UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

NATIONAL ASSOCIATION OF CHAIN DRUG STORES; ET AL. Petitioner, vs. ARNOLD SCHWARZENEGGER; ET AL. Respondent.	Case No. CV 09-7097 CAS (MANx) **ORDER DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

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 the implementation of the AWP reductions violates Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq. (the "Medicaid Act"), and other applicable state and federal regulations. Id.

On November 2, 2009, plaintiffs filed the instant motion for preliminary injunction. Defendants filed their opposition on November 23, 2009. On November 20, 2009, plaintiffs filed a reply. At the hearing, on December 7, 2009, the United States Department of Justice ("DOJ") appeared regarding its Statement of Interest filed on December 4, 2009. The Court took the matter under submission pending supplemental briefing from the DOJ, which it filed on December 21, 2009. After carefully considering the arguments set forth by the parties and DOJ, 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

[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).

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; Mot. at 6. Implementation of these AWP reductions occurred on September 26, 2009. Plaintiffs 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. LEGAL STANDARD

"A preliminary injunction is not a preliminary adjudication on the merits: it is an equitable device for preserving the status quo and preventing the irreparable loss of rights before judgment." Textile Unlimited v. A..BMH & Co., 240 F.3d 781, 786 (9th Cir. 2001). The Ninth Circuit summarized the Supreme Court's recent clarification of the standard for granting preliminary injunctions in Winter v. Natural Res. Def. Council, 129 S. Ct. 365, 374 (2008), as follows: "[a] plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Am. Trucking Ass'n, Inc. v. City of Los Angeles, 559 F.3d 1046, 1052 (9th Cir. 2009).

IV. DISCUSSION

Plaintiffs now move to preliminarily enjoin reductions based on implementation of the AWP reductions. The request for a preliminary injunction is predicated on the following claims. Plaintiffs allege that implementation of the AWP reductions violates § 30(A) 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 that the Department failed to comply with the 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 in the Medicaid program, 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). Mot. at 1-2; FAC ¶¶ 42-47.

As a threshold matter, plaintiffs contend that they have associational standing to invalidate state action under the Supremacy Clause, regardless of whether § 30(A) confers a private right of action.[2] Mot. at 8 (citing Indep. Living Ctr. of So. Cal., Inc. v. Shewry, 543 F.3d 1050, 1065 (9th Cir. 2008); Indep. Living Ctr. of So. Cal., Inc. v. Shewry, 543 F.3d 1047, 1048-49 (9th Cir. 2008)). Namely, plaintiffs argue that their member pharmacies will suffer financial loss due to the AWP reductions. Id.

Plaintiffs further argue that they meet the requirements for granting a preliminary injunction. Id. at 9. Plaintiffs contend that they are likely to succeed on the merits of each of their claims against defendants. Id. Specifically, they argue that this reimbursement reduction is similar to other Medi-Cal rate reductions that this Court preliminary enjoined. Id. at 10 (citing e.g., Managed Pharmacy Care v. David Maxwell Jolly, 603 F. Supp. 3d 1230 (C.D. Cal. 2009)). In support of this argument, plaintiffs contend that there is no indication that the Department considered "efficiency, economy, and quality of care," as required by § 30(A), before accepting the reimbursement reductions for drug products tied to AWPs. Id. at 11. Plaintiffs further argue that with

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[2] Defendants respond that plaintiffs' claims fail as a matter of law because § 30(A) is not enforceable by private parties. Opp'n at 12. However, they recognize that Independent Living, 543 F.3d at 1065, is arguably controlling in this case, and thus raise this argument to preserve it for later appellate proceedings. Id. at 13.

these recent reductions, the Department fails to offer payments "sufficient to enlist enough providers," pursuant to 42 C.F.R. § 447.20, because pharmacies will be economically forced to stop serving Medicaid beneficiaries. Id. at 12 (citing attached declarations). Also, according to plaintiffs, there is no indication that the Department obtained CMS approval before implementing this state plan "amendment," or that it provided public notice of this "significant change" in its methods and standards for setting reimbursement payments. Id. at 12-14. Finally, they argue that by failing to follow these federal regulations and dictates of the state plan, the Department violated California Medi-Cal regulations. Id. at 14.

Defendants respond that plaintiffs do not establish a high likelihood of success on the merits for the following reasons. Opp'n at 6. As a general matter, defendants contend that the reduction in AWPs was not a result of any state law or policy mandating a change in reimbursement.[3] Id. Rather, they argue that the alleged reduction resulted from an independent lawsuit in which the State played no part, and thus there is no causal relationship between the alleged injury and the wrongful conduct. Id. at 6-7 (citing Devose v. Herrington, 42 F.3d 470, 471 (8th Cir. 1994) ("[A] party moving for a preliminary injunction must necessarily establish a relationship between the injury claimed in the party's motion and the conduct asserted in the complaint.")). Defendants further argue that to the extent plaintiffs rely on past injunctions issued by this Court, those cases are distinguishable because the State conduct consisted of legislatively enacted rate reductions codified in the Welfare and Institutions Code.[4] Id.

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[3] Defendants assert that the current reimbursement formula, which includes AWP as a factor, has been in existence since 2004. Opp'n at 7. Furthermore, they contend that the State Plan, which includes this formula, was approved by CMS on June 6, 2006 and requires the Department to use First DataBank as its primary reference source for AWP. Id. at 8.

[4] Likewise, defendants contend that Orthopaedic v. Belshe, 103 F.3d 1491 (9th Cir. 1997), is distinguishable because that case involved specific rate changes effected by state (continued...)

As to plaintiffs' specific claims, defendants respond that fluctuations in AWP do not require notice because they do not constitute a significant change in methods or procedures.[5] Id. at 8-10 (citing 42 C.F.R. § 447.205). They argue that any required notice was provided in 2004 when the pharmacy reimbursement formula, codified at Cal. Welf. & Inst. Code § 14105.45, was enacted. Id. at 10. In addition, defendants contend that the State Plan was approved by the federal government on June 6, 2006, and that the plan reflects the "AWP minus 17%" drug reimbursement formula. Id. Moreover, defendants assert that on October 28, 2009, the Secretary of Health and Human Services wrote a letter to plaintiffs stating that she "did not think it necessary to instruct the States to take any specific action with respect to the [First DataBank] settlement agreements" that reduced AWPs.[6] Id.; Ex. E & F. Finally, defendants argue that the motion should be denied to the extent that the relief sought violates the separation of powers doctrine. Id. at 11. Specifically, they contend that enjoining the definition of AWP would require defendants to violate the State Plan that has been approved by the federal government and would "disrupt over 20 years of established protocol." Id.

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[4](...continued)
statutes or regulations. Opp'n at 8.

[5] The federal regulations provide in pertinent part that 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).

[6] In the letters, the Secretary states that plaintiffs request that CMS "instruct States to modify their reimbursement rates" in light of the First DataBank's change in methodology for determining the AWP. Opp'n; Ex. E & F. In her response, she states that "States continue to have the obligation to appropriately determine [estimated acquisition costs] consistent with the regulations." Id. However, defendants also argue that to the extent plaintiffs claim that the State must make findings that reimbursements represent the estimated acquisition costs, plaintiffs fail to cite to any valid authority for such a proposition because the regulation they cite, 42 C.F.R. § 447.333, was abrogated effective October 1, 2007. Id. at 4. It appears § 447.333 was renumbered as § 447.518.

Plaintiffs reply that the reimbursement reductions at issue, admittedly resulting from changes to the AWPs, have brought rates to levels so low they violate Medicaid law. Reply at 1. Accordingly, they argue that there is a casual relationship between the reimbursement reductions and their alleged injury because "Medi-Cal now reimburses pharmacies below their breakeven cost for many prescription drugs and that pharmacies will be forced to reduce patient access in the Medicaid program." Id. at 5. They reiterate the argument that defendants are required to set reimbursement levels sufficient to enlist an adequate number and quality of providers, and argue that defendants cannot "opportunistically take advantage of the First DataBank settlement."[7] Id. Thus, plaintiffs argue that regardless of whether defendants complied with federal law in setting the reimbursement formulas in 2004, the pertinent question is whether, as of September 26, 2009, the State's reimbursement fell out of compliance.[8] Id. at 1-2. Plaintiffs assert that they are "not asking this Court to tell the State how to set reimbursement, what formulas to use, or what reimbursement should be [but] [r]ather, plaintiffs argue that this Court can enjoin the State from providing reimbursement which is so low that it fails to comply with section 30(A)."

The Ninth Circuit has held that § 30(A) of the Medicaid Act creates certain duties on behalf of the Department when establishing reimbursement rates. See, e.g., Indep. Living Ctr., 572 F.3d 644, 651 (9th Cir. 2009) (citing Orthopaedic Hospital v. Belshe, 103 F.3d 1491, 1492 (9th Cir. 1997)). Namely, when the State of California seeks to

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[7] Plaintiffs contend that this change to AWP is fundamentally different from the "normal fluctuations in AWP that occur regularly" because it was "an across the board reduction." Reply at 6-7.

[8] As to defendants' argument that the current reduction is not mandated by state law or policy, plaintiffs contend that the Court rejected a similar argument in Independent Living, No. CV 08-3315 CAS (MANx) (Aug. 18, 2008) (rejecting the State's argument that "because the Legislature, not the Department" made the decision to cut reimbursements, the State's obligations under § 30(A) were not compromised because "[i]t is clear that the Department will, and in fact has, enforced the [reimbursement reduction]."). Reply at 2.

modify reimbursement rates for services provided under Medi-Cal, it must consider, among other factors, efficiency, economy, and quality of care, as well as the effect of providers' costs on those relevant statutory factors. See id. However, in the instant case, the challenged reductions in reimbursement are the result of changes in how First DataBank, a private party, establishes wholesalers' prices. For this reason, the Court finds that this case is distinguishable from previous cases in which it preliminarily enjoined implementation of State mandated Medi-Cal rate reductions. See, e.g., Managed Pharmacy Care v. David Maxwell Jolly, 603 F. Supp. 3d 1230 (C.D. Cal. 2009) (enjoining the Director from implementing the five percent payment reductions codified in Cal. Welf. & Inst. Code § 14105.191(b)(3), as modified by Assembly Bill 1181); see also, Indep. Living Ctr., No. CV 08-3315 CAS (MANx), 2008 WL 3891211 (C.D. Cal. Aug. 18, 2008)). In the instant case, the State has not affirmatively acted to create a new, or modified, "method or procedure" for establishing reimbursement rates to provider pharmacies, thus triggering its duties under § 30(a) and relevant regulations. Rather, the Department is making payments pursuant to a preexisting formula codified in Cal. Welf. & Inst. Code § 14105.45(b)(2).[9] Thus, the Court concludes that plaintiffs have not made out a sufficient showing they have a strong likelihood of success on the merits of their claims.[10]

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[9] The Court finds that plaintiffs are effectively seeking to change the status quo and obtain affirmative relief that would compensate them for the loss incurred by the AWP reductions effective September 26, 2009.

[10] At the hearing held on December 7, 2009, the DOJ expressed the view that the State was not required to submit a state plan amendment, pursuant to 42 C.F.R. § 430.12(c), before implementing the reduction in Medi-Cal payments based on the average wholesale price ("AWP") for drug products. Likewise, in its memorandum filed on December 21, 2009, the DOJ argues that the State is not obligated to perform cost studies, pursuant to section 30(A), before the rollback in AWPs could be reflected in the State's Medi-Cal payments. See DOJ Statement of Interest (filed Dec. 21, 2009). The DOJ further argues that these changes in the reimbursement formula do not implicate section 30(A), and (continued...)

In light of the Court's finding that plaintiffs have not established a high likelihood of succeeding on the merits, the Court, while acutely cognizant of the potential adverse consequences of the AWP reductions, declines to address plaintiffs' arguments that they have shown irreparable harm and meet the other requirements for a preliminary injunction. See Global Horizons, Inc. v. United States DOL, 510 F.3d 1054, 1058 (9th Cir. 2007) ("Once a court determines a complete lack of probability on the success or serious questions going to the merits, its analysis may end, and no further findings are necessary.").

V. CONCLUSION

In accordance with the foregoing, the Court DENIES plaintiffs' motion for preliminary injunction.

IT IS SO ORDERED

Dated: December 22, 2009

CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE

[10](...continued)
that in any event, the Secretary of Health and Human Services has no reason to believe that problems with efficiency, economy, quality of care, or access, exist in California as a result of the reductions by First Databank in previously overstated published AWPs.