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IN THE UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

California Pharmacists Association; Gerald Shapiro, Pharm.D., dba Uptown Pharmacy & Gift Shoppe; Sharon Steen, dba Central Pharmacy; and Tran Pharmacy, Inc., dba Tran Pharmacy,

Plaintiffs,

-vs.-

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

Defendant. /

No. 2:09-CV-08200 CAS (MANx)

FIRST AMENDED COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

Plaintiffs complain of the defendant DAVID MAXWELL-J0LLY, Director of Department of Health Care Services of the State of California, and for claims for relief allege:

INTRODUCTION[1]

1. The claims in this case are Supremacy Clause claims.

2. Plaintiffs challenge:

- (1) § 14105.45 California Welfare & Institutions ("Welf. & Inst.") Code, and seek an injunction to require the defendant Director to refrain from reducing any payments to pharmacies in respect to prescription drugs in the Medi-Cal fee-for-service program, on account of or related to any provision in the aforesaid § 14105.45 Welf. & Inst. Code which was enacted on July 28, 2009 by Assembly Bill ("AB") X4 5, section 38, (Stats. 2009 Fourth Extraordinary Session, c. 5, § 38);

- (2) § 14105.455 Welf. & Inst. Code, and seek an injunction to require the Director to refrain from reducing any payments to pharmacies in respect to prescription drugs in the Medi-Cal fee-for-service program and Medi-Cal managed care program, on account of or related to any provision in the aforesaid § 14105.455 Welf. & Inst. Code which was enacted on July 28, 2009 by AB X4 5, section 39, (Stats. 2009 Fourth Extraordinary Session, c. 5, § 39);

- (3)

- (A) to refrain from implementing the 4% reduction on September 26, 2009 in payments to pharmacies for reimbursement of brand drug acquisition costs in the Medicaid program in California (which is called "Medi-Cal"), in both the Medi-Cal fee-for-service ("FFS") program and Medi-Cal managed care program, concomitant

[1] Captions, footnotes, and citations of cases are not allegations or part of this First Amended Complaint ("FAC"), hence need not be answered or traversed by the defendant.

with the 4% Average Wholesale Price ("AWP") markdown on September 26, 2009 by the AWP pricing publisher used by the Department of Health Care Services;

- (B) to pay pharmacies in the Medi-Cal FFS program, from and since September 26, 2009, the same amounts that the pharmacy would have received for its prescription had the 4% markdown of published AWP to 1.20 of WAC not occurred;

- (C) to take all steps necessary to cause pharmacies in the Medi-Cal managed care program to be paid the same amounts that the pharmacy would have received for its prescription had the markdown of published AWP to 1.20 of WAC not occurred.

3. (a) The Court has jurisdiction under 28 U.S.C. § 1331. *Shaw v. Delta Air Lines, Inc.,* 463 U.S. 85, 96 n.4 (1983); *Independent. Living Center of So. Cal., Inc. v. Shewry,* 543 F3d. 1047 (9th Cir. 2008), *cert denied* 129 S.Ct. 2828, ("*ILC I*"),; and *California Pharmacists Assn. v. Maxwell-Jolly,* 2:09-CV-0722 (C.D.Cal. 2009), ("*CPhA I*"), *affirmed* in 09-56365 (9th Cir. 2009), ("*CPhA II*").[2]

4. The actions of the Defendant complained were and will be done in all parts of California, including the County of Los Angeles. The injuries which are inflicted and threatened which are complained of, to the plaintiff pharmacies, the pharmacy members of CPhA, and their patients in the Medi-Cal fee-for-service and Medi-Cal managed care program, have occurred and are threatened to continue to occur in all parts of California, including the County of Los Angeles. The Defendant and the California Attorney General has an office in the County of Los Angeles.

Parties

5. The plaintiff CALIFORNIA PHARMACISTS ASSOCIATION ("CPhA") represents more than 5,000 pharmacists in California. CPhA is incorporated in the State of California with its principal office in Sacramento, California. It is the largest state

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[2] A copy of *CPhA I* is at **Exhibit J** of Plaintiffs' Request for Judicial Notice, (Plaintiffs' RJN). A copy of *CPhA II* is at **Exhibit K** of Plaintiffs' RJN.

professional association of pharmacies in the United States. Many of CPhA's members own pharmacies in the State of California. The mission of CPhA is to represent pharmacies in all practice settings in the State, and to advocate the role of pharmacy as an essential venue of health care for patients.

6. (a) The plaintiff GERALD SHAPIRO, Pharm.D., is a duly licensed registered pharmacist with License No. 24377. He owns and operates a duly licensed retail pharmacy under the fictitious name of Uptown Pharmacy & Gift Shoppe, under retail pharmacy license No. PHY 41615, in the City of Los Angeles, California.

(b) The plaintiff SHAPIRO's pharmacy participates in the Medi-Cal fee-for-service program and also in Medi-Cal managed care plans, under Medi-Cal provider identification No. PHA 416150.

7. (a) The plaintiff SHARON STEEN is co-owner and operates a duly licensed retail pharmacy under the fictitious name of Central Pharmacy, under retail licenses No. PHY 38051, in the City of Santa Monica, California.

(b) The plaintiff STEEN's pharmacy participates in the Medi-Cal fee-for-service program and also in Medi-Cal managed care plans, under Medi-Cal provider identification No. PHA 380510.

8. (a) Plaintiff TRAN PHARMACY, INC. is a California corporation which owns and operates a duly licensed retail pharmacy under the fictitious name of Tran Pharmacy, under retail pharmacy license No. PHY 43647, in Garden Grove, California.

(b) The TRAN PHARMACY, INC.'s pharmacy participates in the Medi-Cal fee-for-service program and also in Medi-Cal managed care plans, under Medi-Cal provider identification No. PHA 436470.

9. (a) The defendant DAVID MAXWELL-JOLLY ("Director"), is the director of the Department of Health Care Services ("Department") of the State of California. The Director has an office in the County of Los Angeles.

(b) The Director DAVID MAXWELL-JOLLY is sued in his official capacity only.[3]

Standing

10. Each of the plaintiff providers sue on their own behalf and, also, on behalf of their patients who are beneficiaries in the Medi-Cal FFS program and the Medi-Cal managed care program, to prevent injury and threatened injury to themselves and their patients who are beneficiaries in the Medi-Cal FFS program and Medi-Cal managed care program, from actions of the Director which are contrary to, hence preempted under the Supremacy Clause by, provisions of the Medicaid Act and its regulations, as more particularly set forth below.

11. CPhA sues on its own behalf and, also, on behalf of its pharmacy members who are providers in, and the patients of its members who are beneficiaries in the Medi-Cal FFS program and the Medi-Cal managed care program, to prevent injury and threatened injury to itself, its pharmacy members, and the aforesaid Medi-Cal beneficiaries who are patients of its members, from actions of the Director which are contrary to, hence preempted under the Supremacy Clause by provisions of the Medicaid Act and its regulations, as more particularly set forth below.

FACTS COMMON TO ALL CLAIMS

The Director has exclusive authority and power to set all provider payment rates for both the Medi-Cal FFS program and the Medi-Cal managed care program.

12. The Medicaid Act, 42 U.S.C. § 1396 et seq., provides for medical assistance to be administered and provided to qualified poor or disabled beneficiaries by a single state agency ("Single State Agency"), which has been historically funded 50% with federal funds and 50% with state funds; subject to the proviso that if a State accepts the federal funding then it is bound to comply with all the provisions of the Medicaid Act and its regulations, so

[3] A copy of § 14105 Welf. & Inst. Code is at **Exhibit F** of Plaintiffs' RJN.

long as it continues to voluntarily participate in the Medicaid program.[4]

13. In this First Amended Complaint ("FAC") this federal-state funded program is sometimes referred to as "Medicaid" and sometimes referred to as "Medi-Cal;" but all such references are to the exact same Medicaid program, whichever appellation is used.

14. (a) Under § 1396a(a) a State participating in Medicaid must file and have approved a state Medicaid plan (the "state Plan") by the Secretary of U.S. Department of Health and Human Services ("HHS"). The state Plan must, by § 1396a(a)(5) and by 42 Code of Federal Regulations ("CFR") § 431.10 specify a single State agency ("Single State Agency") to administer or to supervise the administration of the plan.[5] In California, Section 1 of the state Plan designates the Department as the Single State Agency.[6]

(b) 42 CFR § 431.10 provides that if other State agencies or local agencies, (as for example Medi-Cal managed care plans which are local agencies of the State), perform services to the Single State Agency, that they have no authority to change or disapprove any administrative decision of the Single State Agency, or otherwise substitute their judgment for that of the Single State Agency with respect to the application of the policies, rules, and

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[4] All statutory references are to 42 U.S. Code unless otherwise specified. A copy of portions of § 1396a(a)(1) through (a)(30)(A) is at **Exhibit G** of Plaintiffs' RJN.

[5] §1396a(a)(5) provides: "A State plan for medical assistance must–(5) . . . provide for the establishment of a single State agency to administer or to supervise the administration of the plan . . . "

[6] Section 1 of the state Plan is attached as **Exhibit H** of Plaintiffs' RJN.

regulations issued by the Single State Agency.[7]

(c) A copy of 42 CFR § 431.10 is at **Exhibit E** of Plaintiffs' RJN.

(d) Pursuant to the above provisions of § 1396a(a)(5), 42 CFR § 431.10, and Section 1 of the state Plan:

(1) The Department, not the California Legislature, has been exclusively delegated and authorized by Congress in the Medicaid Act to set all payment rates, or cause to be set all payment rates, for pharmacy providers in the Medi-Cal program, including both the Medi-Cal FFS program and the Medi-Cal managed care program, any contract of the Department with any Medi-Cal managed care plan notwithstanding; and,

(2) The Director, within the Department, is the sole officer who, under § 14105 Welf. & Inst. Code, is authorized to exercise the above-stated exclusive authority, jurisdiction, power, and ultimate control over all the rates set or to be set in both the Medi-Cal FFS program and the Medi-Cal managed care program, – any contract of the Department with any Medi-Cal managed care plan notwithstanding.

APPLICABLE STATUTES, REGULATIONS, AND STATE MEDICAID PLAN ("STATE PLAN")

15. The Medicaid Act, in § 1396a, subd. (a)(30)(A), provides:

> "(a) A State plan for medical assistance **must** - (30)(A) **provide** for such methods and procedures relating to the utilization of, and **the payment for, care and services available under the plan** (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) **as may be necessary** to safeguard against unnecessary utilization of such care and services and **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

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[7] 42 CFR § 431.10(e)(3) provides:

> "(3) If other State or local agencies or officers perform services for the Medicaid agency, they must not have the authority to change or disapprove **any administrative decision** of that agency, or otherwise **substitute their judgment** for that of the Medicaid agency with respect to the **application of policies, rules, and regulations** issued by the Medicaid agency." (Boldface emphasis supplied.)

general population in the geographic area; . . . " (Boldface emphasis supplied.) § 1396a(a)(30)(A), shall hereinafter be referred to as "Sec. 30A."

16. The thousands of drug products which require, by federal law, a prescription from a licensed practitioner, – including variations of the differing dosages such as 5 ml. or 75 ml. – each have an assigned National Drug Code ("NDC") identification number.

17. (a) Under Sec. 30A, the Medicaid provider payment statute, a federal upper payment limit ("FUL") has been established by HHS for the maximum amount the Medi-Cal program may reimburse pharmacies for their costs to acquire certain multi-source ("generic") drug products. A state-imposed Maximum Allowable Ingredient Cost upper payment limit ("MAIC") has also been established for the maximum amount the Medi-Cal program may reimburse pharmacies for the costs to certain generic drug products listed by the Department.

(b) The generic drug products which are subject to a FUL or MAIC upper limit account for only approximately 12% of expenditures by the Department for prescription drugs.

18. 42 CFR § 447.512 provides that, – except for those generics which are subject to a FUL or a MAIC upper limit cap, – that the upper limit for payment for both single source ("brand") drugs and generic drugs is the lower of:

> Estimated Acquisition Cost ("EAC") plus a reasonable dispensing fee, or providers' "usual and customary charges to the general public;"

in which "EAC" is defined by 42 CFR § 447.512 as:

> The State agency's best estimate of the price generally and currently paid by providers for a drug market or sold by a particular manufacturer or labeler in the package size of drugs most frequently purchased by providers.

(c) The state Plan filed and approved by HHS provides that Department shall pay EAC plus a dispensing fee of $7.25 for drug products and professional services, in which the EAC is the lowest of:

- Average Wholesale Price ("AWP") minus 17%;

- the state's MAIC cap or the federal FUL cap if the drug is a generic; or,

- the "charges to the general public;"

in which AWP is defined as "the price for a drug product listed in the department's primary price reference source."[8]

(d) At all times relevant and continuing, the primary AWP price reference source of the Department has been and is the AWP publisher, First DataBank, Inc., ("First DataBank").

BACKGROUND

19. In the pharmaceutical industry, drug manufacturers typically sell to drug wholesalers at a list price – called in the industry the "wholesale acquisition cost," or WAC. Discounts may be provided to the wholesaler (e.g., for volume sales). Wholesalers add a markup in selling the drugs to retail pharmacies and other purchasers like hospitals. Pharmacies then add a markup of their own when they sell the drugs to insurers ("3d party payors," or "TPPs").[9]

20. (a) Nearly all TPPs contract with pharmacy benefit managers ("PBMs") to assist in the process of reimbursement to pharmacies. PBMs are the "800-pound gorillas of pharmaceutical reimbursement" and their relationships with TPPs are heavily negotiated and highly individualized. (*In re Pharm. Indus. Average Wholesale Price Litig.,* 230 F.R.D. 61, 71-72 (D.Mass. 2005). TPPs negotiate drug pricing discounts with PBMs based on AWP, and PBMs, in turn, negotiate discounts with pharmacy networks based on AWP.[10]

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[8] Section 1 of the state Plan is at **Exhibit H** of Plaintiffs' RJN.

[9] Page 6 of September 3, 2009 opinion in *New England Carpenters Health Benefits Fund v. First DataBank* (2d Cir. 2009), ("*First DataBank*"). Copy attached as **Exhibit**

[10] Page 6 of March 3, 2009 Memorandum and Order approving settlement in *First DataBank,* 1:05-11148-PBS (D. Mass. 2009). A copy is attached as **Exhibit**

(b) Where the consumer is insured, customarily a pharmacy benefit manager ("PBM") or a pharmacy services administrator organization ("PSAO") which administers a pharmacy network reimburses the pharmacy for the drug acquisition cost plus a dispensing fee pursuant to a contract with the pharmacy.[11]

(c) For drug purchases that are covered by health insurance, the insurer pays the PBM or the PSAO, who contracts to reimburse the pharmacy for the drug products it supplies to the insured beneficiary based on a discount, which varies, from the published AWP price for that drug product.[12]

21. The published AWP figure is usually derived by the publisher by applying a multiplier to the WAC for the drug, and publishers of AWP lists normally obtain their AWP figures from manufacturers or wholesalers. Historically, published AWPs were derived by applying different markups to different drugs, the most common multiplier being 1.20 or 1.25 – percentage markups of 20 and 25 percent, respectively.[13]

22. (a) The March 17, 2009 order approving the *First DataBank* settlement found that First DataBank conspired with McKesson to inflate the AWP for brands from the First DataBank standard of 20% over WAC, to 25% over WAC. This conspiracy commenced in 2001 so that by 2002, 95% of all brand drug manufacturers used First DataBank's inflated 25% markup, and by 2004, 99% of all brand drug manufacturers did so.[14]

(b) In 2001 Myers and Stauffer, C.P.A.s, under retention by the Department,

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[11] *Ibid.*, Pages 6-7.

[12] Declarations of John Cronin, Lynn Rolston, Paul Lofholm, Gerald Shapiro, Thu-Hang Tran, Sharon Steen, Odette Leonelli, and Schedule of Declarations; and Summary of Declarations served herewith.

[13] Page 7 of September 3, 2009 opinion in *First DataBank* (2d Cir. 2009).

[14] Page 5 of **Exhibit C** of Request for Judicial Notice of *First DataBank* Documents, ("*First DataBank* RJN").

surveyed pharmaceutical costs in California, and reported in its 2002 report ("2002 Myers Survey") that as of year 2001, when reimbursement by Medi-Cal for costs to acquire brand drugs was:

AWP minus 5%, or .95 of AWP

and the dispensing fee was $3.80 per prescription,[15] that the average net profit per prescription, (defined as the excess of what Medi-Cal paid the pharmacy, less the pharmacy's costs to acquire-and-dispense), was:

- 9.6% for single source drugs
- 24.7% " multi-source drugs not subject to a FUlL or MAIC cap
- 10.9% " multi-source drugs with a federal FUL cap
- 11.6% " multi-source drugs with a state-imposed MAIC cap.[16]

23. As a result it was well-known to the Department from the 2002 Myers Survey that the published AWP was over-inflated in respect to basing reimbursement to pharmacies for acquisition costs on the AWP published by the Department's AWP publisher.

24. (a) However in 2004 the State **adjusted to any excessive published AWP by reducing** the EAC (i.e., the amount of the Medi-Cal reimbursement for cost to acquire brand and generics drugs) to its present level of **83%** of published AWP,[17] and in 2006 amended the state Plan to provide that the EAC now be 83% of AWP published by its AWP publisher, for both single source and multi-source drug products without a FUL or MAIC.[18]

(b) This was, among other things, a tremendous **12% decrease in the percentage of AWP** payable by Medi-Cal to reimburse pharmacies for their cost to acquire brand drugs, (i.e., a change from 95% of the published AWP in 2002 to now only 83% of the published AWP), – which more than offset the secret markup by the AWP publisher from

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[15] Pages 5 and 41 of 2002 Myers Survey.

[16] Table 5.2 at Page 50 of 2002 Myers Survey.

[17] Senate Bill 1103, enacted as Statutes 2004, Chapter 228.

[18] Supplement 2 to Attachment 4:19-B of state Plan.

1.20 of WAC to 1.25 of WAC as the formula for published AWP for brand drugs.

(c) This Department action in 2004, to reduce the EAC paid to pharmacies for drug acquisition costs, took all the artificial inflation out of the AWP published by First DataBank, by reducing the pharmacy net profit per prescription in the Medi-Cal program to the following lower net profit per prescription:

- **2.95%** for single source drugs
- 12.5% " multi-source drugs not subject to a FUlL or MAIC cap
- 44.2% " multi-source drugs with a federal FUL cap,

as per the analysis by the Department in February 2009.[19]

What the Medi-Cal pharmacy rates were before September 26, 2009

25. Prior to September 26, 2006 and currently, both the Medi-Cal FFS program and managed care plans in the Medi-Cal managed care program used and are using the AWP published by First DataBank for each brand drug product NDC, from which;

- the Medi-Cal FFS program subtracts 17% to arrive at Estimated Acquisition Cost ("EAC") to be paid to pharmacies as reimbursement for brand acquisition costs; and,

- the various Medi-Cal managed care plans, – (under authority granted to them by the Director but subject to ultimate control by the Director pursuant as prior set forth in this FAC), – each subtract a percentage, (typically 15% as in the CalOptima managed care plan in Orange County) from the published AWP for a given brand

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[19] Pages 8 and 9 of Analysis of Assembly Bill 1183, dated February 8, 2009, of Toby Douglas, Chief Deputy Director of the Department. I.e., the analysis claimed that the average amount paid by Medi-Cal, and the average cost to acquire-and-dispense a drug, are currently:
Single source drugs: $204.01, less $198.15 = $6.81 = $2.95% net profit
Multi-source w/o a FUL or MAIC cap: $49.25 less $43.77 = $5.48 = 12.5% net profit
Multi-source with a FUL cap: $28.94 less $20.07 = $8.87 = $44.2% net profit
(Copy of this February 2009 analysis at **Exhibit** of Plaintiffs' RJN.)

NOTES: (1) The actual net profit per prescription is less, because the $11.59 overhead costs figure used by the Department is too low. (2) The Department analysis did not specify figures for net profit/loss for multi-source drugs with a MAIC cap.

product, so as to arrive at the EAC amount be paid to pharmacies in their managed care plan as reimbursement for their brand acquisition costs.

The 4% markdown of published AWP on September 26, 2009

26. (a) However, the Department's AWP publisher marked down published AWP 4% on September 26, 2009 for 18,000 to 20,000 brand drug product NDCs, from a formula or basis of 1.25 of Wholesale Acquisition Cost ("WAC") to 1.20 of WAC.

(b) This caused an automatic reduction of 4% on the amount the Medi-Cal program reimburses for brand drug acquisition costs on at least 3,415 drug products out of the more than 20,000 drug products that the Medi-Cal program has paid for within the past year.[20]

(c) However, the 3,415 drug products in the Medi-Cal program whose EAC was reduced 4% on September 26, 2009 by the 45 markdown of published AWP, included the great majority of the 1,000 top selling brand drug products (ranked by total reimbursement by the Medi-Cal program for the calendar year 2006) in the Medi-Cal program, – which 1,000 top selling brand products comprise 98.7%, or nearly all, the expenditures in the Medi-Cal program for brand drug prescriptions.[21]

The 4% markdown of published AWP causes brand drugs to be acquired-and-dispensed at a net loss, in respect to brand NDCs which comprise 98.7% of the total expenditures in the Medi-Cal program for brand prescriptions: hence preventing pharmacies from dispensing brand drugs in the Medi-Cal program at all, or forcing pharmacies to quit the Medi-Cal FFS program and the Medi-Cal managed care program.

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[20] ¶ 12 of Declaration of Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Branch of the Department, filed as Document 68, (Pages 24-39) in the *MPC* case, 2:09-CV-0382 CAS (MANx)

[21] Pages 35-36, with Table 4.1, of the 2007 Myers Survey, found that the 1,000 top selling brand products, ranked by total reimbursement by the Medi-Cal program for calendar year 2006, comprise 98.7% of the total Medi-Cal expenditures in 2006 for brand drug products.

[20] ¶¶ 13-14 of Declaration of Richard D. Wilson, C.P.A. ("Wilson Declaration"), to be filed herein.

27. In sum, by the foregoing facts, the reimbursement to pharmacies for their cost to acquire was cut 4% on September 26, 2009, **for the vast majority of the 1,000 brand drug products** for which 98.7% of the expenditures for brand drug prescriptions are made by the Medi-Cal program; all, due to the artificial 4% markdown of published AWP on September 26, 2009 by the Department's AWP publisher, First DataBank; – **which 4% reduction in reimbursement** for brand drug acquisition costs causes pharmacies to be unable to acquire-and-dispense most brand drug products **except at a net loss**, in the Medi-Cal FFS program and the Medi-Cal managed care program.

re expended.

28. This allegation is supported by the Declaration of Richard D. Wilson, C.P.A., ("Wilson Declaration"), served herewith, which concludes that the 4% reduction on reimbursement for brand acquisition costs, caused by the 4% markdown on published AWP on September 26, 2009, directly reduces total reimbursement, per brand drug prescription, to **below pharmacies' costs to acquire-and-dispense most of the brand drug products** (ranked by total reimbursement expended for brand drugs by the Medi-Cal program) for which the Medi-Cal program expends 98.7% of its total expenditures for brand drug prescriptions, annually. **20/**

FIRST CLAIM FOR RELIEF
Supremacy Clause Claim

All enactments of Medicaid provider rate reductions by the California Legislature are facially contrary, without more, to the Single State Agency provisions of § 1396a(a)(5), 42 CFR § 431.10, and Section 1 of the state Plan, and Sec. 30A; so that the Director's action to implement the provider rate reductions enacted by the Legislature in §§ 14105.45 and 14105.455 Cal. Welf. & Inst. Code, are contrary to, hence preempted under the Supremacy Clause by, these provisions of the Medicaid Act and its regulations.

29. Plaintiffs refer to the allegations in the preceding Paragraphs and incorporate each of those allegations as if fully set forth herein.

30. This is a Supremacy Clause claim.

31. By the facts alleged above:

(a) Congress in the Medicaid Act elected to assign to the Department, **not to the California Legislature,** – the exclusive power, authority, and jurisdiction to set all provider payments in the California's Medicaid program; so that it is the Department, **not the Legislature,** which is the body responsible for rate-setting under the Medicaid Act.

(b) Also the Department, – even though it is the body which has the exclusive authority, power, and jurisdiction under Sec. 30A and the Single State Agency provisions of the Medicaid Act to set all provider payments, – has no power under state law and California Constitution Article 3.5 to alter any Medicaid provider payment rates enacted, *ultra vires* of the Medicaid Act, by the Legislature, (which latter has no power, as above alleged, to enact any Medicaid rates whatsoever); so that therein, any post hoc analysis by the Department of any provider payment rates enacted by the Legislature does not satisfy the requirement of *Orthopaedic Hospital v. Belshe*, 103 F3d. 1451, 1496, 1499-1500, under Sec. 30A, that the Single State Agency (the Department) which is responsible for Medicaid rate setting, must consider the relevant factors of Sec. 30A contemporaneously with the adoption of the rates, (not, post hoc). (*See,* the *CPhA I* decision, 2:09-CV-0722 CAS (MANx), C.D. Cal. 2009], so holding:[22]

> In [Orthopaedic Hospital v. Belshe, 103 F.3d 1491 (9th Cir. 1997)], . . . the court stated that "the Department 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 (emphasis added); see also *id.* at 1499-1500 ("Since the Department did not adequately consider hospitals' costs *when readopting its rates,* the Department's actions were arbitrary and capricious and contrary to law") (emphasis added). The [Orthopaedic Hospital] holding therefore indicates that the **body responsible for rate setting**[23] must consider the relevant factors [of Sec. 30A] **contemporaneously with the adoption of the rates**. Because the Department **has no authority** to alter the rates set by the Legislature, the Department's post hoc analysis does not satisfy the requirements of [Orthopaedic Hospital]." (Boldface emphasis supplied.)

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[22] The March 9, 2009 decision of the District Court is at **Exhibit J** of Plaintiffs' RJN.

[23] I.e., the Single State Agency, (the Department), as per § 1396a(a)(5).

32. Accordingly, due to this decision of the District Court in *CPhA I* which was sustained in *CPhA II*, (09-55635, 9th Cir. 2009),[24] it is now the law of the Ninth Circuit that all actions of the Department and the Director to implement Medi-Cal rate statutes enacted by the Legislature are always contrary to, **hence preempted under the Supremacy Clause** of the U.S. Constitution, by these contrary provisions of the Medicaid Act and its regulations, (namely, the Single State Agency provisions of § 1296a(a)(5), 42 CFR § 431.10, and Section 1 of the state Plan), and Sec. 30A).

Legislative enactment of the new MAIC payment reduction and the new Upper Billing Limit payment reduction

33. (a) Notwithstanding the foregoing, the Legislature did, on July 28, 2009, enact Assembly Bill ("AB") X4 5, which amended § 14105.45 Welf. & Inst. Code **to reduce reimbursement** to pharmacies for their costs to acquire multi-source drug products (generics) to which a Maximum Allowable Ingredient Cost ("MAIC) limit has been placed by the Department. This rate reduction was estimated by the Legislature in the Assembly Bill Analysis to reduce pharmacies' reimbursements by at least $24 million annually, commencing in June 2009; and

(b) Also, notwithstanding the foregoing, the same AB X4 5 enacted new § 14105.455 Welf. & Inst. Code to impose an upper billing limit **to reduce reimbursement** to pharmacies' for their costs to acquire both brand drug products and generic drug products in both the Medi-Cal FFS program and the Medi-Cal managed care program. This rate reduction was estimated by the Legislature in the Assembly Bill Analysis to reduce pharmacies' reimbursements by at least $45 million annually, commencing at once.

34. The amended § 14105.45 Welf. & Inst. Code is at **Exhibit A of** Plaintiffs' RJN. The new § 14105.455 Welf. & Inst. Code is at **Exhibit B** of Plaintiffs' RJN. The

[24] Copy at **Exhibit K** of Plaintiffs' RJN.

Assembly Floor Analysis for both these measures at **Exhibit C** of Plaintiffs' RJN.

35. Further, when the Legislature reduced provider payments by 5% to adult day care health centers in the *CPhA I* case, *supra,* both the District Court and *CPhA II* held that the actions of the Director to **implement the statutory payment reduction** were **preempted under the Supremacy Clause** due to the fact that:

- the Legislature, – which had no authority under Sec. 30A, and was not the body responsible under Sec. 30A, to et Medicaid provider payments, – had nevertheless enacted AB 1183, *ultra vires* of the Medicaid Act, to set the 5% pharmacy payment reduction,

and that:

- the Department, – who did have the exclusive authority and was the body responsible under Sec. 30A to set Medicaid provider payments, – had no authority under state law, *vis-a-vis* the Legislature, to alter the rate reduction imposed by the Legislature, so that the Department's post hoc analysis of whether the payment cut complied with Sec. 30A "does not satisfy the requirements" of the *Orthopaedic Hospital* decision, (103 F.3d, at 1496 and 1499-1500);[25]

so that, as held in *CPhA I,*[26] and affirmed by the Ninth Circuit in *CPhA II*,[27], the action of the Department to implement the state Legislature's statute which reduced payment rates to ADHCs was facially contrary to, hence **preempted under the Supremacy Clause** by, Sec. 30A.

36. Further, *CPhA II* held that preempted State action which **reduces payments** to Medicaid providers constitutes irreparable injury to providers, due to the fact that the

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[25] Page 12, lines 3-14, of **Exhibit J** of Plaintiffs' RJN.

[26] **Exhibit J** of Plaintiffs' RJN.

[27] **Exhibit K** of Plaintiffs' RJN.

Eleventh Amendment bars a legal remedy in damages. (*See,* Pages 8-10 of *CPhA II,* – at **Exhibit K** of Plaintiffs' RJN.)

(a) Also, *see National Assn. of Chain Drug Stores et al. v. Leavitt,* – 1:07-CV-2017(D. Col. 2007), – ("*NACDS*") – so holding.[28]

Conclusion, from these *CPhA* precedents in the District Court and Ninth Circuit.

37. It is the law in the Ninth Circuit, from *CPhA I* and *CPhA II,* that all implementations by the Director of Medicaid provider payment reductions enacted in the first instance by the state Legislature, are contrary to **hence preempted by the Medicaid Act, (**specifically, the Single State Agency provisions of § 1396a(a)(5), 42 CFR § 431.10, and Section 1 of the state Plan; and Sec. 30A).

Preempted State action

38. By the foregoing, the action of the Legislature to enact, and the action of the Director to implement:

- the MAIC reimbursement reduction enacted and made possible by § 14105.45 Welf. & Inst. Code, and

- the reimbursement reductions due to the Upper Billings Limit payment cut enacted by § 14105.455 Welf. & Inst. Code,

are contrary to, **hence preempted under the Supremacy Clause by**, the Medicaid Act and its regulations (namely, § 1396a(a)(5); 42 CFR § 431.10, and Section 1 of the state Plan, and Sec. 30A), and cause the below irreparable injury:

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[28] In *NACDS* a preliminary injunction issued to protect pharmacy members of the plaintiff organizations from injury by HHS's action of implementing the AMP rate to reimburse pharmacies in the Medicaid program. Held:

"Unless enjoined, Defendant's actions are likely to cause Plaintiffs irreparable injury for which no adequate remedy at law exists as Plaintiffs' members will not be able to recover from the Defendants if the AMP Rule is implemented, . . . " (First page of slip opinion.) (Emphasis supplied). (A copy of this order is at **Exhibit L** of Plaintiffs' RJN.)

(a) The Plaintiff pharmacies and the pharmacy members of CPhA will not be able under the Eleventh Amendment to recover from the Department if these two provider rate cuts are implemented; and (b) by the reductions in reimbursement the Plaintiff pharmacies and pharmacy members of CPhA will be forced to stop filling brand and generic prescriptions in the Medi-Cal FFS program and the Medi-Cal managed care program; and pharmacies will be forced to quit the Medi-Cal program, cease accepting new Medi-Cal patients, reduce hours and services, or be forced to close. (*CPhA II, CPhA II,* and *NACDS*). *See,* declarations of John Cronin, Lynn Rolston, Paul Lofholm, Gerald Shapiro, Thu-Hang Tran, Sharon Steen, Odette Leonelli, and Schedule of Declarations; and Summary of Declarations served herewith, ("Plaintiffs' Supporting Declarations").

- (b) In turn, millions of Medi-Cal beneficiaries who are patients of the Plaintiffs and the pharmacies who are members of the plaintiff CPhA, will suffer irreparable injury for which there is no adequate remedy from being denied access, and equal access, to quality pharmacy services, in both the Medi-Cal FFS program and the Medi-Cal managed care program, (caused by the fact that many if not most pharmacies in the Medi-Cal FFS program and Medi-Cal managed care program will cease to dispense brand drugs and generic drugs to their Medi-Cal patients, if these provider payment cuts are not enjoined. (Plaintiffs' Supporting Declarations.)

39. Accordingly a permanent injunction, preliminary injunction, and temporary restraining order should and must issue to order the Director to refrain from implementing:

- amended § 14105.45 Welf. & Inst. Code and its provider payment reduction;

- new § 14105.455 Welf. & Inst. Code and its provider payment reduction;

and to instead (A) pay all pharmacies in the Medi-Cal FFS program the same rates which they would be paid had the AWP published by the publisher used by the Department not been marked down to 120% of WAC on September 26, 2009, and (B) take all steps

necessary (pursuant to the authority and power granted by the Single State Agency provisions of § 1396a(a)(5), 42 CFR § 431.10, and Section 1 of the state Plan), to direct plans in the Medi-Cal managed care program to pay pharmacy providers in the Medi-Cal managed care program the same amounts they would otherwise receive had the published AWP not been marked down from 1.25 of WAC to 1.20 of WAC on September 26, 2009.

WHEREFORE the plaintiffs pray for orders and judgment as shall hereinafter be specified:

SECOND CLAIM FOR RELIEF
Supremacy Clause Claim

Injunction to prevent injury threatened by Director's actions which are contrary to, hence preempted under the Supremacy Clause by, the equal access provisions of 42 CFR § 447.204 and Sec. 30A.

40. Plaintiffs refer to and incorporate each of the allegations of each of the preceding Paragraphs as if herein fully set forth.

41. This is a Supremacy Clause claim.

Sufficiency of the State's Medicaid program

42. The equal access provision of Sec. 30A and of 42 CFR § 447.204 require that a State must pay sufficient to enlist enough providers so that beneficiaries have the same access to quality services as is available to the general population in the same area.[29] 43. (a) However, as concluded by Richard D. Wilson, C.P.A., –

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[29] A State plan for medical assistance **must** - (30)(A) **provide fo**r such methods and procedures relating to . . . **the payment for, care and services available under the plan** . . . **as may be necessary** . . . **to assure that payments 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; . . . "

42 CFR § 447.204 provides:

> "The agency payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population."

and the Plaintiffs allege – that since September 26, 2009 the Department has cut or will cut payments to pharmacies by more than 5% overall in the Medi-Cal FFS program, and by more than 4.2% in the Medi-Cal managed care program, as follows:

Cut in total payment, annually, to pharmacies in Medi-Cal FFS	**Caused by:**	**Cut in total payment, annually, to pharmacies in Medi-Cal managed care program**
2.6%	The AWP markdown of September 26, 2009	2.6%
1.6%	The Upper Billing Limit statute - (§ 14105.455 Welf. & Inst. Code)	1.6%
.8%.	Change in calculating the MAIC limit - (14105.45 Cal. Welf. & Inst. Code)	n.a.
5.0%	TOTAL OF CUTS IN ANNUAL PAYMENTS TO PHARMACIES	4.2%

– with:

- (1) the first pharmacy provider payment cut of approximately more than 2.6% being due to a 4% cut on September 26, 2009 in reimbursement for brand drug acquisition costs caused by the Director's ultra vires acceptance, in excess of and without jurisdiction so to do, of the September 26, 2009 markdown of published AWP by the Department's AWP publisher;

- (2) the Upper Billing Limit provider payment cut of approximately more than 1.6% overall being due to enactment of § 14105.455 Welf. & Inst. Code on July 28, 2009; and,

- (3) the MAIC payment cut of approximately more than 8/10th of 1% overall being due to enactment of an amendment to § 14105.45 Welf. & Inst. Code on July 28, 2009,

with the direct result of the aggregate amount of this 5% cut by these three provider payment cuts, both in their whole and in their severality, being that – if these 5% payment cuts are not enjoined, – that pharmacies will stop participating in Medi-Cal, – or if they do continue to participate at all, will no longer accept new patients in the Medi-Cal program, or will not dispense brand drug products and generic drugs to the Medi-Cal patients they do continue to serve; – which result of deprivation of pharmaceutical services to beneficiaries in both the Medi-Cal FFS program and the Medi-Cal managed care program by these three provider payments cuts in the Medi-Cal program is **contrary to, hence preempted under the Supremacy Clause by, the equal access provisions of Sec. 30A and 42 CFR § 447.204**.[30]

44. Accordingly, the payment reductions of :

- the 4% markdown of published AWP on brand products on September 26, 2009,
- the 1.6% reduction enacted by the Upper Limit Law (§ 14105.455 Welf. & Inst. Code),
- the 0.8% reduction enacted by the MAIC reduction law (§ 14105.45 Welf. & Inst. Code),

constitute and comprise irreparable injury to pharmacy providers because:

(a) the Plaintiff pharmacies and the pharmacy members of CPhA will not be able under the Eleventh Amendment to recover from the Department if these three provider rate cuts are implemented; and (b) by the reductions in reimbursement the Plaintiff pharmacies and pharmacy members of CPhA will be forced to stop filling brand and generic prescriptions in the Medi-Cal FFS program and the Medi-Cal managed care program; and pharmacies will be forced to quit the Medi-Cal program, cease accepting new Medi-Cal patients, reduce hours and services, or be forced to close. (*CPhA II, CPhA II,* and *NACDS*). (Plaintiffs' Supporting Declarations).

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[30] Pages 10, 11, 16 and ¶ 27 of Wilson Declaration; Plaintiffs' Supporting Declarations.

- (b) In turn, millions of Medi-Cal beneficiaries who are patients of the Plaintiffs and the pharmacies who are members of the plaintiff CPhA, will suffer irreparable injury for which there is no adequate remedy from being denied access, and equal access, to quality pharmacy services, in both the Medi-Cal FFS program and the Medi-Cal managed care program, (caused by the fact that many if not most pharmacies in the Medi-Cal FFS program and Medi-Cal managed care program will cease to dispense brand drugs and generic drugs to their Medi-Cal patients, if these three provider payment cuts are not enjoined. (Wilson Declaration, *supra*; Plaintiffs' Supporting Declarations).

45. Accordingly a permanent injunction, preliminary injunction, and temporary restraining order should and must issue to order the Director to refrain from implementing:

- amended § 14105.45 Welf. & Inst. Code and its provider payment reduction;

- new § 14105.455 Welf. & Inst. Code and its provider payment reduction;

- the 4% reimbursement reduction to pharmacies for brand drug acquisition costs;

and to instead (A) pay all pharmacies in the Medi-Cal FFS program the same rates which they would be paid had the AWP published by the publisher used by the Department not been marked down to 120% of WAC on September 26, 2009, and (B) take all steps necessary (pursuant to the authority and power granted by the Single State Agency provisions of § 1396a(a)(5), 42 CFR § 431.10, and Section 1 of the state Plan), to direct plans in the Medi-Cal managed care program to pay pharmacy providers in the Medi-Cal managed care program the same amounts they would otherwise receive had the published AWP not been marked down from 1.25 of WAC to 1.20 of WAC on September 26, 2009.

WHEREFORE the plaintiffs pray for orders and judgment as shall hereinafter be specified:

THIRD CLAIM FOR RELIEF
Supremacy Clause Claim

Implementation of:
- amended § 14105.45 Welf. & Inst. Code
- new § 14105.455 Welf. & Inst. Code
is contrary to, hence preempted under the Supremacy Clause by Sec. 30A, in that the Legislature prevented itself from any adequate consideration of the EEQA factors by considering and voting upon them as but one single measure.

46. Plaintiffs refer to and incorporate each of the allegations of each of the preceding Paragraphs as if herein fully set forth.

47. This is a Supremacy Clause claim.

48. The Legislature, in enacting Sections 38 and 39 of AB X4 5, containing the § 14105.45 and new § 14105.455 of Welf. & Inst. Code measures as but one single indivisible measure, together, (instead of considering each of them by a separate bill in which one bill contained only the proposed amended § 14105.45 Welf. & Inst. Code and the other bill contained only the proposed new § 14105.455 Welf. & Inst. Code), thereby:

- excluded itself from any ability to separately and adequately consider the EEQA factors in relation to the reduced payments under § 14105.45 Welf. & Inst. Code, and

- excluded itself from any ability to separately and adequately consider the EEQA factors in relation to the reduced payments under new §14105.455 of Welf. & Inst. Code;

so that therein the enactment of each of amended § 14105.45 and new § 14105.455 of Welf. & Inst. Code:

- was **without adequate consideration** of the relevant EEQA factors in respect to the proposed amendment to § 14105.45 Welf. & Inst. Code, and,

- was **without adequate consideration** of the relevant EEQA factors in respect to the proposed new § 14105.45 Welf. & Inst. Code,

so that therein the enactment of these two Medicaid provider rate proposals in one single

indivisible measure, (on a vote to approve both of them or none), was contrary to, **hence preempted under the Supremacy Clause by,** Sec. 30A.

49. Unless enjoined, the preempted actions of the Director to implement the preempted pharmacy payment reductions of §§ 14105.45 and 14105.455 Welf. & Inst. Code will cause irreparable injury to the Plaintiffs, the member pharmacies of the plaintiff CPhA, and the millions of patients of the Plaintiffs and the pharmacy members of CPhA; all as prior alleged in Paragraph 38(a) and (b) of the Second Claim for Relief of this FAC.

50. Accordingly a permanent injunction, preliminary injunction, and temporary restraining order should and must issue to order the Director to act, and to refrain from acting, as specified in Paragraph 39 of the Second Claim for Relief in this FAC.

WHEREFORE the plaintiffs pray for orders and judgment as shall hereinafter be specified:

FOURTH CLAIM FOR RELIEF
Supremacy Clause Claim

Implementation of the Upper Billing Limit law is contrary to, hence preempted under the Supremacy Clause by, the equal access provision of Sec. 30A and 42 CFR 447.204.

51. Plaintiffs refer to and incorporate each of the allegations of each of the preceding Paragraphs as if herein fully set forth.

52. This is a Supremacy Clause claim.

53. The methods and procedures related to payments of pharmacy providers, specified in new Upper Billing Limit law, (§ 14105.455 Welf. & Inst. Code, or"UBL") are antithetical to participation in Medi-Cal, so as to drive pharmacies out of Medi-Cal participation to the degree that equal access to pharmaceutical services is destroyed or threatened to be destroyed by the UBL. Accordingly, implementation of the Upper Billing Limit law is contrary to, **hence preempted under the Supremacy Clause by**, the equal access provision of Sec. 30A and 42 CFR 447.204.

54. Plaintiffs allege in support of but without limitation of the allegations in the preceding Paragraph, as follows:

(a) Third-party payors ("TPP") often contract with pharmacy benefit managers ("PBM")[31] or with wholesaler's organizations (e.g. LeaderNet, Cardinal Health, H.D. Smith),[32] to handle contracting with pharmacies.[33] Depending on the agreement, the PBM may act as an agent for the TPP or on its own behalf.[34] TPPs negotiate drug pricing discounts with PBMs,[35] and PBMs, in turn, negotiate discounts with pharmacy networks.[36] These pharmacy networks are known as Pharmacy Service Administration Organizations ("PSAO") which serve as centralized entities to administer contract negotiations, payments and other administrative tasks for networks of pharmacies.[37] In nearly all cases, the contracts themselves are actually entered into by the TPP and the PSAO and not the individual pharmacies.[38]

(c) Where the consumer is insured, customarily the TPP pays the PBM,[39] or

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[31] Page 6 of March 3, 2009 Memorandum and Order approving settlement in the *First DataBank Case,* 1:05-11148-PBS (D. Mass. 2009), – ("*First Data Bank* Order").

[32] ¶ 13 of Declaration of Paul Lofholm, Pharm.D., ("Lofholm Dec."); ¶ 19 of Declaration of Thu-Hang Tran, Pharm.D., ("Tran Decl."), to be filed herein.

[33] Page 5 of slip opinion in *First DataBank* Case appeal, (2d Cir. Sept. 3, 2009), – "*First DataBank* opinion." (Copy at **Exhibit L** of Plaintiffs' RJN.)

[34] Pages 5-6 of *First DataBank* opinion.

[35] Page 6, *First Data Bank* Order**.**

[36] Page 6 of *First DataBank* Order.

[37] ¶ 17 of Declaration of John Cronin, ("Cronin Decl.").

[38] ¶ 17 of Cronin Decl.

[39] Page 6 of *First DataBank* Order.

a PSAO,[40] or wholesaler organization,[41] who reimburses the pharmacy for the drug product dispensed.

(b) The pharmacy has direct control over their cash charges but in most cases it is the PBM, PSAO or wholesaler organization who contracted with the TPP, who reimburses the pharmacy.[42] The decision by the PBM, PSAO or wholesaler organization (or their electronic claims processor) to accept or deny a prescription claim is done real time while the patient waits at the counter. However, if the claim is accepted electronically and signaled to the pharmacist that the claim is accepted, nevertheless, the pharmacy does not know what amount it will be paid by the PBM, PSAO, wholesaler organization, or their electronic claims processor, until a check is periodically sent with a listing of the accepted prescriptions claims and the amounts paid, per prescription, which equals the total of that reimbursement check for that period.[43]

55. There are over 22,000 drug product NDCs in the Medi-Cal program,[44] which range in different forms (tablet, liquid, etc.), and units dispensed; and many of the rates paid by PBMs, PSAOs, wholesaler organizations, or their electronic claims processors change weekly, and sometimes form day to day.[45] Thus to be presented with a prescription by a Medi-Cal patient and to know whether to charge Medi-Cal the Medi-Cal rate or a lower charge equal to what some PBM, PSAO, wholesaler organization, or their

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[40] ¶ 13 Lofholm Decl.

[41] ¶ 13 Lofholm Decl.

[42] ¶ 13 of Lofholm Decl.

[43] ¶ 19 Tran Declaration. ¶ 13 Lofholm Decl.: "The pharmacy does not know of the payments until the service is performed and only then an electronic message will be sent to the pharmacy, with payment to follow."

[44] ¶ 10 of Declaration of Kevin Gorospe, (to be filed herein).

[45] ¶ 19 Tran Decl.; ¶ 22 Cronin Decl.; § 20 of Gerald Shapiro Dec., to be filed herein.

electronic claims processor has paid the pharmacy for that particular drug NDC, and number of units, – in order to comply with, and, comply with, the new UBL, is impossible or at the very least difficult and impractical to attempt to accomplish for many if not all pharmacies. **(**¶ 13 of Lofholm Decl.;[46] ¶ 19 Tran Decl.;[47] ¶ 24 Cronin Decl.; ¶ 20 Shapiro Decl,.[48] to be filed herein.)

56. Further, the Plaintiffs declare that it is also impossible for the great majority of pharmacies to be able to comply with the requirement of the Upper Billing Limit law to keep and maintain records of their usual and customary charges. **(**¶ 19 Tran Decl.;[49] ¶¶ 21, 23 Cronin Decl.; ¶§ 20 Shapiro Decl.)

57. In conclusion the Plaintiffs' declarants state:

Plaintiff Shapiro (Uptown Pharmacy):

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[46] ¶ 13 Lofholm Decl.: "The pharmacy does not know of the (amount of) payments until the service is performed and only then an electronic message will be sent to the pharmacy, with payment to follow. Thus to be presented with a prescription and to know what to charge the State Government and be compliant with the new legislation is impossible."

[47] ¶ 20 Tran Declaration: "Also, all third party payer contracts of the Tran Pharmacy and all the owner members of VAPA, are all handled exclusively by and through our wholesaler, H. D. Smith. As a result my pharmacy and the pharmacy owner members of VAPA have no knowledge of what the rates are in these third party payer contracts . . . Further, many of the rates in these many, many third party payer contracts, change weekly and sometimes from day to day – so that my pharmacy and the pharmacy owners of VAPA are completely unable to comply with the Upper Billing Limit law which started October 1, 2009."

[48] ¶ 20 of Shapiro Decl.: "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 the tens of thousands of drug NDCs under many different 3d party plans.

[49] ¶ 19 Tran Declaration: "My pharmacy and the pharmacy members of VAPA have no such records. . . . I can only tell you what has been paid when I get my monthly billing statement . . . and these billings do not disclose 3d party payment rates but, primarily, only quantities and medications sold, which are paid me."

"If these cuts are allowed to stand I will be forced out of business."[50]

John Cronin (Community Pharmacy of Escondido, and Community Pharmacy of Valley Center):

"(M)any if not most pharmacies will either discontinue filling Medi-Cal prescriptions; or, pharmacies who continue to accept Medi-Cal will discontinue servicing other third party payer contracts. Unless they make one of these two elections they cannot comply with the requirements of Sec. 14105.455 Welf. & Inst. Code. The result will be that those frail, elderly, and disabled Medi-Cal patients whose pharmacies stop serving Medi-Cal patients will have their access to pharmaceutical services greatly diminished. Many, particularly those who are homebound, will be unable to locate any pharmacy within a reasonable distance that is willing to serve their needs, resulting in a denial of access to medically necessary medicines and a decrease in the quality of their care."[51]

Paul Lofholm, Pharm.D. (Ross Valley Pharmacy):
– Clinical Professor of Pharmacy at U.C.S.F.
– Immediate past president of CPhA.

"In respect to the upper billing limit legislation especially, it does not matter if the pharmacy is a chain or independent, neither can comply and to lessen their exposure to recoupment, many will cease serving Medi-Cal beneficiaries because that will be better for them rather than to try to continue providing services to Medi-Cal beneficiaries under an upper billing limit statute they cannot, as a practical matter, comply with."

58. Hence by each of the facts alleged in this Fifth Claim for Relief, it is impossible and impractical for pharmacies to comply with the Upper Billing Limit law of § 14105.455 Welf. & Inst. Code when dispensing a prescription which is paid by or on behalf of a TPP, or with the requirement of the Upper Billing Law that the pharmacy keep and maintain records of their usual and customary charges for three years from the date the service was rendered; so that thereby, implementation of the preempted provisions of amended § 14105.45 and new § 14105.455 of Welf. & Inst. Code has and will cause irreparable injury to the Plaintiffs, by forcing them, in self-protection, to elect

[50] ¶29 Shapiro Decl.

[51] ¶ 27 Shapiro Decl.

between serving only private pay and insureds, members and employees of TPPs, or serving only Medi-Cal and Medicare Part D patients, which in turn deprives Medi-Cal beneficiaries who are patients of the Plaintiff pharmacies, and of the pharmacies of the plaintiff CPhA, from any access or any equal access to pharmaceutical services in the State's Medicaid program, contrary to, hence preempted **under the Supremacy Clause by,** the equal access provision of Sec. 30A and 42 CFR § 447.204.

WHEREFORE the Plaintiffs pray for orders and judgment as shall be specified hereinafter:

FIFTH CLAIM FOR RELIEF
Supremacy Clause Claim

Fifth Claim for Relief, for injunctive relief in respect to 4% reduced reimbursement for cost to acquire brands, which reduction is contrary to, hence preempted under the Supremacy Clause by, the EEQA factors of Sec. 30A.

59. Plaintiffs refer to the allegations in the preceding Paragraphs and incorporate each of those allegations as if fully alleged herein.

60. This is a Supremacy Clause claim.

61. As prior set forth in this FAC, the Department as the Single State Agency has the exclusive and ultimate power to set or cause provider payment rates to be set in all parts of the State's Medicaid program, including both the Medi-Cal FFS program and the Medi-Cal managed care program; which Department, or agency, and its powers to set or cause to be set provider payment rates in all parts of the State's Medicaid program, is exclusively controlled by the defendant Director.

62. Prior to September 26, 2006 and currently, both the Medi-Cal FFS program and the Medi-Cal managed care program used and are using a published AWP from which:

- the Medi-Cal FFS program subtracts 17% to arrive at Estimated Acquisition Cost ("EAC") to be paid to pharmacies as reimbursement for their brand

acquisition costs;

and,

- the various Medi-Cal managed care plans, – (under authority granted to them by the Director but subject to ultimate control by the Director pursuant as prior set forth), – each subtract various percentages, (typically 15% as in the CalOptima managed care plan in Orange County) from the published AWP for a given brand product, so as to arrive at the EAC amount be paid to pharmacies in their managed care plan as reimbursement for their brand acquisition costs.

63. However, on September 26, 2009, the formula or the published AWP used by both the Medi-Cal FFS program and the Medi-Cal managed care program was unilaterally and artificially changed or marked down 4% by the AWP publisher used by the Department, – from a formula for published AWP of 125% of Wholesale Acquisition Cost ("WAC") to a new formula for published AWP of 120% of WAC, – for 18,000 to 20,000 or more brand drug products each having a National Drug Code ("NDC") identification number or code.[52]

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[52] 1,400 of these NDCs, only, were marked down by First DataBank pursuant to a voluntary class action settlement which First DataBank entered into in the *First DataBank* case, – **after** the Boston court refused to approve markdowns on more than these few 1,400 NDCs. (*See,* Page 2 of March 17, 2009 order in the *First DataBank* case which approved a lass action settlement which authorized a markdown of AWP to 1.20 of WAC for 1,400 NDCs, only.)

Hence it is not true as the Attorney General incorrectly claims or infers, that the 18,000 to 20,000 reduced AWP markdowns were the "result of a lawsuit in Massachusetts." (Page 5:21-26 of Defendants' Memorandum which is Document 58-7 in *MPC,* 2:09-cv-0382 CAS (MANx)).

To the contrary, the Boston court denied a settlement proposal to markdown AWPs of approximately 8,000 brand NDCs, for the reason that:

> "**The Court was also troubled by the proposal that over 8,000 National Drug Codes ("NDCs") for branded drugs were to be rolled back four percent."** (Page 2, *ibid.*). (Emphasis supplied).

Thus the act of unilaterally marking down more than 20,000 brand drug NDCs on February 26,

64. Richard D. Wilson, C.P.A., reviewed public documents and data of the Department and concluded in his supplemental declaration filed herewith,[53] – and Plaintiffs allege – that:

(a) The 18,000 to 20,000 brand drug products whose published AWP was artificially marked down 4% included most of the 1,000 top selling brand drug NDCs the expenditu8res for which comprise 98.7% of all Medi-Cal expenditures for brand drugs,[54]

and sub-included:

- virtually all the 200 top selling brand NDCs the expenditures for which comprised **$313,629,963, or 44.7%** of the total of **$701,454,170** in expenditures by the Medi-Cal program for brand drug prescriptions in the typical 2d Quarter 2009.[55]

65. C.P.A. Wilson further found from printouts of the price that was paid by Medi-Cal for each of these 200 Top Selling Brand Drugs on September 25, 2009,

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2009, was not the act of a person ordered to do so by a federal court who had considered the harms, and approved it, as incorrectly inferred by the Attorney General.

[53] Supplemental Declaration of Richard D. Wilson, C.P.A., ("Wilson Supp. Declaration"),k to be filed herein.

[54] *See,* Table 4.1, and Pages 35-36 of the 2006 study of Myers and Stauffer, C.P.A.s, of pharmaceutical costs in California, which was commissioned by the Department and published in 2007. ("2007 Myers Survey").

The 2007 Myers Survey found on Pages 35-36, and Table 4.1, that the **top 1,000 single source drug products**, – ranked by total reimbursement for all prescriptions in the Medi-Cal program for calendar year 2006, – accounted for **98.7% of all expenditures** by the Medi-Cal program for brand drug products, as well as for **75% of all expenditures** by the Medi-Cal program for all drug products, (brand and generics, combined).

[55] ¶¶ 9, 10, 11 of Wilson Supp. Declaration.

Specifically, C.P.A. Wilson found in ¶ 8 that reimbursement by Medi-Cal was reduced 4% for **168 or 84%** of the 200 Top Selling Brand Drug NDCs, as a result of the 4% markdown of published AWP on September 26, 2009 by the Department's AWP publisher.

compared to printouts of the price that was paid by Medi-Cal for each of these same 200 Top Selling Brand Drugs on the markdown day of September 26, 2009, – and Plaintiffs hereby allege, – that most of the 200 Top Selling Brand NDCs suffered a 4% payment reduction, due to the September 26, 2009 markdown of published AWP.[56]

66. Further, by applying the known pharmacy costs reported by the 2007 Myers Survey to the 4% reduced prices paid by Medi-Cal for the 200 Top Selling Brand Drug NDCs on the markdown day of September 26, 2009 to a spreadsheet, – which costs factors are:

- pharmacies' brand drug acquisition costs which are equal to 79% of AWP (as it existed prior to September 26, 2009), as found by the 2007 Myers Survey at Page 6 of the 2007 Myers Survey;

- pharmacies' average overhead costs of $12.57 per prescription as found by the 2007 Myers Survey, adjusted as per standard inflation factor of 1.725 used by the Department through 2008,[57]

C.P.A. Wilson determined – and the Plaintiffs hereby allege, – that **191 or 95.6%** of the 200 Top Selling Brand Drugs – which account for 44.7% of all prescription expenditures by the Medi-Cal program, – cannot be acquired-and-dispensed except at a **net loss** to the pharmacy, on average, due to the 4% payment reduction in reimbursement for brand drug acquisition costs commenced on September 26, 2009.[58]

67. Similarly, C.P.A. Wilson's conclusion was – and the Plaintiffs hereby

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[56] ¶ 8 and 14 of Wilson Supp. Declaration and **Exhibit I** of his declaration, to be filed herein.

[57] *See,* Page 7 of Analysis of Assembly Bill 1183, dated February 8, 2009, by Toby Douglas, Chief Deputy Director of the Department, in which the Department uses and approves the costs inflation factor of 1.0725 from the common point of December 31, 2006 to March 1, 1009.

[58] ¶ 8, 14, and the spreadsheet which is **Exhibit I** , of the Wilson Supp. Declaration to be filed herein.

allege, – that the majority of the 800 remainder of the 1,000 top selling brand drug NDCs, ranked by amount of expenditures by the Medi-Cal for all brand drug NDCs, – (which together with the 200 Top Selling Brand Drug NDCs account for 98.7% of all Medi-Cal expenditures for brand drugs), – also suffered a 4% reimbursement reduction due to the 4% markdown of published AWP on September 26, 2009; and that the **majority of the 800** remainder of the 1,000 top selling brand drug NDCs also can now no longer be acquired-and-dispensed except at a **net loss** to the pharmacy, on average, due to the 4% payment reduction in reimbursement for brand drug acquisition costs commenced on September 26, 2009.[59]

68. Thus in summary, the effect of the September 26, 2009 markdown of published AWP on 18,000 to 20,000 brand drug NDCs by the AWP publisher used by the Medi-Cal FFS program and the Medi-Cal managed care program, was devastating, as if a cyclone had hit the Medi-Ca program, in that:

- virtually **all** of the 200 Top Selling Brand Drug products for which 44.7% of all Medi-Cal drug expenditures are expended, and,

- many if not most of the remaining 800 of the 1000 top selling brand drug products (for which 1,000 top selling drug products 98.7% of all Medi-Cal drug expenditures are expended),

suffered a **4% reduction** in reimbursement paid to the pharmacy by the Medi-Cal FFS program and the Medi-Cal managed care program; and, most significant at all, **can now be acquired-and-dispensed only at a net loss, per brand drug prescription**, in the Medi-Cal FFS and managed care programs.

69. In contrast to the vast majority of state Medicaid programs and PBMs

[59] ¶¶ 13 and 14 of the Wilson Supp. Declaration, to be filed herein.

throughout the country, the Director has unconscionably taken advantage of pharmacies in the Medi-Cal program:

- by refusing to adjust or adopt a new payment rate to offset and neutralize the 4% reduction in brand acquisition reimbursement to pharmacies in the Medi-Cal FFS program,

- by refusing to order all managed care plans and their officers, in the Medi-Cal managed care program, to adjust or adopt a new payment rate to offset and neutralize the 4% reduction in brand acquisition reimbursement to pharmacies in the Medi-Cal managed care program,

so as to offset and eliminate the devastating effect on the brand drug part of the Medi-Cal pharmacy program, of the 4% markdown of published AWP on September 26, 2009.

70. Instead the Director, by the **action of passively doing nothing** except paying 4% less to pharmacies for reimbursement for brand drug acquisition costs in the Medi-Cal FFS program (as the result of the publisher's 4% AWP markdown of September 26, 2009) and allowing all managed care plans in the Medi-Cal managed care program to pay 4% less to pharmacies since September 26, 2009, (as the result of the publisher's 4% AWP markdown of September 26, 2009), has therein *de facto* and *de jure* adopted a new formula or rate for reimbursing pharmacies in the Medi-Cal FFS program and the Medi-Cal managed care program for their brand drug acquisition costs; namely:

- a new EAC rate, reduced by 4%, in the Medi-Cal FFS program for reimbursing providers for brand drug acquisition costs, which is a formula or EAC rate which is now equal to only:

120% of WAC, minus 17%, and,

- a new EAC rate, reduced by 4%, in each Medi-Cal managed care plan for reimbursing pharmacies for brand drug acquisition costs, which is now a new formula or EAC rate which is now equal to only:

> 120% of WAC, minus (whatever percentage of subtraction from AWP is provided by the particular Medi-Cal managed care plan).

71. The Department, in passively so adopting the change in AWP formula from a *de facto* formula of 125% of WAC to 125% of WAC, – entirely failed and refused to consider the EEQA factors required by Sec. 30A to be considered, including whether the reduced payments bear any reasonable relationship to pharmacy costs, (*Orthopaedic*, *supra*, 103 F.3d at 1496, 1500).

72. More particularly, but without limitation thereby, the Department failed to consider EEQA or pharmacies' costs in so adopting the change of formula for AWP because the Department has a fixed (erroneous) policy and fiction, to wit, that the change in formula for AWP in the Medi-Cal program for brand drug NDCs, 1.25 of WAC to 1.20 of WAC, on September 26, 2009, did not involve any change in any Medi-Cal statute, regulation, or reimbursement policy, (sic);[60] and that any impact on a provider's reimbursement for a drug was based on an existing Medi-Cal reimbursement statute,

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[60] Statement of Department policy by the Director in the Defendant's Memorandum filed as Document 68 in *Managed Pharmacy Care v. Maxwell-Jolly*, 2:09-CV-0382 CAS (MANx), which states, (at *ibid.* 5:21-24) that the 4% reduced payment from the September 26, 2009 markdown of published AWP:

> " . . . does not involve any change in Medi-Cal statute, regulation, or reimbursement policy,"

citing the statement of Department policy by Kevin Gorospe, Chief of Medi-Cal Pharmacy Policy Branch of the Department, speaking for the Department, who states in Paragraph 10 of his declaration that this 4% reduced payment

> " . . . does not involve any change in Medi-Cal statute, regulation, or policy," (*ibid.* 26:21-22).

regulation, or policy, not any new statute, regulation, or policy, (sic);[61]– and that the AWP markdowns are simply changes in the specific numbers that go into reimbursement equation federally approved in the state Plan in Supplement 2 to Attachment 4:19-B.[62]

73. **Therein and thereby**, the Director's and the Department's aforesaid actions in so adopting the aforesaid reduced 4% rates in the Medi-Cal FFS program and the Medi-Cal managed care program without consideration of the EEQA factors required by Sec. 30A to be considered, – (including failure to consider whether pharmacies, in light of their costs, could sustain the 4% cut in reimbursement for brand acquisition without a loss of quality or equal access for Medi-Cal beneficiaries) – were arbitrary and capricious and contrary to, **hence preempted under the Supremacy Clause by**, the EEQA provisions of 30A. (*See, Orthopedic Hospital v. Belshe,* 103 F.3d 1491,1500 (9th Cir. 1997; *Clayworth v. Bonta*, 295 F.Supp.2d 1110, 1128 (E.D.Cal. 2003);[63] and *ILC II*, 572 F.3d 644 (9th Cir.2009).

Direct irreparable injury to pharmacies

74. Further, such preempted State action, (which is contrary to the EEQA provisions of Sec. 30A), directly results in irreparable injury to pharmacies in both the Medi-Cal FFS program and the Medi-Cal managed care program, due to inability of pharmacies, under the Eleventh Amendment in this federal court litigation, ever recovering the amount of these preempted payment cuts, – for which the plaintiff Medi-

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[61] *Ibid.* 6:1-4: "To reiterate, any impact on a provider's reimbursement for a drug will be based on existing Medi-Cal reimbursement statute, regulation, or policy, not any new statute, regulation, or policy.".

[62] ¶ 26 of Gorospe Declaration, (*ibid*, 36:7-14):
"Rather, these are simply changes in the specific numbers that go into the federally approved reimbursement equation."

[63] Reversed on other grounds on appeal.

Cal pharmacies in the Medi-Cal FFS program and the Medi-Cal managed care program are entitled to a permanent injunction, preliminary injunction, and a temporary restraining order to prevent such injury to them from such preempted State action of the Department and its Director. *See, California Pharmacists Association v. Maxwell-Jolly,* ("*CPhA II"*), 563 F.3d 847 (9th Cir. 2009)

Direct irreparable injury and threat of injury to Medi-Cal beneficiaries.

75. Also, such preempted State action directly results in irreparable injury to Medi-Cal beneficiaries from being denied access to, or being threatened to be denied equal access to, quality pharmacy care and services, in both the Medi-Cal FFS program and the Medi-Cal managed care program, due to the fact that many if not most pharmacies in the Medi-Cal FFS program and Medi-Cal managed care program will cease to dispense brand drugs to them, if this 4% reduction in reimbursement to pharmacies for brand drug acquisition cost is not stopped by a court injunction; for which:

- the 5,000-plus homebound Medi-Cal beneficiaries to whom the plaintiff Gerald Shapiro, Pharm.D. delivers brand prescriptions in the Medi-Cal FFS program and the Medi-Cal managed care program;

- the patients of the plaintiff Tran Pharmacy and the plaintiff Sharon Steen, dba Central Pharmacy, who receive their services both under the Medi-Cal FFS program and the Medi-Cal managed care program;

- the several million patients of the thousands of pharmacies who are members of the co-plaintiff California Pharmacists Association ("CPhA"), who are beneficiaries in the Medi-Cal FFS program and the Medi-Cal managed care program,

are entitled to a permanent injunction, preliminary injunction, and a temporary restraining order to prevent injury to them from such preempted State action of the Department and its Director.

76. The aforesaid remedies to prevent injury from the preempted action of the

Director which is complained of, must include the following relief, at the minimum, that the Director must be enjoined permanently, preliminarily, and by temporary restraining order from implementing the 4% reimbursement reduction for brand drug acquisition costs; and to instead take all steps, at once and without delay, which are reasonably necessary in order to continue to pharmacies the same rates which would be paid had the AWP published by the publisher used by the Department not been marked down to 120% of WAC on September 26, 2009, (at least, so long AWP remains a component of EAC in the state Plan filed by the Department with HHS).

WHEREFORE the plaintiffs pray for orders and judgment as shall hereinafter be specified:

SIXTH CLAIM FOR RELIEF
Supremacy Clause Claim

The Director is deemed in law to have himself made the change in the AWP formula, from 1.25 of WAC to 1.20 of WAC; so that for disregard of providers' costs the Director's action to reduce the rate of payment of September 26, 2009 was contrary to, hence preempted under the Supremacy Clause by, the quality of care provision of Sec. 30A: for which an appropriate preliminary injunction must issue.

77. It was the Director who selected, approved, and ratified all that First DataBank has done in respect to marking down published AWP for 18,000 to 20,000 or more brand NDCs on September 26, 2009, and, who had the power to amend the state Plan to adjust the formula for paying pharmacies in the Medi-Cal FFS program, before First DataBank promulgated the change in AWP formula from 1.25 of WAC to 1.20 of WAC.

78. Hence the Director stands in law the same as if the Director himself promulgated the change in formula of AWP for brand NDCs from 1.25 of WAC to 1.20 of WAC.

79. Here the maxim and rule of the Field Code applies:

> He who can and does not forbid that which is done on his behalf, is deemed to have bidden it. § 3521 California Civil Code.

I.e., he who has the power to stop the guillotine blade from falling, is as responsible for the blade falling, as he were the executioner himself.

80. Accordingly, this September 26, 2009 change in formula from 1.25 of WAC to 1.20 of WAC for 18,000 to 20,000 or more brand NDCs, was in law the action of the Director, to wit, a change by the Director himself of the pharmacy payment rate in the Medi-Cal program.

81. Therein and thereby, the Director's action on September 26, 2009 to reduce the AWP formula for 18,000 to 20,000 or more brand NDCs, from 1.25 of WAC to 1.20 of WAC, was contrary to, **hence preempted under the Supremacy Clause by,** the quality of care and equal access provisions of Sec. 30A, (which required that (1) this reduced Medicaid provider payment rate bear a reasonable relationship to provider's costs to furnish quality care, (2) that the Director consider providers' costs to furnish quality pharmaceutical care, contemporaneously with changing the rate formula from 1.25 of WAC to 1.20 of WAC; and (3) that the reduced rates ultimately, be sufficient to assure equal access to pharmaceutical services for Medi-Cal beneficiaries).

SEVENTH CLAIM FOR RELIEF
(Supremacy Clause Claim)

A seventh and alternative Claim for Relief, for injunctive relief in respect to the 4% reduced reimbursement for cost to acquire brands, which reduction is contrary to, hence preempted under the Supremacy Clause by, the EEQA provisions of Sec. 30A.

82. The 1,000 top selling brand NDCs, ranked by total reimbursement for an annual period, typically comprise 98.7% of Medi-Cal program expenditure for brand proscriptions on an annual basis.[64]

83. However, Richard D. Wilson, C.P.A., concluded in his November 16, 2009

[64] Table 4.1 on Pages 35-36 of 2007 Myers Survey.

analysis of the effect of the 4% markdown of published AWP for 18,000 to 20,000 or more brand NDCs, on September 26, 2009, that:

One: This reduced the total reimbursement by the Medi-Cal program (in both the Medi-Cal FFS program and the Medi-Cal managed care program) for a brand NDC prescription, to less than what it costs the pharmacy to acquire-and-dispense the majority of the brand NDCs which are among the 1,000 top selling brand NDCs in the Medi-Cal program (which comprise 98.7% of all the annual expenditures in the Medi-Cal program for brand drug prescriptions);[65] such that,

Two: If this 4% cut in reimbursement for brand drug acquisition costs is not stopped, then pharmacies will have no choice except to quit the Medi-Cal program entirely; or if they do continue, to only accept their present Medi-Cal patients and exclude all new Medi-Cal patients, or only dispense those few drug products in the Medi-Cal program which they can acquire and dispense at a net profit. (Pages 10-11 of Wilson Supp. Declaration.

84. Accordingly **it is manifest** that the methods and procedures now specified in the state Plan (at Pages 1 and 2 of Supplement 2 of Attachment 14-B of the state Plan), relating to payments for care and services available under the Plan are **no longer sufficient or constitute any assurance**, – **as required by Sec. 30A** – (and have become insufficient and do not assure), – that payments for prescription drugs (especially, brand prescriptions), are consistent with efficiency, economy, quality of care and are sufficient to enlist enough pharmacy providers so as to provide equal access to pharmaceutical services; so that therein, **the actions of the Director to continue to use the present methods and procedures specified in the state Plan**, relating to payments for brand drugs, are contrary to, **hence preempted under the Supremacy Clause by:**

[65] ¶ 14 of Wilson Supp. Declaration.

- the methods and procedures provisions of Sec. 30A,

- the quality of care provision of Sec. 30A, and,

- the equal access provisions of Sec. 30A and 42 CFR § 447.204;

for which appropriate preliminary injunction must issue to prevent irreparable harm to Medi-Cal beneficiaries who are patients of the Plaintiffs and the members of CPhA.

85. Further, pharmacies also suffer irreparable injury from these preempted actions of the Director because they are being paid less than what they would receive if the Department methods and procedures relating to payments for brand drugs complied with Sec. 30A, but cannot recover the same due to the Eleventh Amendment; hence the Plaintiff pharmacies are also entitled to preliminary injunction.

EIGHTH CLAIM FOR RELIEF
Supremacy Clause Claim

Implementation of the MAIC law enacted by § 14105.45 Cal. Welf. & Inst. Code, by:

- Stats. 2004, c. 228, section 17, enacted August 16, 2004, (Senate Bill ("SB") 1103, section 17;

- Stats. 2007, c. 188, section 64, enacted August 24, 2007, (Assembly Bill ("AB") 203, section 64;

- Stats. 2009, c. 5, section 38, enacted July 28, 2009, AB X4 5, section 38;

is contrary to hence preempted by the quality and equal access requirements of Sec. 30A.

86. Plaintiffs refer to and incorporate each of the allegations of each of the preceding Paragraphs as if herein fully set forth.

87. This is a Supremacy Clause claim.

88. Prior to 1990 the Department placed a maximum allowable ingredient cost ("MAIC") cap on certain multi-source drug products, under then-22 California Code of Regulations § 51513.3. However, in 1990 the Legislature enacted Senate Bill 2097, section 17, which abolished the MAIC regulation, established a MAIC list of multi-source

drugs by grandfathering in the then-existing regulatory list of MAIC drugs, and instructed the Department to update and establish additional MAIC drugs.

89. The Department has ever since administered a list of MAIC multi-source drugs at a MAIC cap or limit which allows a large margin of gross profit, (excess of what the pharmacy is paid by Medi-Cal FFS to acquire a MAIC drug, over what it costs the pharmacy to acquire the MAIC drug). Thus both the 2002 Myers Survey and the 2007 Myers Survey of pharmaceutical costs in California, reported that although MAIC multi-source drugs are low-price drugs, nevertheless, that there is a large percentage of gross profit to pharmacies (defined as the excess of what Medi-Cal pays a pharmacy to acquire a drug product, less what it costs the pharmacy to acquire the drug product).[66]

90. In 2004 the Legislature decided to take all the gross profit out of the acquisition side of the MAIC transaction.

91. To do this, the Legislature first enacted SB 1103, § 17 in 2004, to cut the amount paid by Medi-Cal to the pharmacy for a MAIC drug to the "manufacturer's average sale price," (which is a price which is actually less than what it costs retail pharmacies to acquire MAIC drugs wholesale): which would result in **net loss** to pharmacy per MAIC transaction, (due to the fact, among other things, that the $7.25 dispensing fee does not cover pharmacy overhead costs, per prescription).

92. Then in August 2007 the Legislature enacted AB 203 to cut the acquisition reimbursement amount to only "average manufacturer's price" or "AMP," plus a markup to "average purchase price," on MAIC drugs; and, instructed the Department **to increase the**

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[66] Table 5.2 of 2002 Myers Survey, and Page 41 of 2007 Myers Survey.
(The large percentage of gross profit on the acquisition side of the MAIC transaction is needed to enable the pharmacy to offset a loss on the dispensing side of the transaction, in order to have any net profit at all on these small-priced MAIC drugs.)

dispensing fee to match the aggregate savings to the State which would occur once the Department commenced to implement AB 203.

> 93. However, AB 203 never got off the ground, due to the fact that in December 2007 the U.S. District Court, District of Columbia, enjoined HHS from implementing AMP, and from providing AMP figures to the States. Therefore the Department has never hand any AMP figures by which to implement the MAIC reimbursement provisions of AB 203.

94. (a) Accordingly on July 28, 2009, the Legislature, to jumpstart the AB 203 MAIC reimbursement scheme, enacted AB X4 5, section 38, amended § 14105.45 Welf. & Inst. Code again to now add, in new subd. (b)(3)(B) that so long as AMP figures are not available, that the Department shall instead reimburse pharmacies for their cost to acquire-and-dispense a MAIC drug product **first,** an amount equal to wholesaler average cost ("WAC), with a percent markup to the "average purchase price" paid by retail pharmacies in California to acquire a given MAIC drug product, **plus a new dispensing fee** calculated (as per subd. (d) of § 14105.45 Welf. & Inst. Code) to equal the aggregate savings to the State from the implementation of this new MAIC reimbursement scheme, of amended § 14105.45 (of AB X4 5, section 38).

The new MAIC reimbursement formula is contrary to, hence is preempted under the Supremacy Clause by, the quality and equal access provisions of Sec. 30A.

FIRST NET LOSS ON THE NEW MAIC RATE TRANSACTION

95. (a) First, assuming *arguendo* that the Department correctly calculates the new increased dispensing fee for MAIC drugs to be exactly equal to the amount of savings to the State accruing from cutting out the net profit on a pharmacy's acquisition-and-dispensing a MAIC drug product, nevertheless, **approximately half the pharmacies will still suffer a net loss** on any new MAIC transaction.

(b) This net loss is due to the fact that because the new MAIC reimbursement formula of the amended § 14105.45 Welf. & Inst. Code (enacted by AB X4 5 in July 2009), is based on an average, (i.e.,"**average purchase price**") to reimburse pharmacy acquisition costs, it follows that the **approximately one-half of all pharmacies** who, by definition, comprise the group who expend **more than the average amount** to acquire a given MAIC drug product, **suffer a net loss** in the transaction.

(c) Accordingly, approximately one-half of all pharmacies will, foreseeably, not fill MAIC prescriptions because, by mathematical definition, they suffer a net loss on the transaction.

SECOND NET LOSS ON THE NEW MAIC RATE TRANSACTION

96. (a) Worse, the new increased dispensing fee called for by the AB 203 version and now the AB X4 5 version of § 14105.45 Welf. & Inst. Code is **only a one-time dispensing fee increase** which (1) does not return a **net profit** to pharmacies on the MAIC transaction on Day One of initial implementation of the new MAIC rate, and (2) devolves into a bigger and bigger **net loss** per MAIC transaction as time goes forward, due to the fact that inflation increases pharmacy overhead costs as time goes forward.

Summary of this sub-point:

97. (a) By the above facts, all the MAIC payment rates under § 14105.45 Cal. Welf. & Inst. Code under all three of the versions, – namely, under SB 1103,[67] under AB 203,[68] and now AB X4 5,[69] – are contrary to, **hence preempted under the Supremacy Clause by**, the quality and equal access clauses of Sec. 30A, due to the fact that **some**

[67] Enacted 2004.

[68] Enacted 2007.

[69] Enacted July 28, 2009.

pharmacies suffer a net loss **at the outset of implementation** of the new MAIC provider payment rates of § 14105.45 Cal. Welf. & Inst. Code, and **all pharmacies** suffer a **net loss** which increases as time moves forward, due to inflation in overhead costs as time moves forward: so that, therein, the Director's actions to implement the new MAIC provider reimbursement rates of § 14105.45 Cal. Welf. & Inst. Code – (in all three of its SB 1103, AB 203, and AB X4 5 versions), – are contrary to, **hence preempted under the Supremacy Clause by,** the quality and equal access provisions of Sec. 30A.

98. As a result of the foregoing, pharmacies will not reasonably dispense MAIC prescriptions under the rates in each of these three versions of § 14105.45 Cal. Welf. & Inst. Code, so that (1) pharmacies are injured irreparably because they are not reimbursed their costs to acquire-and-dispense MAIC drugs under § 14105.45 Cal. Welf. & Inst. Code ; and (2) Medi-Cal beneficiaries on whose behalf the Plaintiffs sue, will be unable to obtain those multi-source drug prescriptions which are placed under a MAIC cap, under § 14105.45 Cal. Welf. & Inst. Code, (under any of the three versions of § 14105.45 Cal. Welf. & Inst. Code in SB 1103, AB 203, and now AB X4 5).

WHEREFORE, Plaintiffs pray for orders and judgments as shall be specified hereinafter.

NINTH CLAIM FOR RELIEF
Supremacy Clause Claim

The provision of the Upper Billing Limit statute of § 14105.455 Cal. Welf. & Inst. Code is contrary to, hence preempted under the Supremacy Clause by, both 42 CFR § 447.512 and the state Plan.

99. Plaintiffs refer to and incorporate each of the allegations of each of the preceding Paragraphs as if herein fully set forth.

100. This is a Supremacy Clause claim.

101. § 14105.455 Cal. Welf. & Inst. Code, implemented as of October 1, 2009,

provides in subd. (a) that pharmacies shall submit their "usual and customary charge" when billing the Medi-Cal Medi-Cal FFS program or the Medi-Cal managed care program for prescribed drugs; and that "usual and customary price" means:

> "(1) The lowest price reimbursed to the pharmacy by other third-party payers in California, excluding Medi-Cal managed care plans and Medicare Part D prescription drug plans.
>
> (2) The lowest price routinely offered to any segment of the general public."

The state Plan does not permit an upper payment limit of "usual and customary charge.

102. However, Supplement 2 of Attachment 4:19-B of the state Plan does not permit any methods or standards for establishing a payment limit of "usual and customary charge." To the contrary, Supplement 2 of Attachment 4:19-B of the state Plan only permits an upper payment limit in this respect of the pharmacy's "charges to the general public."

Thus, ¶ A at Page 1 of Supplement 2 of Attachment 4:19-B of the state Plan, which is entitled:

> "METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES-PRESCRIBED DRUGS"

provides:

> "A. The method used to establish maximum drug product payments is that payments for drugs dispensed by pharmacists shall consist of the state's Estimated Acquisition Cost (EAC) of the drug product dispensed plus a dispensing fee that is added to the drug product payment . . . The EAC is the lowest of the Average Wholesale Price (AWP) minus 17 percent, the Maximum Allowable Ingredient Cost (MAIC); the federal upper limit of reimbursement for listed multiple source drugs (called "Federal Upper Limit" or FUL), or the charges to the general public." (Boldface emphasis supplied.)

Also, 42 CFR § 447.512 does not permit an upper payment limit of "usual and customary charge."

103. Thus, 42 CFR §§ 447.512 provides that except for multi-source drugs for

which a payment cap has been established under 42 CFR § 447.518, that agency payments for brand name drugs and other drugs:

> " . . . must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the--
>
> (1) EAC plus reasonable dispensing fees established by the agency; or
>
> (2) Providers' **usual and customary charges to the public**."

(Boldface emphasis supplied.)

104. I.e., the term, "usual and customary" is and always has been a regulatory term descriptive of and referring, in 42 CFR § 447.512 to "charges to the public." The new State law, (the UBL), legislates a different meaning to the phrase, "usual and customary" charge or price, to mean and refer in the state UBL to usual and customary charges or price to entities which are both not a part of the general public, and not included in the phrase, "charges to the general public" is utilized to indicate the maximum charges which a provider is permitted to charge the Medi-Cal program in California.

Thus, third party payers ("TPPs) are **not** the general public and have always been construed by HHS and the Department not to be included in the phrase, "charges to the general public," so that the new UBL is contrary to, **hence preempted under the Supremacy Clause by,** the Medicaid rate-setting statute, (namely, Sec. 30A) and 42 CFR § 447.512 in which HHS implements Sec. 30A.

In sum, the federal regulatory meaning in the state Plan and in 42 CFR § 447.512, which were adopted and approved by HHS to carry out Sec. 30A, (among other provisions of the Medicaid Act), cannot be injected and given a new and different meaning by California legislature, – especially as in case at bar the "new" legislative meaning or definition is in flat contradiction to plain words in the state Plan and in 42 CFR § 447.512 which prohibit the State from imposing a Medi-Cal upper billing limit which is different

from the meaning of "charges to the public;" and when HHS and the Department have never construed or enforced "usual and customary" in respect to TPPs, (in the manner and meaning to be ascribed to "usual and customary" charge or price enacted by the UBL), in more than 40 years of the Medicaid program in California: which establish a de facto and de jure federal regulatory meaning that "usual and customary" refers to charges to the public, not, to charges to TPPs, and is not a term or meaning which may be changed by the State Legislature to now mean, that "usual and customary" means and refers to TPPs, (so that in respect also, the UBL of § 14105.455 Welf. & Inst. Code is contrary to, **hence preempted under the Supremacy Clause by,** Sec. 30A and the aforesaid state Plan provisions and 42 CFR § 447.512 which implement Sec. 30A.

WHEREFORE, each of the Plaintiffs prays for orders and judgment as follows;

FIRST:

A. That judgment be entered against the defendant DAVID MAXWELL-JOLLY, Director of the Department of Health Care Services and in favor of each of the Plaintiffs;

B. That a permanent injunction, preliminary injunction, and temporary restraining order be rendered and filed which orders the Director, and his agents, servants, attorneys, and those working in concert with him, as follows;

- (1) To refrain from implementing, and to stay, § 14105.455 California Welfare & Institutions ("Welf. & Inst.") Code, including (without limitation thereby) refraining from reducing any payments to pharmacies in respect to or on account of any provision in § 14105.455 Welf. & Inst. Code:

- (2) To refrain from implementing, and to stay, § 14105.45 Welf. & Inst. Code, including (without limitation thereby) refraining from reducing any payments to pharmacies in respect to drug products which are subject to a MAIC limit or cap in the Medi-Cal fee-for-service program, on account of or related to any provision in the aforesaid §

14105.45 Welf. & Inst. Code, both in its present form and wording and in each of its prior forms and wordings, including:

- as it was enacted or amended on July 28, 2009 by Section 38 of Assembly Bill ("AB) X4 5, (Chapter 5, Statutes of 2009 Fourth Extraordinary Session);

- as it was enacted or amended on August 24, 2007 by Section 64 of AB 203, (Chapter 188, Statutes 2007);

- as it was enacted or amended on August 16, 2004 by Section 17 of Senate Bill 1103, (Chapter 228, Statutes 2004);

- (3) (a) To refrain from implementing or allowing the implementation of the September 26, 2009 markdown of published Average Wholesale Price ("AWP") to 1.20 of Wholesale Average Cost ("WAC") by the AWP pricing publisher, First DataBank, Inc., used by the Department, in the Medi-Cal fee-for-service program and in all plans, plan, or organization in the Medi-Cal managed care program; and to pay pharmacies and to take all steps necessary to cause pharmacies in both the Medi-Cal fee-for-service program and the Medi-Cal managed care program to be paid the same amounts, from and since September 26, 2009, that they would otherwise have received for covered pharmacy services had the published AWP not been marked down from over 1.20 of WAC to 1.20 of WAC on September 26, 2009 by the AWP publisher used by the Department.

C. That this above-entitled Court issue a judgment for declaratory relief which states the rights and duties of the respective parities in respect to the matters which are the subject of this action.

D, That Plaintiffs have reasonable attorneys fees by all statutes made and

provided therefore, together with costs and such other and further relief as may be just.

Dated: December 2, 2009

t

LYNN S. CARMAN
STANLEY L. FRIEDMAN

By: /s/ Lynn S. Carman
Attorneys for Plaintiffs