UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

MANAGED PHARMACY CARE; ET AL; et al., Plaintiffs, vs. KATHLEEN SEBELIUS; et al.; Defendants.	Case No. CV 11-9211 CAS (MANx) **ORDER GRANTING PRELIMINARY INJUNCTION**

I. INTRODUCTION AND BACKGROUND

On November 4, 2011, plaintiffs filed the instant action against Toby Douglas, Director of the California Department of Health Care Services (the "Director") and Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services (the "Secretary").

The California Department of Health Care Services ("DHCS") is a California agency charged with the administration of California's Medicaid program, Medi-Cal. The Secretary is responsible for administering the Medicaid program at the federal level. Through her designated agent, the Centers for Medicare and Medicaid Services

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("CMS"), the Secretary is responsible for reviewing and approving policy changes that states make to their Medicaid programs.

Plaintiffs are a Medi-Cal beneficiary, five pharmacies that participate in the Med-Cal fee-for-service program, a large pharmacy organization with 340 member pharmacies throughout California, an independent living center, and the state association of independent living centers.

On March 25, 2011, California Governor Edmund G. Brown Jr. signed into law Assembly Bill 97 ("AB 97"), the health budget trailer bill for California fiscal year 2011–2012. AB 97 enacted significant payment reductions for many classes of services provided under the Medi-Cal program. Most significantly for the purposes of the instant action, AB 97 enacted California Welfare and Institutions Code § 14105.192, which provides that the Director shall reduce fee-for-service payments to pharmacies by 10 percent for services provided on or after June 1, 2011, and reduce payments to managed health care plans by the actuarial equivalent amount of the Medi-Cal fee-for-service payment reduction. Section 14105.192(o) provides that the rate reduction shall not be implemented until federal approval is obtained, but that when federal approval is obtained, rate reductions should be implemented retroactively to June 1, 2011.

DHCS submitted proposed State Plan Amendment ("SPA") 11-009 to CMS on July 15, 2011, seeking federal approval of the rate reduction and incorporation of that reduction into California's Medi-Cal State Plan. DHCS submitted an access analysis regarding pharmacy services as well as a plan for monitoring the effects of the rate reduction. On October 27, 2011, in a letter from the Associate Regional Administrator of the CMS Division of Medicaid and Children's Health Operations, CMS provided notice to the Director and DHCS that it had approved the SPA.

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Plaintiffs allege that CMS's approval of the SPA was in violation of 42 U.S.C. § 1396a(a)(30)(A) ("Section 30(A)"), the Supremacy Clause,[1] the Due Process Clause of the 14th Amendment to the U.S. Constitution,[2] and the Privileges and Immunities Clause.[3] Compl. ¶ 32. Plaintiffs further allege that the Secretary's approval of the SPA violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 706 et seq. because the Secretary failed to consider certain factors including the impact of the rate reduction on access to and quality of pharmacy services. Id. ¶ 35.

On November 7, 2011, plaintiffs filed the present motion seeking a preliminary injunction restraining the Director from implementing the rate reduction. Plaintiffs filed an amended motion for preliminary injunction on November 21, 2011. The Court denied the Director's ex parte application to stay the proceedings on December 2, 2011. On December 5, 2011, the Secretary and Director filed separate oppositions.[4] Plaintiffs replied on December 9, 2011. The Court heard oral argument on December 19, 2011. After carefully considering the parties' arguments, the Court finds and concludes as follows.

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[1] U.S. Const. art. VI, cl. 2.

[2] U.S. Const. amend. XIV.

[3] U.S. Const. art. IV, § 2.

[4] Contemporaneously with his opposition, the Director submitted evidentiary objections to substantially all of plaintiffs' declarations in support of their motion for preliminary injunction. Dkt. No. 26. The Director argues that plaintiffs' declarations are inadmissible because they are irrelevant, not based on personal knowledge, improper opinion testimony by a lay witness, and include inadmissible hearsay evidence. Id. To the extent the Court relies on evidence contained within plaintiffs' declarations, as noted below, the Director's objections are overruled. The Director's other objections are overruled as moot.

II. LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy." Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 9 (2008). The Ninth Circuit summarized the Supreme Court's recent clarification of the standard for granting preliminary injunctions in Winter 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); see also Cal Pharms. Ass'n v. Maxwell-Jolly, 563 F.3d 847, 849 (9th Cir. 2009) ("Cal Pharm. I"). Alternatively, "'serious questions going to the merits' and a hardship balance that tips sharply towards the plaintiff can support issuance of an injunction, so long as the plaintiff also shows a likelihood of irreparable injury and that the injunction is in the public interest." Alliance for the Wild Rockies v. Cottrell, 632 F.3d 1127, 1132 (9th Cir. 2011); see also Indep. Living Ctr. of So. Cal. v. Maxwell-Jolly, 572 F. 3d 644, 657–58 (9th Cir. 2009) ("ILC II"). A "serious question" is one on which the movant "has a fair chance of success on the merits." Sierra On-Line, Inc. v. Phoenix Software, Inc., 739 F.2d 1415, 1421 (9th Cir. 1984).

III. DISCUSSION

A. Standing

Before turning to the merits of plaintiffs' motion, the Court first addresses the Director's arguments that plaintiffs lack standing to bring this case.

1. Prudential Standing

The Director argues that plaintiffs' lack prudential standing to enforce Section 30(A)[5] because plaintiffs seek to enforce rights belonging to a third party, CMS.

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[5] Section 30(A) states in pertinent part that a State plan for medical assistance must:

> provide such methods and procedures relating to the utilization of, and the payment

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According to the Director, this Section does not confer individual entitlements on any private parties, but instead serves as a "yardstick" by which the federal government may assess a state's performance under the Medicaid Act. Director's Opp'n at 4. Moreover, the Director argues that plaintiffs' claims run afoul of the bar against considering generalized grievances in that plaintiffs are not attempting to vindicate any right personal to them, but instead assert nothing more than "'the generalized interest of all citizens in constitutional governance.'" Id. (quoting Valley Forge Christian Coll. v. Amer. United for Sep. of Church and State, 454 U.S. 464, 483 (1982)).

The Court finds the Director's prudential standing arguments unavailing. In assessing prudential standing, a court need not "inquire whether there has been a congressional intent to benefit the would-be plaintiff," but instead must determine only whether the plaintiff's interests are among those "arguably . . . to be protected" by the statutory provision. Nat'l Credit Union v. First Nat'l Bank & Trust Co., 552 U.S. 478, 489 (1998). This "zone of interest" test "is not meant to be demanding." Clarke v. Secs. Indus. Ass'n, 479 U.S. 388, 399–400 (1987). To this end, Section 30(A) establishes standards to assure that payments to providers are "consistent with efficiency, economy, and quality of care . . . sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population." Accordingly, Medi-Cal providers and beneficiaries are undoubtedly within the zone of interests protected by Section 30(A). Further, the Court finds that contrary to the Director's assertion, plaintiffs are not

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for, care and services available under the plan . . . to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

alleging a "generalized grievance." This is so because plaintiffs have alleged that they will be specifically and particularly harmed by the implementation of the rate reduction.

2. Associational Standing

The Director maintains that the pharmacy owner and association plaintiffs cannot establish associational standing on behalf of Medi-Cal beneficiaries because those beneficiaries are not members of the pharmacies or the associations, because plaintiffs fail to allege how representing Medi-Cal recipients' interests is germane their purposes, and because whether an individual beneficiary has a claim under Section 30(A) will require individualized determinations. Id. at 5–6.

The Director's associational standing arguments also fail. An association has standing to sue on behalf of its members if (1) they would have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) participation by the individual members is not necessary to resolve the claim. Hunt v. Wash. State Apple Advertising Comm'n, 432 U.S. 333, 343 (1997). The Ninth Circuit has recognized that when an association is pursuing an action for only declaratory and injunctive relief on behalf of its members, participation in the action by individual members is not required. See Associated Gen'l Contractors of Am. v. Metropolitan Water Dist. of Southern California, 159 F. 3d 1178, 1181 (9th Cir. 1998). Here, plaintiffs are not seeking monetary relief, so participation of individual Medi-Cal beneficiaries is not required. Next, other courts have held that because individual medical providers would have third-party standing to represent the interests of their patients, associations representing those providers can also represent the interests of patients. See, e.g., Penn. Psychiatric Soc'y v. Green Spring Health Srvcs., Inc., 280 F. 3d 278, 288–94 (3d Cir. 2002); New Jersey Protection & Advocacy v. New Jersey Dep't of Educ., 563 F. Supp. 2d 474, 481–84 (D.N.J 2008). Accordingly, in this case, the individual pharmacies and their associations would have standing to represent the interests of Medi-Cal patients served by the pharmacies. More fundamentally, even if these entities did not have standing to represent Medi-Cal beneficiaries, it would not

alter the Court's ability to reach the merits of the controversy because there is an individual Medi-Cal beneficiary who is a plaintiff to this case whose standing is not challenged.

Having rejected each of the Director's standing arguments, the Court now turns to the merits of plaintiffs' motion.

B. Likelihood of Success on the Merits

1. Plaintiffs' Section 30(A) Claim Against the Secretary

Plaintiffs argue that they are likely to succeed on the merits of their Section 30(A) claim against the Secretary because CMS failed to apply controlling law in evaluating SPA 11-009 and therefore acted arbitrarily and capriciously.

Under the APA, a reviewing court must affirm an agency's determination unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "A decision is arbitrary and capricious if the agency 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" O'Keefe's, Inc. v. U.S. Consumer Prod. Safety Comm'n, 92 F. 3d 940, 942 (9th Cir. 1996) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

If a statute is silent or ambiguous with respect to a specific question, the issue for the court is whether the agency's answer is based on a permissible construction of the statute. Chevron U.S.A. v. NRDC, 467 U.S. 837, 842–43 (1984). Chevron deference is required "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and . . . the agency interpretation claiming deference was promulgated in the exercise of that authority." United States v. Mead Corp., 533 U.S. 218, 226–27 (2001).

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a. Cost Studies

Plaintiffs first contend that CMS's approval of SPA 11-009 was arbitrary and capricious because CMS failed to consider whether DHCS relied on credible cost studies and developed rates reasonably related to provider costs as the Ninth Circuit has held is required under Section 30(A). Mot. at 9 (citing Orthopaedic Hosp. v. Belshe, 103 F. 3d 1491, 1492, 1496, 1500 (9th Cir. 1997) cert. denied, Belshe v. Orthopaedic Hosp., 522 U.S. 1044 (1998)).

In opposition, the Secretary contends that CMS's contrary interpretation of Section 30(A), upon which it based its approval of SPA 11-009, is entitled to Chevron deference notwithstanding the Ninth Circuit's decision in Orthopaedic Hospital that a state must consider "responsible cost studies." According to the Secretary, she has "consistently taken the position" that Section 30(A) does not require states to base payment rates on the costs incurred by providers even though this interpretation has not yet been incorporated into a final rule. Secretary's Opp'n at 8. The Secretary cites Nat'l Cable & Telecom. Ass'n v. Brand X Internet Servs. ("Brand X"), for the principle that "[a] court's prior judicial construction of a statute trumps an agency construction otherwise entitled to Chevron deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." Id. at 9–10 (quoting Brand X, 545 U.S. 967, 982 (2005)). Because the Ninth Circuit has not held that its interpretation follows from the unambiguous terms of the statute, the Secretary contends that her interpretation of the statute controls because it was made within the context of an adjudication that would normally be afforded Chevron deference. Id. at 10. The Secretary further argues that the Ninth Circuit has held that the Secretary's interpretation of Section 30(A), which formed the basis of the disapproval of a State Plan Amendment, is entitled to Chevron deference. Id. (citing Alaska Dept. of Health and Social Servs. v. CMS, 424 F. 3d 931 (9th Cir. 2005) ("Alaska")). The Secretary contends that any distinction between the approval and the disapproval of a SPA is irrelevant to whether Congress delegated

interpretative authority to the agency, thus mandating Chevron deference. Id. at 11 n. 3. The Secretary also notes that Court of Appeals for the District of Columbia Circuit has determined that the Secretary's interpretation of the Medicaid made in connection with the approval of an SPA is entitled to Chevron deference. Id. at 11 (citing PhRMA v. Thompson, 362 F.3d 817, 822 (D.C. Cir. 2004)).

Although the Court agrees with the Secretary that Section 30(A) leaves room for interpretation,[6] the Court does not believe the Secretary's interpretation is owed Chevron deference with respect to the approval at issue in this case. In this respect, the Court finds significant that the Secretary's approval of SPA 11-009 did not involve a formal adjudication accompanied by the procedural safeguards justifying Chevron deference. Instead, the Secretary's issued her interpretation of Section 30(A) in a letter to DHCS. This kind of interpretation is of the very type for which the Supreme Court has declined to extend Chevron deference. See e.g., Christensen v. Harris County, 529 U.S. 576, 586–88 (2000) (holding that informal agency interpretations of a statute such as those contained in an opinion letter, policy statement, agency manuals, or enforcement guidelines, are not entitled to Chevron-style deference). The Secretary's reliance on Alaska misplaced. In Alaska, the Ninth Circuit deferred to the Secretary's interpretation of Section 30(A) and upheld the denial of a State Plan Amendment. In finding that the CMS Administrator's final determination "carr[ied] the force of law" necessary for Chevron deference, the court highlighted "the formal administrative process afforded the State," with "opportunities to petition for reconsideration, brief its legal arguments, be heard at a formal hearing, receive reasoned decisions at multiple levels of review and

[6] The Court notes that Section 30(A) does not explicitly mention provider costs or cost studies and that three other circuit courts have determined that CMS need not consider provider costs in deciding whether or not to approve a State Plan Amendment. See Rite Aid of Pa. Inc. v. Houstoun, 171 F. 3d 842, 853 (3d Cir. 1999); Methodist Hosps., Inc. v. Sullivan, 91 F. 3d 1026, 1030 (7th Cir. 1996); Minn. Homecare Ass'n v. Gomez, 108 F. 3d 917, 918 (8th Cir. 1997) (per curiam).

submit exceptions to those decision." Alaska, 424 F. 3d at 939. None of these procedural safeguards was incorporated in the SPA approval process at issue in this case, in which there was no hearing, no record, no opportunity for interested parties to present evidence, and no formal decision in which the Secretary set forth her reasoning.[7] Accordingly, the Secretary's approval of SPA 11-009 did not include the "hallmarks of 'fairness and deliberation,'" to which Chevron deference is owed. See Alaska, 424 F. 3d at 939 (quoting Mead, 533, U.S. at 226–27).[8]

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[7] 42 U.S.C. § 1316(a), which governs CMS's consideration of State Plan Amendments, does not require any type of hearing when the Secretary approves a State Plan Amendment. 42 U.S.C. § 1316(a)(1). In contrast, where the Secretary rejects a State's proposed Amendment, the State is entitled to petition the Secretary for reconsideration of the issue, and the Secretary is required to hold a hearing. 42 U.S.C. § 1316(a)(2). For this reason, Chevron deference is more appropriate for the disapproval of a State Plan Amendment.

[8] The Secretary's reliance on Dickson v. Hood, 391 F. 3d 581 (5th Cir. 2004), Harris v. Olszewski, 442 F. 3d 456, 460 (6th Cir. 2006), and West Virginia v. Thompson, 475 F. 3d 204, 210–11 (4th Cir. 2007) is similarly misplaced. In Dickson, a Medicaid recipient alleged that the Louisiana Department of Health and Hospitals violated his federal rights by refusing to pay for medically prescribed disposable incontinence underwear. Id. at 584. The court merely afforded deference to the Secretary's interpretation of "home health care services" as embodied in a regulation previously promulgated pursuant to formal notice-and-comment rulemaking. Id. at 594. Harris involved a challenge to Michigan's single source provider contract for incontinence supplies as violating the Medicaid Act's freedom of choice provisions. 442 F. 3d at 460. West Virginia v. Thompson merely held that the Secretary's interpretation of the Medicaid statute as embodied in the *disapproval* of a SPA was entitled to deference. None of these cases involved a challenge to the Secretary's approval of a State Plan Amendment or the appropriate level of deference required to be afforded such approvals.

Similarly, the Supreme Court's decision in Chase Bank U.S.A, N.A. v. McCoy, 131 S. Ct. 871 (2011), cited by the Director for the proposition that an agency's amicus brief deserves deference, does not compel a contrary result. This is so because that case involved an agency's interpretation of its own regulation rather than the statutory scheme itself. See id., 131 S. Ct at 880.

The Court does not believe that the Court of Appeals for the District of Columbia Circuit's determination in PhRMA, 362 F.3d at 822, compels a contrary result in this case. Here, the decision of the Associate Regional Administrator of the Division of Medicaid & Children's Health Operations approving the SPA, as set forth in the October 27 approval letter, is conclusory in nature. It does not provide any reasons on its face as to why provider costs should not be considered in determining whether the SPA's reduction in reimbursement rates will result in lower quality of care or decreased access to services. Given the logical and empirical relationship between reimbursement rates and the willingness of providers to make services available that the Ninth Circuit found was the case in Orthopaedic Hospital, the absence of a reasoned decision to not require cost studies to justify the SPA makes the decision to approve the SPA less appropriate for Chevron deference. Further, the record reflects that CMS states even though it "does not currently interpret [Section 30(A)] of the Act to require cost studies in order to demonstrate compliance," CMS is "currently reviewing and refining, in a rulemaking proceeding, guidance on how states can adequately document access to services," suggesting that a formal notice and comment rulemaking process, accompanied by the procedural safeguards of such a proceeding, is contemplated by CMS. See Cal. Hosp. Ass'n v. Douglas, CV 11-9078 CAS (MANx), Dkt. No. 47-2, at 1; June 17, 2011 Letter from CMS to DHCS. Besides the fact that no explanation is given for not requiring cost studies other than the statement that CMS "believe[s] the appropriate focus in on access," this statement by CMS suggests that its position regarding cost studies is not necessarily settled. Thus, as the court noted in PhRMA, Chevron deference may be warranted even when no administrative formality was required and none was afforded, the circumstances of this case call into question whether Chevron deference is appropriate.[9]

[9] Further, in PhRMA, not only did the record support the reasonableness of the continue...

Having determined that Chevron deference is inappropriate, the Court now turns to whether the Secretary's interpretation that cost studies are not required under Section 30(A) is "entitled to respect" under Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

The Court answers this question in the negative. Skidmore instructs that "[t]he weight accorded to an administrative judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control." 333 U.S. at 140. Skidmore respect is not owed for two reasons. First, in apparent conflict with the Secretary's position in this case, in Alaska, the Secretary asked the Ninth Circuit to uphold her disapproval of a State Plan Amendment because Alaska failed to analyze provider costs. Specifically, the Secretary argued:

> The requirements of § 1396(a)(30)(A) are . . . not so flexible as to allow the [State] to ignore the costs of providing services. For payment rates to be consistent with efficiency, economy, quality of care and access, they must bear a reasonable relationship to provider costs."

Alaska, Resp. Br., 2004 WL 3155124, at 32 (citing Orthopaedic Hospital, 103 F. 3d at 1499).[10] In addition to this inconsistency in agency position, the Secretary's proffered interpretation directly contradicts the law in the Ninth Circuit. See Orthopaedic Hospital, 103 F. 3d at 1497. Thus, while the Court recognizes that in appropriate circumstances, an agency may change its position on the construction of a statute, the

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[9]...continue
Secretary's decision that the SPA at issue would make it less likely that needy persons would become eligible for Medicaid, thereby impacting Medicaid services, the court noted that an intervening decision of the Supreme Court supported the trial court's decision to grant summary judgment in favor of the Secretary. 362 F. 3d at 821.

[10] Importantly, under Skidmore, courts consider whether the agency has acted consistently. See Federal Express Corp. v. Holowecki, 552 U.S. 389, 399 (2008); Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993).

Court finds that in light of the circumstances of this case, the Secretary's conclusory interpretation that Section 30(A) does not require consideration of cost studies is of limited "power to persuade," and is therefore not entitled to respect under Skidmore.

In any event, the Court finds that whether the Secretary's interpretation of Section 30(A) as embodied in the approval of SPA 11-009 is owed deference presents a "serious question going to the merits." See Alliance for the Wild Rockies, 632 F.3d at 1132; ILC II 572 F. 3d at 657–58; Sierra On-Line, Inc., 739 F.2d at 1421. In light of the balance of the hardships, which the Court believes tips strongly in plaintiffs' favor as discussed below, the Court finds that the issuance of a preliminary injunction would be warranted if the Secretary failed to consider whether DHCS relied on responsible cost studies. The Court now turns to that issue.

Plaintiffs contend that it is "abundantly clear" that AB 97 was enacted solely for budgetary considerations, and thus that the neither the State nor CMS considered provider costs in setting or approving the rate reduction contained in SPA 11-009. Id. at 8–10.[11]

In response, the Secretary contends that CMS reviewed pharmacy cost data submitted by the State that analyzed the impact of a ten percent reduction on pharmacy costs, and determined that pharmacies would be reimbursed close to 100 percent of their costs. Secretary's Opp'n at 15–16.

The Court finds it likely that despite CMS's review of pharmacy cost data, the Secretary's approval of SPA 11-009 will be found to be arbitrary and capricious. The Ninth Circuit has held that "Medicaid rate reductions may not be based solely on state

[11] In support of this argument, plaintiffs point to Sections 106–108 of AB 97 which state that the rate reduction "addresses the fiscal emergency declared and reaffirmed by the Governor," for the purpose of providing "for appropriations related to the Budget Bill," and that its provisions must take effect immediately "in order to make the necessary statutory changes to implement the Budget Bill." Mot. at 8–9. Plaintiffs also note that the Director publicly admitted that the State's analysis of AB 97 did not consider costs. Id. at 8.

budgetary concerns." Indep. Living Ctr. of So. Cal. v. Maxwell-Jolly, 572 F. 3d 644, 644 (9th Cir. 2009) ("ILC II"). In this case, although CMS reviewed cost data, there is no evidence that DHCS or the State legislature did so prior to submitting SPA 11-009 for approval. Instead, the language of AB 97 makes clear that the only reason for imposing the rate reductions was California's ongoing fiscal emergency. Such a justification plainly fails to meet the requirements of Section 30(A). See id. at 656 ("[T]he State's decision to reduce Medi-Cal reimbursement rates based solely on state budgetary concerns violated federal law.").

b. Access and Quality

Plaintiffs next contend that even if the Secretary's approval of SPA 11-010 is owed deference, the approval still may be found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Specifically, plaintiffs contend that the approval was arbitrary and capricious because DHCS failed to consider facts that bear on the impact of the rate reduction on access to services and quality of care. Plaintiffs argue that the analysis was "fatally flawed" because: (1) the list of participating pharmacies used in assessing access included providers that have stopped filling Medi-Cal prescriptions; (2) the analysis does not provide any comparison between the number of pharmacies actively participating in third-party insurance plans and the number participating in the Medi-Cal fee-for-service program; (3) the analysis does not consider whether quality services are being delivered to beneficiaries; and (4) the "utilization" rate employed in the analysis is a direct function of the number of Medi-Cal beneficiaries using fee-for-service pharmacies and therefore that it does not provide an accurate measure of whether certain pharmacies are no longer accepting new Medi-Cal patients, refusing to fill prescriptions for certain brands of drugs, or refusing to fill prescriptions entirely. Mot. at 14–16.

The Secretary responds that the State appropriately considered the effect of the rate reduction on access to and quality of pharmacy services. As to plaintiffs' contention that the list of participating pharmacies improperly includes certain pharmacies, the

Secretary contends that the State did not merely rely on a static list of providers to show participation, but rather used information obtained from providers' own files and claims data as well as from the Department of Consumer Affairs Board of Pharmacy. Secretary's Opp'n at 17. As to plaintiffs' argument regarding utilization rates, the Secretary contends that these rates increased during the period in 2008 when a previously enacted ten percent rate reduction was in effect. Id. at 18. In any event, the Secretary argues that CMS based its decision to approve SPA 11-009 in part on the State's implementation of a monitoring plan that would measure pharmacy participation in Medi-Cal on a quarterly basis. Id. As to plaintiffs' charge that CMS's analysis ignored quality of service, the Secretary argues that the State's monitoring plan repeatedly makes clear that it does not simply address access to any care, but rather that it addresses access to high quality care. Id. at 19. The Secretary notes also that the monitoring plan acknowledges that "[p]rovisions in both Federal and State [law] mandate that administrators ensure access to high quality healthcare for its Medi-Cal beneficiaries." Id.

The Court finds that plaintiffs have shown a high probability of success on the claim that the Secretary's approval based on its acceptance of the access analysis and monitoring plan was arbitrary and capricious.[12] With respect to the access analysis, the Court believes it is likely that the Director's pharmacy participation list inappropriately includes certain pharmacies. That is, because an enrolled pharmacy cannot be deactivated for a full year after it has submitted a claim for reimbursement, all pharmacies that have ceased servicing Medi-Cal beneficiaries within the past year are still deemed "participants" in Medi-Cal. Moreover, absent data of how many pharmacies participate in third-party insurance plans, DHCS's analysis is not a useful

[12] The Court notes that counsel for the Secretary conceded at oral argument in the related case, Cal. Hosp. Ass'n v. Douglas, CV 11-9078 CAS (MANx), that if the State's access analysis were inherently flawed, the Secretary's decision to approve the SPA may be found arbitrary and capricious. Transcript of Oral Argument, at 36: 13–15.

gauge of whether or not Medi-Cal pharmacy payment rates are sufficient to enlist enough pharmacies so that Medi-Cal beneficiaries have the same access to pharmacy services as does the general public. Next, the Court believes it was likely unreasonable for the Secretary to accept DHCS's "utilization" rate, which merely considered the number of prescriptions dispensed by Medi-Cal participating pharmacies in the aggregate. Such a measure ignores that the number of prescriptions filled will necessarily rise with an increase in Medi-Cal beneficiaries such that it is of limited use for determining the rate reduction's impact on access to services. Finally, the Court finds that plaintiffs are likely to succeed on their claim that the Secretary's acceptance of DHCS's monitoring plan was arbitrary and capricious. First, the monitoring plan merely creates a potential response after an access or quality deficiency has been identified. To the extent reduced rates cause pharmacies to close their doors, increased rates will not necessarily result in their reopening. More fundamentally, during the period between the detection of an access or quality problem and its potential remedy through increased reimbursements, Medi-Cal beneficiaries will necessarily suffer from reduced access to and diminished quality of pharmacy services. Moreover, the Ninth Circuit has found it unreasonable to rely on independent provisions of federal and state law to ensure quality of care, precisely what the monitoring plan purports to do here. See Orthopaedic Hospital, 103 F. 3d at 1497 ("The Department, itself, must satisfy the requirement that the payments themselves be consistent with quality care."). For the reasons stated above, the Secretary's contrary interpretation in this case is not owed Chevron deference because the approval of a State Plan Amendment does not include the "hallmarks of 'fairness and deliberation" to which deference is owed. See Alaska, 424 F. 3d at 939 (quoting Mead, 533 U.S. at 226–27).[13]

[13] Furthermore, whether the Secretary's acceptance of the access analysis and monitoring plan as sufficiently ensuring access to skilled nursing services will be found to be arbitrary and capricious at least presents a "serious question going to the merits." continue...

2. Plaintiffs' Section 30(A) Claim Against the Director

The Director argues that plaintiffs are unlikely to succeed on the merits of their Section 30(A) claim because they have no basis for asserting a private right of action under Section 30(A). Director's Opp'n at 6–7. The Director further contends that even if plaintiffs have a private right of action, they cannot demonstrate that AB 97 violates, and is thus preempted by, Section 30(A). In support of this argument, the Director points to CMS's approval of SPA 11-009, which the Director contends is owed deference, and the concession of California Hospital Association's counsel at oral argument before the Supreme Court that if CMS were to approve an SPA, Medicaid providers and recipients would not prevail in litigation. Id. at 8 (citing Tr. Oral Arg. at 53, Douglas v. Indep. Living Ctr., No. 09-958).

At this juncture, the Director's argument that plaintiffs lack a private right of action to enforce Section 30(A) fails. While plaintiffs lack a private right of action under 42 U.S.C. § 1983, see Developmental Servs. Network v. Douglas, No. 11-55851 slip op. at 20533 (9th Cir. Nov. 30, 2011), Ninth Circuit case law establishes that Section 30(A) is enforceable by private parties under the Supremacy Clause.[14] See ILC I, 543 F. 3d at 1050-52; ILC II, 572 F. 3d at 644; Cal. Pharms. I, 563 F. 3d at 850–51. Although

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[13]...continue
Because the Court finds that the balance of hardships tips strongly in plaintiffs' favor, a preliminary injunction is appropriate on this basis as well. See Alliance for the Wild Rockies, 632 F.3d at 1132; ILC II 572 F. 3d at 657–58; Sierra On-Line, Inc., 739 F.2d at 1421.

[14] In their memorandum of points and authorities in support of their motion for preliminary injunction, plaintiffs argue that they are suing under the APA and § 1983 and not under the Supremacy Clause. See Mot. at 2. The APA does not create a private right of action against a state agency. See 5 U.S.C. § 701(b)(1); see also Johnson v. Rodriguez, 943 F. 2d 104, 109 n. 5 (1st Cir. 1991). However, in their complaint, plaintiffs allege that CMS acted contrary to the Supremacy Clause. Compl. ¶ 32. At oral argument, counsel for plaintiffs affirmed that plaintiffs intend to proceed with their Section 30(A) claim against the Director pursuant to the Supremacy Clause.

this issue is presently before the Supreme Court, unless and until this precedent is overruled, it controls here. See Hart v. Massanari, 266 F. 3d 1155, 1171 (9th Cir. 2001). For the reasons articulated in Section B(1) supra, the Court finds that plaintiffs are likely to succeed on their claim that DHCS's failure to consider responsible cost studies and failure to appropriately consider the effect of the rate reduction on access to and quality of pharmacy services may be found to have violated Section 30(A).[15] As discussed above, the Court finds that these issues at least present "serious questions as to the merits" of plaintiffs' claim, and that the balance of hardships tips strongly in plaintiffs' favor. See Alliance for the Wild Rockies, 632 F.3d at 1132; ILC II 572 F. 3d at 657–58; Sierra On-Line, Inc., 739 F.2d at 1421.

3. Plaintiffs' Takings Clause Claim

Plaintiffs assert that the rate reduction violates the Takings Clause of the Fifth Amendment of the U.S. Constitution as incorporated against the states through the Fourteenth Amendment of the U.S. Constitution. Compl. ¶ 31; Mot. at 3.

The "Takings Clause" of the Fifth Amendment provides that private property shall not "be taken for public use, without just compensation." U.S. Const. amend. V. "In order to state a claim under the Takings Clause, a plaintiff must first demonstrate that he possesses a 'property interest' that is constitutionally protected." Turnacliff v. Westly, 546 F. 3d 1113, 1118–19 (9th Cir. 2008) (internal citations omitted).

The Court does not believe that plaintiffs have adequately shown a likelihood of success on their Takings Clause claim. Ordinarily, health care providers "do not possess a property interest in continued participation in Medicare, Medicaid, or the federally-

[15] The Court reaches this conclusion in spite of the statement by California Hospital Association's counsel before the Supreme Court in Douglas v. Indep. Living Ctr. that litigation was unlikely to succeed if CMS approved a SPA. That statement was made in another case, on an issue that had not been briefed prior to argument. In addition, because the individual-beneficiary plaintiff in this case was not involved in any way with Douglas v. Indep. Living Ctr. a statement by counsel for another party in those proceedings should not be deemed to be a concession by the individual-beneficiary plaintiff here.

funded state health care programs." Erickson v. U.S. ex rel. Dept. of Health and Human Srvcs., 67 F. 3d 858, 862 (9th Cir. 1995). In this respect, plaintiffs have failed to establish a protected property interest because the pharmacies voluntarily participate in the Medi-Cal program. Although pharmacies will receive reduced reimbursements as a result of the rate reduction, they are under no obligation to continue servicing Medi-Cal patients.

C. Risk of Irreparable Injury

Plaintiffs contend that pharmacy providers and their patients face irreparable injury as a result of the rate reduction. Specifically, plaintiffs argue that pharmacy providers will suffer financial losses as a result of the cuts, given that they will receive reduced reimbursement. See, e.g., Declaration of Odette Leonelli ("Leonelli Decl."), ¶¶ 6, 10; Declaration of Gerald Shapiro ("Shapiro Decl."), ¶ 20. Furthermore, plaintiffs contend that Medi-Cal beneficiaries will suffer reduced access to the medications they need as a result of pharmacy closures or the elimination of pharmacy services including filling prescriptions and making home deliveries. See, e.g., Leonelli Decl., ¶ 11; Shapiro Decl., ¶ 27.[16]

In opposition, both the Secretary and the Director rely on the mitigating impact of the monitoring plan that California has adopted. Secretary's Opp'n at 22–23; Director's Opp'n at 18. The Secretary cites Midgett v. Tri-County Metro. Transp. Dist. of Or., 254 F. 3d 846, 850 (9th Cir. 2001) (holding that a defendant's procedures for monitoring

[16] The Court notes that in addition to the declarations submitted in this case, plaintiffs also rely on declarations in prior cases regarding similar rate reductions for pharmacy services in which the Ninth Circuit found plaintiffs had adequately shown irreparable harm. The Court rejects the Director's contention that declarations in prior cases are irrelevant in this case due to the State's access analysis and monitoring plan and the Secretary's approval thereof. Regardless of the distinguishable features of this case, the declarations submitted in prior cases provide strong evidence that in response to a rate reduction, pharmacy owners reduce or eliminate services and that Medi-Cal beneficiaries are thereby harmed.

compliance in the ADA context "show that Plaintiff does not face a threat of immediate irreparable harm without an injunction"), and argues that given the procedural safeguards of the monitoring plan, plaintiffs cannot prove irreparable harm as a result of the rate reduction. Secretary's Opp'n at 23. Additionally, the Director argues that the financial injury to pharmacy providers is speculative, and, in any event, not a proper basis for an injunction because providers are merely "indirect beneficiaries" of the program. Director's Opp'n at 17 (citing Sanchez v. Johnson, 416 F. 3d 1051, 1059). Finally, the Director contends that the claims of irreparable harm to beneficiaries are based entirely on hearsay and conjecture that their current providers will stop treating them and that, in such case, they will not be able to find adequate care at another facility. Id.

The Court finds that plaintiffs have met their burden of showing irreparable harm in the absence of an injunction. In reaching this conclusion, the Court rejects defendants' contention that California's monitoring plan will necessarily prevent beneficiaries from being harmed. As discussed above, the Court believes that the monitoring plan at best presents a potential remedy *after* an access or quality problem has been detected. Even if the monitoring plan could ensure that beneficiaries' access to quality services would not be reduced in the aggregate, the Ninth Circuit has held that as long as there is evidence showing that at least some Medi-Cal beneficiaries might lose services as a result of a rate reduction, irreparable harm is adequately demonstrated. Cal. Pharms. Ass'n v. Maxwell-Jolly, 596 F. 3d 1098, 1114 (9th Cir. 2010) ("Cal Pharms. II"). Here, plaintiffs have proffered substantial evidence that numerous pharmacies will eliminate services or shutter their doors in response to the implementation of the rate reduction, suggesting that at least some beneficiaries would suffer reduced access to pharmacy services. Furthermore, because pharmacies would be barred from recovering any reimbursement short fall in an action at law due to California's Eleventh Amendment immunity, the Court finds plaintiffs have shown

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adequate irreparable injury to support an injunction on this basis as well. See Cal. Pharms. I, 563 F. 3d at 850–52.[17]

D. Balance of Hardships and Public Interest

The Secretary and Director each argue that injunctive relief would have a serious impact on the continuing financial health of the State of California. Secretary's Opp'n at 24; Director's Opp'n at 20. The Director also maintains that the public will suffer harm if an injunction issues because any injunction that prevents the implementation of a state statue inflicts injury on the State. Director's Opp'n at 25 (citing Coalition for Economic Equity v. Wilson, 122 F. 3d 718, 719 (9th Cir. 1997)).

While the Court is mindful of the State's fiscal crisis, the Court believes that the balance of the equities and the public interest strongly favor the issuance of an injunction. In reaching this conclusion, the Court notes that the Ninth Circuit has held that "[s]tate budgetary considerations do not . . . in social welfare cases, constitute a critical public interest that would be injured by the grant of preliminary relief. In contrast, there is a robust public interest in safeguarding access to health care for those eligible for Medicaid." ILC II, 572 F. 3d at 659. Further, the Ninth Circuit has explained that "it would not be equitable or in the public's interest to allow the state to continue to violate the requirements of federal law." Cal. Pharms. I, 563 F. 3d at 852–53. Here, for the reasons set forth above, the Court has found it likely that the Secretary's approval of the SPA would be found to be arbitrary and capricious resulting in a continuing violation of federal law. Finally, the Court notes that the Ninth Circuit has repeatedly held that the injury to a state caused by the injunction of one of its statutes does not outweigh the public's interest in ensuring that state agencies comply

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[17] In this respect, the Director's argument that monetary loss to providers cannot be a basis for an injunction is unavailing. The Ninth Circuit has repeatedly rejected this precise argument. See, e.g., Cal. Pharms. I, 563 F. 3d at 850–51; ILC II, 572 F.3d at 658; Cal. Pharms. II, 596 F. 3d at 1113–14.

with the law and protect beneficiaries' access to services. ILC II, 573 F. 3d at 658; Cal. Pharms. II, 596 F. 3d at 1114–15.

IV. CONCLUSION

In accordance with the foregoing, the Court hereby GRANTS plaintiffs' motion for a preliminary injunction.

IT IS HEREBY ORDERED as follows:

Defendant Toby Douglas, Director of the California Department of Health Care Services, his employees, his agents, and others acting in concert with him shall be, and hereby are, enjoined and restrained from violating federal law by implementing or otherwise applying the reduction on Medi-Cal reimbursement to providers of pharmacy services in the Medi-Cal fee-for-service program on or after June 1, 2011, pursuant to Assembly Bill 97 enacted by the California Legislature in March 2011, as codified at California Welfare and Institutions Code § 14105.192, or to any other degree reducing current Medi-Cal rates for pharmacy service providers in the Medi-Cal fee-for-service program.

IT IS HEREBY FURTHER ORDERED that, consistent with the foregoing, the October 27, 2011 decision by Defendant Kathleen Sebelius, Secretary of the Department of the United States Department of Health and Human Services, approving the Medi-Cal reimbursement reduction codified at Welfare and Institutions Code § 14105.192, is hereby stayed.

Dated: December 28, 2011

CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE