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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION,)	CASE NO. CV 09-8199-R
)	
Plaintiff,)	AMENDED FINDINGS OF
)	UNCONTROVERTED FACTS AND
vs.)	CONCLUSIONS OF LAW
)	IN SUPPORT OF JUDGMENT
TOBY DOUGLAS, Director of the)	
California Department of Health Care)	
Services,)	
)	
Defendant.)	
)	

INTRODUCTION

Plaintiff Aids Healthcare Foundation (“Plaintiff” or “AHF”) initiated this action against Defendant Toby Douglas, Director of the California Department of Health Care Services (“Defendant” or the “Department”), in response to Section 14105.46 of the California Welfare and Institutions Code (“Section 14105.46”), which imposed new requirements on prescription drug providers that participate in the 340B program of Section 602 of the Veterans Health Care Act of 1992, codified at Title 42 U.S.C. § 256b. The parties filed cross motions for summary judgment on the Plaintiff’s remaining claims. The Court granted, in part, and denied, in part, each party’s motion. The Ninth Circuit remanded this case in light of the January 30, 2014 approval of the State Plan Amendment by the Centers for Medicare and Medicaid Services (“CMS”). Having

1 considered the 2014 CMS approval, in support of its Judgment, the Court makes the following
2 amended findings of fact and conclusions of law:

3 **FINDINGS OF UNCONTROVERTED FACT**

- 4 1. Plaintiff AHF is a California nonprofit corporation that voluntarily participates in Medi-
5 Cal's 340B program as a provider of health care services and, among other things,
6 furnishes outpatient prescription drugs to Medi-Cal patients.
- 7 2. Plaintiff AHF obtains savings on purchases of drugs as a participant of the 340B program.
- 8 3. The Department is the single state agency that administers California's Medicaid program,
9 known as Medi-Cal.
- 10 4. On July 28, 2009, the Governor signed into law Assembly Bill X4-5 (the Special Session
11 healthcare trailer bill).
- 12 5. Section 40 of Assembly Bill X4-5 added Section 14105.46 to the Welfare and Institutions
13 Code.
- 14 6. Section 14105.46 requires 340B safety net providers to dispense to Medi-Cal beneficiaries
15 only drugs purchased through the 340B Program.
- 16 7. Prior to the enactment of Section 14105.46, 340B safety net providers who also
17 participated in Medi-Cal had the option of purchasing drugs dispensed to Medi-Cal
18 beneficiaries through the 340B program or on the open market.
- 19 8. Before Section 14105.46, safety net providers that dispensed 340B drugs for their
20 Medicaid patients would be reimbursed under Welfare & Institutions Code § 14105.45.
- 21 9. Under Welfare & Institutions Code §14105.45(b), pharmacy providers are reimbursed the
22 lower of the estimated acquisition cost of the drug plus a dispensing fee or the pharmacy's
23 usual and customary charge as defined in Welfare and Institutions Code § 14105.455.
- 24 10. Welfare & Institutions Code states that pharmacy providers shall be paid at the lesser of
25 their usual and customary charges or the reimbursement rate established under Welfare &
26 Institutions Code § 14105.45(b).
- 27 11. The amount reimbursed by Medi-Cal to pharmacy providers under Welfare & Institutions
28 Code § 14105.455 does not depend on the actual acquisition cost of the drugs to pharmacy

- 1 services providers.
- 2 12. Section 14105.46 requires providers that participate in the 340B drug pricing program to
3 dispense only 340B drugs to Medi-Cal beneficiaries.
- 4 13. Section 14105.46 requires providers that participate in the 340B drug pricing program to
5 bill Medi-Cal an amount not to exceed the provider's actual acquisition cost for the drug,
6 plus a statutorily-set dispensing fee.
- 7 14. Section 14015.46 was enacted to: (1) reduce the risk of double discounts, (2) reduce drug
8 manufacturer rebate disputes, (3) reduce Medi-Cal's overpayments on drugs, and (4)
9 streamline the Department's Claims Review process.
- 10 15. The State has a legitimate interest in: (1) reducing the risk of drug manufacturers paying
11 duplicate discounts; (2) reducing the number of drug manufacturer rebate disputes; (3)
12 eliminating Medi-Cal's overpayment on 340B drugs; and (4) streamlining the
13 administration of the 340B program.
- 14 16. Due to the operation of Section 14105.46, 340B safety net providers like AHF in most
15 cases are reimbursed less than non-340B providers for dispensing the same drugs to Medi-
16 Cal beneficiaries.
- 17 17. 340B safety net providers are permitted to dispense drugs to Medi-Cal beneficiaries
18 through a contractual arrangement with another pharmacy.
- 19 18. To the extent 340B safety net providers dispense drugs to Medi-Cal beneficiaries through a
20 contractual arrangement with a pharmacy, Section 14105.46 does not apply and the
21 contract pharmacy is not required to dispense only drugs purchased through the 340B
22 program to Medi-Cal beneficiary patients of the 340B safety net provider.
- 23 19. The amount of reimbursement received by a 340B safety net provider is less than the
24 amount that provider would receive if it contracted with a pharmacy to dispense those very
25 same drugs to the same beneficiaries, because the contract pharmacy does not have to use
26 340B drugs and therefore can be reimbursed at the higher fee-for-service price.
- 27 20. The California Department of Health Care Services ("Department") submitted a proposed
28 State Plan Amendment ("SPA") seeking approval from the Centers for Medicare and

- 1 Medicaid Services (“CMS”) to modify California’s Medicaid State Plan in conjunction
2 with the terms of Section 14015.46.
- 3 21. The SPA the Department submitted to CMS corresponding to the relevant portions of
4 Section 14105.46 have now been approved by CMS.
- 5 22. The portion of the State Plan that Defendant sought to amend in conjunction with Section
6 14105.46 is entitled “Payment Methodology for Prescription Drugs,” and the page of the
7 SPA that incorporates Section 14015.46 is captioned “Methods and Standards for
8 Establishing Payment Rates for Prescription Drugs.”
- 9 23. In correspondence regarding the SPA related to Section 14105.46 both the Department and
10 CMS refer to the reimbursement change called for by the statute as a “rate reduction.”
- 11 24. The California Legislature enacted Section 14105.46 for the purpose of responding to the
12 State’s fiscal problems.
- 13 25. The California Legislature did not consider whether the impact that Section 14105.46
14 would have on 340B safety net providers would be consistent with efficiency, economy
15 and quality of care before enacting Section 14105.46.
- 16 26. The California Legislature did not consider whether Section 14105.46 would have an
17 adverse impact on whether Medi-Cal beneficiaries would have access to health care
18 services to the same extent as the general public before enacting Section 14105.46.
- 19 27. The California Legislature did not consider the relationship between provider costs and the
20 payments that would be made under the policy set forth in Section 14105.46 before
21 enacting Section 14105.46.
- 22 28. The Department did not supply the California Legislature with any documents evaluating
23 the impact of the Section 14105.46 on the Section 30(A) factors of efficiency, economy,
24 quality and Access to Care prior to the enactment of Section 14105.46.
- 25 29. The Department did not consider cost studies in connection with Section 14105.46.
- 26 30. At no time before or after submitting the SPA corresponding to Section 14105.46 to CMS,
27 did the Department evaluate the impact of Section 14105.46 on efficiency, economy,
28 quality of care or access to care.

- 1 31. At no time either before or after submitting the SPA corresponding to the elements of
2 Section 14105.46 to CMS did the Department perform or otherwise rely on any study
3 concerning the costs 340B providers incur furnishing drugs to Medi-Cal beneficiaries and
4 the impact the changes called for by Section 14105.46 would have on those costs.
- 5 32. There is no genuine dispute that the state failed to obtain federal approval before enacting a
6 state plan amendment as required by federal law.
- 7 33. Further, there is no genuine dispute that neither the Legislature nor the Department
8 considered the relevant Section 30(A) factors before enactment.
- 9 34. Indeed, Defendant previously took the position that it was not required to, and thus did not
10 consider the Section 30(A) factors before submitting the state plan amendment for
11 approval.

12 **CONCLUSIONS OF LAW**

- 13 1. No State shall make or enforce any law which shall abridge the privileges or immunities of
14 citizens of the United States; nor shall any State deprive any person of life, liberty, or
15 property, without due process of law; nor deny to any person within its jurisdiction the
16 equal protection of the laws. U.S. Const. amend. XIV, § 1.
- 17 2. A person may not be deprived of life, liberty, or property without due process of law or
18 denied equal protection of the laws. Cal. Const. art.1, § 7(a).
- 19 3. The Equal Protection Clause of the Fourteenth Amendment to the United States
20 Constitution and the Equal Protection and Privileges and Immunities Clauses of the
21 California Constitution guarantee substantially similar rights, and the courts analyze them
22 in similar fashion. *In re David Kirkor Dermegian*, 48 Cal. 3d 284, 291-292 (1989).
- 23 4. The “similarly situated” requirement means that an equal protection claim cannot succeed,
24 and does not require further analysis, unless the claimant can show that the two groups are
25 sufficiently similar with respect to the purpose of the law in question, and that some level
26 of scrutiny is required to determine whether the distinction is justified. *Safeway, Inc. v.*
27 *City and County of San Francisco*, 797 F. Supp. 2d 964, 971-72 (N.D. Cal. 2011.)
- 28 5. 340B safety net providers are similarly situated to non-340B providers with respect to

- 1 participation in Medi-Cal and dispensing drugs to Medi-Cal beneficiaries.
- 2 6. The rational basis test applies to challenges made to the Medi-Cal program under the
3 California Constitution. *Serrano v. Priest*, 5 Cal. 3d 584, 596 n.11 (1971).
- 4 7. Statutory classifications will not be set aside if any facts reasonably may be conceived to
5 justify it. *McDonald v. Board of Election Commissioners of Chicago*, 394 U.S. 802, 808-
6 809 (1969).
- 7 8. For the purposes of equal protection analysis, whether the “posited reason for the
8 challenged distinction actually motivated [the Legislature] is ‘constitutionally irrelevant.’”
9 *F.C.C. v. Beach Communications, Inc.*, 508 U.S. at 318.
- 10 9. “Legislative choice . . . may be based on rational speculation unsupported by evidence or
11 empirical data.” *F.C.C. v. Beach Communications, Inc.*, 508 U.S. at 318. Rational basis
12 review does not require that the Legislature “actually articulate at any time the purpose or
13 rationale supporting its classification.” *Jordlinger v. Hahn*, 505 U.S. U.S. 1, 15 (1992).
- 14 10. The assumptions underlying the rationale for the statute may even be erroneous, “but the
15 very fact that they are ‘arguable’ is sufficient, on rational-basis review, to immunize the
16 [legislative] choice from constitutional challenge.” *F.C.C. v. Beach Communications, Inc.*,
17 508 U.S. at 320.
- 18 11. The reimbursement treatment of 340B safety net providers called for by Section 14105.46
19 is rationally related to a legitimate State purpose: Namely, Section 12105.46 serves the
20 State’s rational effort to simplify management of the 340(b) program and ensure more
21 accurate determinations of whether or not a drug it is paying for has been purchased under
22 the 340(b) program, and these are not purely economic reasons.
- 23 12. Plaintiff has failed to meet its burden to prove all of the elements of its Equal Protection
24 claims in its first and second causes of action by a preponderance of the evidence.
- 25 13. AHF may enforce the federal Medicaid regulations concerning SPA approval, as well as
26 the requirements of 42 U.S.C. § 1396a(a)(30)(A), under the Supremacy Clause of the
27 United States Constitution. *Arizona Hospital & Healthcare Association v. Betlach*, 2012
28 WL 99066 (D. Ariz. 2012).

- 1 14. The terms of Section 14105.46 constitute a material change in California's Medi-Cal
2 policy concerning reimbursement for drugs for which an amendment to the Medicaid State
3 Plan was required to be submitted. *Development Services Network v. Douglas*, 666 F.3d
4 540 (9th Cir. 2011).
- 5 15. The terms of Section 14105.46 constitute a material change in California's methodology
6 for reimbursing 340B safety net providers for drugs under the Medi-Cal program and
7 therefore the State was required to comply with the requirements of Section 30(A) in
8 adopting and implementing Section 14105.46.
- 9 16. Section 14105.46 conflicts with Section 30(A) because the California Legislature did not
10 consider factors of efficiency, economy, and quality of care and Medi-Cal beneficiary
11 access to health care services before enacting Section 14105.46.
- 12 17. Section 14105.46 conflicts with Section 30(A) because neither the California Legislature,
13 nor the Department, considered the costs that 340B safety net providers incur in dispensing
14 drugs to Medi-Cal beneficiaries before Section 14105.46 was enacted.
- 15 18. Section 14105.46 is preempted under the Supremacy Clause of the United States
16 Constitution and therefore is invalid because it conflicts with the requirements of Section
17 30(A) in multiple respects.
- 18 19. There is no adequate legal remedy available to AHF to afford relief from the Defendant's
19 application of the unlawful terms of Section 14105.46, set forth above.
- 20 20. A permanent injunction is an appropriate remedy in this case because AHF has prevailed
21 on the merits and does not have an adequate remedy at law. Moreover, an injunction will
22 prevent a multiplicity of lawsuits. *Continental Airlines, Inc. v. Intra Brokers, Inc.*, 24 F.3d
23 1099 (9th Cir. 1994).

24 Dated: June 18, 2014.



MANUEL L. REAL
UNITED STATES DISTRICT JUDGE