UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 09-7097 CAS (MANx)	Date	December 22, 2009
Title	NATIONAL ASSOCIATION OF CHAIN DRUG STORES; ET AL. v. ARNOLD SCHWARZENEGGER; ET AL.		

Present: The Honorable	CHRISTINA A. SNYDER, U.S. DISTRICT JUDGE	
PAUL PIERSON	NOT PRESENT	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: **DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT** (filed 11/20/09)

I. INTRODUCTION

On September 30, 2009, plaintiffs, the National Association of Chain Drug Stores ("NACDS") and the National Community Pharmacists Associations ("NCPA"), filed the instant action. On October 2, 2009, plaintiffs filed an amended complaint ("FAC") against defendants Arnold Schwarzenegger, Governor of the State of California; Kim Belshe, Secretary of the California Health and Human Services Agency; David Maxwell-Jolly, Director the California Department of Health Care Services; and the California Department of Health Care Services (the "Department"). The Department is a California agency charged with the administration of California's Medicaid program, Medi-Cal. Plaintiffs represent certain Medi-Cal pharmacy providers.

Plaintiffs seek to enjoin defendants from "reducing by, on average, slightly more than four percent (4%) Medicaid reimbursement based on Average Wholesale Price ("AWP") for drug products paid to pharmacies for dispensing prescription drugs reimbursed" by Medi-Cal (the "AWP reductions"). FAC at 2. Plaintiffs allege that implementation of the AWP reductions violates § 30(A) of the Social Security Act, 42 U.S.C. § 1396a(a)(30)(A) ("§ 30(A)"), because the Department failed to consider the "quality of care" and "equal access" provisions of § 30(A), and that therefore, it is invalid under the Supremacy Clause of the United States Constitution. U.S. CONST. art. VI, cl. 2. Plaintiffs further allege, and seek declaratory judgment, that the Department failed to comply with additional requirements of federal law, state regulations, and the state plan. Specifically, plaintiffs allege that the Department failed to (1) "set payment rates at such a level to ensure that sufficient providers" enlist, pursuant to 42 C.F.R. § 447.204; (2)

obtain approval of this "State Plan amendment" from the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services ("CMS"), pursuant to 42 C.F.R. § 430.12(c); (3) give adequate notice or obtain public comment, as required by 42 C.F.R. § 447.205; and (4) make a finding or determination that the reimbursement rate, after the AWP reduction, represents the best estimate of acquisition cost, pursuant to 42 C.F.R. § 447.333; and (5) to administer Medi-Cal in compliance with federal regulations and the California State Plan, pursuant to 22 C.C.R. § 50004(b). FAC ¶¶ 42-47.

On December 7, 2009, the Court held a hearing on plaintiffs' motion for preliminary injunction, filed November 2, 2009. At the hearing, the United States Department of Justice ("DOJ") appeared regarding its Statement of Interest filed on December 4, 2009. On December 22, 2009, the Court denied plaintiffs' request for preliminary injunction.

On November 20, 2009, defendant filed the instant motion to dismiss the FAC. Plaintiffs filed their opposition on November 30, 2009. A reply was filed on December 7, 2009. On December 11, 2009, the Court took the matter under submission and vacated the hearing. After carefully considering the arguments set forth by both parties, the Court finds and concludes as follows.

II. BACKGROUND

Medicaid is a cooperative federal program: the federal government provides federal funding to the states so that states may provide medical care to their needy citizens. State participation is voluntary; however, once a state chooses to participate by accepting federal funds, it must comply with requirements imposed by the Medicaid Act. Because California has elected to participate in the Medicaid program, it must administer its state Medicaid program, Medi-Cal, in compliance with a state plan that has been pre-approved by the Secretary of the U.S. Department of Health and Human Services (the "Secretary"), and which complies with the requirements set forth in 42 U.S.C. § 1396a(a)(1)-(70). In accordance with these requirements, California must provide "methods and procedures" for the payment of care and services that (1) are "consistent with efficiency, economy, and quality of care," and (2) ensure their availability to the Medicaid population to the same "extent as they are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A). These requirements are known,

respectively, as the "quality of care" and "equal access" provisions of § 30(A) of the Medicaid Act. Further, under California law, the Department must administer Medi-Cal in accordance with the state plan; applicable state law, as specified in sections 14000 to 14124 of the Welfare and Institutions Code; and Medi-Cal regulation. Cal. Code Regs. tit. 22, § 50004(b).

The subject of this case is pharmacy reimbursement in the Medicaid program. Medi-Cal reimburses pharmacies that dispense prescription drugs to patients covered by Medicaid. The department reimburses these pharmacies for the "estimated acquisition cost" of drugs along with a fixed dispensing fee per prescription. Cal. Welf. & Inst. Code § 14105.45(b)(1). Pursuant to the California state plan and state law, the reimbursement of drug costs is based on the lesser of four alternatives: (1) AWP minus 17%; (2) the selling price; (3) the federal upper limit; or (4) the maximum ingredient cost ("MAIC"). Id. § 14105.45(b)(2).

In the instant action, plaintiffs challenge an alleged 4% reduction in reimbursements tied to the AWP, which is the "price for a drug product listed as the average wholesale price in the department's primary price reference source." The Department uses First DataBank, Inc. ("First DataBank"), a drug pricing publisher, as its primary price reference source for determining the AWP. On March 17, 2009, as part of a class action settlement in a separate lawsuit, First DataBank agreed to reduce the mark-up of 1.25 over the wholesale acquisition cost ("WAC") to 1.20 over WAC, when setting the AWP for approximately 1,400 drug products.[1] See New England Carpenters Health Benefits Fund v. First DataBank, Inc., 602 F. Supp. 2d 277 (D. Mass. 2009) (approving the settlements). The settlement agreements were affirmed by the First Circuit on appeal. See 582 F.3d 30 (1st Cir. 2009). Plaintiffs allege that First DataBank also voluntarily reduced the markup to 1.20 over WAC when setting the AWP for approximately 18,000 additional drug products, where the mark-up previously exceeded 1.20. FAC ¶ 25. Implementation of these AWP reductions occurred on September 26, 2009. Plaintiffs

[1] The AWP figure is usually derived by applying a multiplier to the wholesale acquisition cost ("WAC"). See Nat'l Ass'n of Chain Drug Stores v. New England Carpenters Health Benefits Fund, 582 F.3d 30, 36-37 (1st Cir. 2009) (providing a background to drug pricing and the controversy in the underlying case).

contend that the practical effect of these reductions is that the reimbursement for drug products tied to AWP has been reduced by slightly more than 4%. FAC ¶ 26.

III. MOTION TO DISMISS

Defendants move to dismiss plaintiffs' FAC on the grounds that plaintiffs fail to satisfy the "case or controversy" requirements of Article III constitutional standing, and in any event, fail to state a claim for relief.[2] Defendants' arguments are considered in turn.

A. Constitutional Standing

1. Legal Standard

In order to establish standing to assert a claim, a plaintiff must do the following: (1) demonstrate an injury in fact, which is concrete, distinct and palpable, and actual or imminent; (2) establish a causal connection between the injury and the conduct complained of; and (3) show a substantial likelihood that the requested relief will remedy the alleged injury in fact. See McConnell v. Federal Election Comm'n, 540 U.S. 93, 225-26 (2003).

Because standing relates to a federal court's subject matter jurisdiction under Article III, it is properly raised in a motion to dismiss under Fed. R. Civ. P. 12(b)(1), not Rule 12(b)(6). White v. Lee, 227 F.3d 1214, 1242 (9th Cir. 2000). The Ninth Circuit has noted a distinction between facial and factual jurisdictional attacks under Rule 12(b)(1).

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[2] Defendants request that the Court take judicial notice of nine filings with the Court, including sections of Cal. Welf. & Inst. Code, and court filings in First DataBank and related matters. Under Fed. R. Evid. 201, a court may take judicial notice of "matters of public record." Mack v. South Bay Beer Distrib., 798 F.2d 1279, 1282 (9th Cir. 1986). As such, judicial notice is proper insofar as judicial notice is taken that these nine court filings were made. The Court GRANTS defendants' request.

White, 227 F.3d at 1242 ("Rule 12(b)(1) jurisdictional attacks can be either facial or factual."). "Where the motion presents a facial jurisdictional attack -- that is, where the motion is based solely on the allegations in the complaint -- the court must accept these allegations as true. Where, however, the challenge is factual -- where it is based on extrinsic evidence, apart from the pleadings -- the court may resolve factual disputes in order to determine whether it has jurisdiction." Nat'l Licensing Ass'n, LLC v. Inland Joseph Fruit Co., 361 F. Supp. 2d 1244, 1247 (E.D. Wash. 2004) (citing Roberts v. Corrothers, 812 F.2d 1173, 1177 (9th Cir. 1987)). The court, however, may not resolve these disputes "'if issues of jurisdiction and substance are intertwined,' that is, if the jurisdictional question is dependent on the resolution of factual issues going to the merits." Id. (quoting Roberts, 812 F.2d at 1177).

"It is the responsibility of the complainant clearly to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute and the exercise of the court's remedial powers." Warth v. Seldin, 422 U.S. 490, 518 (1975). "For the purposes of ruling on a motion to dismiss for want of standing, both the trial and the reviewing courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party." Id. at 501; Takhar v. Kessler, 76 F.3d 995, 1000 (9th Cir. 1996). "At the same time, it is within the trial court's power to allow or to require the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of plaintiff's standing. If, after this opportunity, the plaintiff's standing does not adequately appear from all materials of record, the complaint must be dismissed." Warth, 422 U.S. at 501-02.

2. Discussion

Defendants contend that plaintiffs lack constitutional standing because they cannot plead "injury in fact." Mot. at 9. They argue that because the AWP reductions resulted from a class action settlement in First DataBank, a matter in which defendants were not a party, that there is no casual connection between any reduction in Medi-Cal reimbursement based on readjusted AWPs and any action by defendants. Id.; Reply at 3. They further argue that because plaintiffs were members of the class in First DataBank, they are bound by the express terms of the settlement, including the 4% readjustment of the AWP, and thus the action is moot. Mot. at 9-10; Reply at 4-5. Moreover, defendants contend that the principle of non-mutual collateral estoppel bars plaintiffs from

attempting to relitigate the issue of whether the 4% readjusted AWP adequately reflects the actual average wholesale price.[3] Mot. at 10-11. Finally, defendants argue that the alleged injury is not redressable because the published AWP is "beyond the control of the parties to this action," and the federally approved Medi-Cal State Plan requires the Department to use the readjusted AWPs in the methodology for determining reimbursement. Id. at 11-12.

Plaintiffs respond that they have standing to seek injunctive and declaratory relief under the Supremacy Clause, to enjoin implementation of preempted state legislation.[4] Opp'n at 4. Plaintiffs argue that they clearly allege "injury in fact" and a "redressable" injury. Id. at 5. Namely, they allege that as a result of defendants' reimbursement reductions, Medi-Cal now reimburses NACDS and NCPA members below their breakeven cost for many prescription drugs and that this may result in members discontinuing participation in the Medi-Cal program. Id. at 5-6. Furthermore, plaintiffs argue that the Court has authority to order defendants to comply with section 30(A)'s requirements, and thus remedy this injury. Id. As for defendants' collateral estoppel argument, plaintiffs contend that the settlement in First DataBank does not bar plaintiffs in this matter for two reasons: (1) the cases present entirely different claims and the issues

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[3] In support of this argument, defendants assert that the settlement agreement in First Databank noted that the underlying class complaint was filed because "First DataBank, wrongly increased the so-called WAC to AWP markup factor applied to numerous prescribed pharmaceuticals through a scheme begun in 2001 and 2002, thereby causing members of the proposed Private Payer Class, whose payments for pharmaceuticals are tied to the published AWP, to make substantial excess payments to those pharmaceuticals." Mot. at 10-11; Def.'s RJN, Ex. 6 (Settlement Agreement).

[4] Plaintiffs allege that defendants failed to comply with the meet and confer requirements of Local Rule 7-3 before filing the instant motion. Opp'n at 3. Defendants respond that immediately after plaintiffs filed their FAC, defendants communicated their intent to file a responsive pleading no later than November 20, 2009. Reply at 1. Despite these alleged procedural deficiencies, the Court considers the motion. However, the Court admonishes all parties that they must comply with the Local Rules of Court in the future.

are not identical;[5] and (2) only one of the plaintiffs, NACDS, was a party in the First DataBank case and the other plaintiff NCPA cannot be barred from asserting its rights. Id. at 8-11.

The Court finds that plaintiffs have standing to pursue this action. In so far as plaintiffs allege that their member pharmacies suffer a direct pecuniary loss resulting from defendants reducing Medicaid reimbursements, without first making certain findings required by section 30(A), plaintiffs sufficiently allege an injury in fact.[6] See Indep. Living Ctr. of S. Cal., Inc. v. Shewry, 543 F.3d 1050, 1065 (9th Cir. 2008) (citing Craig v. Boren, 429 U.S. 190, 194-95 (1976), for the principle that direct economic injuries establish the threshold requirements of Article III standing). In addition, the Court finds that the alleged injury would be redressed in the event that this Court were to enjoin defendants from implementing the September 26, 2009 markdown of AWPs, when providing reimbursements based on AWP. In addition, the Court concludes that the First DataBank settlement may not be accorded collateral estoppel effect in the instant case. As the Ninth Circuit recently noted, "settlements generally do not bar claims against non-parties or have issue-preclusive effect (sometimes referred to as 'collateral estoppel') on the subsequent litigation of issues not expressly resolved in the settlement." Cell Therapeutics, Inc. v. Lash Group, Inc., 586 F.3d 1204, 1210 (9th Cir. 2009). Further, "settlement agreements generally preclude further litigation on the claims by and against parties to the initial settlement, but issue preclusion generally does not attach to a settlement agreement." Id. at 1211 (citing Arizona v. California, 530 U.S. 392 (2000)). The issues presented in this case are not identical to the issue in First DataBank; namely

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[5] Specifically, plaintiffs contend that the First DataBank action addressed whether First DataBank improperly inflated its reported AWP rates for a small set of drug products, whereas this action addresses whether defendants have met their obligations under state and federal law in administering Medi-Cal. Opp'n at 9.

[6] The analysis of Article III standing is "not fundamentally changed" by the fact that a plaintiff asserts a "procedural," rather than a "substantive" injury. See City of Sausalito v. O'Neill, 386 F.3d 1186, 1197 (9th Cir. 2004). In a "procedural injury" case: to show a cognizable injury in fact, plaintiff must allege that (1) the [agency] violated certain procedural rules; (2) these rules protect [a plaintiff's] concrete interests; and (3) it is reasonably probable that the challenged action will threaten their concrete interests. Id.

the issue of whether the State administers Medi-Cal in accordance with applicable federal and state law, was not resolved by the First DataBank settlement. Moreover, plaintiffs are challenging Medi-Cal reimbursement reductions resulting from changes in AWPs allegedly not covered by the terms of the settlement agreement.[7] Thus, the Court denies defendants' motion to dismiss the FAC on these grounds.

B. Legal Sufficiency of the Claims for Relief

1. Legal Standard

A Rule 12(b)(6) motion tests the legal sufficiency of the claims asserted in a complaint. "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level." Id. Stated differently, only a complaint that states a claim for relief that is "plausible on its face" survives a motion to dismiss. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009) (quoting Twombly, 550 U.S. at 570). "The plausibility standard is not akin to the 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id.

In considering a motion pursuant to Fed. R. Civ. P. 12(b)(6), a court must accept as true all material allegations in the complaint, as well as all reasonable inferences to be drawn from them. Pareto v. F.D.I.C., 139 F.3d 696, 699 (9th Cir. 1998). The complaint must be read in the light most favorable to the nonmoving party. Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001); Parks Sch. of Bus., Inc. v. Symington, 51 F.3d 1480, 1484 (9th Cir. 1995). However, a court need not accept as true unreasonable inferences or conclusory legal allegations cast in the form of factual allegations. Sprewell, 266 F.3d at 988; W. Mining Council v. Watt, 643 F.2d 618, 624 (9th Cir. 1981).

[7] According to plaintiffs, First DataBank voluntarily reduced the AWP for approximately 18,000 additional drug products. FAC ¶ 25.

Dismissal pursuant to Rule 12(b)(6) is proper only where there is either a "lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Balistreri v. Pacifica Police Dept., 901 F.2d 696, 699 (9th Cir. 1990).

Furthermore, unless a court converts a Rule 12(b)(6) motion into a motion for summary judgment, a court cannot consider material outside of the complaint (e.g., facts presented in briefs, affidavits, or discovery materials). In re American Cont'l Corp./Lincoln Sav. & Loan Sec. Litig., 102 F.3d 1524, 1537 (9th Cir. 1996), rev'd on other grounds sub nom Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26 (1998). A court may, however, consider exhibits submitted with or alleged in the complaint and matters that may be judicially noticed pursuant to Federal Rule of Evidence 201. In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 986 (9th Cir. 1999); Lee v. City of Los Angeles, 250 F.3d 668, 689 (9th Cir. 2001).

For all of these reasons, it is only under extraordinary circumstances that dismissal is proper under Rule 12(b)(6). United States v. City of Redwood City, 640 F.2d 963, 966 (9th Cir. 1981).

As a general rule, leave to amend a complaint which has been dismissed should be freely granted. Fed. R. Civ. P. 15(a). However, leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986); see Lopez v. Smith, 203 F.3d 1122, 1127 (9th Cir. 2000).

2. Discussion

Defendants move to dismiss the FAC, in its entirety, on the basis that plaintiffs fail to state a claim for relief as to each of their various claims for relief. Mot. at 13. In their first claim for injunctive relief, plaintiffs cite to other cases in which this Court preliminarily enjoined Medi-Cal reimbursement reductions, such as Indep. Living Ctr. of S. Cal., Inc. v. Shewry, Case No. CV 08-3316 CAS (MANx) and Managed Pharmacy Care v. Jolly, Case No. CV 09-0382 CAS (MANx). Defendants contend that those cases are distinguishable because the State conduct consisted of legislatively enacted rate reductions, and accordingly, those injunctions have no binding authority on this case and

the claim should be dismissed. Id. at 13-14. Defendants further contend that plaintiffs' claims for declaratory judgment, set forth in the second through sixth claims for relief, should be dismissed. As to the second claim, defendants argue that the reductions in AWP do not require public notice, pursuant to 42 C.F.R. § 447.205, because they do not constitute a significant change in "methods and standards."[8] Id. at 14. As for the third claim, in which plaintiffs allege that the State fails to "set payment rates at such a level to ensure that sufficient providers" enlist, pursuant to 42 C.F.R. § 447.204, defendants assert that the State Plan, reflecting the reimbursement formulas codified at Cal. Welf. & Inst. Code § 14105.45, was approved by the federal government on June 6, 2006. Id. at 14. They argue that this claim should be dismissed because it is not directed at the federally approved State Plan methodology but rather the AWP reductions resulting from a private settlement. Id. at 15. In addition, defendants argue that the fourth claim should be dismissed because the cited regulation, 42 C.F.R. § 447.333, was removed effective October 1, 2007. Id. As for the fifth claim, defendants contend that plaintiffs' "generalized and unsubstantiated reference to 22 C.C.R. § 50004(b), and 42 C.F.R. § 447.204 and § 447.205, is unavailing" because such speculative and conclusory statements are insufficient to establish a right to relief. Id. at 16. Similarly, defendants contend that the sixth claim should be dismissed because plaintiffs' "threadbare recitals" are insufficient to state a claim for relief under Iqbal, 129 S. Ct. at 1949.[9] Id. at 17. They further contend that section 30(A) is inapplicable to the instant suit. Id.

Finally, defendants argue that Arnold Schwarzenegger, Governor of the State of California, and Kim Belshe, Secretary of the California Health and Human Services

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[8] 42 C.F.R. § 447.205 provides that the Department must "provide public notice of any significant proposed change in its methods and standards for setting payment rates for services." However, public notice is not required if the "change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement is based on material cost plus a professional fee." 42 C.F.R. § 447.205(b)(3).

[9] In claim VI, plaintiffs seek declaratory relief that "the reimbursement cut violates both federal and state law as being preempted by Section 30(A) of the Social Security Act, contrary to Federal Regulations, contrary to state regulations, and contrary to the Medicaid State Plan." FAC ¶ 72.

Agency, are not proper parties in this action and should be dismissed. Id. at 17, n.1. They contend that while the Court has jurisdiction to grant prospective relief under the Eleventh Amendment of the United States Constitution against state officials in their "official capacity," neither the Governor or Agency Secretary have official duties with regard to the Medicaid statutes. Id. According to defendants, the Department is the designated state agency to administer the statutes, and thus, the only defendant to have any official duties is the Director. Id.

Plaintiffs respond that each claim is sufficiently pled. Opp'n at 12. Specifically, as to the first claim, plaintiffs argue that regardless of whether the related cases they cite are distinguishable, they have pled a sufficient claim for injunctive relief. Id. As to the second claim, plaintiffs contend that public notice is required because the AWP reductions at issue are distinguishable from normal price fluctuations and reflect a change in the methods and standards used for setting reimbursement. Id. at 13. Next, regarding the third claim, plaintiffs argue that federal approval of the State Plan does not insulate defendants from their continuing duty to ensure that reimbursements comply with federal law. Id. at 13-14. As to the fourth claim, plaintiffs request that the Court deem the FAC amended *nunc pro tunc* to cite to section 447.518, because § 447.333 was renumbered as § 447.518. Id. at 14. As for the fifth claim, plaintiffs reiterate that defendants are required to issue public notice regarding the AWP reductions. Id. Finally, plaintiffs contend that count VI does not rely upon "threadbare recitals" because the count incorporates all the previous factual allegations in the FAC. Id. at 15.

The Court finds that all of plaintiffs' claims are premised on the theory that the Department violated section 30(A) and relevant regulations when it reduced Medicaid payments based on the markdown of AWPs. Assuming the truth of plaintiffs' allegations, for purposes of this motion to dismiss, namely that the State did not make certain findings and provide public notice prior to implementing these changes, the Court finds that plaintiffs sufficiently state their claims for relief. In any event, the Court finds that defendants' arguments to be more appropriately decided on a motion for summary judgment.

IV. CONCLUSION

In accordance with the foregoing, the Court DENIES defendants' motion to

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dismiss.

IT IS SO ORDERED.

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