

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

SUBJECT: West Virginia Department of
Health and Human Resources
Docket No. A-07-135
Decision No. 2185

DATE: July 14, 2008

DECISION

On September 5, 2007, the West Virginia Department of Health and Human Resources (DHHR) appealed a decision by the Centers for Medicare & Medicaid Services (CMS) to disallow \$4,143,075 in federal financial participation (FFP) for West Virginia's Medicaid program. The disallowance stems from a lawsuit filed by the state of West Virginia (State) against companies that manufacture and market the drug OxyContin. The lawsuit was settled before trial, with the defendants agreeing to pay \$10 million to the Consumer Protection Fund of the Office of the West Virginia Attorney General. CMS found that because the lawsuit had alleged harm to West Virginia's Medicaid program, the costs of which are borne in part by the federal government, a portion of the settlement proceeds should have been shared with the federal government. Accordingly, CMS issued the challenged disallowance decision in order to recoup what it believed is the federal government's rightful share of the OxyContin settlement proceeds.

We uphold CMS's decision in part and remand for further proceedings consistent with this decision. We conclude that CMS was authorized to disallow FFP in order to recoup the federal government's share of the OxyContin settlement proceeds. However, we also conclude that CMS has not articulated a sufficient basis for upholding the amount of the disallowance. We also note that CMS has indicated a willingness to revisit the issue of the disallowance amount. Thus, we remand the case to CMS to recalculate the disallowance in a manner consistent with this decision and taking into consideration any additional information that the parties may exchange on that issue. If DHHR is dissatisfied with CMS's revised determination of the disallowance amount, it may appeal the revised determination to the Board.

Legal Background

The federal Medicaid statute, title XIX of the Social Security (Act), authorizes a program that furnishes medical assistance to certain needy and disabled persons. Act § 1901. The program is jointly financed by the federal and state governments and administered by the states. Id. § 1903; 42 C.F.R. § 430.0. Each state administers its own Medicaid program pursuant to broad federal requirements and the terms of its "plan for medical assistance," which must be approved by CMS on behalf of the Secretary of Health and Human Services (HHS). Act § 1902; 42 C.F.R. §§ 430.10-430.16. Once its Medicaid plan is approved, a state becomes entitled to receive federal reimbursement, or FFP, for "an amount equal to the Federal medical assistance percentage [FMAP] . . . of the total amount expended . . . as medical assistance under the State plan." Act § 1903(a) (emphasis added). The term "medical assistance" means "payment of part or all of the cost" of specified care and services provided to Medicaid-eligible individuals. Act § 1905(a). The FMAP is the percentage of the state's medical assistance expenditures for which the federal government provides FFP. 42 C.F.R. § 433.10. At the time of the OxyContin settlement (December 2004), West Virginia's FMAP was 75%. CMS Ex. 3.

Section 1903(d) of the Act establishes the following process for awarding FFP to a state Medicaid program. First, prior to the start of a quarter, the state estimates the FFP it will be entitled to receive for its Medicaid program expenditures in that quarter. Act § 1903(d)(1). CMS then pays the state in advance (that is, before the quarter's program expenditures are made) "the amount [of FFP] so estimated." Id. § 1902(d)(2)(A). CMS's advance payment of FFP is "reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made . . . to such State in any prior quarter[.]" Id. Thus, under this system of advance payments, the federal government recoups an overpayment of FFP for a given quarter through a reduction in the amount of FFP paid for a later quarter. See Arkansas Dept. of Human Services, DAB No. 717, at 6-7 (1986).

The Act uses the term "overpayment" in two related senses. In section 1903(d)(2)(A), the term refers to excessive FFP paid to a state in a given quarter. In section 1903(d)(2)(C), the term is used to describe a payment that is made by a state Medicaid program to a Medicaid provider. The latter overpayment is defined in CMS's regulations as "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 (emphasis added). A key principle in section 1903(d)(2) is that FFP may be paid only for "allowable" costs or expenditures. New Jersey Dept. of Human Services, DAB No. 480, at 6 (1983), aff'd, New Jersey Dep't of Human Servs. v. Bowen, No. 84-2771 (GEB) (D. N.J. Nov. 13, 1986). "An overpayment to a provider represents a determination that an expense has been found to be unallowable, and hence not medical assistance under the Medicaid program. It results in the State having received an overpayment of FFP for that provider, which [CMS] is entitled to recoup under section 1903(d)(2)." Id.

Two other provisions in section 1903 are relevant here. The first, section 1903(d)(3), provides:

The 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 assistance furnished under the State plan shall be considered an overpayment to be adjusted under this subsection.

Act § 1903(d)(3) (emphasis added). In general, this provision "permits [CMS] to recoup the federal share of medical assistance payments which have been recovered by a state." New York Dept. of Social Services, DAB No. 1321, at 13 (1992). The Board has held that because section 1903(d)(3) refers to amounts recovered "with respect to medical assistance," the State's recovery must relate to state expenditures that are allowable as medical assistance under the state plan.¹ Id.; see also California Dept. of Health Services, DAB No. 1254, at 3 (1991). A recovery under section 1903(d)(3) may include funds obtained from third parties. California Dept. of Health Services at 3. On the other hand, the Board has held that section 1903(d)(3) does not preclude treating amounts unallowable as Medicaid assistance as overpayments under section 1903(d)(2) for which CMS could require adjustment of FFP. Id. at 2-3; Missouri Dept. of Social Services, DAB No. 1018, at

¹ In New York Dept. of Social Services, DAB No. 311, at 5 n.2 (1982), aff'd, Perales v. Heckler, 611 F. Supp. 333 (N.D.N.Y. 1984), aff'd, 762 F.2d 226 (2nd Cir. 1985), the Board noted that section 1903(d)(3) was "similar" to pre-existing provisions under the Act's public assistance titles, and that the legislative history of those "comparable" provisions "shows that [their] purpose was to treat recoveries of certain otherwise allowable costs as overpayments in order to permit the federal share to be recouped through an offset against the state's next award of funds."

2-3 (1989), aff'd, Alabama Dept. of Human Resources v. DHHS, 478 F.Supp.2d 85 (D.D.C 2007).

Section 1902(a)(25) of the Act requires a state to take "all reasonable measures to ascertain the legal liability of third parties . . . to pay for care and services available under the [Medicaid state] plan" This provision further provides that when third party liability is found to exist after medical assistance is provided, a state will seek reimbursement from the third party "to the extent of such legal liability." Act § 1902(a)(25)(B). CMS regulations provide that "[i]f the State receives FFP in Medicaid payments for which it receives third party reimbursement, the State must pay the Federal government a portion of the reimbursement determined in accordance with the FMAP for the State." 42 C.F.R. § 433.140(c); see also Act § 1903(d)(2)(B) (providing that Medicaid "[e]xpenditures for which [FFP] payments were made to the State under [section 1903(a)] shall be treated as an overpayment to the extent that the State or local agency administering [the state] plan has been reimbursed for such expenditures by a third party").

Also relevant here is Office of Management and Budget (OMB) Circular A-87, which establishes uniform principles for determining the allowability of costs for which states may receive funding under a federal "award," a term that includes a Medicaid grant.² 2 C.F.R. Part 225, App. A, ¶ A.1., B.2.; see also 42 C.F.R. § 430.30; 45 C.F.R. §§ 92.1, 92.4, 92.22; Pennsylvania Dept. of Public Welfare, DAB No. 2152, at 11 n.10 (2008). The Circular provides that the costs for which a state program may receive a federal award consist of the program's allowable direct costs, plus the program's allocable share of allowable indirect costs, "less applicable credits." 2 C.F.R. Part 255, App. A, ¶ D.1. "Applicable credits refer to those receipts or reduction of expenditure-type transactions that offset or reduce expense items allocable to Federal awards as direct or indirect costs."³ Id. ¶ C.4.a. "To the extent that such credits accruing to or received by the governmental unit relate to allowable costs, they shall be credited to the Federal

² OMB Circular A-87 was recently codified in 2 C.F.R. Part 225, Appendix A. 70 Fed. Reg. 51,910 (Aug. 31, 2005).

³ Examples of applicable credits include, but are not limited to, purchase discounts; rebates or allowances, recoveries or indemnities on losses; sale of publications, equipment, and scrap; income from personal or incidental services; and adjustments of overpayments or erroneous charges. 2 C.F.R. Part 225, App. A, ¶ C.4.a.

award either as a cost reduction or cash refund, as appropriate.” Id. In short, an applicable credit reduces the amount of a state program cost or expenditure in which FFP may be claimed. Minnesota Dept. of Human Services, DAB No. 2122, at 6 (2007) (“Under the cost principles, ‘applicable credits’ . . . generally must be subtracted from claims for federal funding.”).

Case Background

OxyContin is an opioid pain reliever manufactured by Purdue Pharma L.P. (Purdue). WV Ex. 5 ¶ 17. The drug was launched in 1995 and approved for the treatment of moderate or severe pain lasting more than a few days. Id. ¶ 19.

In June 2001, the State, acting through its Attorney General, filed a complaint in state circuit court against Purdue, Abbott Laboratories, Inc., and two other related companies. WV Ex. 5. The State was the sole plaintiff named in the June 2001 complaint. Id. The complaint alleged that the defendants had engaged in a marketing campaign that misrepresented the “appropriate uses, risks, and safety” of OxyContin. Id. ¶ 2. As a result of this “inappropriate marketing,” said the complaint, OxyContin was “inappropriately prescribed and used, unnecessarily putting people at risk of addiction [to] OxyContin, causing many users of the drug to become addicted to OxyContin and suffering the consequences of addiction.” Id. ¶ 30. Based on these and other allegations, the complaint asserted various causes of action, including violation of the Virginia Consumer Credit Protection Act (WVCCPA) (count I), public nuisance (count II), negligence (count V), and violation of state antitrust law (count VI). Id. ¶¶ 44-97.

After the defendants challenged the Attorney General’s authority to pursue certain causes of action, the original complaint was amended to add the following additional parties as plaintiffs: the Bureau of Employment Programs (BEP), the Public Employees Insurance Agency (PEIA), and the DHHR.⁴ WV Ex. 8. DHHR administers various public assistance programs. DHHR’s Bureau for Medical Services administers West Virginia’s Medicaid program. See CMS Ex. 2 (n.2). DHHR’s Bureau for Behavioral Health and Health Facilities administers substance abuse programs, which have a variety of funding sources, including Medicaid. Id.; CMS Ex. 45 (Transcript at 66-67).

⁴ The amended complaint indicates that the plaintiffs are referred to collectively as “the State” or the “State of West Virginia.” WV Ex. 5, at 1.

After several months of discovery and pre-trial motions, the plaintiffs informed the court of their intention to pursue only two causes of action at trial: (1) the cause of action under count I, which alleged that the defendants' marketing and promotion of OxyContin had violated the WVCCPA; (2) the cause of action under count II, which alleged that the defendants' marketing and promotion of OxyContin had created a "public nuisance." WV Ex. 10, at 3-4.

In connection with the two counts on which it planned to proceed to trial, West Virginia developed what it calls "two distinct theories of damage." See WV Br. at 6. The first, applicable to count I, sought "restitution and reimbursement" for expenditures by the plaintiffs on OxyContin prescriptions. Id.; WV Ex. 9 ¶ 54.A. The second damage theory, applicable to count II, sought "restitution and reimbursement" for the plaintiffs' expenditures on substance abuse treatment and related services for citizens of West Virginia who had become addicted to OxyContin.⁵ WV Br. at 7; WV Ex. 9 ¶ 62.B.

In December 2004, on the eve of trial, the litigants reached a settlement, which the court approved. CMS Ex. 1 (Settlement Agreement and Release); WV Ex. 2 (Final Order). In exchange for the plaintiffs releasing all claims against the defendants relating to the marketing and sale of OxyContin, including claims of injury to the West Virginia Medicaid program,⁶ the defendants agreed to pay \$10 million (in installments) to the Consumer Protection Fund of the Office of the West Virginia Attorney General, with the understanding that these funds would be "used by the Attorney General in support of the General Welfare of the People of West Virginia in the following areas only:

(1) Accredited continuing medical education programs directed at the use, abuse, and diversion of prescription drugs; (2) Law Enforcement Training, Education, and Funding relating to abuse and diversion of prescription drugs; and (3) Community based drug and diversion education programs." WV Ex. 2, at 2; see also CMS

⁵ DHHR asserts that a claim for punitive damages also remained "viable at the time of the settlement." WV Br. at 8.

⁶ The Settlement Agreement and Release states in part: "This is a full, final, and complete release of any and all claims and demands from Darrell V. McGraw, Attorney General for the State of West Virginia, on behalf of the State of West Virginia, [and] . . . the West Virginia [DHHR] . . . sustained or incurred as a result of the manufacture, marketing and sale of OxyContin® Tablets in the State of West Virginia as more fully detailed in the Complaint" CMS Ex. 1.

Ex. 1. The court subsequently ordered that the plaintiffs' attorneys fees and expenses be paid from settlement proceeds. CMS Ex. 9. These fees and expenses totaled in excess of \$3 million. Id. It is undisputed that the State did not share any portion of the settlement proceeds with the federal government.

In May 2007, CMS notified DHHR that it had learned of the settlement. CMS Ex. 8. Noting that the OxyContin lawsuit had alleged harm to West Virginia's federally financed Medicaid program, CMS asked DHHR for the reasons why none of the settlement proceeds had been "paid or credited to the federal government as repayment of the Federal share of Medicaid expenses." Id. DHHR responded that the "Medicaid Program [was] excluded from the settlement" and was not entitled to any of the settlement proceeds because the "settlement was based upon the damages suffered by all the citizens of West Virginia as opposed to any particular State agency." CMS Ex. 2.

On August 7, 2007, CMS issued a written notice of disallowance for \$4,143,075 in FFP in order to obtain what it believed was the federal government's proper "share of the portion of the settlement proceeds attributable to harm to the State of West Virginia's Medicaid program." WV Ex. 1. The notice of disallowance asserted the following legal justification for CMS's action:

Consistent with the cost principles set out in Office of Management and Budget (OMB) Circular A-87, Attachment A, Paragraph C.1.i, made applicable to Medicaid by 45 C.F.R. 92.22(b), the payments made by Purdue Pharma to resolve potential overpayments with respect to prescription drugs must be used to reduce the overall costs of the program before you submit your claim for FFP. The payments collected represent an applicable credit under the OMB Circular and since your agency did not reduce its claim for FFP appropriately, your claims represent an overpayment under section 1903(d)(2) of the Social Security Act (the Act).

Id. at 1. The August 7, 2007 notice also indicated that CMS had fixed the amount of the disallowance by "equitably distributing" or allocating the \$10 million in settlement proceeds among the three state agencies named as plaintiffs (BEP, PEIA, and DHHR) in the lawsuit. Id. CMS allocated \$5.55 million of the \$10 million to DHHR. The amount of the disallowance - \$4,143,075 - is equal to \$5.55 million multiplied by West Virginia's FMAP (74.65%).

West Virginia's Contentions on Appeal

DHHR contends that CMS lacks a factual and legal basis for the disallowance. It asserts that the disallowance is based on "nothing more than . . . eight paragraphs in a ninety-nine paragraph Complaint" and an unspecified article in the *West Virginia Record*, a publication owned by the U.S. Chamber of Commerce.⁷ WV Br. at 1. DHHR further contends that sections 1903(d)(2), 1903(d)(3), and 1902(a)(25) of the Act are "completely inapplicable." *Id.* at 13-17. According to DHHR, these provisions permit the Secretary to "declare and recover" an overpayment in only two situations, neither of which exists here. *Id.* at 14. The first situation, DHHR says, is when "an individual Medicaid recipient has other insurance to recover all or a part of his/her medical expenses." *Id.* at 14-15. The second situation is when "an individual Medicaid recipient has recovered a third party tort award; the State is then ' . . . subrogated to the recipient's rights against the recovery from any liable party and has a lien to the extent of the value of the medical assistance provided.'" *Id.* at 15 (quoting Washington State Department of Social and Health Services, DAB No. 1561 (1996)).

DHHR also contends that, assuming Medicaid is entitled to a share of the settlement proceeds, CMS's allocation of 55% of those proceeds to the Medicaid program is "completely arbitrary." WV Br. at 9-13. In support of that contention, DHHR asserts that CMS disregarded the fact that there were more than three plaintiffs in the underlying litigation, noting that the amended complaint has asserted claims on behalf of the all the "citizens and consumers" of West Virginia. *Id.* at 10. DHHR also asserts that CMS: (1) should have looked beyond the complaint's allegations and focused on the plaintiffs' ability to prove its "damages" (*id.* at 11-12); (2) failed to account for costs of obtaining the settlement (*id.* at 12); and (3) failed to consider the condition placed on the use of the settlement proceeds (*id.* at 12).

⁷ DHHR's briefs allude several times to this article but do not specify a title or publication date, and DHHR did not submit a copy of any such article in its appeal file. CMS's appeal file contains copies of two articles from the *West Virginia Record*, CMS Exhibits 15 and 17, but both articles postdate the disallowance. In any event, the notice of disallowance does not state that CMS based its disallowance decision on any *West Virginia Record* article.

Discussion

In its August 7, 2007 notice of disallowance, CMS stated that the OxyContin settlement proceeds represented "payments made by Purdue Pharma to resolve potential overpayments with respect to prescription drugs." WV Ex. 1, at 1. The notice further stated that Purdue Pharma's payments were "applicable credits" under OMB Circular A-87, and that these credits must be used to "reduce the overall costs" of West Virginia's Medicaid program. In addition, the disallowance notice stated that because West Virginia did not reduce its claims for FFP to reflect the applicable credits, its "claims [for FFP] represent an overpayment under section 1903(d)(2) of the Social Security Act (Act)."

In response to DHHR's appeal, CMS clarifies and expands its justification for the disallowance. In particular, CMS contends that the disallowance is justified not only under OMB Circular A-87 and section 1903(d)(2), but under sections 1902(a)(25) and 1903(d)(3) of the Act as well. CMS also cites additional factual grounds for the disallowance. As noted, the notice of disallowance states that Purdue Pharma's payments under the settlement were made to resolve Medicaid "overpayments" – i.e., unallowable program expenditures – on OxyContin. CMS now asserts that the settlement proceeds also resolved a claim for reimbursement of *allowable* Medicaid expenditures on OxyContin as well as a claim for reimbursement of allowable Medicaid expenditures for substance abuse treatment.

We have consistently held that a federal agency may raise new grounds for a disallowance after a notice of disallowance is issued as long as the appellant is afforded an opportunity to respond. West Virginia Dept. of Health and Human Resources, DAB No. 2017, at 2 n.1 (2006). Here, DHHR had an opportunity in its reply brief to respond to CMS's expanded justification for the disallowance. DHHR does not allege that this opportunity was inadequate. Accordingly, our decision is not limited to a consideration of the grounds for disallowance stated in CMS's notice of disallowance.

The parties agree that we must resolve two general issues in deciding the legality of the disallowance.⁸ First, we must

⁸ West Virginia accuses CMS of attempting to "attribute bad motives" to the West Virginia Attorney General, Reply Brief at 2, and suggests that the disallowance was the result of "political" efforts to unseat that official, *id.* at 7 n.9. However, as West Virginia recognizes, *id.* at 7, issues of politics and motive are irrelevant to our inquiry. Our proper inquiry is to determine

(continued...)

decide whether the facts (as shown by the documentary evidence in the parties' appeal files) and law support CMS's determination that the Medicaid program – and hence the federal government – was entitled to a share of the OxyContin settlement proceeds. If so, we must then decide whether the amount of the settlement proceeds that CMS attributed to Medicaid (and used to calculate the disallowance amount) was reasonable. We address these issues in turn.

1. *The federal government was entitled to a share of the OxyContin settlement proceeds.*

We conclude that the federal government was entitled to a share of the OxyContin settlement proceeds under either section 1903(d)(2) of the Act, 1903(d)(3) of the Act, or OMB Circular A-87's provision regarding applicable credits.⁹ Before discussing our reasons for this conclusion, we note that the parties' arguments on appeal are inextricably linked to what DHHR calls the plaintiffs' two "theories of damage" – that is, (1) the underlying lawsuit's claim for reimbursement of OxyContin prescription costs, and (2) the lawsuit's claim for reimbursement of substance abuse treatment expenditures. Because these theories provide the foundation or framework for our legal analysis, we organize our discussion around them.

- a. Pursuant to sections 1903(d)(2) and 1903(d)(3) of the Act, the federal government is entitled to a share of the OxyContin settlement proceeds that the State received to resolve claims for reimbursement of Medicaid expenditures on OxyContin.

Under Count I of the amended complaint, the plaintiffs sought "restitution and reimbursement sufficient to cover all prescription costs the State has incurred related to OxyContin due to defendants' wrongful conduct[.]" WV Ex. 9 ¶ 54.A. (emphasis added). In support of that request, the amended complaint alleged that as a result of the defendants'

⁸(...continued)

whether the facts and law support the disallowance, and that is the inquiry we make in this decision.

⁹ Because these provisions provide sufficient legal authority for CMS's determination that the federal government was entitled to a share of the OxyContin settlement proceeds, we do not address whether that determination was proper under the other statutory provisions cited by CMS in this appeal.

"inappropriate marketing" of OxyContin, that drug was "inappropriately prescribed, unnecessarily putting people at risk of addiction." Id. ¶ 30. The amended complaint further alleged that DHHR had incurred "excessive and unnecessary" expenses because "Medicaid recipients" had been "inappropriately and unnecessarily prescribed OxyContin." Id. ¶ 36.

It is clear from these passages that, under count I, the plaintiffs sought reimbursement for Medicaid expenditures on OxyContin. DHHR does not deny this, yet it maintains that there is no connection between the claim for reimbursement and the settlement because the plaintiffs in fact had "no evidence to differentiate between OxyContin prescriptions that were medically necessary and those that weren't." WV Br. at 6 n.5. In this vein, DHHR further contends:

[W]hen push came to shove, the State had no evidence to prove that any of its prescription costs were either excessive or unnecessary because it had no doctor witnesses who would so testify. The defendants could have been the worst tortfeasors in the world, but if their product was prescribed by physicians acting in good faith, for DHHR, PEIA or BEP recipients who needed the product and benefitted from it, the State had no theory on which to claim an entitlement to reimbursement for every prescription of OxyContin.

Id. (emphasis added); see also Reply Br. at 3 (asserting that it was "probable" that the reimbursement claim under count I "would have been struck at the conclusion" of the plaintiffs' case-in-chief had the case gone to trial). Because the Medicaid reimbursement claim under count I was not viable, says DHHR, none of the settlement proceeds can or should be attributed to that claim. Id. at 5-6.

We find this argument unpersuasive. Whatever the actual strength of the plaintiffs' reimbursement claim under count I, that claim remained alive at the time of the settlement and was released in partial consideration for the defendants' payment of \$10 million. Thus, the claim was part of the settlement.

Furthermore, CMS points to evidence that the plaintiffs did not, during the underlying litigation, regard the lack of evidence of medical necessity as fatal to count I's reimbursement claim. The amended complaint expressly sought reimbursement for "all prescription costs the State" had incurred. WV Ex. 9, ¶ 54.A. Furthermore, the plaintiffs suggested in pre-trial legal arguments that they were not obligated to prove that any

particular Medicaid expenditures were "unnecessary" or "excessive." In an August 2004 legal memorandum, the plaintiffs asserted:

Contrary to [the defendants'] assertions, . . . the plaintiffs' claims do not hinge on whether any particular patient became addicted to OxyContin or even whether any particular patient's prescription for OxyContin was "appropriate," as the Purdue Defendants may choose to define that term.

. . . .

. . . In this case, as a result of the deceptive practices of the defendant in marketing its product, the plaintiffs actually incurred substantial expense just by paying for the product itself. Therefore, even if no one who took Oxycontin was actually harmed by it (and clearly the plaintiffs do not concede this point), the plaintiffs were directly harmed by the aggressive and deceptive marketing scheme which resulted in over prescription of the drug.

CMS Ex. 34, at 2-3 (emphasis added). The plaintiffs further stated:

[I]n order to establish an "ascertainable loss" Plaintiffs need only show that the aggregate OxyContin they purchased did not conform or "measure up" to the false and deceptive marketing claims made by defendants. Since all OxyContin dispensed in the State of West Virginia was sold by Defendants in the course of the marketing campaign of which these deceptive acts and omissions were part and parcel, this defines the "ascertainable loss" under the statute. In short, defendants represented OxyContin as a less addictive opioid medication which provides continuous and sustained twelve hour analgesia with less potential for abuse than other opioids. This is not the case. As such, the plaintiffs are entitled to the full range of remedies under the statute, including but not limited to recovery of the monies paid by the state and restitutionary relief. . . .

Id. at 5 (emphasis added). In short, the plaintiffs argued that they were entitled to reimbursement of Medicaid's OxyContin expenditures not because they were excessive, medically unnecessary, or otherwise unallowable with respect to particular

patients, but because the drug failed to "measure up" to the defendants' marketing claims. In view of these representations during the litigation, we reject DHHR's assertion that the plaintiffs "had no theory on which to claim an entitlement to reimbursement for every prescription of OxyContin."

We thus conclude that the State received funds to resolve a claim for reimbursement of Medicaid expenditures on OxyContin. To the extent that those expenditures were unallowable (by virtue of being "excessive" or medically "unnecessary"), a portion of the settlement funds represents a recovery of overpayments. An overpayment in this sense means that the state Medicaid program has made expenditures for medical items or services, such as prescription drugs, that were not "allowable" as "medical assistance." 42 C.F.R. § 433.304 (definition of "overpayment"). The Board has held that "excess or improper payments" are not "medical assistance" within the meaning of sections 1903(a)(1) and 1905(a) of the Act.¹⁰ Utah Dept. of Health, DAB No. 1307, at 3 (1992) (citing cases). When a state's Medicaid program has made payments to providers that do not qualify as medical assistance, and has obtained FFP in those payments, "the state has received an overpayment of FFP, which is properly adjusted under section 1903(d)(2)(A) of the Act." New Jersey Dept. of Human Resources, DAB No. 1046, at 6 (1989). Thus, to the extent the settlement proceeds obtained by the State represent a recovery of unallowable Medicaid expenditures for which FFP was provided, CMS was authorized to recoup a share of those proceeds under section 1903(d)(2)(A).

To the extent that all or part of the Medicaid expenditures embraced by count I's reimbursement claim were allowable Medicaid expenditures – i.e., medical assistance – section 1903(d)(3) provided CMS with the necessary legal authority to take a disallowance. Section 1903(d)(3) permits CMS to recoup, as an overpayment of FFP, its "equitable share" of the amount "recovered . . . by the State . . . with respect to medical assistance furnished under the State plan[.]" This provision "applies in instances . . . where a State has recouped benefits that have been correctly paid to recipients," and the Board has held that the types of "recoveries" covered by section 1903(d)(3) are "not qualified in any way." Massachusetts Dept. of Public Welfare, DAB No. 1288, at 5 n.2 (1991).

¹⁰ OMB Circular A-87 provides that a program expenditure may not be charged to a federal award unless it is "necessary and reasonable for proper and efficient performance and administration" of the award. 2 C.F.R. Part 225, App. A, ¶ C.1.a.

As we have determined, the plaintiffs were, at the time of settlement, pursuing count I's claim for reimbursement of allowable Medicaid expenditures on OxyContin. As part of the settlement, the plaintiffs released that claim (and others) in exchange for a monetary payment by the defendants. Given this clear and substantial connection between the reimbursement claim and the settlement, we find that the State's receipt of the settlement proceeds constituted a "recover[y] . . . by the State . . . with respect to medical assistance." Consequently, CMS was authorized to obtain the federal government's "equitable share" of the recovery that relates to count I of the amended complaint.

- b. Pursuant to section 1903(d)(3) of the Act, the federal government is entitled to a share of the OxyContin settlement proceeds that the State received to resolve claims for reimbursement of Medicaid expenditures on substance abuse treatment.

Section 1903(d)(3) applies in the same way to the plaintiffs' second "theory of damage," which was based on an allegation that defendants' misconduct had resulted in West Virginia residents becoming addicted to OxyContin. WV Ex. 9 ¶ 30. In pursuing that theory, the plaintiffs demanded "reimbursement" for "all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use, including but not limited to addiction[.]" *Id.* ¶ 62.B. CMS has submitted evidence that Medicaid covered, or may have covered, some of these costs and that the plaintiffs were in fact seeking reimbursement for Medicaid expenditures under count II. For example, CMS submitted a portion of West Virginia's state Medicaid plan, which indicates that, as of August 1, 2001, the West Virginia Medicaid program covered "medical" or "remedial" services for "individuals with conditions associated with . . . substance abuse and/or drug dependency." CMS Ex. 41. CMS also submitted a DHHR publication entitled *Healthy People*, which indicates that \$6,600,000 in Medicaid funds is spent annually in West Virginia on substance abuse and treatment and related services. CMS Ex. 46. In addition, CMS furnished a Substance Abuse and Mental Health Services Administration (SAMHSA) publication entitled *Mental Health and Substance Abuse Services in Medicaid and SCHIP in West Virginia*.¹¹ CMS Ex. 53. This publication outlines the substance abuse services covered by West Virginia's Medicaid program as of July 2003. *Id.*

¹¹ This document was obtained from the following SAMHSA website address: http://mentalhealth.samhsa.gov/Publications/allpubs/State_Med/West_Virginia.pdf.

Finally, CMS introduced deposition testimony of Merritt Moore, the Adult Treatment Coordinator for West Virginia's Bureau for Behavioral Health Services' Division on Alcoholism & Drug Abuse, who, according to litigation papers filed by the plaintiffs, played a role in estimating the State's "damages" under count II. See CMS Ex. 44, at 2. Moore testified in relevant part:

Q. What are the patients at these facilities . . . What I'm really trying to find out is, are the patients at – let's use the residential facility first – under the Medicaid program or under other programs?

A: They would have a variety of funding sources. Some would have a medical card that would pay for their treatment. Many would be indigent, with no funding source; and our block grant funds would be used to pay for their treatment.

. . . .

Q: You have also referred to medical cards that patients may have to pay for treatment. Can you explain what you mean by that?

A: A Medicaid card through the Bureau of Medical Services, which many of those are women with children.

CMS Ex. 45 (Transcript at 66-67). In short, Moore indicated that Medicaid does pay for some substance abuse treatment in West Virginia.

During the pre-settlement litigation, the plaintiffs asserted that DHHR's Bureau for Behavioral Health, which administers the State's drug and alcohol abuse programs, had spent \$2 million annually since 1996 on "detoxification and in-patient substance abuse treatment[.]" WV Ex. 11, at 10-11. DHHR now asserts that "no expenditures of DHHR having anything to do with Medicaid Federal Financial Participation Funds" were at issue under its second damages theory. WV Br. at 7. However, DHHR presented nothing to rebut CMS's evidence of Medicaid's involvement in financing substance abuse treatment in West Virginia, nor did it point to any representations or concessions by the plaintiffs during the underlying litigation that their claim for reimbursement under count II excluded Medicaid expenditures. Moreover, DHHR's current statements on this issue are equivocal. DHHR asserts, on one hand, that no Medicaid expenditures were at issue, WV Brief at 7, but then indicates that "[m]ost if not all DHHR Behavior Health Service detox and treatment programs utilize

non-Medicaid funding streams," WV Reply Brief at 5 (emphasis added). The "most-if-not-all" formulation seemingly acknowledges the possibility that Medicaid dollars paid for some substance abuse treatment services for which the State was claiming reimbursement under count II. As noted, that count expressly sought reimbursement for all of the plaintiffs' costs – which by definition include any Medicaid-financed costs incurred by plaintiff DHHR – of diagnosing and treating adverse consequences of OxyContin use.

DHHR asserts that its second damage theory was based on "estimates of past and future expenditures," not on "documentation" of "actual expenditures or the funding streams from which those expenditures were or would be made." Reply Br. at 5. We do not see how this statement helps DHHR. The statement merely suggests that its claim for damages would be proved by "estimates" of past or future expenditures. The use of such estimates does not, in itself, prove that the scope of count II's reimbursement claim was limited to non-Medicaid expenditures. Moreover, the fact that the State was relying on estimates, rather than "documentation," does not mean that the plaintiffs were not seeking reimbursement for actual Medicaid expenditures.¹²

In short, we find that, at the time of settlement, the plaintiffs were pursuing a claim for reimbursement of allowable Medicaid expenditures on substance abuse treatment. As part of the settlement, the plaintiffs released that claim (and others) in exchange for a monetary payment by the defendants. Given this clear and substantial connection between count II's reimbursement claim and the settlement, we find that the State's receipt of the settlement proceeds constituted a "recover[y] . . . by the State . . . with respect to medical assistance" for OxyContin-related substance abuse treatment. Consequently, CMS was authorized under section 1903(d)(3) to claim the federal government's "equitable share" of the recovery that relates to count II of the amended complaint.¹³

¹² We do not understand DHHR's assertion that the plaintiffs were seeking to recover "future" expenditures under count II to mean that the plaintiffs were seeking to recover any OxyContin-related treatment expenditure that might occur after the conclusion of the litigation. The damages claim in question was for "reimbursement" of costs "expended," implying that it covered expenditures that had already occurred.

¹³ On remand, West Virginia may seek to establish that an allocation of settlement proceeds to Medicaid based on count II

- c. The federal government is entitled to a share of the OxyContin settlement proceeds that the State received to resolve claims for reimbursement of Medicaid expenditures on OxyContin and treatment for OxyContin addiction because those proceeds constitute "applicable credits."

OMB Circular A-87 requires a federal award recipient to provide the federal government with its share of any "applicable credits," which are "receipts or reduction of expenditure-type transactions that offset or reduce expense items allocable to Federal awards as direct or indirect costs." 2 C.F.R. Part 225, App. A, ¶ C.4.a. If the award recipient obtains funds that offset or reduce an expense item allocable to the federal award, then the recipient must share that cost reduction with the federal government. Maine Dept. of Health and Human Services, DAB No. 2168, at 10 (2008).

We have held that a "common theme in cases where states have had to account for applicable credits is the receipt of monies (or reductions of expenditures) by a state related to its federally funded program which, if unaccounted for in the program, would result in a savings or gain to the state alone." Maine Dept. of Health and Human Services at 6 (citations and internal quotation marks omitted). A receipt of funds is "applicable" to a program expenditure "when there is a direct relationship or nexus between the questioned receipt and the federally-funded program." Id. The Circular provides examples of applicable credits, see infra footnote 3, but we have stated that the "determination of whether funds received by a grantee constitute applicable credits should not turn on whether the grantee, in describing the funds, has or has not utilized words in the list of examples of applicable credits provided at OMB A-97." Oregon Dept. of Human Resources, DAB No. 1298, at 9 (1992). Examples of funds the Board has found to be applicable credits include interest received by a state on federal funds, fees or income generated by federally funded activities, discounts and refunds received by a grantee as a result of the expenditure of federal funds, unused or excessive federal funds received by grantee, and reimbursement for costs a state receives from another federal program. Id. at 10.

¹³(...continued)

should be limited given the level of Medicaid's involvement in financing OxyContin-related substance abuse services relative to the involvement of other funding sources. At this moment, we decide only that count II's reimbursement claim provides a basis for distributing some "equitable" share of the settlement proceeds to Medicaid.

We agree with CMS that the settlement proceeds satisfy the criteria for being an applicable credit. There is, of course, a clear and "direct relationship or nexus" between those funds and the State's federally funded Medicaid program because the State obtained the funds to settle claims for reimbursement of that program's expenditures. Given that relationship, there is a sufficient basis for finding that receipt of the settlement proceeds effectively reduced the State's overall costs of providing Medicaid-covered medical or health services (such as prescription drugs and substance abuse treatment) to Medicaid recipients. Absent a disallowance, that cost reduction or savings would accrue to the State alone.

In its reply brief, DHHR states that it "agrees that if any part of the OxyContin settlement had been for reimbursement of DHHR's Medicaid expenditures, the [settlement proceeds] would be an applicable credit." Reply Br. at 24 (emphasis added). In the previous section, we found that the OxyContin settlement proceeds were in fact paid to resolve reimbursement claims for Medicaid expenditures. Since we have answered in the affirmative the premise of DHHR's statement, we find that DHHR has conceded that there is a legal basis for treating the settlement proceeds as applicable credits.

For the reasons above, we conclude that the OxyContin settlement proceeds received by the State were applicable credits that reduced the State's costs of medical assistance for which the State had claimed FFP. That cost reduction must be shared with the federal government.

d. DHHR's other contentions lack merit.

We have considered but rejected all of DHHR's other contentions, two of which we mention here. DHHR suggests that no part of the settlement may be regarded as being related to the plaintiffs' claim for reimbursement of OxyContin prescription costs because the "defendants didn't want to settle the reimbursement claims; rather, they wanted to get some positive 'P.R.' by settling the claims for prospective relief, thereby funding some worthy programs and getting some good press." WV Br. at 12. DHHR presented no evidence of the defendants' intentions or motives in agreeing to settle the lawsuit. Such evidence would not, in any event, persuade us to overturn the disallowance because it would conflict with the settlement agreement's express terms, which indicate that the settlement released "any and all" of the lawsuit's outstanding claims, which included the reimbursement claims under counts I and II of the amended complaint.

DHHR suggests that it was improper for CMS to claim a share of the settlement proceeds for the Medicaid program if, as DHHR asserts, no part of those proceeds were directly received by the state Medicaid agency but, instead, were paid into the Consumer Protection Fund of the Office of the West Virginia Attorney General.¹⁴ WV Br. at 19. We reject that suggestion. "The Board has long held that a state as a whole must be viewed as a single unit responsible for the administration of federal grant programs and funds." Alabama Dept. of Human Resources, et al., DAB No. 1989, at 22 (2005). Thus, it does not matter which state agency received the settlement proceeds, or that the proceeds have already been used for non-Medicaid purposes. CMS was authorized to disallow FFP if it properly determined (as we find that it did) that the Medicaid program must be credited with a share of settlement proceeds received by any state agency. As discussed in the previous sections, the plaintiffs' two theories of damage provide a basis for distributing a share of the settlement proceeds to the Medicaid program pursuant to section 1903(d)(2) of the Act, section 1903(d)(3) of the Act, and OMB Circular A-87.

DHHR asserts that "CMS waited two and one-half years before instituting any action to pursue its Disallowance, which resulted in severe prejudice" to the State. WV Br. at 22. It asserts that almost all of the settlement proceeds were spent before the State was notified of the disallowance, and that "[h]ad CMS raised the issues set forth in the Notice of Disallowance within a reasonable time after settlement of the underlying lawsuit, DHHR could have taken steps to protect its interests." Id. DHHR also asserts that CMS "based its disallowance on the bare allegations" of the amended complaint "without any consideration of what happened after that Complaint was filed; without any attempt to discuss the case with the attorneys who tried it; and without any analysis of the governing statutes and regulations." Id. at 23. DHHR asserts that "CMS has an absolute duty to do at least some reasonable investigation before it issues a disallowance; it cannot, as a matter of law, simply assume that the bare allegations of a Complaint contain all the information necessary for it to swoop down and take \$4,143,075.00 from the Medicaid account of one of the poorest states in this country."

¹⁴ DHHR appears to disavow this suggestion in its reply brief, saying that it "is not claiming immunity from disallowance because ' . . . it ha[s] secreted [DHHR's] funds in some other state account.'" Reply Br. at 14. Rather, says DHHR, the settlement should be viewed as having no relationship to the two damage theories because they in fact lacked viability. Id. DHHR also acknowledges that it received \$250,000 from the settlement proceeds in the Consumer Protection Fund which DHHR spent on certain law enforcement and education programs. WV Br. at 19.

Id. Given these and other circumstances, says DHHR, it "would be completely inequitable" to permit a disallowance. Id. at 22.

This claim for equitable relief is not a proper basis for overturning a disallowance because the Board lacks authority to grant such relief. Utah Dept. of Health, DAB No. 2131, at 23 (2007); see also Juniata County Child Care and Development Services, Inc., DAB No. 2089, at 5 (2007) ("[T]he burden of financial hardship which repayment might cause the grantee is not relevant to our consideration of whether grant costs are allowable."). The Board is bound by applicable statutes and regulations, which contain no statute of limitations or other time limit on the issuance of Medicaid disallowances. 45 C.F.R. § 16.14; 42 C.F.R. § 430.42. We must uphold a disallowance if it is supported by the evidence submitted and is consistent with the applicable statutes and regulations. 45 C.F.R. §§ 16.14, 16.21. We conclude that the disallowance satisfies those criteria.

In any event, we find the claim for equitable relief less than compelling in light of West Virginia's own conduct. In a letter dated June 5, 2007, West Virginia Deputy Attorney General Frances Hughes stated:

The Oxycontin settlement was purposely structured to avoid CMS taking a majority of the money. The complaint was brought on behalf of not only PEIA, Medicaid and Workers' Compensation, but also on behalf of all consumers who have been victimized by Purdue Pharma's unlawful activities. CMS has no viable claim to the Oxycontin settlement moneys because of how the settlement was structured. . . . While we appreciate [that] there has been a difference of opinion concerning the distribution of this money, we believe that the way the settlement was structured greatly enhances West Virginia's position and minimizes the chances that CMS will be able to receive any of this money.

CMS Ex. 11. These comments – and the State's efforts to "structure" the settlement – indicate that the State was aware when it settled the OxyContin lawsuit of (1) the federal government's potential financial interest in the settlement, and (2) the possibility that CMS might in the future lay a claim to a share of the settlement proceeds. Confident in its legal position, the State proceeded to spend the settlement funds without (it appears) consulting with CMS. In spending those funds, the State assumed a calculated risk that CMS would reject its legal position and successfully pursue a disallowance. We see nothing unfair about allowing the State to bear the

consequences of running that risk.

2. *CMS has not articulated a sufficient basis for upholding the amount of the disallowance.*

According to the August 7, 2007 notice of disallowance, CMS calculated the disallowance amount by first "equitably distributing" \$5.55 million of the \$10 million in OxyContin settlement proceeds to the Medicaid program. WV Ex. 1. However, the disallowance notice did not describe in any significant detail how or on what basis the so-called equitable distribution was actually made, other than to say it was based on paragraphs 35-42 of the amended complaint and that CMS took into account the fact that three state agencies were named as plaintiffs in the lawsuit. *Id.* Most notably, the notice does not explain why more than one-half of the settlement proceeds were distributed to Medicaid when there were two other named plaintiffs – as well as other, non-Medicaid health programs (e.g., programs administered by DHHR's Bureau for Behavioral Health) – on whose behalf the plaintiffs sought "reimbursement."

CMS's appeal brief is similarly unilluminating: it states only that CMS made "best efforts" using the available information to make the allocation. CMS Response Br. at 11 n.33. Moreover, CMS concedes that it did not take into account the fact that the plaintiffs' attorneys fees and expenses were paid out of the settlement proceeds. *See* CMS Ex. 9. Given these circumstances, we conclude that the allocation of \$5.55 million to Medicaid appears unreasonable on its face and that CMS has not articulated a sufficient basis for upholding the amount of the disallowance.

Apparently anticipating that conclusion, CMS indicates that it is prepared to "reassess" the amount of the disallowance based on any "sound evidence" that the State may provide.¹⁵ Response Br. at 40, 52. Given CMS's apparent willingness to revisit and consult with DHHR on this issue, we remand the case to CMS to recalculate the disallowance. On remand, CMS shall give DHHR a reasonable opportunity to submit additional evidence and argument about what would constitute an appropriate or equitable distribution of the OxyContin settlement proceeds to Medicaid.

¹⁵ CMS indicates that it is also prepared to consider evidence "demonstrating error with respect to [its] analysis" regarding its right to recover settlement proceeds on third party liability grounds. *Id.* at 52. As noted, we have concluded that CMS is entitled to recover some share of the settlement proceeds based on statutory provisions other than the Act's third party liability provisions (i.e., section 1903(a)(25)) and, therefore, have reached no conclusions on the third party liability issue.

After considering the State's submissions (and assuming there is no voluntary settlement of this dispute), CMS may issue a revised disallowance determination. That revised determination should explain the criteria and methods used by CMS to calculate the disallowance amount. If dissatisfied with the revised determination, DHHR may appeal to the Board in accordance with the procedures in 45 C.F.R. Part 16.

Conclusion

In this decision, we uphold CMS's determination that the federal government was entitled to an appropriate or equitable share of the funds received by the state of West Virginia pursuant to the Settlement Agreement and Release in State of West Virginia ex rel. Darrell V. McGraw, Jr., et al. v. Purdue Pharma, L.P., et al. We do not, however, uphold CMS's determination that the federal government's appropriate or equitable share was \$4,143,075. Accordingly, we remand this case to CMS for further action consistent with this decision.

_____/s/
Judith A. Ballard

_____/s/
Leslie A. Sussan

_____/s/
Sheila Ann Hegy
Presiding Board Member