UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

CALIFORNIA PHARMACISTS ASSOCIATION; GERALD SHAPIRO, Pharm. D. dba Uptown Pharmacy and Gift Shoppe; SHARON STEEN, dba Central Pharmacy; TRAN PHARMACY, INC. dba Tran Pharma,

Plaintiffs,

vs.

DAVID MAXWELL-JOLLY, Director of Department of Health Care Services of the State of California

Defendant.

Case No. CV 09-8200 CAS (MANx)

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

On November 9, 2009, plaintiffs California Pharmacists Association; Gerald Shapiro, Pharm. D., dba Uptown Pharmacy & Gift Shoppe; Sharon Steen, dba Central Pharmacy; and Tran Pharmacy, Inc., dba Tran Pharmacy, filed the instant action against David Maxwell-Jolly, Director of the Department of Health Care Services of the State of California (the "Director"). The Department of Health Care Services of the State of California (the "Department") is a California agency charged with the administration of California's Medicaid program, Medi-Cal. Plaintiffs represent certain providers of

Medi-Cal pharmaceutical services. On December 5, 2009, plaintiffs filed an amended complaint ("FAC") for injunctive and declaratory relief, alleging nine claims for relief.

On December 7, 2009, plaintiffs filed the instant motion for preliminary injunction. On December 28, 2009, the Court denied plaintiffs' December 10, 2009 application for temporary restraining order, pending final determination of their motion for preliminary injunction. On February 1, 2010, defendant filed his opposition. Plaintiffs' reply was filed on February 8, 2010. The Court heard oral argument on February 22, 2010, and then took this matter under submission. 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 the 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 Medicaid Plan ("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 federal Medicaid law, including 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.

The subject of this case is reimbursement to pharmacies in the Medicaid program. Medi-Cal reimburses pharmacies that dispense prescription drugs to patients covered by

Medicaid. The department reimburses these pharmacies the lower of the pharmacy's "usual and customary charge," (known as the Upper Billing Limit, "UBL") or the reimbursement rate outlined in § 14105.45. See Cal. Welf. & Inst. Code § 14105.455(e). Under § 14105.45, the department reimburses pharmacies the "estimated acquisition cost" of drugs along with a fixed dispensing fee per prescription. Cal. Welf. & Inst. Code § 14105.45(b)(1). The reimbursement of drug costs is based on the lesser of four alternatives: (1) average wholesale price ("AWP") minus 17%; (2) the selling price; (3) the federal upper limit; or (4) the maximum ingredient cost ("MAIC").[1] Id. § 14105.45(b)(2).

Plaintiffs here challenge three different pharmacy provider cuts. First, is 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."[2] 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.[3] See New

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[1] MAIC means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs. Cal. Welf. & Inst. Code § 14105.45(8).

[2] The AWP reductions are the subject of plaintiffs' fifth, sixth, and seventh claims for relief. Specifically, plaintiffs request that the Court order the Director to (1) "refrain from implementing" the September 26, 2009, markdown of published AWP; (2) "pay all pharmacies in the Medi-Cal fee-for-service program the same amounts that they would otherwise have received" absent the markdown in published AWP; and (3) "take all steps necessary, at once, to order and to cause all managed care plans" to pay the same amount to all pharmacy providers had the published AWP not been marked down. Mot. at 1-2.

[3] 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

(continued...)

England Carpenters Health Benefits Fund v. First DataBank, Inc., 602 F. Supp. 2d 277 (D. Mass. 2009) (approving the settlements). On appeal, the district court's order approving the settlement agreements was affirmed by the First Circuit. See 582 F.3d 30 (1st Cir. 2009). Plaintiffs allege that the settlements in First DataBank had the effect of reducing the markup to 1.20 over WAC when setting the AWP for approximately 18,000 to 20,000 additional drug products. FAC ¶ 26. 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%. Id.

Second, is the alleged payment reduction pursuant to the UBL statute, codified at Cal. Welf. & Inst. Code § 14105.455, and enacted by the California legislature on July 28, 2009, when California Governor Arnold Schwarzenegger signed into law Assembly Bill X4 5 ("AB 5"). The relevant code section provides that pharmacy providers are required to submit their usual and customary charge when billing the Medi-Cal program for prescription drugs.[4] Id. § 14105.455(a). The "usual and customary charge" means the lower of the following: (1) the lowest price reimbursed to the pharmacy by other third-party payers in California; or (2) the lowest price routinely offered to any segment of the general public. Id. § 14105.455(b). Plaintiffs allege that as a practical matter compliance with the record keeping requirements of the UBL statute is impossible for the great majority of pharmacies because of the way pharmacies handle third-party payer claims—namely, third-party payers usually contract with pharmacy benefit managers or wholesaler's organizations to contract with pharmacy networks, which are called

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[3](...continued)
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).

[4] Further, pharmacy providers are required now "to keep and maintain records of their usual and customary charges for a period of three years from the date the service was rendered." Cal. Welf. & Inst. Code § 14105.455(d).

Pharmacy Service Administration Organizations; in this way, third-party payers do not directly contract with the individual pharmacies. FAC ¶¶ 54-56; Mot. at 11. Accordingly, plaintiffs allege, in their fourth claim for relief, that because pharmacy providers do not know when they submit a claim, whether the claim is higher or lower than the Medi-Cal rate for the same prescription, many pharmacy providers will simply elect to fill only third-party payer claims, rather than Medi-Cal claims. Id.; Reply at 12.

Finally, plaintiffs challenge any reduction in reimbursement for generic drugs which are subject to a MAIC cap, commencing in June 2010. According to plaintiffs, since 1990, the Department has administered a list of MAIC multi-source drugs at a MAIC cap or limit which allows a large percentage of gross profit, which however is only a small dollar amount of gross profit per MAIC prescription because MAIC generics are low-priced drugs. Mot. at 19. Plaintiffs allege that since 2004, the legislature has enacted a series of measures to reduce this profit. Id. First in 2004, the legislature reduced payment for a MAIC drug to the "manufacturer's average sale price." Id. Then, § 14105.45, as enacted by Assembly Bill 203 ("AB 203") in August 2007, required the Department to establish a MAIC list for generically equivalent drugs; and to update the list and establish new MAICs based on the mean of the "average manufacturers price" of drugs generically equivalent to the particular innovator drug, plus a percent markup determined by the department to be necessary for the MAIC to represent the "average purchase price" paid by retail pharmacies in California.[5] According to plaintiffs, because the U.S. District Court for the District of Columbia enjoined the Department from implementing average manufacturers prices, the legislature enacted the new MAIC reimbursement provisions of AB 5. As amended by AB 5, § 14105.45 now provides that if "average manufacturer prices" are unavailable, the Department shall establish the MAIC, either

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[5] "Average manufacturers price" means the "price reported to the department by the Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8." Cal. Welf. & Inst. Code § 14105.45.

> (i) based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the *average purchase price* paid by retail pharmacies in California; or (ii) pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.

Cal. Welf. & Inst. Code § 14105.45(b)(2)(B) (emphasis added). Further, subsection (d) provides that "in order to maintain beneficiary access to prescription drug services," the Department shall make a "one-time adjustment to the dispensing fees paid to pharmacy providers" calculated to equal the aggregate savings to the State from implementing the new MAIC reimbursement scheme.[6] See id. § 14105.45(d). Finally, the Department is required to establish a process for providers to seek a change to a specific MAIC when the providers believe the MAIC does not reflect current available market prices. Id. § 14105.45(b)(3)(E). Plaintiffs allege that this change in calculating the MAIC results in a reduction in payments to pharmacy providers of more than .8%. Mot. at 7. Further, plaintiffs allege in their eighth claim that because the new MAIC formula is based on an average, i.e. "average purchase price," that approximately one-half of all pharmacies which by definition comprise the group who expend more than the average amount to acquire a given MAIC drug product, will suffer a net loss. FAC ¶ 95. Moreover,

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[6] Specifically, subsection (d) provides, in pertinent part, that

> no later than 30 days after the department initially implements selling price as a component of estimated acquisition cost, pursuant to paragraph (2) of subdivision (b), the department shall make a one-time adjustment to the dispensing fees paid to pharmacy providers in accordance with paragraph (1) of subdivision (b). This change shall only be made if selling price results in a lower aggregate drug reimbursement. Any increase in dispensing fee made pursuant to this subdivision shall not exceed the aggregate savings associated with the implementation of selling price.

Cal. Welf. & Inst. Code § 14105.45(d).

plaintiffs allege that because the new dispensing fee that is set by the amended § 1405.45 is fixed and increased only one time, all pharmacy providers will suffer a net loss over time, "due to inflation in overhead costs." Id. ¶ 97.

III. LEGAL STANDARD

The purpose of a temporary restraining order is to "preserve the status quo pending hearing on the moving party's application for a preliminary injunction." William A. Schwarzer et al., California Practice Guide: Federal Civil Procedure Before Trial § 13:11 (The Rutter Group 2002) (citing Granny Goose Foods, Inc. v. Brotherhood of Teamsters & Auto Truck Drivers, 415 U.S. 423, 439 (1974)). "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); see also Cal Pharms. Ass'n v. Maxwell-Jolly, 563 F.3d 847, 849 (9th Cir. 2009).

IV. DISCUSSION

A. LIKELIHOOD OF SUCCESS ON THE MERITS

As noted above, plaintiff brings nine claims for relief based on the allegation that the three pharmacy provider cuts are preempted by § 30(A). The Ninth Circuit has held that plaintiff may bring suit under the Supremacy Clause to enjoin implementation of state legislation preempted by the Medicaid Act. See, e.g., Indep. Living Ctr. of S. Cal. v. Shewry, 543 F.3d 1050, 1065-66 (9th Cir. 2008) ("ILC I"). Under general principles of federal conflict preemption, state law is preempted only to the extent that it actually

conflicts with state law. Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983). Such a conflict may arise either where "compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id. at 203-04. In so far as the California Legislature and the Department fail to consider the factors required by § 30(A) before setting Medi-Cal reimbursement rates, the Court may find that such state legislation frustrates the purpose underlying § 30(A), and is thus preempted. See Indep. Living Ctr. of S. Cal. v. Maxwell-Jolly, 572 F.3 644, 653 (9th Cir. 2009) ("ILC II"). Section 30(A) creates duties on behalf of the Department, i.e., the duty to consider efficiency, economy, and quality of care when establishing reimbursement rates. Id. at 65 (citing Orthopedic Hospital v. Belshe, 103 F.3d 1491, 1492, 1496-97 (9th Cir. 1997)). Thus when the State of California seeks to modify reimbursement rates for health care services provided under the Medi-Cal program, it must consider efficiency, economy, quality of care, and equality of access, as well as the effect of providers' costs on those relevant factors. See ILC II, 572 F.3d at 651-53. As the Ninth Circuit held in Orthopedic Hospital, 103 F.3d at 1496, § 30(A) requires that the Director set reimbursement rates that "bear a reasonable relationship to efficient and economical hospitals' costs of providing quality services, unless the Department shows some justification for rates that substantially deviate from such costs." See also ILC II, 572 F.3d at 651-52 (affirming the standards established in Orthopedic Hospital). To meet this statutory requirement, the Director "must rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting." 103 F.3d at 1496. Further, the Ninth Circuit clarified in Cal. Pharms. Ass'n v. Maxwell-Jolly, 596 F.3d 1098, 1105-07, 1115 (9th Cir. 2010), that when the California legislature "elects to by-pass the Department, and set rates itself," the legislature "must study the impact of the contemplated rate reduction on the statutory factors of efficiency, economy, quality of care, and access to care *prior* to setting or adjusting payment rates," "or in a manner that allows those studies to have a meaningful

impact on rates before they are finalized."[7]

1. Claims One, Two, and Three

In their first three claims for relief, plaintiffs challenge the three pharmacy provider cuts for the following same reasons. First, plaintiffs claim that all the Medi-Cal rate reductions by the legislature are facially contrary to the single state agency provisions of 42 U.S.C. § 1396a(a)(5), and are thus preempted under the Supremacy Clause. FAC at 13-17; Mot at 4-6. The Ninth Circuit has not interpreted the Medicaid Act to require that rate setting be the exclusive purview of the Department. To the contrary, the Ninth Circuit recently clarified in Cal. Pharms. Ass'n, 596 F.3d at 1105-07, that the legislature may "by-pass the Department, and set rates itself" so long as it considers the relevant § 30(A) factors prior to setting or adjusting rates. Second, plaintiffs claim that the three provider cuts constitute a substantive violation of § 30(A) because their cumulative effect is allegedly a 5% reduction in total reimbursement, which in turn will cause a reduction in participation by pharmacy providers to such a degree that equal access to services is threatened. FAC at 19-22; Mot at 6-8. For the reasons articulated infra subsection IV.A.1, the Court finds that the claimed 4% reduction in payments tied to AWP does not implicate § 30(A). Accordingly, plaintiffs' challenge to the cumulative effect of the provider cuts, most notably the 4% AWP

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[7] In Cal. Pharms. Ass'n, the Ninth Circuit rejected the State's argument that the holding in Orthopedic Hospital stood for the proposition that only the Department is required to consider the § 30(A) factors and in any way "absolves the legislature of the same requirements when it sets rates." 596 F.3d at 1105-06. The Ninth Circuit emphasized that none of the disputed rate-settings in Orthopedic Hospital were actually set by the legislature because the legislative enactments granted the Director broad discretion to set applicable rates in the face of general governing criteria. Id. Because "the Director set the challenged rates, [Orthopedic Hospital] addressed whether the Medicaid Act 'requires the Department to consider the costs hospitals incur in delivering services *when setting* specific payment rates under [§ 30(A)]", and found that "the Department cannot know *that is setting rates* that are consistent with [§ 30(A)'s relevant factors] without considering the costs of providing such services. Id. (quoting 103 F.3d at 1496 (emphasis added)).

markdown, is denied. Third, plaintiffs claim that the legislature precluded itself from an adequate consideration of the relevant § 30(A) factors by virtue of its merging the MAIC limitation and UBL provision in one bill. FAC at 23-24; Mot. at 8. As this Court has noted in related matters, the State is free to exercise its "considered judgment" and reduce Medi-Cal reimbursement rates, so long as the decision is not based solely on budgetary constraints. See accord Cal. Pharms. Ass'n, 596 F.3d at 1115. The fact that the legislature chose to enact the payment cuts in the same bill, AB 5, by itself does not demonstrate that the legislature failed to consider the relevant § 30(A) factors. Accordingly, the Court concludes that plaintiffs have not made out a sufficient showing that they have a strong likelihood of success on the merits of their first, second, and third claims.

2. Claims Five, Six, and Seven

In their fifth and sixth claims, plaintiffs contend that the 4% reduction resulting from the FirstData Bank settlements constitutes a rate reduction in violation of § 30(A). For the reasons stated in the Court's December 28, 2009 order denying plaintiffs' application for a temporary restraining order, the Court disagrees.

Plaintiffs alternatively contend that assuming that the 4% reduction in reimbursements tied to the AWP is not a "rate cut" caused by a state action, the Court should nevertheless find that the payment reduction is a substantive violation of § 30(A). In support of their seventh claim for relief, plaintiffs argue that the reduction in payments violates § 30(A)'s substantive requirements because pharmacies will cease filling brand drug prescriptions, thereby denying recipients both quality pharmaceutical services and equal access to brand drugs. Reply at 12. In other words, plaintiffs are arguing that it is immaterial under § 30(A) whether the state acted to reduce reimbursement rates because § 30(A) requires that payments not be effectively reduced in such a way that would undermine the requirements mandated by the quality of care and equal access provisions. Plaintiffs point to the language of § 30(A) which provides, in pertinent part, that the State Plan "must . . . provide . . . payment for, care and services

available under the plan . . . to assure that payments are consistent" with the relevant § 30(A) factors, to argue that the State has an affirmative obligation to assure that payments are substantively consistent with quality of care and equal access. Mot. at 3-4.

In ILC II, the Ninth Circuit discussed the distinction between § 30(A)'s procedural and substantive requirements. 572 F.3d at 657; see also Cal. Pharms. Ass'n, 596 F.3d at 1113 (discussing the distinction). The court noted the "potential difficulties inherent in assessing substantive compliance with the factors laid out in § 30(A)," which made more attractive, by comparison, the "process-oriented view of the statute espoused in [Orthopedic Hospital]." Id. Moreover, the Ninth Circuit explained that while there is a difference between the substantive and procedural compliance with § 30(A), the two requirements are interdependent. Id. at 656 ("[I]t is fair to assume that a rate that is set arbitrarily, without reference to the Section 30(A) requirements, is unlikely to meet the equal access and quality requirements."). Finally, the Ninth Circuit suggested that "[e]ven if we were to interpret § 30(A) to mandate a substantive rather than procedural result, [the rate reduction] might still conflict with the quality of care and access provisions of § 30(A)" if at least some providers stop treating Medi-Cal beneficiaries. Id. at 656-57; see also Cal. Pharms. Ass'n, 596 at 1114 (finding in the alternative that even if the court were to require a substantive violation of the statute to support a finding of irreparable harm, the court would find a violation in this case because at least some providers would stop treating beneficiaries due to the five percent rate reduction enacted by AB 1183).

Notwithstanding the fact that there is a difference between substantive and procedural compliance with § 30(A), it appears that the obligations created by § 30(A) are not implicated in circumstances such as these where the State has not affirmatively acted to create a new, or modified, "method or procedure" for establishing reimbursement rates to Medi-Cal providers. 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 this case is distinguishable from every case in this circuit in which the court has 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 absence of such a duty under § 30(A), it is inappropriate to order the Department to remediate the effects of a reduction in payments occasioned by a private settlement. Moreover, to the extent that these external changes in published prices may allow California's State Plan to fall out of compliance with §30(A), the Secretary may in her discretion initiate a compliance action and withhold federal funds.[8] See 42 U.S.C. § 1396c. The Court concludes that the Secretary is better able to address the potential impact of the markdown in AWP, as it pertains to Medicaid reimbursement rates nationally, than is the State.

For all these reasons, the Court concludes that plaintiffs have not made out a sufficient showing that they have a strong likelihood of success on the merits of their seventh claim for relief. As to plaintiffs' alternative request for preliminary injunction pending appeal, under Fed. R. Civ. P. 8(a), the Court denies such a request for the same reasons stated in the Court's February 22, 2010 order denying the same request by

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[8] In the related matter, Nat'l Assoc. of Chain Drug Stores, et al. v. Arnold Schwarzenegger, et al., No. 09-7097 CAS (MANx), plaintiffs sought to enjoin the same 4% reduction in payments tied to AWP. The United States Department of Justice ("DOJ") filed a Statement of Interest in that case arguing that these changes in the reimbursement formula do not implicate § 30(A), and that in any event, the Secretary 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. See DOJ Statement of Interest (filed Dec. 21, 2009). The DOJ noted that to the contrary, "the widespread abuse of the AWP system has cost the federal government, states, and third-party payors billions in inflated payments." Id. at 4.

plaintiffs in the related matter of Nat'l Assoc. of Chain Drug Stores, CV 09-7097 CAS (MANx).

3. Claims Four and Nine

As previously discussed, in their fourth claim for relief, plaintiffs contend that the UBL provision, codified at § 14105.455, substantively violates the quality of care and equal access provisions of § 30(A) because many pharmacists will elect to not participate in Medi-Cal, so as to prevent their being penalized by Medi-Cal for filling third-party payer prescriptions for less than Medi-Cal pays. Reply at 12. Further, in their ninth claim for relief, plaintiffs allege that the UBL statute violates the State Plan, as well as 42 C.F.R. § 447.512, because these laws do not permit any methods or standards for establishing a payment limitation other than a limitation of "charges to the public." Reply at 14; FAC at 45-48. According to plaintiffs, "charges to the public" has always been interpreted by the Department so as to not refer to, or include, charges to third-party payers. Id.

Defendant responds that the UBL statute merely codifies existing anti-discriminatory billing and record-keeping requirements mandated by longstanding Medi-Cal regulations, and affirmed by the California Court of Appeal in Physician and Surgeons Laboratories, Inc. v. Dept. of Health Care Services, 6 Cal. App. 4th 968 (1992). Opp'n at 2, 11-12, 14 (citing Cal. Code Regs., tit. 22, §§ 51501(a) (2000); 51480 (1974); 51513(b)(1)(A) (2009); 51516 (1999); 51516.1 (2004)). Accordingly, defendant argues that the cases challenging legislatively mandated rate changes do not apply to this provision. Id. at 2, 10-12. However, even if the rate-setting cases applied, defendant contends that the legislature relied upon responsible cost studies to determine that Medi-Cal reimbursement after the proposed changes enacted by AB 5 comply with § 30(A). Id. In support of this argument, defendant points to the fact that in 2007, the Department contracted with the accounting firm Myers and Stauffer to perform a study of pharmacy provider costs and reimbursements under the Medi-Cal program ("Myers and Stauffer Study"). Id. at 5; Def.'s Req. For Judicial Notice ("RJN"), Ex. B.

In Indep. Living Ctr. of S. Cal. v. Maxwell-Jolly, No. 09-55692, 2010 WL 737650, at *1 (9th Cir. Mar. 3, 2010) (unpublished), the Ninth Circuit had occasion to consider whether the Director could rely on the Myers and Stauffer Study to demonstrate that the legislature in 2008 studied the impact of the rate changes proposed by AB 1183, on the statutory factors prior to setting rates, or in a manner that allowed those studies to have a meaningful impact on rates before they were finalized. The Ninth Circuit rejected the Director's reliance because "while the Myers and Stauffer Study provides detailed discussion of costs, it is bereft of any analysis of the remaining § 30(A) factors."[9] 2010 WL 737650, at *1 (citing Cal. Pharms. Ass'n, 596 F.3d at 1115, holding that the State must consider costs *and* study the impact of the rate change on the statutory factors). To the contrary, the Ninth Circuit noted that the Myers and Stauffer Study recommends that the Department consider additional analysis in light of these costs. Id. (quoting passages in the study in support).

In considering whether to enact the UBL provision, defendant contends that the legislature considered that "private third-party payers have contractual agreements with pharmacies to limit drug reimbursement, and these reimbursement rates are often lower than the Medi-Cal reimbursement."[10] Opp'n at 5, 14-15; Def.'s RJN, Ex. D-1, D-10 at 968-69 (noting that the Myers and Stauffer Study found that Medi-Cal pharmacy reimbursement covers 105% of providers' costs). Defendant argues that the legislature complied with the procedural requirements outlined in ILC II, 572 F.3d at 657, and

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[9] The Ninth Circuit also rejected the Director's reliance because the Director could point to only one sentence in the May 30, 2008 agenda released by the Assembly Budget Subcommittee No. 1 on Health and Human Services that read: "Dec. 2007 Myers and Stauffer study found that current Medi-Cal drug pricing averages around 5 percent over cost." The Ninth Circuit held that the one-sentence citation did not show adequate consideration of the § 30(A) factors. 2010 WL 737650, at *1.

[10] Further, the legislature noted that the purpose of § 14105.455 is "to ensure the Medi-Cal Program is billed at a third-party payer rate, and not subsidizing pharmacies or other payers." Id.

related cases, because it considered the Myers and Stauffer Study before enacting § 14015.55. Id. at 12-13. Furthermore, to the extent plaintiffs claim that the record keeping requirements of the UBL will drive pharmacy providers out of business, defendant argues that plaintiffs should not be excused from complying with existing law that prohibits discriminatory billing practices because plaintiffs have delegated this duty to a third party. Id. at 16-17 (citing § 14124.1 which requires every provider billing Medi-Cal to "keep and maintain records of each service rendered, the date of service rendered, and such additional information as the department make require").

Plaintiffs reply that despite defendant's assertion that the UBL provision merely enacts existing law, the State Plan only provides an upper limit on payments to pharmacies equal to "charges to the general public." Reply at 2-6. Further, they emphasize that based on the Director's estimation, the UBL is estimated to result in a savings to the State of $45 million, or more, annually. Id. at 4. Accordingly, plaintiffs argue that it cannot be said that the UBL provision does not constitute a payment reduction. Id.

As a threshold issue, the Court finds that the UBL provision created by AB5, and codified at § 14105.455, constitutes an act of rate-setting, thus triggering the State's duties under § 30(A). Moreover, in so far as the UBL seeks to create a "lower" reimbursement rate under § 14105.455(e), than previously existed, it is a provider cut. Accordingly, even if it could be said that the legislature considered provider costs prior to enacting § 14105.455, based on its review of the Myers and Stauffer Study, the Court finds that the legislative history shows no indication, nor does defendant even argue, that the legislature studied the impact of the UBL provision on the § 30(A) factors of efficiency, economy, quality, and access to care. Moreover, although Medi-Cal providers may be required under existing law to maintain records and to not bill the Medi-Cal program more than they charge other purchasers, § 14105.455 enacted new administrative requirements and a reimbursement rate based explicitly on the definition

of "usual and customary charges" to third-party payers.[11] See Cal. Welf. & Inst. Code § 14105.455(a), (d). To the extent this new provision forces pharmacy providers to modify business practices, and thus increases provider costs, or otherwise to forgo participating with Medi-Cal, as discussed infra section IV.B, the legislature is required to consider the relevant § 30(A) factors prior to enacting such a provision. Accordingly, the Court concludes that plaintiffs have demonstrated a likelihood of success on the merits of their fourth claim given that it appears that the legislature did not procedurally comply with the factors laid out in § 30(A), and thus it is fair to assume that the UBL provision is unlikely to meet the substantive requirements of equal access and quality of service. See Cal. Pharms. Ass'n, 596 F.3d at 1113, 1115.

Because the Court concludes that plaintiffs have demonstrated a likelihood of success on their fourth claim based on a violation of § 30(A), the Court need not address the merits of plaintiffs' ninth claim, in the alternative, that the UBL provision also violates the State Plan, as well as 42 C.F.R. § 447.512.

4. Claim Eight

As discussed previously, in their eighth claim for relief, plaintiffs allege that the new MAIC reimbursement formula constitutes a substantive violation of § 30(A) because it will cause pharmacy providers to stop dispensing generic drugs subject to the MAIC cap given that the new formula will force them to dispense these drugs at a net loss. Mot. at 18-22. Accordingly, they argue that Medi-Cal beneficiaries will be unable to obtain their drug prescriptions subject to the MAIC formula. Id.

Defendant raises many of the same arguments in response to the challenge to the MAIC formulas, as he did in the context of the UBL provision. First, he argues that the rate setting cases do not apply because § 14105.45, as amended by AB 5, merely

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[11] Current regulation requires generally that "[n]otwithstanding any other provisions of these regulations, no provider shall charge for any service or any article more than would have been charged for the same service or article to other purchasers of comparable services or articles under comparable circumstances." 22 C.C.R. § 51501(a).

authorizes the Department to set MAICs and was made necessary because the existing formula based on average manufacturers price was enjoined. Opp'n at 1, 4; Def.'s RJN, Ex. D-3 at 832. In addition, defendant contends that prior to enacting the new MAIC formula, the legislature considered the Myers and Stauffer study, and considered that "a shift away from brand name drugs to generics with MAICs can be expected to financially benefit pharmaceutical providers." Id. at 4, 13-14. He argues moreover, that § 14104.45 requires the Department to consider provider input and costs in the MAIC setting process. Id. (citing Cal. Welf. & Inst. Code § 14105.45(b)(3)(E)-(F)).

Again, the Court finds that the new MAIC reimbursement formula enacted by AB 5, and codified at § 14105.45, constitutes an act of rate-setting, thus triggering the State's duties under § 30(A). For the same reasons discussed in the context of the UBL provision, the Court finds that the legislature's review of the Myers and Stauffer Study of provider costs, is not sufficient to demonstrate that the legislature studied the impact of the UBL provision on the § 30(A) factors of efficiency, economy, quality, and access to care, prior to enacting AB 5. Finally, in so far as § 1401.45(b)(3)(E) requires the Department to establish a process for providers to challenge a specific MAIC, or subsection (F) requires it to consider providers' costs in determining the "average purchase price," such provisions fail to demonstrate that the Department has the discretion to alter reimbursement rates based on a study of their impact before the rates are finalized. See Cal. Pharms. Ass'n, 596 F.3d at 1110-11 (rejecting the Director's argument that he has the discretion regarding rates under a similar provision). For these reasons, the Court concludes that plaintiffs have demonstrated a likelihood of success on the merits of their eighth claim given that it appears that the legislature did not procedurally comply with the factors laid out in § 30(A), and thus it is fair to assume that the amended MAIC reimbursement formula is unlikely to meet the substantive requirements of equal access and quality of service. See Cal. Pharms. Ass'n, 596 F.3d at 1113, 1115.

B. IRREPARABLE HARM

Plaintiffs contend that pharmacy providers and their patients are being irreparably harmed by the reduction in reimbursements tied to AWP and the payment cuts enacted by AB 5.[12] Plaintiff argues that pharmacy providers will suffer pecuniary harm as a result of the provider cuts, given that they will receive less reimbursement than they would otherwise receive absent the markdown in AWP and the limitations in AB 5. Specifically, plaintiffs assert that Richard D. Wilson, C.P.A., finds that the cumulative effect of these three provider cuts is a reduction in payments by more than 5%, and thus payment rates will not assure that sufficient providers enlist to provide equal access. Mot. at 6-8; Wilson Decl. at 10, 11, 16.

In light of the Court's finding that plaintiffs have not established a high likelihood of succeeding on the merits of their claims challenging the reduction in payments tied to the 4% markdown in AWP, the Court, while acutely cognizant of the potential adverse consequences of these 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.")

As to the UBL provision, plaintiffs submit declarations of pharmacy providers attesting that because of the way third-party payer claims are handled, it is impossible for them to know the specific rates as they compare to Medi-Cal rates, and thus comply with the new UBL provision. Mot. at 10 (citing Lofholm Decl. ¶ 13; Tran Decl. ¶ 19; Shapiro Decl. ¶ 20 ("It is impossible for me to ascertain exactly what my usual and customary rates to third party payers are because there are so many variables for each of

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[12] Defendant files numerous objections to plaintiffs' evidence on the basis that many of the statements made by the declarants are speculative and lack foundation. To the extent the Court relies on the evidence, the Court overrules defendant's objection.

the tens of thousands of drug NDCs under many different third party plans.")). Accordingly, plaintiffs maintain that many pharmacies will be forced to quit the Medi-Cal program, thus harming beneficiary equal access. Id. (citing, e.g., Lofholm Decl. "[I]t does not matter if the pharmacy is a chain or independent, neither can comply [with the UBL provision] and to lessen their exposure to recoupment, many will cease serving Medi-Cal beneficiaries . . . .").

With regard to the MAIC, plaintiffs submit declarations of pharmacy providers that the new reimbursement formula will cause them to suffer a net loss on filling prescriptions for drugs subject to the MAIC cap. For example, Sharon Steen declares that "Medi-Cal, under the new MAIC formula, will reimburse my pharmacy for our costs to acquire a generic drug no more than the average purchase price paid by California retail pharmacies for a given MAICed generic drug transaction. This takes all gross profit out of the acquisition side of the MAIC generic drug transaction. Then because the $7.25 dispensing fee is much less than my overhead costs, per prescription, my pharmacy will suffer a net loss on the total transaction for every MAIC generic drug dispensed." Plaintiffs assert that this will cause pharmacy providers to no longer dispense such prescriptions. Armen Tatevossian declares, "[a]s for the reduction for the MAIC calculations for generics, generics are the only thing that is helping keep my pharmacy above water. If this is taken away from us as well, then there is no point in keeping our door open."

Defendant responds that the conclusions reached by plaintiffs' expert Richard Wilson are speculative and "reach far beyond his expertise or findings." Opp'n at 19. Further, he argues that plaintiffs cannot demonstrate they will suffer irreparable harm because of the limitations enacted by AB 5 because provider reimbursement will still exceed 100% of provider costs.[13] Id. at 21. Specifically, as to the amended MAIC

[13] In support of this argum ent, defendant relies on the theory that the Myers and Stauffer Study found that pharmacy providers are reimbursed at least 105% of their costs (continued...)

formula, defendant argues that a .8% reimbursement reduction, as alleged by plaintiffs, for multi-source drugs subject to the MAIC cap will still result in providers being reimbursed 109.2% to 139.2% of costs. Id. at 22; Defs. RJN A ¶ 31. Finally, defendant contends that plaintiffs' alleged harm to their businesses or to Medi-Cal recipients is speculative at best and thus does not constitute irreparable injury. Id. at 22.

The Court finds that plaintiffs have sufficiently demonstrated that there is a likelihood certain pharmacy providers will suffer monetary losses as a result of the limitations enacted by AB 5, and codified at § 14105.45 and § 14105.455. In addition, beneficiary access will be harmed to the extent pharmacy providers will elect to not fill Medi-Cal prescriptions as a result of these rate reductions. Finally, the Court concludes that plaintiffs have shown irreparable harm if an injunction is not granted, given that plaintiffs' will be barred by the Eleventh Amendment from obtaining retroactive relief in federal court. See Cal. Pharms., 563 F.3d at 851-52.

C. BALANCE OF HARDSHIPS AND PUBLIC INTEREST

While the Court is mindful of the enormous challenge faced by the State of California in light of its fiscal crisis, 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 determined 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., 563 F.3d at 852-53. Given that the State may decide to implement a rate change upon making a properly reasoned and supported analysis, the Court finds that the balance of equities and the public interest weigh in

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[13](...continued)
by Medi-Cal. Opp'n at 21. Thus, defenda nt argues, even assuming the accuracy of plaintiffs' allegations that § 14105.45 a nd § 14105.455 will result in a 2.5% reduction, providers will still be reimbursed 102-103% of their aggregate costs. Id.

favor of granting the injunctions as to the limitations enacted by AB 5, codified at § 14105.455 and § 14105.45.

V. CONCLUSION

In accordance with the foregoing, the Court GRANTS in part and DENIES in part plaintiffs' motion for preliminary injunction. The Court hereby orders respondent Director, his agents, servants, employees, attorneys, and all those working in concert with him to (1) refrain from enforcing the Upper Billing Limit codified at Cal. Welf. & Inst. Code § 14105.455; and (2) to refrain from enforcing that portion of Cal. Welf. & Inst. Code § 14105.45, as amended by AB 5, which provides a new MAIC reimbursement formula.

IT IS SO ORDERED

Dated: May 5, 2010

Christina A. Snyder

CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE