U.S.C. § 1396r-8(c)(2)(A) (increasing "rebate[s]" for single source drugs by the product of "the total number of units . . . dispensed . . . for which *payment was made* under the State plan" and another statutory multiplier (emphasis added)). Further, Medicaid regulations require CMS to calculate FULs based on a percentage of the AMP—the "average price *paid* to the manufacturer for the drug . . . by wholesalers for drugs distributed to the retail pharmacy . . . ." 42

C.F.R. § 447.504(a) (emphasis added). CMS is thus prohibited from taking into account "[r]ebates under the national rebate agreement or a . . . State supplemental rebate agreement" when it calculates AMP. Id. § 447.504(h)(24). Because CMS must calculate AMP and establish FULs based on up-front prices, it is entirely reasonable for CMS to require states to meet FULs based on up-front payments.

Finally, as CMS observed, the Secretary expressly rejected Iowa's approach when he issued new FUL regulations in 2007. See 72 Fed. Reg. 39,142, 39,214. Iowa now invites this court to second-guess the agency's expertise by attacking the policies underlying CMS's decision. However appealing Iowa's approach may appear to be as a matter of policy, we must give CMS the deference it is owed as a matter of law. Because we find CMS's interpretation of 42 CFR §§ 447.512 and 447.514 to be reasonable, we hold that CMS's disapproval of Iowa's Plan was not "arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or contrary to law." Minnesota v. CMS, 495 F.3d at 996. Therefore, we need not determine whether the Plan violated Medicaid regulations by failing to include a physician certification requirement for medically necessary brand name drugs.

III.

Accordingly, we deny the state's petition.
