Doc. 403417519

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, Bureau for Medical Services, *Plaintiff-Appellant,* v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services; CHARLENE FRIZZERA, in her official capacity of Acting Administrator, Centers for Medicare and Medicaid Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Defendants-Appellees.*	No. 10-1592

Appeal from the United States District Court
for the Southern District of West Virginia, at Charleston.
Joseph R. Goodwin, Chief District Judge.
(2:09-cv-00847)

Argued: May 12, 2011

Decided: July 6, 2011

Before MOTZ and DIAZ, Circuit Judges, and
HAMILTON, Senior Circuit Judge.

Dockets.Justia.com

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 2 of 16

Affirmed by published opinion. Judge Diaz wrote the opinion, in which Judge Motz and Senior Judge Hamilton joined.

COUNSEL

ARGUED: Scott E. Johnson, Kings Mountain, North Carolina, for Appellant. Alisa Beth Klein, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** Frances A. Hughes, Thomas W. Smith, Mary McQuain, OFFICE OF THE ATTORNEY GENERAL OF WEST VIRGINIA, Charleston, West Virginia, for Appellant. Mark B. Childress, Acting General Counsel, Janice L. Hoffman, Associate General Counsel, Carol J. Bennett, Deputy General Counsel for Program Integrity, Howard Cohen, Department of Health and Human Services, Tony West, Assistant Attorney General, Mark B. Stern, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; R. Booth Goodwin II, United States Attorney, Charleston, West Virginia, for Appellees.

OPINION

DIAZ, Circuit Judge:

This appeal arises from a grant of summary judgment. The district court dismissed appellant's challenge to an administrative ruling that sustained a disallowance in federal funding for its Medicaid program. The unambiguous text of the governing statute authorized the disallowance, and agency approval of the amount disallowed was neither arbitrary nor capricious. Accordingly, we affirm.

I.

A.

Congress created Medicaid in 1965 when it added Title XIX to the Social Security Act. Medicaid Act, Title XIX, Pub.

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 3 of 16

L. No. 89-97, 79 Stat. 343. Medicaid operates as a partnership between the federal government and states choosing to participate in the program. It provides federal funding to enable states to furnish medical assistance to the most vulnerable members of society. 42 U.S.C. § 1396-1. Congress has enumerated a number of conditions regulating a state's receipt of federal funds. *Id.* § 1396a. Each state wishing to receive such funds is required to submit a plan for medical assistance, and the Secretary of the U.S. Department of Health and Human Services ("HHS") must approve the plan before funds are disbursed. *Id.* § 1396-1. "Although participation in the Medicaid program is entirely optional, once a State elects to participate, it must comply with the requirements of Title XIX." *Harris v. McRae*, 448 U.S. 297, 301 (1980).

The Secretary of HHS ("Secretary") disburses quarterly to each participating state "an amount equal to the Federal medical assistance percentage ["FMAP"] . . . of the total amount expended during such quarter as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(1). The Secretary estimates the quarterly "amount to which a State will be entitled" and pays the funds so projected to the state. *Id.* §§ 1396b(d)(1)–(2)(A). Adjustments are built into each quarterly disbursement, and the amount must be "reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section to such State for any prior quarter." *Id.* § 1396b(d)(2)(A).

According to the accompanying regulations, an overpayment is "the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act." 42 C.F.R. § 433.304; *see also* 42 U.S.C. § 1396b(d)(3)(A) (explaining "overpayment" as "[t]he pro rata share to which the United States is equitably entitled, as determined by the Secretary, of the net amount recovered during any quarter by the State or any political subdivision thereof with respect to medical assis-

tance furnished under the State plan"). A "provider" is "any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency." 42 C.F.R. § 433.304.

The Medicaid Act sets out a procedure for recouping overpayments made by the states:

> [W]hen an overpayment is discovered, which was made by a State to a person or other entity, the State shall have a period of 1 year in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment.

42 U.S.C. § 1396b(d)(2)(C).[1] After the one-year window has expired, the federal government's right to collect overpaid funds operates independent of a state's recovery of funds wrongfully disbursed, subject to two exceptions not relevant here. *See id.* ("[T]he adjustment in the Federal Payment shall be made at the end of the 1-year period, whether or not recovery was made.").

B.

In 2001, West Virginia filed suit in West Virginia state court against a group of pharmaceutical manufacturers, including Dey, Inc. ("Dey"), a company that manufactured and sold albuterol sulfate. West Virginia proceeded against the defendants on behalf of three state agencies: the Department of Health and Human Resources ("DHHR"), the entity

[1]At all times relevant to this litigation, the state had sixty days, rather than one year, to recover the overpayment before the federal government adjusted funding. 42 U.S.C. § 1396b(d)(2)(C), *amended by* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). The parties agree that this altered time frame does not affect the analysis here.

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 5 of 16

that administers the state's Medicaid program; the Public Employees Insurance Agency ("PEIA"); and the State Worker's Compensation Division ("WCD"). West Virginia claimed that the defendants artificially inflated the reimbursement values of certain drugs, in violation of the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101 *et seq.*, and a state statute prohibiting fraud and abuse in the Medicaid program, *id.* § 9-7-6 *et seq.*

West Virginia's claims centered on the links in the reimbursement process between pharmaceutical manufacturers, providers, and insurance companies. Pharmacists—the providers at issue in this case—purchase drugs from pharmaceutical manufacturers, like Dey, and then dispense them to patients. Assuming the patient is insured, the pharmacist submits a claim for reimbursement for the drug purchase to the patient's health-insurance program. If the patient is covered by Medicaid, the pharmacist submits the claim to the state Medicaid program, which is funded largely through federal dollars. The state Medicaid program then reimburses the pharmacist for the drug sale. Reimbursement value is tied to the industry-defined average wholesale price ("AWP") of the particular drug.

West Virginia's complaint alleged that the defendants inflated the AWP of certain drugs. According to the state, the defendants "then sold the drugs to providers . . . for a price considerably below the published AWP," "knowing that health insurers [specifically, West Virginia's DHHR, PEIA, and WCD] . . . relied on AWPs to determine the amount of reimbursement to providers for most drugs." J.A. 98. "Defendants' fraud," West Virginia alleged, thus "caused the State to pay an artificially inflated amount of reimbursement for these drugs," because legitimate reimbursement rates must hew closely to the actual cost of the drugs. *Id.*

According to West Virginia, Dey fraudulently raised AWPs to enhance its profits. Dey actually sold the drugs to providers

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 6 of 16

at prices lower than the AWP, which meant that providers would receive reimbursement much greater than the amount that they actually spent on the drugs. And because Dey's "spread"—the difference between the reimbursement rate and the price actually charged the provider—was substantial, more providers purchased drugs from the company, in turn enhancing Dey's profitability.

In 2004, West Virginia settled its claims against Dey, which agreed to pay West Virginia $850,000, of which $100,000 was earmarked for the Consumer Protection Fund of the Office of the West Virginia Attorney General. The settlement further mandated that Dey reimburse the state for attorneys' fees and costs. West Virginia in turn released Dey from further claims arising out of the alleged overpayment. The Kanawha County Circuit Court, in which the action was originally filed, ratified the settlement and dismissed with prejudice all claims against Dey.

C.

After learning of the Dey settlement in 2007, the federal Centers for Medicare & Medicaid Services ("CMS") notified West Virginia's DHHR of a disallowance in federal funding for the state's Medicaid program. CMS advised West Virginia that "DHHR failed to credit the Federal government its share of the settlement proceeds." J.A. 59. As a result, CMS intended to withhold $634,525 in Medicaid funding, the amount that it maintained represented its share of overpayments made to providers as a result of Dey's alleged fraud.

West Virginia appealed the disallowance to the HHS Departmental Appeals Board ("Board"), arguing that CMS was not entitled to any portion of the settlement proceeds. And even assuming that CMS rightfully claimed some of the money, West Virginia continued, it erroneously calculated the proper amount. The Board sustained the disallowance, ruling

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 7 of 16

"that the federal government is entitled to a share of the Dey settlement proceeds." *Id.* 18.

The Board first concluded that the settlement proceeds qualified as an overpayment. Looking to the applicable statutory text and analogizing to a previous administrative decision, the Board determined that the government was entitled to its share of an overpayment pursuant to 42 U.S.C. § 1396b(d)(2). West Virginia's recovery of settlement proceeds "effectively reduced the Medicaid program's overall cost of providing medical and health services . . . to Medicaid recipients," and CMS was authorized to recoup the money already paid to cover the fraudulently inflated reimbursements. J.A. 24. Because the state as a whole is responsible for administering Medicaid, that some of the settlement proceeds were earmarked for the Consumer Protection Fund did not, in the view of the Board, affect the federal government's rightful share.

Turning to CMS's calculation of the disallowance, the Board concluded that it was reasonable. CMS had previously claimed that it was entitled to $634,525, but it had reduced that figure to $446,607 prior to adjudication before the Board. CMS arrived at this number as follows: Looking to West Virginia's complaint in the Dey litigation, it first multiplied the $850,000 settlement by the share of the state's estimated damages allocable to Medicaid, 67.24 percent, which yielded $571,546.80. CMS then multiplied this figure by West Virginia's FMAP rate of 78.14 percent—the share of state Medicaid expenses covered by the federal government—and arrived at the final amount of $446,607.

Reasoning that "an allocation need only have some reasonable basis," the Board held that CMS's calculation satisfied this standard. *Id.* 29–30. CMS based its allocation on the state's own damages estimate from the Dey litigation, and there was no evidence to suggest that this method of computation was seriously flawed. And, in any event, West Virginia

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 8 of 16

had proffered no alternative way to calculate the amount owed to the federal government.

West Virginia responded to the administrative ruling by filing suit in the U.S. District Court for the Southern District of West Virginia, seeking judicial review of the Board's decision. The district court upheld the agency's action.

The district court first addressed the issue of waiver. In briefing before the court, West Virginia had proffered several new grounds for challenging the disallowance. Because these arguments had not been presented before the Board, the court held that they had been waived. In the alternative, the court summarily found that the arguments lacked merit.

Turning to the merits of the appeal, the court reasoned that the Secretary possesses statutory authority "to withhold funds when she determines that a state made an overpayment." *Id.* 190. As the court explained, a disallowance need not be predicated on state action against the wrongful party; federal right to recovery of an overpayment is not dependent on whether a state recovers from the putative wrongdoer. Rejecting the state's argument that a disallowance was improper because Dey was not a provider, the court summarized its holding as follows:

> The regulations define an overpayment as amounts *paid* to a provider in the first instance. But they do not say that a party settling an overpayment claim must be a provider.
>
> . . . The overpayments in this case were paid to providers pursuant to the Medicaid program. HHS is entitled to its share of those recovered overpayments regardless of the source of the recovery.

Id. 192.

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 9 of 16

The district court similarly rebuffed West Virginia's objections to the calculation of the overpayment. Because it was based on the state's own damages estimates, the amount was reasonable, concluded the court. Moreover, the state never proposed an alternate method of computation or cogently explained why the model used was flawed.

West Virginia now appeals the district court's decision.

II.

Before reaching the merits of the appeal, we address three threshold issues.

A.

The dictates of the Administrative Procedure Act ("APA") govern our standard of review on appeal. Pursuant to the APA, a reviewing court must "set aside agency action, findings, and conclusions" when they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

We review de novo a district court's evaluation of agency action, as to questions of both law and fact. *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 189 (4th Cir. 2009).

B.

With the general standard of review established, we consider whether deference to CMS's statutory construction is appropriate. West Virginia argues throughout its briefs that this court should extend little deference to CMS's interpretation of the "overpayment" statutory provisions. But deference to agency construction of statutes enters the equation only when legislation is ambiguous. *See Chevron, USA, Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984)

("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). Because we conclude that the statutory provisions governing overpayments are plain on their face, we need not accord deference to the interpretation of CMS.

C.

The Secretary argues that West Virginia has waived presentation of two arguments that it presses on appeal: CMS misconstrued the definition of "provider" in 42 C.F.R. § 433.304, and the notice of disallowance constitutes a new rule that may not be imposed absent prior notice-and-comment rulemaking. Because West Virginia neglected to raise these contentions before the Board, the Secretary urges us to refuse consideration of them here.

We doubt whether the waiver doctrine properly applies here. *See Toler v. E. Associated Coal Co.*, 43 F.3d 109, 113 (4th Cir. 1995) (rejecting waiver argument where petitioner asserted same fundamental claim before the agency and district court, but merely used different arguments in each forum to press that claim). And, in any event, because waiver is a prudential bar, we decline to invoke it in this case. *See id.* ("[W]aiver is a nonjurisdictional doctrine that calls for flexible application."). Thus we will consider all of the arguments raised on appeal by West Virginia.

III.

West Virginia principally contends that CMS's disallowance was not authorized by statute. Invoking a wooden "super-clear-statement" rule, the state argues that the definition of "overpayment" advanced by CMS is untethered to the statutory text. CMS thus lacks authority to withhold funds from West Virginia, the state maintains, because the disallowance was supported by neither the clear statutory text nor a

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 11 of 16

prior rule promulgated pursuant to the notice-and-comment framework.

We disagree. Not only does the plain and unambiguous text of the Medicaid Act authorize the disallowance here even under West Virginia's rigid model of interpretation, but the state's "super-clear-statement" rule misreads Supreme Court precedent. As we explain below, applicable statutory text gave CMS the authority to disallow payments to West Virginia's Medicaid program based on the state's settlement with Dey, and West Virginia may not shirk this obligation.

A.

West Virginia first asserts that a state has the right to "informed consent" when participating in a federally financed program. Relying primarily on *Pennhurst State School & Hospital v. Halderman*, 451 U.S. 1 (1981), the state argues that this court must require a "super-clear statement" of conditions in the Medicaid Act. Such an unambiguous condition is lacking in the statute, West Virginia continues, and as a result the state must be allowed to retain all of the money obtained from the Dey settlement. We find West Virginia's argument unavailing. The Medicaid Act sets out obligations clear enough to satisfy any standard of precision, and the state's position misreads *Pennhurst* and its progeny.

A quick survey of the U.S. Code reveals a multitude of statutes enacted pursuant to Congress's spending power. Most are variations on a familiar theme: Congress disburses funds to states, and in exchange the states agree to comply with a number of conditions. In this way, Congress can foster compliance with a national objective through persuasion rather than coercion, and states have the option of declining funding and avoiding federal regulation. Limits are imposed, however, on Congress's ability to attach conditions to funding provided to states. A state's requisite "knowing acceptance" of the conditions prescribed by Congress through its exercise of the

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 12 of 16

spending power is impossible, the Supreme Court has held, "if [the] State is unaware of the conditions or is unable to ascertain what is expected of it." *Pennhurst*, 451 U.S. at 17. "Accordingly, if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously." *Id.*

Of course, given the ever-increasing complexity of modern legislation, Congress need not spell out every condition with flawless precision for a provision to be enforceable. *See Bennett v. Ky. Dep't of Educ.*, 470 U.S. 656, 666–69 (1985). In *Bennett*, the federal government sought to recover funds used by Kentucky allegedly in contravention of Title I of the Elementary and Secondary Education Act of 1965. *Id.* at 658–59. Rejecting Kentucky's argument that *Pennhurst* commanded application of a standard analogous to West Virginia's "super-clear-statement" rule, the Court concluded that "*Pennhurst* does not suggest that the Federal Government may recover misused *federal* funds only if every improper expenditure has been specifically identified and proscribed in advance." *Id.* at 666.

The Court further rejected analogies between standard bilateral contracts and federal grant programs, finding general legislative guidelines sufficient to mandate state compliance. *Id.* at 669. "Given the structure of the grant program, the Federal Government simply could not prospectively resolve every possible ambiguity concerning particular applications of the requirements of Title I." *Id.* And, continued the Court, states must bear some responsibility for any harm to them allegedly caused by an ambiguous provision, as they "had an opportunity to seek clarification of the program requirements." *Id.*

With these principles in tow, we turn to interpretation of the Medicaid Act.

B.

The thrust of West Virginia's interpretive argument is that the Medicaid Act authorizes a disallowance only when the

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 13 of 16

state has recovered from a "provider." Because Dey is a third party and not a "provider," asserts the state, CMS lacks authority to withhold funds on account of the settlement. Yet a closer reading of the Medicaid legislation reveals that West Virginia's interpretation lacks a textual basis and must be rejected. We conclude that the Medicaid Act plainly authorizes CMS to disallow payments to a state when that state overpays a provider, regardless of whether the state has recovered from a provider or a third party—or, indeed, recovered from anyone at all.

The sine qua non of a proper disallowance is an overpayment: "The Secretary shall . . . pay to the State . . . the [quarterly estimated] amount . . . , reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made." 42 U.S.C. § 1396b(d)(2)(A). Once the Secretary discovers an overpayment, she must give the state one year to recover from the wrongdoer before adjusting federal funding. *Id.* § 1396b(d)(2)(C). But once the one-year period has expired, "the adjustment in the Federal payment shall be made . . . , *whether or not recovery was made* [by the state]." *Id.* (emphasis added). Thus aside from its effect on the appropriate timing of a disallowance, from whom a state recovers—or whether it recovers at all—is immaterial.

An overpayment is "the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act." 42 C.F.R. § 433.304. The Medicaid Act gives the Secretary latitude to determine whether an overpayment has been made and, if so, the amount of funding that CMS is entitled to withhold from the state. 42 U.S.C. § 1396b(d)(3)(A).

Straightforward application of the Medicaid Act compels us to uphold the Board's determination that there was an overpayment and the Secretary is entitled to her equitable share.

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 14 of 16

We need look no further than West Virginia's own allegations in the Dey litigation to confirm the existence of an overpayment. "[Dey] knew that State Medicaid programs . . . rely on AWP to pay for the drugs," West Virginia alleged, "and [Dey] knew that [its] inflation of AWP would *cause the State and its citizens to overpay for these drugs*." J.A. 110 (emphasis added). By increasing the AWP of albuterol sulfate, West Virginia claimed, Dey enabled providers to receive artificially inflated reimbursements, some of which were provided by the federally funded state Medicaid program. Thus the wrongdoing of Dey caused "the amount paid by a Medicaid agency to a provider [to be] in excess of the amount that is allowable [under the Medicaid Act]," 42 C.F.R. § 433.304. Because CMS previously disbursed funds to West Virginia that covered the improperly high reimbursement rates, it is entitled to disallow a portion of its future funding to recoup this overpayment. *See* 42 U.S.C. § 1396b(d)(2)(A).

That West Virginia recovered from a third party, not a provider, has no effect on the Secretary's entitlement to a portion of the settlement proceeds. To be sure, an overpayment requires money "paid by a Medicaid agency to a *provider*." 42 C.F.R. § 433.304 (emphasis added). This requirement was met in this case when West Virginia's Medicaid program paid pharmacists—indisputably providers—inflated prices to cover Medicaid patients' drug purchases. Indeed, the state's complaint in the Dey litigation alleged that Dey "marketed and promoted the sale of the drugs to the *providers* based upon the availability of the fraudulently inflated reimbursement payments from government and commercial health insurance programs." J.A. 98 (emphasis added). Once CMS has established an overpayment to a provider, it may issue a disallowance after the state has had one year to attempt a recovery. Indeed, the Medicaid Act expressly rejects requiring state recovery from a provider as a condition of issuing a disallowance;

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 15 of 16

rather, it authorizes CMS to act even if the state has recovered from no one at all. 42 U.S.C. § 1396b(d)(2)(C).[2]

IV.

Even if the federal government is entitled to a portion of the Dey settlement, West Virginia argues that CMS arbitrarily calculated the proper amount of the disallowance. Notably, however, the state has not come forward with an alternative estimate. We conclude that the Board's decision to uphold the calculation of the disallowance was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A).[3]

CMS's calculation of the disallowance was elegantly simple. Drawing on West Virginia's own damages estimate from the Dey litigation, CMS merely multiplied the amount of loss suffered by West Virginia's Medicaid program by the percentage of funds that the federal government contributes to the state's Medicaid program. The resulting figure was $446,607. We fully endorse the Board's rejection of West Virginia's argument:

> [A]bsent complete or perfect information, an allocation need only have some reasonable basis. Because CMS's allocation rests on the State's own damages estimate in preparation for litigation, an estimate that in turn was based on a substantial volume of claims

[2]Because we hold that the Medicaid Act's clear and unambiguous overpayment provisions authorized the agency action here, we reject West Virginia's contention that CMS could not issue a disallowance absent prior notice-and-comment rulemaking codifying its interpretation of the statute. We find West Virginia's reliance on *Alabama v. Ctrs. for Medicare & Medicaid Servs.*, No. 08-881, 2011 WL 671676 (M.D. Ala. Feb. 18, 2011), unpersuasive for the same reason.

[3]At oral argument, counsel for West Virginia conceded the tenuous nature of the calculation argument. Although counsel was unwilling to waive the point, he declined to advocate in its favor.

Appeal: 10-1592 Document: 42 Date Filed: 07/06/2011 Page: 16 of 16

> and reimbursement data supplied by the affected programs, and because there is no indication in the [litigation materials] that the estimates were seriously flawed or substantially overstated the alleged relative loss to Medicaid, we conclude that a reasonable basis exists for CMS to allocate approximately 67 percent of the Dey settlement proceeds to Medicaid.

J.A. 29-30 (citation and footnote omitted).

V.

West Virginia received federal Medicaid funding in excess of that authorized by statute. The federal government is entitled to recoup the overage. Accordingly, the judgment of the district court is affirmed.

AFFIRMED