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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. /

CIVIL NO.

CV09 08200 CAS (RZx)

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. This is a Supremacy Clause claim.

Plaintiffs challenge the validity of the reduction of reimbursement to pharmacies of new §14105.455 Cal. Welf. & Inst. ("Welf. & Inst.") Code in the Medi-Cal FFS program and Medi-Cal managed care program which commenced October 1, 2009, and the reduction of reimbursement to pharmacies of amended § 14105.45 Cal. Welf. & Inst. Code in the Medi-Cal FFS program which is stated by defendant to commence in June 2010.

2. (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, and *California Pharmacists Assn. v. Maxwell-Jolly,* Case No. 2:09-CV-0722 (C.D.Cal. 2009), ("*CPhA I*"), *affirmed* in Appeals Case 09-56365 (9th Cir. 2009), ("*CPhA II*").[2]

3. 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

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[1] Captions and footnotes are not allegations or part of this Complaint, hence need not be answered or traversed by the defendant.

[2] A copy of *CPhA I* is attached as **Exhibit J**. A copy of *CPhA II* is attached as **Exhibit K**.

has an office in the County of Los Angeles.

Parties

4. 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 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. CPhA brings this action on its own behalf and its representative capacity on behalf of its members, and on behalf of the millions of Medi-Cal patients served by its members, who will be directly and adversely affected by the existing and threatened rate reductions which are the subject of this complaint.

5. (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.

6. (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.

7. (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.

8. The defendant DAVID MAXWELL-JOLLY ("Director"), is the director of the Department of Health Care Services ("Department") of the State of California. The Director is exclusively empowered by §§ 14100.1 and 14105 Welf. & Inst. Code to set all policies, rules and regulations in the joint federal-state Medicaid program in California, under the Medicaid Act, 42 U.S.C. § 1395 et seq., – which is called "Medi-Cal," – including setting all the rates payable to Medi-Cal providers which the Department is exclusively authorized by the Single State Agency provisions of the Medicaid Act and its regulations to set and administer. The Director has an office in the County of Los Angeles. The Director DAVID MAXWELL-JOLLY is sued in his official capacity only.[3]

Standing

9. Each of the plaintiffs 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.

10. 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 patients of its members, from actions of the Director which are contrary to, hence preempted under the

[3] A copy of § 14105 Cal. Welf. & Inst. Code is attached as **Exhibit F**.

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

11. The Medicaid Act, 42 U.S.C. § 1395 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 long as it continues to voluntarily participate in the Medicaid program.[4]

12. In California the State's federal-state funded Medicaid program is called "Medi-Cal." In this Complaint, this federal-state program is sometimes referred to as "Medicaid" and sometimes referred to as "Medi-Cal;" but all such references are to the exact same federal-state funded Medicaid program, whichever appellation is used.

13. (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. Health and Human Services. 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, the state Plan designates the Department as the Single State Agency.[6]

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

[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] Relevant portions of the state Plan are attached as **Exhibit H.**

(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 regulations issued by the Single State Agency.[7]

(c) A copy of 42 CFR § 431.10 is attached labeled **Exhibit E.**

(d) Pursuant to the above provisions of § 1396a(a)(5) and 42 CFR § 431.10, the Department, not the California Legislature, has been exclusively delegated and authorized by Congress in the Medicaid Act to 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.

(e) Consequently, by the facts above alleged, the Director has and retains at all times, under both the Single State Agency provisions of § 1396a(a)(5), 42 CFR § 431.10 and § 14105 Cal. Welf. & Inst. Code, the exclusive authority, power, and jurisdiction to adopt all regulations and to set all pharmacy provider rates in both the Medi-Cal FFS program and the Medi-Cal managed care program of the State; – including the ultimate exclusive power to require all managed care plans in the Medi-Cal managed care program to adopt pharmacy payment rates set or directed by the Director to be set for payment of pharmacies in Medi-Cal managed care plans.

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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.)

14. 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 general population in the geographic area; . . . " (Boldface emphasis supplied.)

15. § 1396a(a)(30)(A), shall hereinafter be referred to as "Sec. 30A."

FIRST CLAIM FOR RELIEF

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

17. By each and all of 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.

(b) Also the Department, – 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, – is precluded by state law and by California Constitution Article 3.5 from doing anything except carry out, *willy nilly*, all enactments of the Legislature which reduce payments to pharmacies in the Medi-Cal fee-for-service ("FFS") program and the Medi-Cal managed care program.[8]

(c) Therein the Department has **no ability or power** (under state law and California Constitution Article 3.5), of doing anything except a post hoc analysis of the

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[8] Article 3.5, California Constitution, provides:
"An administrative agency, including an administrative agency created by the Constitution or an initiative statute, has no power: . . . (c) To declare a statute unenforceable, or to refuse to enforce a statute on the basis that federal law or federal regulations prohibit the enforcement of such statute unless an appellate court has made a determination that the enforcement of such statute is prohibited by federal law or federal regulations."
A copy of Article 3.5 is attached as **Exhibit I.**

enacted rate reduction; which post-hoc analysis, however, 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* decision, so holding. Case No. 2:09-CV-0722 CAS (MANx), [C.D. Cal. 2009];[9] *affirmed,* Appeal Case 09-55365 (9th Cir. 2009).[10])

18. By each and all of the facts alleged above, and by the *stare decisis* decision of Hon. Christina A. Snyder in the *CPhA* case, (**Exhibit J** attached), which was affirmed by the 9th Circuit, (**Exhibit** K attached), it follows, and is the law in the 9th Circuit, that:

(1) the California Legislature has no authority, power, or jurisdiction under the Single State Agency provision of the Medicaid Act and its regulations to set any payments for pharmacies in the Medi-Cal FFS and managed care programs; and,

(2) the Department and its Director have no authority, power, or jurisdiction under the Medicaid Act, and are precluded by and **are preempted under the Supremacy Clause** by the contrary provisions of Sec. 30A of the Medicaid Act and its above-mentioned regulations, from implementing any Medicaid provider payment reductions which are enacted by the Legislature.

19. In this respect the *CPhA* decision, (**Exhibit J** attached), specifically held that Assembly Bill 1183, – which was enacted by the Legislature to reduce pharmacy reimbursement 5% in the Medi-Cal FFS program as of March 1, 2009, – was preempted by the Medicaid Act **because it was the Legislature**, not the Department, which promulgated the 5% provider payment reduction. Thus the *CPhA* decision held, at Page 11, as follows:

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[9] A copy of this March 9, 2009 decision of the Hon. Christina A. Snyder is attached, labeled **Exhibit J.**

[10] A copy of this April 6, 2009 decision of the 9th Circuit is attached, labeled **Exhibit K.**

> 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**[11] 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.)

20. Accordingly, due to this decision by Judge Christina A. Snyder which was sustained by the 9th Circuit in respect to the provisions of the Single State Agency requirement of § 1396a(a)(5) and 42 CFR § 431.10, and the efficiency, economy, quality of care, and equal access provisions of Sec. 30A, it follows 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.

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

21. Notwithstanding the foregoing, the Legislature did, on July 28, 2009, enact Assembly Bill ("AB") X4 5, which amended § 14105.45 Cal. 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

22. Also, the same AB X4 5 enacted new § 14105.455 Cal. Welf. & Inst. Code

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

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.

23. A copy of the amended § 14105.45 Cal. Welf. & Inst. Code is attached to this Complaint as **Exhibit A**. A copy of the new § 14105.455 Cal. Welf. & Inst. Code is attached to this Complaint as **Exhibit B**. A copy of the Assembly Floor Analysis for both of these measures is attached to this Complaint as **Exhibit C**.

24. The Legislature found in Sec. 62 of AB X4 5 that:

> **Sec. 62.** This act addresses the fiscal emergency declared by the Governor by proclamation on July 1, 2009, pursuant to subdivision (f) of Section 10 of Article IV of the California Constitution.

25. The Legislature also found in Sec. 63 of AB X4 5 that

> **Sec. 63.** This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the emergency are:
>
> In order to make changes necessary for the implementation of the Budget Act of 2009, it is necessary that this act take effect immediately.

26. Also, the Director published a notice in the California Regulatory Notice Register, dated August 28, 2009, which admits that these two changes in payments to pharmacies are expected to generate a General Fund savings of $20.9 million in the Medi-Cal program in budget year 2009-2010. So, this is a reduction **of $41.8 million** in payments to pharmacy providers in the Medi-Cal FFS program and Medi-Cal managed care program, when the matching 50% of federal Medicaid funds are counted.[12]

27. Further, when the Legislature reduced provider payments by 5% to adult day care health centers in the *CPhA* case, *supra,* both Judge Snyder and the 9th Circuit held

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[12] A copy of this August 28, 2009 public notice in the Registry is attached to this Complaint as **Exhibit D**.

that actions of the Director to **implement the statutory payment reduction** were **preempted under the Supremacy Clause** due to the fact that:

- the Legislature, – who had no authority under the Single State Agency provision of the Medicaid Act and 42 CFR § 431.10 to set Medicaid provider payments, -- had nevertheless enacted AB 1183 to set the 5% pharmacy payment reduction,

and that:

- the Department, – who did have the exclusive authority to set Medicaid provider payments, – had no authority *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);[13]

so that, as held by Judge Snyder and affirmed by the 9th Circuit, the action of the Department to implement the state Legislature's statute which reduced payment rates to ADHCs was ipso facto contrary to, hence **preempted under the Supremacy Clause** by Sec. 30A.

28. Further, the 9th Circuit held in the *CPhA* case that preempted State action which **reduces payments** to Medicaid providers constitutes and comprises irreparable injury to providers, due to the fact that the Eleventh Amendment bars a legal remedy in damages. (*See,* Pages 8-10 of the 9th Circuit's *CPhA* decision, – a copy of which is attached to this Complaint as **Exhibit K**).

Conclusion, from these precedents in the *CPhA* District Court and 9th Circuit rulings.

29. It follows from these *CPhA* District Court and 9th Circuit rulings in the *CPhA* case, (a copy of which rulings are set forth in **Exhibits J** and **K** attached to this Complaint), that the 9th Circuit has definitively ruled, *stare decisis,* that all implementations by the Director of Medicaid provider payment reductions enacted in the

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[13] Page 11, lines 3-14, of **Exhibit J.**

first instance by the state Legislature, are contrary to hence preempted by the Medicaid Act, (specifically, the Single State Agency and the EEQA factors of Sec. 30A), and that the resultant reductions in Medicaid pharmacy payments, – as in case at bar, – constitute and comprise irreparable injury, without more: so that a preliminary injunction should and must issue in this case at bar, as requested by the Plaintiffs.

30. Plaintiffs have no administrative relief and have no plain, speedy, or adequate relief at law or equity except by the remedy prayed for in this Complaint.

WHEREFORE, each of the Plaintiffs prays for judgment as shall hereinafter be specified:

SECOND CLAIM FOR RELIEF

For Declaratory Relief

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

32. By all the facts hereinbefore alleged, a controversy exists between the Plaintiffs and the Defendant, for which the Court is respectfully requested to issue its declaratory judgment which specifies the rights and duties of the parties in this matter.

WHEREFORE the Plaintiffs pray for judgment and orders as follows:

A. That Plaintiffs have judgment against the defendant, and that the defendant take nothing.

B. That the defendant DAVID MAXWELL-JOLLY, the Director of the Department of Health Care Services of the State of California, and his agents, servants, employees, attorneys, successors, and all those working in concert with him, shall, pending the final determination of the within action or until further order of the Court, refrain from the following acts:

- (1) refrain from implementing, and to stay, § 14105.45 California Welfare & Institutions ("Welf. & Inst.") Code, including (without limitation thereby) refraining 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 Section 38 of Assembly Bill ("AB") X4 5, (Chapter 5, Statutes of 2009-10 Fourth Extraordinary Session);

- (2) refrain from implementing, and to stay, § 14105.455 Welf. & Inst. Code, including (without limitation thereby) refraining 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 § 14105.455 Welf. & Inst. Code which was enacted on July 28, 2009 by Section 39 of AB X4 5;

C. That Plaintiffs have costs of suit, reasonable attorneys' fees as may be provided by law, and such other and further relief as may be just.

LYNN S. CARMAN
STANLEY L. FRIEDMAN

By: s/ Lynn S. Carman
Attorneys for Plaintiffs

EXHIBIT A

Assembly Bill No. 5

CHAPTER 5

An act to add Section 293 to the Financial Code, to amend Sections 1250, 1265.5, 1266, 1275.3, 1324.20, 1326, 1337, 1418, 1567.50, 104820, 105250, 116565, 125175, 130500, 130507, 130509, and 130543 of, to amend and repeal Section 125165 of, and to add Sections 125155.1, 125157, and 125166 to, the Health and Safety Code, to amend Section 12739 of the Insurance Code, and to amend Sections 4107, 4684.60, 4684.74, 4684.75, 7502.5, 14005.40, 14007.9, 14011.2, 14087.9, 14105.191, 14105.436, 14105.45, 14110.55, 14126.033, 14132, 14132.951, 14166.20, 14166.225, 14166.23, 14166.245, 14495.10, and 14526.1 of, to add Sections 5783, 14005.50, 14013.5, 14105.455, 14105.46, 14132.20, 14132.952, 14166.115, 14522.4, 14525.1, 14526.2, and 14550.6 to, and to repeal Section 14522.3, 14526.1, and 14550.5 of, the Welfare and Institutions Code, relating to health, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor July 28, 2009. Filed with Secretary of State July 28, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 5, Evans. Health.

Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health, including an intermediate care facility/developmentally disabled-nursing. Violation of these provisions is a misdemeanor.

This bill would create as a new category of health facility for, and require the department to license and regulate, intermediate care facility/developmentally disabled-continuous nursing (ICF/DD-CN) facilities, as defined. This bill would require facilities providing continuous skilled nursing services to persons with developmental disabilities pursuant to the above-described provisions to apply for licensure as an ICF/DD-CN within 90 days after licensing regulations become effective. This bill would make other conforming changes. By creating a new crime, this bill would impose a state-mandated local program.

Existing law, until January 1, 2010, authorizes the State Department of Social Services and the State Department of Developmental Services, to jointly establish and administer a pilot project for licensing and regulating Adult Residential Facilities for Persons with Special Health Care Needs (ARFPSHN), to the extent that funds are appropriated for this purpose in the annual Budget Act. Under existing law, a licensed ARFPSHN may provide 24-hour services to up to 3 adults with developmental disabilities who have special health care and intensive support needs.

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pharmaceutical manufacturer's drug product shall be made available only through an approved treatment authorization request pursuant to subdivision (h). For supplemental rebate agreements executed more than 120 days after the addition of the drug product to the Medi-Cal list of contract drugs, the state rebate shall equal an amount not less than 20 percent of the average manufacturers price based on Medi-Cal utilization data for any drug products that have been added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2.

(h) Notwithstanding any other provision of law, drug products added to the Medi-Cal list of contract drugs pursuant to Section 14105.43 or 14133.2 of manufacturers who do not execute an agreement to pay additional rebates pursuant to this section, shall be available only through an approved treatment authorization request.

(i) For drug products added on or before December 31, 2009, a beneficiary may obtain a drug product that requires a treatment authorization request pursuant to subdivision (h) if the beneficiary qualifies for continuing care status. To be eligible for continuing care status, a beneficiary must be taking the drug product and the department must have record of a reimbursed claim for the drug product with a date of service that is within 100 days prior to the date the drug product was placed on treatment authorization request status. A beneficiary may remain eligible for continuing care status, provided that a claim is submitted for the drug product in question at least every 100 days and the date of service of the claim is within 100 days of the date of service of the last claim submitted for the same drug product.

(j) Changes made to the Medi-Cal list of contract drugs under this section shall be exempt from the requirements of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code), and shall not be subject to the review and approval of the Office of Administrative Law.

SEC. 38. Section 14105.45 of the Welfare and Institutions Code is amended to read:

14105.45. (a) For purposes of this section, the following definitions shall apply:

(1) "Average manufacturers price" means the price reported to the department by the Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8). In the event an average manufacturer's price is not available, the department shall use the direct price as the average manufacturer's price.

(2) "Average wholesale price" means the price for a drug product listed as the average wholesale price in the department's primary price reference source.

(3) "Direct price" means the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source.

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(4) "Estimated acquisition cost" means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.

(5) "Federal upper limit" means the maximum per unit reimbursement when established by the Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

(6) "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

(7) "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(8) "Maximum allowable ingredient cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

(9) "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code.

(10) "Nonlegend drug" means any drug whose labeling does not contain the statement referenced in paragraph (7).

(11) "Selling price" means the price used in the establishment of the estimated acquisition cost. The department shall base the selling price on the average manufacturer's price plus a percent markup determined by the department to be necessary for the selling price to represent the average purchase price paid by retail pharmacies in California. The selling price shall not be considered confidential and shall be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(12) "Volume weighted average" means the aggregated average volume for generically equivalent drugs, weighted by each drug's percentage of the total volume in the Medi-Cal fee-for-service program during the previous six months. For purposes of this paragraph, volume is based on the standard billing unit used for the generically equivalent drugs.

(13) "Wholesaler acquisition cost" means the price for a drug product listed as the wholesaler acquisition cost in the department's primary price reference source.

(b) (1) Reimbursement to Medi-Cal pharmacy providers for legend and nonlegend drugs shall consist of the estimated acquisition cost of the drug plus a professional fee for dispensing. The professional fee shall be seven dollars and twenty-five cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility shall be eight dollars ($8) per dispensed prescription. For purposes of this paragraph "skilled

nursing facility" and "intermediate care facility" shall have the same meaning as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

(2) The department shall establish the estimated acquisition cost of legend and nonlegend drugs as follows:

(A) For single source and innovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, the federal upper limit, or the MAIC.

(B) For noninnovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, the federal upper limit, or the MAIC.

(3) For purposes of paragraph (2), the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall establish a MAIC only when three or more generically equivalent drugs are available for purchase and dispensing by retail pharmacies in California. The department shall update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) The department shall base the MAIC on the mean of the average manufacturer's price of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(B) If average manufacturer prices are unavailable, the department shall establish the MAIC in either of the following ways:

(i) Based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(ii) Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.

(C) The department may enter into contracts with a vendor for the purpose of this section on a bid or nonbid basis. In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into on a nonbid basis shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(D) The department shall update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

(E) The department shall establish a process for providers to seek a change to a specific MAIC when the providers believe the MAIC does not reflect current available market prices. If the department determines a MAIC change is warranted, the department may update a specific MAIC prior to notifying providers.

(F) In determining the average purchase price, the department shall consider the provider-related costs of the products that include, but are not

limited to, shipping, handling, storage, and delivery. Costs of the provider that are included in the costs of the dispensing shall not be used to determine the average purchase price.

(c) The department shall update the Medi-Cal claims processing system to reflect the selling price of drugs not later than 30 days after receiving the average manufacturer's price.

(d) In order to maintain beneficiary access to prescription drug services, no later than 30 days after the department initially implements selling price as a component of estimated acquisition cost, pursuant to paragraph (2) of subdivision (b), the department shall make a one-time adjustment to the dispensing fees paid to pharmacy providers in accordance with paragraph (1) of subdivision (b). This change shall only be made if selling price results in a lower aggregate drug reimbursement. Any increase in dispensing fee made pursuant to this subdivision shall not exceed the aggregate savings associated with the implementation of selling price. At least 30-days prior to implementing the dispensing fee increase, the department shall issue a copy of the department's request for federal approval pursuant to subdivision (e), to the chairperson in each house that considers appropriations and the Chairperson of the Joint Legislative Budget Committee, or whatever lesser time the Chairperson of the Joint Legislative Budget Committee or his or her designee may determine.

(e) The director shall implement this section in a manner that is consistent with federal Medicaid law and regulations. The director shall seek any necessary federal approvals for the implementation of this section. This section shall be implemented only to the extent that federal approval is obtained.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

(g) The department shall issue a Medi-Cal pharmacy reimbursement fact sheet to the chairperson of the committee in each house of the Legislature that considers appropriations no later than March 1, 2008. The reimbursement fact sheet shall contain, but not be limited to, available data and information regarding the change in reimbursement due to the federal Deficit Reduction Act of 2005 implementation of average manufacturer's price based federal upper limits, the implementation of selling price, change in the average wholesale price reported to the department by the primary price reference source, change in pharmacy dispensing fees, prescription drug volume trends, and the number of active Medi-Cal pharmacy providers. The fact sheet shall also contain general information and definitions regarding drug pricing terminology and a description of pharmacy claims processing in Medi-Cal.

~~SEC. 39. Section 14105.455 is added to the Welfare and Institutions Code, to read:~~

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-18-

all waiver programs. This quarterly update shall be provided to the fiscal and policy committees of the Legislature within 14 working days of the close of the quarter, that commences July 1, 2009. The first quarterly update to be received by the Legislature in July 2009, shall reflect key issues and fiscal data as it pertains to the federal ARRA retroactive claiming from October 1, 2008, to June 30, 2009.

SEC. 59. Due to continued concerns regarding coordination of core programmatic functions between the State Department of Mental Health and the State Department of Health Care Services as they pertain to: (a) the reimbursement of county mental health plans and providers for services provided under Medi-Cal; (b) activities for the development and maintenance of the state's Medicaid waiver for the operation of mental health care services; (c) implementation of the state's Short-Doyle II data system; and (d) implementation of audit recommendations from the Office of State Evaluation and Audits (OSEA), and the federal Centers for Medicare and Medicaid Services (CMS), the California Health and Human Services Agency or a successor entity, shall develop an action plan.

The purpose of this action plan is to address the need to have a coordinated approach between these two departments in order to produce tangible outcomes for addressing core functions as outlined. This action plan shall be provided to the Legislature no later than February 1, 2010.

SEC. 60. The State Department of Health Care Services shall provide the applicable fiscal and policy committees of the Legislature with copies of all federal audits and their findings that pertain to any component of the Medi-Cal Program, including program components administered by other state departments. This information shall be provided in a timely manner to the Legislature and preferably within seven working days of receipt of a final determination by the federal Centers for Medicare and Medicaid Services (CMS) or other applicable federal departments or agencies.

SEC. 61. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 62. This act addresses the fiscal emergency declared by the Governor by proclamation on July 1, 2009, pursuant to subdivision (f) of Section 10 of Article IV of the California Constitution.

SEC. 63. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to make changes necessary for implementation of the Budget Act of 2009, it is necessary that this act take effect immediately.

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-20-

EXHIBIT B

Assembly Bill No. 5

CHAPTER 5

An act to add Section 293 to the Financial Code, to amend Sections 1250, 1265.5, 1266, 1275.3, 1324.20, 1326, 1337, 1418, 1567.50, 104820, 105250, 116565, 125175, 130500, 130507, 130509, and 130543 of, to amend and repeal Section 125165 of, and to add Sections 125155.1, 125157, and 125166 to, the Health and Safety Code, to amend Section 12739 of the Insurance Code, and to amend Sections 4107, 4684.60, 4684.74, 4684.75, 7502.5, 14005.40, 14007.9, 14011.2, 14087.9, 14105.191, 14105.436, 14105.45, 14110.55, 14126.033, 14132, 14132.951, 14166.20, 14166.225, 14166.23, 14166.245, 14495.10, and 14526.1 of, to add Sections 5783, 14005.50, 14013.5, 14105.455, 14105.46, 14132.20, 14132.952, 14166.115, 14522.4, 14525.1, 14526.2, and 14550.6 to, and to repeal Section 14522.3, 14526.1, and 14550.5 of, the Welfare and Institutions Code, relating to health, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor July 28, 2009. Filed with Secretary of State July 28, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 5, Evans. Health.

Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health, including an intermediate care facility/developmentally disabled-nursing. Violation of these provisions is a misdemeanor.

This bill would create as a new category of health facility for, and require the department to license and regulate, intermediate care facility/developmentally disabled-continuous nursing (ICF/DD-CN) facilities, as defined. This bill would require facilities providing continuous skilled nursing services to persons with developmental disabilities pursuant to the above-described provisions to apply for licensure as an ICF/DD-CN within 90 days after licensing regulations become effective. This bill would make other conforming changes. By creating a new crime, this bill would impose a state-mandated local program.

Existing law, until January 1, 2010, authorizes the State Department of Social Services and the State Department of Developmental Services, to jointly establish and administer a pilot project for licensing and regulating Adult Residential Facilities for Persons with Special Health Care Needs (ARFPSHN), to the extent that funds are appropriated for this purpose in the annual Budget Act. Under existing law, a licensed ARFPSHN may provide 24-hour services to up to 5 adults with developmental disabilities who have special health care and intensive support needs.

limited to, shipping, handling, storage, and delivery. Costs of the provider that are included in the costs of the dispensing shall not be used to determine the average purchase price.

(c) The department shall update the Medi-Cal claims processing system to reflect the selling price of drugs not later than 30 days after receiving the average manufacturer's price.

(d) In order to maintain beneficiary access to prescription drug services, no later than 30 days after the department initially implements selling price as a component of estimated acquisition cost, pursuant to paragraph (2) of subdivision (b), the department shall make a one-time adjustment to the dispensing fees paid to pharmacy providers in accordance with paragraph (1) of subdivision (b). This change shall only be made if selling price results in a lower aggregate drug reimbursement. Any increase in dispensing fee made pursuant to this subdivision shall not exceed the aggregate savings associated with the implementation of selling price. At least 30-days prior to implementing the dispensing fee increase, the department shall issue a copy of the department's request for federal approval pursuant to subdivision (e), to the chairperson in each house that considers appropriations and the Chairperson of the Joint Legislative Budget Committee, or whatever lesser time the Chairperson of the Joint Legislative Budget Committee or his or her designee may determine.

(e) The director shall implement this section in a manner that is consistent with federal Medicaid law and regulations. The director shall seek any necessary federal approvals for the implementation of this section. This section shall be implemented only to the extent that federal approval is obtained.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

(g) The department shall issue a Medi-Cal pharmacy reimbursement fact sheet to the chairperson of the committee in each house of the Legislature that considers appropriations no later than March 1, 2008. The reimbursement fact sheet shall contain, but not be limited to, available data and information regarding the change in reimbursement due to the federal Deficit Reduction Act of 2005 implementation of average manufacturer's price based federal upper limits, the implementation of selling price, change in the average wholesale price reported to the department by the primary price reference source, change in pharmacy dispensing fees, prescription drug volume trends, and the number of active Medi-Cal pharmacy providers. The fact sheet shall also contain general information and definitions regarding drug pricing terminology and a description of pharmacy claims processing in Medi-Cal.

SEC. 39. Section 14105.455 is added to the Welfare and Institutions Code, to read:

10

-23-

14105.455. (a) Pharmacy providers shall submit their usual and customary charge when billing the Medi-Cal program for prescribed drugs.

(b) "Usual and customary charge" means the lower of the following:

(1) The lowest price reimbursed to the pharmacy by other third-party payers in California, 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.

(c) Donations or discounts provided to a charitable organization are not considered usual and customary charges.

(d) Pharmacy providers shall keep and maintain records of their usual and customary charges for a period of three years from the date the service was rendered.

(e) Payment to pharmacy providers shall be the lower of the pharmacy's usual and customary charge or the reimbursement rate pursuant to subdivision (b) of Section 14105.45.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

SEC. 40. Section 14105.46 is added to the Welfare and Institutions Code, to read:

14105.46. (a) For purposes of this section:

(1) "Covered entity" means a provider defined as a covered entity in Section 256b of Title 42 of the United States Code.

(2) "340B" means the discount drug purchasing program described in Section 256b of Title 42 of the United States Code.

(b) A covered entity shall dispense only 340B drugs to Medi-Cal beneficiaries.

(c) If a covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary. If a covered entity dispenses a drug purchased at regular drug wholesale rates pursuant to this subdivision, the covered entity is required to maintain documentation of their inability to obtain the 340B drug.

(d) A covered entity shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01.

(e) A covered entity shall identify a 340B drug on the claim submitted to the Medi-Cal program for reimbursement.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in this section by means of a provider bulletin or

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all waiver programs. This quarterly update shall be provided to the fiscal and policy committees of the Legislature within 14 working days of the close of the quarter, that commences July 1, 2009. The first quarterly update to be received by the Legislature in July 2009, shall reflect key issues and fiscal data as it pertains to the federal ARRA retroactive claiming from October 1, 2008, to June 30, 2009.

SEC. 59. Due to continued concerns regarding coordination of core programmatic functions between the State Department of Mental Health and the State Department of Health Care Services as they pertain to: (a) the reimbursement of county mental health plans and providers for services provided under Medi-Cal; (b) activities for the development and maintenance of the state's Medicaid waiver for the operation of mental health care services; (c) implementation of the state's Short-Doyle II data system; and (d) implementation of audit recommendations from the Office of State Evaluation and Audits (OSEA), and the federal Centers for Medicare and Medicaid Services (CMS), the California Health and Human Services Agency or a successor entity, shall develop an action plan.

The purpose of this action plan is to address the need to have a coordinated approach between these two departments in order to produce tangible outcomes for addressing core functions as outlined. This action plan shall be provided to the Legislature no later than February 1, 2010.

SEC. 60. The State Department of Health Care Services shall provide the applicable fiscal and policy committees of the Legislature with copies of all federal audits and their findings that pertain to any component of the Medi-Cal Program, including program components administered by other state departments. This information shall be provided in a timely manner to the Legislature and preferably within seven working days of receipt of a final determination by the federal Centers for Medicare and Medicaid Services (CMS) or other applicable federal departments or agencies.

SEC. 61. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 62. This act addresses the fiscal emergency declared by the Governor by proclamation on July 1, 2009, pursuant to subdivision (f) of Section 10 of Article IV of the California Constitution.

SEC. 63. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

12

In order to make changes necessary for implementation of the Budget Act of 2009, it is necessary that this act take effect immediately.

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EXHIBIT C

established by the DHCS. Second, it establishes definitions of medical acuity for enrollment into ADHCs and provides a comprehensive framework for implementation of this change, including a work group with constituency groups for implementation of the new standards. Third, it provides for enhanced review of treatment authorization requests by enabling the DHCS to conduct on-site reviews of ADHCs and related functions. Savings attributable to these

changes are $36.6 million ($18.3 million General Fund (GF)) for 2009-2010. In addition, this bill freezes the rates paid to ADHCs at the 2008 reimbursement level for a savings of $3.7 million (GF).

c) Freeze on Rates Paid to Nursing Homes and Other Long-Term Care. This bill freezes the reimbursement rate paid to Level B Nursing Homes (AB 1629 homes), as well as all other long-term care facilities for a savings of about $75 million (GF). This proposal was part of the Governor's May Revision.

d) Expansion of Quality Assurance Fee for AB 1629 Nursing Homes. AB 1629 nursing homes presently pay a quality assurance fee. These fees are used as revenue by the state to provide certain rate adjustments and to offset GF expenditures. The Governor's May Revision expanded this fee to include Medicare revenues in the calculation, for approximately $18 million in increased revenue to the state.

e) Changes to Pharmacy Acquisition Costs. This bill makes changes to the "estimated acquisition cost" (EAC) component of pharmacy reimbursement paid under the Medi-Cal Program, as requested by the Governor. Specifically it revises the threshold for determining the "maximum allowable ingredient cost" (MAIC). The new MAIC process for generic drugs will commence in June 2010.

Under the Medi-Cal Program, DHCS reimburses pharmacies for drugs at the EAC and a dispensing fee. The EAC for generic drugs is defined as the lowest of the MAIC, the federal upper limit, or the average wholesale price. A savings of $2 million ($1 million GF) is estimated for changes to the MAIC.

f) Upper Billing Limit for Pharmacy Providers. This bill requires pharmacies participating in the Medi-Cal Program to bill Medi-Cal at a rate that is no higher than the lower of:

i) the lowest price reimbursed to pharmacies by other third party payers, excluding Medi-Cal Managed Care plans and Medicare Part D prescription drug plans; or,

ii) the lowest price routinely offered to any segment of the general public. The DHCS contends that private third-party payers have contractual agreements with pharmacies to limit drug reimbursement, and these reimbursement rates are often lower than the Medi-Cal reimbursement. A savings of $22.5 million (GF) is estimated for this action. This proposal was part of the Governor's May Revision.

g) HIV/AIDS and Cancer Drug Manufacturer Rebate. Since 2002 drug manufacturers have been required to negotiate a state supplemental rebate on drugs used to treat HIV/AIDS and Cancer reimbursed in Medi-Cal. However, the DHCS states that several manufacturers do not participate in the rebate program and added measures are necessary. This bill makes changes to leverage drug manufacturers who are not providing rebates of 10 % or greater on all of its HIV/AIDS and Cancer drugs to either agree to such level of rebate or have their drugs placed on prior treatment authorization. Savings of $2.5 million ($1.250 million GF) are assumed from this action. This proposal was part of the Governor's May Revision.

h) Require Use of 340B Pricing for Medi-Cal Enrollees. The 340B public health services drug pricing is a federal

92

EXHIBIT D

ARNOLD SCHWARZENEGGER, GOVERNOR OFFICE OF ADMINISTRATIVE LAW

California Regulatory Notice Register

REGISTER 2009, NO. 35–Z PUBLISHED WEEKLY BY THE OFFICE OF ADMINISTRATIVE LAW AUGUST 28, 2009

PROPOSED ACTION ON REGULATIONS

(Continued on next page)

Time-Dated Material

15

(Continued on next page)

PROPOSING STATE AGENCY CONTACT PERSON FOR SUBSTANTIVE AND/OR TECHNICAL QUESTIONS ON THE PROPOSED BUILDING STANDARDS

Specific questions regarding the substantive and/or technical aspects of the proposed changes to the building standards should be addressed to:

Doug Hensel
Assistant Deputy Director
Division of Codes and Standards
Department of Housing and Community Development
E-mail: dhensel@hcd.ca.gov
Telephone: (916) 445-9471
Fax: (916) 327-4712

Back-up:

Shawn Huff
Housing Standards Programs Manager
Division of Codes and Standards
Department of Housing and Community Development
E-mail: shuff@hcd.ca.gov
Telephone: (916) 445-9471
Fax: (916) 327-4712

GENERAL PUBLIC INTEREST

DEPARTMENT OF HEALTH CARE SERVICES

2009 BUDGET ACT CHANGES TO BILLING REQUIREMENTS AND REIMBURSEMENT OF DRUGS DISPENSED BY PHARMACY PROVIDERS AND 340B COVERED ENTITIES

This notice is being given to provide information of public interest with respect to the changes being made by the Medi-Cal fee-for-service program, in compliance with ABX4 5 (2009). It is the intent of the Department of Health Care Services (DHCS) to submit to the federal Centers for Medicare & Medicaid Services an amendment to California's Medicaid State Plan under Title XIX the Social Security Act to implement a change to pharmacy provider reimbursement rates, for dates of service on or after October 1, 2009. The significant elements of the proposed amendment are as follows:

- Pharmacy providers have been required to bill Medi-Cal a price that does not exceed that charged to the general public often referred to by pharmacy providers as the "usual and customary" price. For dates of service on or after October 1, 2009, "Usual and Customary" is now defined as the lower of:
  - 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.
  - The lowest price routinely offered to any segment of the general public.
- Statute allows the DHCS to base the state Maximum Allowable Ingredient Cost (MAIC) on the mean of the average manufacturer's price of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the DHCS to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California. Effective October 1, 2009, if the average manufacturer prices are unavailable, the DHCS will establish the MAIC in either of the following ways:
  - Based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the DHCS to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.
  - Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.
- Effective October 1, 2009, covered entities that purchase drugs under the 340B Drug Pricing Program shall dispense only 340B purchased drugs to Medi-Cal beneficiaries. Providers are also required to bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Welfare and Institutions (W&I) Code section 14105.45 or the dispensing fee pursuant to W&I Code section 14132.01.
- The above changes in reimbursement to providers are expected to generate a total General Fund savings of $20.9 million in the Medi-Cal program in budget year 2009-2010.

PUBLIC REVIEW

The proposed amendment to the California's Medicaid State Plan, which details the changes discussed

above, will be available for review at local county welfare offices throughout the State. Copies of the proposed amendment may be requested from:

Kathleen Henry, Pharmaceutical Analyst
Pharmacy Benefits Division
Department of Health Care Services
1501 Capitol Avenue
Suite 71.5131, MS 4604
Sacramento, CA 95814

Written comments may be submitted as follows:

Mailing Address via the U.S. Postal Office:
California Department of Health Care Services
Pharmacy Benefits Division
(Attn: K Henry)
MS 4604
P.O. Box 997417
Sacramento, CA 95899–7417

Mailing Address for Courier Deliveries ONLY (UPS, FedEx, Golden State Overnight, etc):
California Department of Health Care Services
Pharmacy Benefits Division
(Attn: K Henry)
1501 Capitol Avenue,
Suite 71.5131, MS 4604
Sacramento, CA 95814–5005

Email–PharBene@dhcs.ca.gov
By FAX: (916) 552–9563

All comments should include the author's name, organization or affiliation, phone number and Provider ID number, if appropriate.

DEPARTMENT OF HEALTH CARE SERVICES

NOTICE OF GENERAL PUBLIC INTEREST

THE CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES WILL ADOPT REVISED BILLING CODES FOR MEDI–CAL PROGRAM 2009 CURRENT PROCEDURAL TERMINOLOGY — 4TH EDITION (CPT–4) AND 2009 HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II

Effective for dates of service on or after September 1, 2009, the California Department of Health Care Services (DHCS) will adopt the 2009 Healthcare Common Procedure Coding System (HCPCS) Update, including the 2009 Current Procedural Terminology — 4th Edition (CPT–4), and the 2009 HCPCS Level II codes and modifiers. DHCS will establish specific reimbursement rates as follows:

- The maximum reimbursement for durable medical equipment using the updated billing codes, except wheelchairs and wheelchair accessories, will be established at an amount not to exceed 80 percent of the 2009 Medicare rates. Reimbursement for wheelchair and wheelchair accessories will be established at an amount not to exceed 100 percent of the 2009 Medicare rates (Welfare and Institutions Code section 14105.48).
- The maximum reimbursement for orthotic and prosthetic appliances and clinical laboratory services using the updated billing codes will be established at an amount not to exceed 80 percent of the 2009 Medicare rates (Welfare and Institutions Code sections 14105.21 and 14105.22).
- Maximum reimbursement for physician services, including surgical procedures, using the updated billing codes will be established at an amount not to exceed 80 percent of the 2009 Medicare rate for the same service.

These proposed changes will impact the following provider categories:

- Clinical laboratories
- Durable medical equipment
- Hospital outpatient departments and clinics
- Long–term care facilities
- Ground medical transportation
- Other outpatient clinics
- Optometrists
- Orthotists and prosthetists
- Pharmacies/pharmacists
- Physicians
- Podiatrists
- Providers of services under the California Children's Services/Genetically Handicapped Persons Program

PUBLIC REVIEW

The proposed changes are available for public review at local county welfare offices throughout California. Written comments must be submitted within 45 days from the publication date of these changes in the California Regulatory Notice Register. All comments should include the author's name, organization or affiliation, phone number and Provider ID number, if appropriate. Members of the public may request the proposed list of billing codes, and proposed reimbursement rates under the 2009 HCPCS Update from, and submit comments to:

EXHIBIT E

Electronic Code of Federal Regulations
e-CFR™

e-CFR Data is current as of November 5, 2009

Title 42: Public Health

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION
Subpart A—Single State Agency

Browse Next

§ 431.10 Single State agency.

(a) *Basis and purpose.* This section implements section 1902(a)(5) of the Act, which provides for designation of a single State agency for the Medicaid program.

(b) *Designation and certification.* A State plan must—

(1) Specify a single State agency established or designated to administer or supervise the administration of the plan; and

(2) Include a certification by the State Attorney General, citing the legal authority for the single State agency to—

(i) Administer or supervise the administration of the plan; and

(ii) Make rules and regulations that it follows in administering the plan or that are binding upon local agencies that administer the plan.

(c) *Determination of eligibility.* (1) The plan must specify whether the agency that determines eligibility for families and for individuals under 21 is—

(i) The Medicaid agency; or

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia), or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands.

(2) The plan must specify whether the agency that determines eligibility for the aged, blind, or disabled is—

(i) The Medicaid agency;

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia) or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands; or

(iii) The Federal agency administering the supplemental security income program under title XVI (SSI). In this case, the plan must also specify whether the Medicaid agency or the title IV-A agency determines eligibility for any groups whose eligibility is not determined by the Federal agency.

(d) *Agreement with Federal or State agencies.* The plan must provide for written agreements between the Medicaid agency and the Federal or other State agencies that determine eligibility for Medicaid, stating the relationships and respective responsibilities of the agencies.

(e) *Authority of the single State agency.* In order for an agency to qualify as the Medicaid agency—

(1) The agency must not delegate, to other than its own officials, authority to—

(i) Exercise administrative discretion in the administration or supervision of the plan, or

(ii) Issue policies, rules, and regulations on program matters.

(2) The authority of the agency must not be impaired if any of its rules, regulations, or decisions are subject to review, clearance, or similar action by other offices or agencies of the State.

(3) If other State or local agencies or offices 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.

[44 FR 17930, Mar. 23, 1979]

Browse Next

EXHIBIT F

14105. (a) The director shall prescribe the policies to be followed in the administration of this chapter, may limit the rates of payment for health care services, and shall adopt any rules and regulations as are necessary for carrying out, but are not inconsistent with, the provisions thereof. The policies and regulations shall include rates for payment for services not rendered under a contract pursuant to Chapter 8 (commencing with Section 14200).

In order to implement expeditiously the budgeting decisions of the Legislature, the director shall, to the extent permitted by federal law, adopt regulations setting rates that reflect these budgeting decisions within one month after the enactment of the Budget Act and of any other appropriation that changes the level of funding for Medi-Cal services. The proposed regulations shall be submitted to the Department of Finance no later than five days prior to the date of adoption.

With the written approval of the Department of Finance, the director shall adopt the regulations as emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Part 1, Division 3, Title 2 of the Government **Code**). For purposes of that act, the adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, and safety or general welfare.

(b) (1) Insofar as practical, consistent with the efficient and economical administration of this part, the department shall afford recipients of public assistance a choice of managed care arrangements under which they shall receive health care benefits and a choice of primary care providers under each managed care arrangement.

(2) Notwithstanding any other provision of law, Medi-Cal beneficiaries shall be entitled to affirmatively select, or to be assigned by default to, any primary care provider as defined in paragraph (1) of subdivision (b) of Section 14088.

(3) Notwithstanding any other provision of law, when a Medi-Cal beneficiary is assigned, from any source, to a primary care physician, as defined in Section 14254, and that primary care physician is an employee of a primary care provider, as defined in paragraph (1) of subdivision (b) of Section 14088, the assignment shall constitute an assignment to the primary care provider.

(c) If, in the judgment of the director, the actions taken by the director under subdivision (c) of Section 14120 will not be sufficient to operate the Medi-Cal program within the limits of appropriated funds, he or she may limit the scope and kinds of health care services, except for minimum coverage as defined in Section 14056, available to persons who are not eligible under Section 14005.1. When and if necessary, that action shall be taken by the director in ways consistent with the requirements of the federal Social Security Act.

(d) The director shall adopt regulations implementing regulatory changes required to initially implement, and annually update, the United States Health Care Financing Administration's common procedure coding system as emergency regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the

Government **Code**. For the purposes of the Administrative Procedure Act, the adoption of the regulations shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. These regulations shall become effective immediately upon filing with the Secretary of State.

(e) Notwithstanding any other provision of law, prospective reimbursement for any services provided to a Medi-Cal beneficiary in a nursing facility that is a distinct part of an acute care hospital shall not exceed the audited costs of the facility providing the services.

(f) Notwithstanding any other provision of law, reimbursement for anesthesiology, surgical services, and the professional component of radiology procedures except for comprehensive perinatal and obstetrical services shall be reduced by 9.5 percent of the amount of reimbursement provided for any of those services prior to the operative date of this subdivision. The director may exclude emergency surgical services performed in the emergency department of a general acute care hospital. To be excluded, emergency surgical services must be performed by an emergency room physician or a physician on the emergency department's on-call list.

(g) (1) It is the intent of the Legislature in enacting this subdivision to enable the department to obtain Medicare cost reports for the purpose of evaluating its Medi-Cal reimbursement rate methodology for nursing facilities.

(2) Skilled nursing facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety **Code** shall submit copies of all Medicare cost reports to the department by October 1, 1995, for reporting periods that ended between July 1, 1993, and June 30, 1995. On or after July 1, 1995, those facilities shall submit the copies to the department on the date that the Medicare cost reports are submitted to the Medicare fiscal intermediary.

(3) Hospitals providing skilled nursing care licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety **Code** shall submit a copy of all Medicare cost reports for reporting periods ended: (A) January 1, 1993, through June 30, 1995, to the department by October 1, 1995. (B) On or after July 1, 1995, to the department when the Medicare cost reports are submitted to the Medicare fiscal intermediary.

EXHIBIT G

Compilation of the Social Security Laws

Social Security Online

Social Security Act Home

STATE PLANS FOR MEDICAL ASSISTANCE[3]

Sec. 1902. [42 U.S.C. 1396a] (a) A State plan for medical assistance must—

(1) provide that it shall be in effect in all political subdivisions of the State, and, if administered by them, be mandatory upon them;

(2) provide for financial participation by the State equal to not less than 40 per centum of the non-Federal share of the expenditures under the plan with respect to which payments under section 1903 are authorized by this title; and, effective July 1, 1969, provide for financial participation by the State equal to all of such non-Federal share or provide for distribution of funds from Federal or State sources, for carrying out the State plan, on an equalization or other basis which will assure that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan;

(3) provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness;

(4) provide (A) such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods, and including provision for utilization of professional medical personnel in the administration and, where administered locally, supervision of administration of the plan) as are found by the Secretary to be necessary for the proper and efficient operation of the plan,[4] (B) for the training and effective use of paid subprofessional staff, with particular emphasis on the full-time or part-time employment of recipients and other persons of low income, as community service aides, in the administration of the plan and for the use of nonpaid or partially paid volunteers in a social service volunteer program in providing services to applicants and recipients and in assisting any advisory committees established by the State agency, (C) that each State or local officer, employee, or independent contractor who is responsible for the expenditure of substantial amounts of funds under the State plan, each individual who formerly was such an officer, employee, or contractor and each partner of such an officer or employee shall be prohibited from committing any act, in relation to any activity under the plan, the commission of which, in connection with any activity concerning the United States Government, by an officer or employee of the United States Government, an individual who was such an officer, employee, or contractor or a

partner of such an officer or employee is prohibited by section 207 or 208 of title 18, United States Code[5], and (D) that each State or local officer, employee, or independent contractor who is responsible for selecting, awarding, or otherwise obtaining items and services under the State plan shall be subject to safeguards against conflicts of interest that are at least as stringent as the safeguards that apply under section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423) to persons described in subsection (a)(2) of such section of that Act;

(5) either provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan; or provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan, except that the determination of eligibility for medical assistance under the plan shall be made by the State or local agency administering the State plan approved under title I or XVI (insofar as it relates to the aged) if the State is eligible to participate in the State plan program established under title XVI, or by the agency or agencies administering the supplemental security income program established under title XVI or the State plan approved under part A of title IV if the State is not eligible to participate in the State plan program established under title XVI;

(6) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports;

(7) provide safeguards which restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with—

(A) the administration of the plan; and

(B) at State option, the exchange of information necessary to verify the certification of eligibility of children for free or reduced price breakfasts under the Child Nutrition Act of 1966[6] and free or reduced price lunches under the Richard B. Russell National School Lunch Act[7], in accordance with section 9(b) of that Act, using data standards and formats established by the State agency;

(8) provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals;

(9) provide—

(A) that the State health agency, or other appropriate State medical agency (whichever is utilized by the Secretary for the purpose specified in the first sentence of section 1864(a)), shall be responsible for establishing and maintaining health standards for private or public institutions in which recipients of medical assistance under the plan may receive care or services,

(B) for the establishment or designation of a State authority or authorities which shall be responsible for establishing and maintaining standards, other than those relating to health, for such institutions, and

-42-

medical treatment within the institution, and that there will be a periodic determination of his need for continued treatment in the institution; and

(C) provide for the development of alternate plans of care, making maximum utilization of available resources, for recipients 65 years of age or older who would otherwise need care in such institutions, including appropriate medical treatment and other aid or assistance; for services referred to in section 3(a)(4)(A)(i) and (ii)[12] or section 1603(a)(4)(A)(i) and (ii)[13] which are appropriate for such recipients and for such patients; and for methods of administration necessary to assure that the responsibilities of the State agency under the State plan with respect to such recipients and such patients will be effectively carried out;

(21) if the State plan includes medical assistance in behalf of individuals 65 years of age or older who are patients in public institutions for mental diseases, show that the State is making satisfactory progress toward developing and implementing a comprehensive mental health program, including provision for utilization of community mental health centers, nursing facilities, and other alternatives to care in public institutions for mental diseases;

(22) include descriptions of (A) the kinds and numbers of professional medical personnel and supporting staff that will be used in the administration of the plan and of the responsibilities they will have, (B) the standards, for private or public institutions in which recipients of medical assistance under the plan may receive care or services, that will be utilized by the State authority or authorities responsible for establishing and maintaining such standards, (C) the cooperative arrangements with State health agencies and State vocational rehabilitation agencies entered into with a view to maximum utilization of and coordination of the provision of medical assistance with the services administered or supervised by such agencies, and (D) other standards and methods that the State will use to assure that medical or remedial care and services provided to recipients of medical assistance are of high quality;

(23) provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services, and (B) an enrollment of an individual eligible for medical assistance in a primary care case-management system (described in section 1915(b)(1)), a medicaid managed care organization, or a similar entity shall not restrict the choice of the qualified person from whom the individual may receive services under section 1905(a)(4)(C), except as provided in subsection (g), in section 1915, and in section 1932(a), except that this paragraph shall not apply in the case of Puerto Rico, the Virgin Islands, and Guam, and except that nothing in this paragraph shall be construed as requiring a State to provide medical assistance for such services furnished by a person or entity convicted of a felony under Federal or State law for an offense which the State agency determines is inconsistent with the best interests of beneficiaries under the State plan;

(24) effective July 1, 1969, provide for consultative services by health agencies and other appropriate agencies of the State to hospitals, nursing facilities, home health agencies, clinics, laboratories, and such other institutions as the Secretary may specify in order to assist them (A) to qualify for payments under this Act, (B) to establish and maintain such fiscal records as may be necessary for the proper and efficient administration of this Act to provide information needed to determine payments due under this Act on account of care and services furnished to individuals;

-43-

(I) the claim is submitted by the State within the 3-year period beginning on the date on which the item or service was furnished; and

(II) any action by the State to enforce its rights with respect to such claim is commenced within 6 years of the State's submission of such claim;

(26) if the State plan includes medical assistance for inpatient mental hospital services, provide, with respect to each patient receiving such services, for a regular program of medical review (including medical evaluation) of his need for such services, and for a written plan of care;

(27) provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency or the Secretary with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request;

(28) provide—

(A) that any nursing facility receiving payments under such plan must satisfy all the requirements of subsections (b) through (d) of section 1919 as they apply to such facilities;

(B) for including in "nursing facility services" at least the items and services specified (or deemed to be specified) by the Secretary under section 1919(f)(7) and making available upon request a description of the items and services so included;

(C) for procedures to make available to the public the data and methodology used in establishing payment rates for nursing facilities under this title; and

(D) for compliance (by the date specified in the respective sections) with the requirements of—

(i) section 1919(e);

(ii) section 1919(g) (relating to responsibility for survey and certification of nursing facilities); and

(iii) sections 1919(h)(2)(B) and 1919(h)(2)(D) (relating to establishment and application of remedies);

(29) include a State program which meets the requirements set forth in section 1908, for the licensing of administrators of nursing homes;

(30)(A) provide 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 1903(i)(4)) 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 general population in the geographic area; and

-44-

(B) provide, under the program described in subparagraph (A), that—

(i) each admission to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved, and who do not have a significant financial interest in any such institution and are not, except in the case of a hospital, employed by the institution providing the care involved, and

(ii) the information developed from such review or screening, along with the data obtained from prior reviews of the necessity for admission and continued stay of patients by such professional personnel, shall be used as the basis for establishing the size and composition of the sample of admissions to be subject to review and evaluation by such personnel, and any such sample may be of any size up to 100 percent of all admissions and must be of sufficient size to serve the purpose of (I) identifying the patterns of care being provided and the changes occurring over time in such patterns so that the need for modification may be ascertained, and (II) subjecting admissions to early or more extensive review where information indicates that such consideration is warranted to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases;

(31) with respect to services in an intermediate care facility for the mentally retarded (where the State plan includes medical assistance for such services) provide, with respect to each patient receiving such services, for a written plan of care, prior to admission to or authorization of benefits in such facility, in accordance with regulations of the Secretary, and for a regular program of independent professional review (including medical evaluation) which shall periodically review his need for such services;

(32) provide that no payment under the plan for any care or service provided to an individual shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise; except that—

(A) in the case of any care or service provided by a physician, dentist, or other individual practitioner, such payment may be made (i) to the employer of such physician, dentist, or other practitioner if such physician, dentist, or practitioner is required as a condition of his employment to turn over his fee for such care or service to his employer, or (ii) (where the care or service was provided in a hospital, clinic, or other facility) to the facility in which the care or service was provided if there is a contractual arrangement between such physician, dentist, or practitioner and such facility under which such facility submits the bill for such care or service;

(B) nothing in this paragraph shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the person or institution providing the care or service involved if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of such person or institution from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such person or institution under the plan is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment;

(C) in the case of services furnished (during a period that does not exceed 14 continuous days

EXHIBIT H

Revision: HCFA-PM-91-4 (BPD) OMB No. 0938-
AUGUST 1991

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM

State/Territory: CALIFORNIA

Citation

42 CFR
430.10

As a condition for receipt of Federal funds under title XIX of the Social Security Act, the

Department of Health Services
(Single State Agency)

submits the following State plan for the medical assistance program, and hereby agrees to administer the program in accordance with the provisions of this State plan, the requirements of titles XI and XIX of the Act, and all applicable Federal regulations and other official issuances of the Department.

Revision: HCFA-AT-80-38 (BPP)
May 22, 1980

State California

SECTION 1 SINGLE STATE AGENCY ORGANIZATION

Citation
42 CFR 431.10
AT-79-29

1.1 Designation and Authority

(a) The Department of Health Services is the single State agency designated to administer or supervise the administration of the Medicaid program under title XIX of the Social Security Act. (All references in this plan to "the Medicaid agency" mean the agency named in this paragraph.)

ATTACHMENT 1.1-A is a certification signed by the State Attorney General identifying the single State agency and citing the legal authority under which it administers or supervises administration of the program.

Revision: HCFA-AT-80-38 (BPP)
May 22, 1980

State California

Citation
Sec. 1902(a)
of the Act

1.1(b) The State agency that administered or supervised the administration of the plan approved under title X of the Act as of January 1, 1965, has been separately designated to administer or supervise the administration of that part of this plan which relates to blind individuals.

☐ Yes. The State agency so designated is

_____

_____.

This agency has a separate plan covering that portion of the State plan under title XIX for which it is responsible.

☒ Not applicable. The entire plan under title XIX is administered or supervised by the State agency named in paragraph 1.1(a).

TN # _____
Supersedes
TN # _____

Approval Date _____ Effective Date _____

Revision: HCFA-AT-80-38 (BPP)
May 22, 1980

State California

Citation		
Intergovernmental Cooporation Act of 1968	1.1(c)	Waivers of the single State agency requirement which are currently operative have been granted under authority of the Intergovernmental Cooperation Act of 1968.

☐ Yes. ATTACHMENT 1.1-B describes these waivers and the approved alternative organizational arrangements.

☐ Not applicable. Waivers are no longer in effect.

☒ Not applicable. No waivers have ever been granted.

TN #
Supersedes
TN #

Approval Date Effective Date

Revision: HCFA-AT-80-38 (BPP)
May 22, 1980

State California

Citation		
42 CFR 431.10 AT-79-29	1.1(d)	☐ The agency named in paragraph 1.1(a) has responsibility for all determinations of eligibility for Medicaid under this plan.
		☒ Determinations of eligibility for Medicaid under this plan are made by the agency(ies) specified in ATTACHMENT 2.2-A. There is a written agreement between the agency named in paragraph 1.1(a) and other agency(ies) making such determinations for specific groups covered under this plan. The agreement defines the relationships and respective responsibilities of the agencies.

TN #_____
Supersedes
TN #_____

Approval Date_____ Effective Date_____

Revision: HCFA-AT-80-38 (BPP)
May 22, 1980

State California

Citation		
42 CFR 431.10 AT-79-29	1.1(e)	All other provisions of this plan are administered by the Medicaid agency except for those functions for which final authority has been granted to a Professional Standards Review Organization under title XI of the Act.
	(f)	All other requirements of 42 CFR 431.10 are met.

TN #
Supersedes
TN #

Approval Date Effective Date

EXHIBIT I

SEC. 3.5. An administrative agency, including an administrative agency created by the Constitution or an initiative statute, has no power:

(a) To declare a statute unenforceable, or refuse to enforce a statute, on the basis of it being unconstitutional unless an appellate court has made a determination that such statute is unconstitutional;

(b) To declare a statute unconstitutional;

(c) To declare a statute unenforceable, or to refuse to enforce a statute on the basis that federal law or federal regulations prohibit the enforcement of such statute unless an appellate court has made a determination that the enforcement of such statute is prohibited by federal law or federal regulations.

EXHIBIT J

O

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

Managed Pharmacy Care, et al.

Plaintiff(s),

vs.

David Maxwell Jolly

Defendant(s).

Case No. CV 09-382 CAS (MANx)

ORDER GRANTING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION AND BACKGROUND

On September 16, 2008, the California Legislature passed Assembly Bill 1183 ("AB 1183"), which was subsequently signed by the Governor and filed with the Secretary of State on September 30, 2008. AB 1183 amends Cal. Welf. & Inst. Code. § 14105.19 and mandates that, effective March 1, 2009, Medi-Cal reimbursement payments to some fee-for-service providers will be reduced by one percent or five percent, depending on provider type. Particularly relevant to the instant action, AB 1183 enacts a modified Cal. Welf. Inst. Code § 14105.191(b)(3) so as to require that Medi-Cal fee-for-service payments to pharmacies be reduced by 5 percent.

These reductions mandated in AB 1183 replace the ten percent rate reduction put into place by Assembly Bill X3 5 ("AB 5"), which is scheduled to terminate on February 28, 2009. See Cal. Welf. & Inst. Code § 14105.19(b)(1). AB 5 was passed by the California Legislature on February 16, 2008. On August 18, 2008, the ten percent rate reduction mandated by AB 5 was partially enjoined by this Court in a related action, Independent Living Center of Southern California, Inc. v. Sandra Shewry, CV-08-3315 CAS (MANx). In issuing the preliminary injunction, this Court found that petitioners had, *inter alia*, demonstrated a strong likelihood of success in showing that AB 5 was preempted by § 30(A) of the Medicaid Act (referred to herein as "§ 30(A)"). The Court's August 18, 2008 order is currently being appealed to the Court of Appeals for the Ninth Circuit.[1]

On January 16, 2009, Managed Pharmacy Care, Independent Living Center of Southern California, Inc., Gerald Shapiro, Sharon Steen, and Tran Pharmacy, Inc. filed the instant action against David Maxwell-Jolly, Director of the Department of Health Care Services of the State of California. Plaintiffs' complaint challenges the five percent Medi-Cal reimbursement rate reduction to providers of pharmacy services under AB 1183. Plaintiffs seek an order directing defendant "to set aside his preempted policy to implement § 14105.19 Welf. & Inst. Code, of AB 1183, and the 5% Rate Reduction, and, to refrain from implementing the same; including but not limited to refraining from reducing payments by five percent or by any other deduction, / / /

[1] The Court's August 18, 2008 order was issued on remand from the Ninth Circuit, after plaintiffs appealed this Court's original June 25, 2008 ruling on their preliminary injunction motion. The Court's June 25, 2008 order found that plaintiffs in Independent Living lacked any federal rights under § 30(A), and therefore had denied petitioners' motion for preliminary injunction. On appeal, the Ninth Circuit held that plaintiffs could bring suit under the Supremacy Clause to enjoin AB 5 as preempted under the Medicaid Act, and remanded to this Court. See Independent Living Center of Southern California et. al. v. Sandra Shewry et al., 543 F.3d 1050 (9th Cir. 2008).

to pharmacy providers in the Medi-Cal FFS program, for services furnished on and after March 1, 2009."[2] Compl. at 8; Mot. at 1.

On February 2, 2009, plaintiffs filed the instant motion for a preliminary injunction. Defendant filed an opposition thereto on February 11, 2009. A reply was filed on February 16, 2009. Plaintiffs' motion for a preliminary injunction is currently before the Court.

II. LEGAL STANDARD

A preliminary injunction is appropriate when the moving party shows either (1) a combination of probable success on the merits and the possibility of irreparable harm, or (2) the existence of serious questions going to the merits and that the balance of hardships tips sharply in the moving party's favor. See Rodeo Collection, Ltd. v. West Seventh, 812 F.2d 1215, 1217 (9th Cir. 1987). These are not two distinct tests, but rather "the opposite ends of a single 'continuum in which the required showing of harm varies inversely with the required showing of meritoriousness.'" Id. A "serious question" is one on which the movant "has a fair chance of success on the merits." Sierra On-Line, Inc. v. Phoenix Software, Inc., 739 F.2d 1415, 1421 (9th Cir. 1984).

III. DISCUSSION

A. ELEVENTH AMENDMENT AND PRUDENTIAL STANDING

Before addressing the merits of plaintiffs' argument for preliminary injunction, the Court must first address two arguments raised by defendant: (1) that plaintiffs' suit is barred by the Eleventh Amendment and (2) that plaintiffs lack standing. The Court finds that neither of these arguments is persuasive.

The essence of defendant's Eleventh Amendment argument is that plaintiffs' suit effectively amounts to a request for money damages to be paid out of the state treasury, in violation of the Eleventh Amendment. See Opp'n at 20 ("the primary purpose

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[2] On January 26, 2009, plaintiff Managed Pharmacy Care was voluntarily dismissed as a plaintiff in this action.

driving this lawsuit is to obtain funds from the State above the 5% payment reduction"), citing Edelman v. Jordan, 415 U.S. 651 ("Thus the rule has evolved that a suit by private parties seeking to impose a liability which must be paid from public funds in the state treasury is barred by the Eleventh Amendment"). However, the Court disagrees with defendant's characterization of plaintiffs' claim. Plaintiffs complaint does not seek money damages, but instead seeks only prospective injunctive relief – namely, an injunction preventing defendant from enforcing a state law that, defendants argue, is preempted by the Medicaid Act. Such prospective injunctive relief against a state official is permissible under Ex Parte Young, 209 U.S. 123 (1908), even where such an injunction will have an effect on the state treasury. See, e.g., Miliken v. Bradley, 433 U.S. 267 (federal courts permitted "to enjoin state officials to conform their conduct to requirements of federal law, notwithstanding a direct and substantial impact on the state treasury").

Defendant also argues that plaintiffs lack prudential standing, because they are health care providers who have no "rights" under the federal law they seek to enforce. Opp'n at 22. The Court disagrees. In its September 17, 2008 order in the related action Independent Living, 543 F.3d at 1065, the Ninth Circuit determined that petitioners in that action had standing:

> Petitioners include independent pharmacies and health care providers participating in the State's Medi-Cal program that, according to their complaint, will be directly injured, by loss of gross income, when the ten-percent rate reduction takes effect. The Supreme Court repeatedly has recognized that such [direct economic] injuries establish the threshold requirements of Article III standing. Moreover, this injury is directly traceable to the Director's implementation of AB 5, and would certainly be redressed by a favorable decision of this court enjoining the ten-percent rate reduction.

As in Independent Living, plaintiffs in the instant action include independent pharmacies participating in the Medi-Cal program, and an independent living center which serves over 8,000 individuals with disabilities annually, 96 percent of whom are Medi-Cal beneficiaries, who, plaintiffs allege, would be directly injured by the five percent Medi-Cal reimbursement rate reduction. See Vescovo Decl. ¶ 5. Therefore, the Ninth Circuit's holding in Independent Living, 543 F.3d at 1065, with regard to standing applies in this case as well, and the Court finds defendant's argument that plaintiffs lack standing to be without merit.

B. LIKELIHOOD OF SUCCESS ON THE MERITS

Pursuant to the holding of the Ninth Circuit in the related action Independent Living, 543 F.3d at 1065, the Court finds, as an initial matter, that plaintiffs may pursue a claim for relief under the Supremacy Clause based on the allegation that AB 1183 is preempted by § 30(A). Here, plaintiffs' Supremacy Clause claim is predicated upon federal conflict preemption. Under general principles of federal preemption, state law is preempted only to the extent that it actually conflicts with federal law. Pacific Gas & Elec. Co. v. State Energy Comm'n, 461 U.S. 190, 204 (1983). Such a conflict may arise either where "compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id. at 203-04 (citations omitted).

Thus, to prevail on the merits plaintiffs will have to prove either that it is not possible for the Department to comply with both AB 1183 and the Medicaid Act or that AB 1183 stands as an obstacle to the enforcement of § 30(A). As such, the Court turns to the statutory provisions at issue here.

The "quality of care" provision of § (30)(A) provides that

> [a] State plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . 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.

42 U.S.C. § 1396a(30)(A). The "equal access" provision of § 30(A) provides that

> [a] State plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and 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.

Id.

In Orthopaedic Hospital v. Kizer, 1992 WL 345652 (C.D. Cal. 1992) ("Orthopaedic I"), plaintiff-hospital providers filed suit pursuant to 42 U.S.C. § 1983 ("§ 1983"), claiming that the Director violated § 30(A) by setting reimbursement rates for hospital outpatient services without considering the effect of hospital costs on efficiency, economy, and quality of care.[3] Id. at *1. The district court concluded that § 30(A) was enforceable in a § 1983 action, and that the Department "had a judicially enforceable obligation" to consider and make findings each time it modified reimbursement rates. Id. at *2. According to the district court, § 30(A) obligated the Department to consider efficiency, economy, and quality of care, which it referred to as the "relevant factors." Id. at *4. The district court found that the Director had acted arbitrarily and capriciously in establishing six of the seven challenged rates. Id. The court then remanded the matter to the Department for further consideration. Id. at *14.

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[3] The hospitals did not, however, challenge the rates under the "equal access" provision. Orthopaedic I, 1992 WL 345652 at *14 n.4.

Upon remand, the Department conducted a rate study, and readopted the reimbursement rates without change. Orthopaedic Hospital II/III, 103 F.3d at 1495.

The hospitals returned to the district court, filing two lawsuits (Orthopaedic II/III) that the district court consolidated, arguing that the adopted rates did not comply with § 30(A). Id. The district court entered judgment in favor of the Department, finding that the Department was not statutorily required to consider hospital costs when setting reimbursement rates. Id. The hospitals appealed, and the Ninth Circuit reversed. The Ninth Circuit's interpretation held that § 30(A) "provides that payments for services must be consistent with efficiency, economy, and quality of care, and that those *payments* must be sufficient to enlist enough providers to provide access to Medicaid recipients." Id. at 1496 (emphasis in original). The Ninth Circuit therefore concluded that under § 30(A)

> the Director must set hospital outpatient reimbursement rates that bear a reasonable relationship to efficient and economical hospitals' costs of providing quality services, unless the Department shows some justification for rates that substantially deviate from such costs. To do this, the Department must rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting.

Id.[4] Further, the Ninth Circuit found that "[i]t is not justifiable for the Department to

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[4] See e.g., Alaska Dep't of Health & Soc. Servs. v. Ctrs. for Medicare & Medicaid Servs., 424 F.3d 931, 940-41 (9th Cir. 2005); see also Arkansas Med. Soc'y v. Reynolds, 6 F.3d 519, 530 (8th Cir. 1993) ("We agree with the trial court's conclusion that the relevant factors that DHS is obliged to consider in its rate-making decisions are the factors outlined in 42 U.S.C. § 1396a(a)(30)(A)."); cf. Methodist Hosps. v. Sullivan, 91 F.3d 1026, 1030 (7th Cir. 1996) (finding that § 30(A) does not require a state to consider any particular factors, but rather, requires that the state arrive at substantive results consistent with the Medicaid Act); Rite Aid, Inc. v. Houstoun, 171 F.3d 842 (3d Cir. 1999) (same).

reimburse providers substantially less than their costs for purely budgetary reasons." Id. at 1499 n.3.[5]

Whatever else its effect may have been, it is clear that Sanchez v. Johnson, 416 F.3d 1051 (9th Cir. 2005) left undisturbed the rule announced in Orthopaedic II/III that § 30(A) creates duties on behalf of the Department, i.e., the duty to consider efficiency, economy, and quality of care when establishing reimbursement rates. Indeed, the Sanchez court recognized that "[§ 30(A)] speaks . . . of the *State's obligation* to develop 'methods and procedures' for providing services generally."[6] Sanchez, 416 F.3d at

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[5] Subsequently, in Sanchez v. Johnson, 416 F.3d 1051 (9th Cir. 2005), the Ninth Circuit held that § 30(A) does not confer individual rights that are enforceable under 42 U.S.C. § 1983. Id. at 1060. However, in Independent Living, 543 F.3d 1050 (9th Cir. 2008), the Ninth Circuit held that "a plaintiff seeking injunctive relief under the Supremacy Clause on the basis of federal preemption need not assert a federally created 'right,' in the sense that term has been recently used in suits brought under § 1983, but need only satisfy traditional standing requirements." Independent Living, 543 F.3d 1050, 1058 (9th Cir. 2008).

[6] Defendant nevertheless argues herein that under Sanchez v. Johnson, 416 F.3d 1051, plaintiffs are precluded from obtaining a judicial remedy, and that "Plaintiffs are attempting to have this Court undercut decades of federal jurisprudence to say that, merely by claiming to be suing under the Supremacy Clause instead of § 1983, a party can obtain a remedy in federal court against a state agency for non-compliance with a provision of the Medicaid Act . . . " Opp'n at 18. Defendant argues that the Ninth Circuit's holding in Independent Living, 543 F.3d 1050, does not contradict this argument, because the issue presented herein is substantially different from the issue presented in that case. Opp'n at 16 ("the only issue in front of the Court of Appeals in the Independent Living Center matter was 'whether ILC may maintain a valid cause of action to enjoin implementation of AB 5 on the basis of federal preemption"). However, the Court finds defendant's arguments unpersuasive. The Court disagrees that the issue presented herein is substantially different from the issue before the Ninth Circuit in Independent Living, 543 F.3d at 1063, and further notes that the Ninth Circuit in Independent Living specifically distinguished Sanchez:

> [In Sanchez] [w]e held that the quality of care and access provisions of § 30(A) do not give rise to the type of unambiguously conferred rights

(continued...)

1059 (emphasis added).

Because Orthopaedic II/III is binding authority on this Court, the Court finds that when the State of California seeks to modify reimbursement rates for health care

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[6](...continued)
required under Gonzaga. But our decision in [Sanchez] had nothing to say about a claim for injunctive relief brought under the Supremacy Clause. Indeed, even as the Supreme Court has tightened the requirements for seeking damages under § 1983, it has consistently reaffirmed the availability of injunctive relief to prevent state officials from implementing state legislation allegedly preempted by federal law.

Defendant also argues herein that Congress has evinced an intent that § (30)(a) not be judicially enforced. Opp'n at 17, n.8. Specifically, defendant notes that the so-called "Boren Amendment," which required that states provide the Secretary with assurances that Medicaid reimbursements according to rates that were "reasonable and adequate" to meet costs, was repealed by Congress subsequent to a Supreme Court decision finding that providers had rights under the Boren Amendment to challenge the adequacy of a state's reimbursement rates under the Medicaid statute. Opp'n at 5. However, defendant's arguments are belied by Orthopaedic II/III, which held that the Department's obligations under §30(a) were independent of the obligations imposed by the Boren Amendment:

> The Boren Amendment requires the Department to make assurances to the Secretary of Health and Human Services that rates are reasonable and adequate to meet the hospitals' costs, and requires periodic cost reports from hospitals subject to audit by the Department. These requirements are not part of § 1396a(a)(30)(A). The requirements of § 1396a(a)(30)(A) are more flexible than the Boren Amendment, but not so flexible as to allow the Department to ignore the costs of providing services. For payment rates to be consistent with efficiency, economy, quality of care and access, they must bear a reasonable relationship to provider costs, unless there is some justification for rates that do not substantially reimburse providers their costs.

Orthopaedic II/III, 103 F.3d at 1499.

services provided under the Medi-Cal program, it must consider efficiency, economy, and quality of care, as well as the effect of providers' costs on those relevant statutory factors.

In the instant motion for preliminary injunction, plaintiffs argue that AB 1183's five percent reimbursement rate reduction to pharmacies is preempted by § 30(A), because the Legislature did not consider any of the relevant factors as required by Orthopaedic II/III. To demonstrate that the Legislature did not consider any of the relevant factors, plaintiffs first note that Sec. 76 of AB 1183 indicates that the purpose of the bill was budgetary:

> [t]his act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are: In order to make the necessary statutory changes to implement the Budget Act of 2008 at the earliest possible time, it is necessary that this act take effect immediately.

Plaintiffs further describe the legislative history of AB 1183, which, they argue, demonstrates that the Legislature did not consider any of the relevant factors:

> AB 1183 was introduced Feb. 2, 2008 as a hazardous material bill and was amended several times as solely a hazardous material bill. However, on September 15, 2008, the bill was amended in the Senate so as to be at once turned into a trailer bill, on many different subjects . . . All without any public hearings or any hearing by any committee of the Legislature; was passed shortly before midnight of the same day of September 15, 2008 by the Senate; was sent to the Assembly, and was immediately passed by the Assembly before 2:08 a.m. of September 16, 2008, – all within the space of a few hours. . .

Mot. at 8.

Defendant does not appear to contest that the Legislature did not in fact consider the relevant factors prior to passing AB 1183. However, defendant appears to argue that the requirements of Orthopaedic II/III are nevertheless satisfied, because the Department itself performed a detailed analysis of the relevant factors. Opp'n at 11. Specifically, defendant submits the Department's report "Analysis of Pharmacy Reimbursement under AB 1183," ("Department Analysis") completed in February 2009, well after the enactment of AB 1183 on September 16, 2008. Opp'n at 11. The Department Analysis analyzes the impact of the five percent rate reduction, and ultimately concludes:

> After a 5% payment reduction is implemented on March 1, 2009, Medi-Cal reimbursement paid to pharmacies will comply with title 42, United States Code, section 1396(a)(30)(A). The available data indicates that Medi-Cal recipients will continue to have sufficient access to pharmacy services as required by federal law. Reimbursement will be below applicable federal upper payment limits. The 5% payment reduction will result in more efficient and economical Medi-Cal coverage. It will not have any negative impact for Medi-Cal recipients. Finally, the Department determined that Medi-Cal reimbursement will in the aggregate compensate pharmacy drug costs at a level that is well above the "range of reasonableness" that was acceptable under the repealed Boren Amendment. Thus, reimbursement will be sufficient under the more flexible requirements of section 1396(a)(30)(A).

Def's Ex. A-A (Analysis of Assembly Bill 1183 Medi-Cal Reimbursement for Pharmacies) at 12-13. The Department Analysis further concludes that the Legislature "had other alternatives for reducing spending in the Medi-Cal program, which would have had a much more negative impact on Medi-Cal recipients. Def's Ex. A-A (Analysis of Assembly Bill 1183 Medi-Cal Reimbursement for Pharmacies) at 4.

Plaintiffs, however, argue that the Department's post-hoc analysis does not satisfy the requirements of Orthopaedic II/III. The Court agrees. First, the Court notes that AB 1183, as passed by the Legislature, does not provide the Department with any discretion to determine whether the five percent rate reduction should be implemented based on the Department's consideration of the relevant factors. See Mot. at 5-6; Cal. Welf. & Inst. Code. § 14105.191 ("Notwithstanding any other provision of law, or order to implement changes in the level of funding for health care services, the *director shall reduce* provider payments, as specified in this section . . .") (emphasis added). In Orthopaedic II/III, in which rates set by the Department, rather than the Legislature, were at issue, the court stated that the "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 II/III holding therefore indicates that the body responsible for rate setting must consider the relevant factors contemporaneously with the adoption of the rates. Here, the legislative history shows no indication that the Legislature considered any of the relevant factors before implementing AB 1183. Instead, it appears that the Legislature enacted the rate reduction purely for budgetary reasons. Because the Department has no authority to alter the rate reduction imposed by the Legislature, the Department's post hoc analysis does not satisfy the requirements of Orthopaedic II/III.

Therefore, because the Legislature did not consider any of the relevant factors prior to implementing the five percent rate reduction in AB 1183, the Court finds that plaintiffs have a strong likelihood of success on the merits.

C. IRREPARABLE HARM

The next question before this Court is whether plaintiffs have shown that Medi-Cal beneficiaries will be irreparably harmed if the five percent rate reduction to pharmacies is permitted to go into effect. After reviewing the declarations submitted by

plaintiffs and defendant, the Court finds that plaintiffs have made a sufficient showing of irreparable harm to warrant an injunction.

Plaintiffs submit the declaration of Richard Wilson, a Certified Public Accountant who has examined various data regarding Medi-Cal prescription drug reimbursement – including the Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of California, a December 2007 study prepared by Myers and Stauffer, CPA's ("Myers Stauffer study") – in order to examine the impact of the five percent rate reduction on pharmacies.

Wilson notes that there are two primary cost components in the provision of prescription drugs: dispensing cost and drug acquisition cost. Wilson states that the average cost to a pharmacy for dispensing a prescription is currently $11.49 per prescription, and that the five percent reimbursement rate reduction will reduce Medi-Cal coverage for pharmacies' dispensing fees, from an average of $7.25 per prescription to an average of $6.88 per prescription. Wilson Decl. ¶ 21-22. Wilson states that the five percent reduction will therefore increase the loss incurred by pharmacies on dispensing fees from $3.56 per Medi-Cal prescription to $4.61 per Medi-Cal prescription. Wilson Decl. ¶ 22.

Furthermore, Wilson, states that the five percent rate reduction will also cause pharmacies to experience a loss on the acquisition of many brand and generic drugs. For example, Wilson states that the average acquisition costs for brand drugs is 79 percent of average wholesale price, while the amount of reimbursement that pharmacies will receive under the five percent rate reduction is only 78.85 percent of average wholesale price. Wilson Decl. ¶ 24. As a result, Wilson states that the five percent rate reduction will cause pharmacies to operate at a loss in the acquisition of 51 percent of the 200 top-selling brand drugs, and that pharmacies will make only a very small gross profit on an additional 12.5 percent of the top-selling brand drugs, a profit which will generally be insufficient to compensate for the loss that the pharmacies incur in dispensing costs. Wilson Decl. ¶ 25. With regard to generic drugs, Wilson states that

the five percent rate reduction will cause pharmacies to operate at a loss or obtain only a very small gross profit on 39 percent of the top-selling generic drugs. Wilson Decl. ¶ 31.

Wilson concludes that because pharmacies, on average, will suffer a financial loss to acquire and dispense brand drugs as a result of the five percent rate reduction, many will be forced to stop dispensing many if not most brand products to Medi-Cal patients. Wilson Decl. ¶ 28. Wilson further concludes that, as a result of the five percent rate reduction, many pharmacies will also be forced to stop dispensing many of the generic drugs to Medi-Cal patients. Wilson Decl. ¶ 32.

Petitioners also submit additional declarations providing further evidence to the effect that the five percent rate reduction will cause independent pharmacy owners to limit the scope of the services they provide to Medi-Cal beneficiaries. Specifically, plaintiffs submit the declarations of ten independent pharmacists, many of whom state that the five percent rate reduction will significantly affect their ability to provide services to Medi-Cal patients. See Davis Decl. ¶ 8; Dunckel Decl. ¶ 8; Faast Decl. ¶ 8. For example, the pharmacists' declarations state that the total reimbursement under AB 1183 will cover neither their acquisition costs nor their dispensing costs on many drugs, and that, as a result, they will not be able to fill all Medi-Cal prescriptions, including some prescriptions for AIDS medications and name-brand antipsychotropics, and will not be able to serve all existing Medi-Cal customers. See Davis Decl. ¶ 8, 11; Dunckel Decl. ¶ 8, 11; Faast Decl. ¶ 11; Shapiro Decl. ¶ 26; Tran Decl. ¶ 17; Medina Decl. ¶ 11; Tran Decl. ¶ 20. Some of the pharmacists also state that the five percent rate reduction will prevent them from accepting new Medi-Cal patients. See Dunckel Decl. ¶ 11; Jeha Decl. ¶ 11. In addition, some pharmacists say they will be forced to cut the business hours of the pharmacy and lay off employees in order to remain profitable, while others state that the five percent rate reduction will force them out of business. See, e.g., Jeha Decl. ¶ 11; Leonelli Decl. ¶ 11. Some pharmacists state that the five percent rate reduction will prevent them from providing prescription delivery service to their Medi-

Cal beneficiary patients who are unable to leave their homes. See Medina Decl. ¶ 9; Shapiro Decl. ¶ 26.

Defendant counters that plaintiffs' showing of harm is speculative and that, in fact, under the five percent rate reduction, "an extremely high percentage of pharmacy costs will be compensated and the more efficient pharmacies should be able to obtain a substantial profit from providing services under the Medi-Cal program." Opp'n at 5. For example, defendant notes that the Department Analysis estimates that under the five percent rate reduction, pharmacies will continue, on average, to be compensated above their costs for Medi-Cal prescriptions. See Def's Ex. A-A at 8 (stating that the five percent rate reduction will reduce the aggregate Medi-Cal reimbursement for prescription drugs from compensating approximately 108.7 percent of pharmacy costs to approximately 103 percent of pharmacy costs).

Defendant also submits the declaration of Kevin Gorospe, who is employed as the Department's Chief of Medi-Cal Pharmacy Policy Branch. Gorospe states that he has examined plaintiffs' submitted declarations, and has calculated that, with one exception, the total revenue loss after the five percent rate reduction for each pharmacist submitting a declaration in support of plaintiffs' motion will be less than 2 percent. Gorospe Decl. ¶ 12. Gorospe further argues that some of plaintiffs' cost estimates are misleading, because much of the average dispensing fee costs are costs of operation that a pharmacy incurs regardless of whether it provides drugs to Medi-Cal recipients, so that "continued participation in Medi-Cal by these pharmacies brings in additional reimbursement that will help to pay for many of the costs of operating a pharmacy that the pharmacy would incur even if [it] didn't participate in Medi-Cal." Gorospe Decl. ¶ 13. Gorospe further echoes the Department Analysis, stating that dispensing cost increases will not cause irreparable harm, because "Medi-Cal reimbursement for the drug itself frequently is well above pharmacy acquisition cost, that any loss on the dispensing fee portion of reimbursement is made up for by a significant profit on MediCal reimbursement for the drug itself." Gorospe Decl. ¶ 21.

The Court concludes that defendant has failed to refute plaintiffs' showing of irreparable harm. Even if defendant is correct that, on average, pharmacies will be compensated above their acquisition costs even after the five percent rate reduction, defendant has not refuted plaintiffs' findings that many brand and generic drugs will be reimbursed at a level below cost, thereby preventing pharmacies from providing those drugs and limiting access for Medi-Cal patients. Indeed, the Gorospe declaration confirms that only 98-99 percent, on average, of pharmacy costs for single source drugs will be compensated after the five percent rate reduction. Because many single source drugs are protected from competition by patents, there are no available generic alternatives. See August 18, 2008 Preliminary Injunction Order. There can be little or no doubt that Medi-Cal patients will be harmed if these necessary drugs are placed outside of their reach.

Furthermore, if pharmacists are forced to curtail services or go out of business, there is no indication that all existing customers will have access to other pharmacies in which to obtain their medication and, in some cases, home-delivery services for such medication. Indeed, the many declarations submitted by petitioners show that independent pharmacy providers, who constitute approximately thirty-three percent of the licensed community pharmacies in California, will be hard-hit by the five percent rate reduction, and may discontinue, or at least severely reduce, services to Medi-Cal beneficiaries. See August 18, 2008 Preliminary Injunction Order. Therefore, the Court concludes that plaintiffs have demonstrates a significant likelihood of irreparable harm.

D. BALANCE OF HARDSHIPS

The Court is mindful of the difficulty facing the State of California in light of its fiscal crisis.[7] However, the State has accepted federal funds under the Medicaid Act. In

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[7] The Court notes that there is evidence to suggest that if the five percent rate reduction is given effect, many Medi-Cal beneficiaries will turn to more costly forms of medical care, such as emergency room care, thereby diminishing the State's projected (continued...)

so doing, the State agreed to abide by the conditions imposed by Congress. Further, retroactive relief for Medi-Cal beneficiaries will likely be inadequate and, and it will come too late, to remedy their pain, suffering, and harm to their mental and physical well-being. See e.g., Lopez v. Heckler, 713 F.2d 1432, 1437 (9th Cir. 1983). In light of the significant threat to the health of Medi-Cal recipients, reducing payments to health-care service providers will likely cause, and given that nothing in this Court's order prevents respondent from imposing a rate reduction after she has appropriately considered and applied the relevant factors, the Court finds that the balance of hardships tips in favor of granting the preliminary injunction.

E. PUBLIC INTEREST

"The district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." Hybritech, 849 F.2d at 1458. Clearly, there is a public interest in ensuring that the State has enough money to meet its financial obligations in the face of competing demands. However, there is also a public interest in ensuring access to health care. In light of all the circumstances, including the fact that the State may decide to implement a rate change upon making a properly reasoned and supported analysis, the Court finds that the public interest does not weigh against the issuance of a preliminary injunction.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS plaintiffs' motion for preliminary injunction. The Court hereby orders respondent Director, his agents, servants, employees, attorneys, successors, and all those working in concert with him to refrain from enforcing Cal. Welf. & Inst. Code § 14105.191(b)(3), as modified by AB 1183 beginning on March 1, 2009, by refraining from reducing by five percent payments to pharmacies for prescription drugs (including prescription drugs and traditional over-the-

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[7](...continued)
savings. See e.g., Rodde v. Bonta, 357 F.3d 988, 999 (9th Cir. 2004).

counter drugs provided by prescription) provided under the Medi-Cal fee-for-service program.[8]

Dated: February 27, 2009

CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE

[8] Plaintiff's motion appears to seek an injunction as to the five percent rate reduction for all pharmacy products, not just drugs. However, plaintiffs' arguments regarding irreparable harm focus on brand and generic drugs dispensed by pharmacies; plaintiffs have not shown irreparable harm as to the effect of the five percent rate reduction on other pharmacy products. Therefore, the Court limits the scope of the injunction to drug products dispensed by pharmacies.

EXHIBIT K

FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CALIFORNIA PHARMACISTS ASSOCIATION, et al., Plaintiffs - Appellants, v. DAVID MAXWELL-JOLLY, Director of the Department of Health Care Services, State of California, Defendant - Appellee.	No. 09-55365 D.C. No. 2:09-cv-722-CAS-MAN Central District of California, Los Angeles ORDER

Before: REINHARDT, BERZON, and M. SMITH, Circuit Judges.

Plaintiffs-Appellants, the California Pharmacists Association, et al., filed this suit to challenge the Medi-Cal reimbursement rate reductions to various providers as set forth in AB 1183. A group of the plaintiffs, the Hospital Plaintiffs, which comprises the California Hospital Association and some individual hospitals, filed a motion in the district court for a preliminary injunction to enjoin the defendant from reducing Medi-Cal fee-for-service rates to hospitals,[1] arguing

[1] Specifically, the Hospital Plaintiffs sought to enjoin the rate reductions as to four types of services: (1) inpatient services for non-contract hospitals, (2)

that AB 1183 was enacted in violation of § 1396a(a)(30)(A) of Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (§ (a)(30)(A)). The district court denied the preliminary injunction. The Hospital Plaintiffs filed an Emergency Motion Pursuant to Circuit Rule 27-3 for Preliminary Injunction Pending Appeal.

We review the denial of a preliminary injunction for abuse of discretion. *Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1156 (9th Cir. 2006). A district court abuses its discretion in denying a request for a preliminary injunction if it "base[s] its decision on an erroneous legal standard or clearly erroneous findings of fact." *Id.* (citation omitted). It also does so if in reaching its decision it makes a material error of law. We review conclusions of law de novo and findings of fact for clear error. *Id.*

Plaintiffs seeking a preliminary injunction in a case in which the public interest is involved must establish that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365, 376 (2008). When deciding whether to issue a stay, including a stay of a state action that the

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outpatient services, (3) Distinct Part Nursing Facilities, and (4) subacute services.

district court has declined to enjoin, we consider: (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *See Humane Soc'y of U.S. v. Gutierrez*, 527 F.3d 788, 789–90 (9th Cir. 2008).

In this case, the district court found that the Hospital Plaintiffs were likely to succeed on the merits, but that they failed to demonstrate irreparable harm. We address these issues in turn, and, in view of the time-urgency and the irreparability of the harm, also consider the other *Winter* factors which necessarily follow.

I. Likelihood of Success on the Merits

In *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997), we held that 42 U.S.C. § 1396a(a)(30)(A) requires the state to consider efficiency, economy, quality of care, and access before setting Medi-Cal reimbursement rates. *Id.* at 1496. The district court concluded that the Hospital Plaintiffs have shown a likelihood of success on the merits under *Orthopaedic* because the Legislature did not consider any such factors before passing the rate cuts in AB 1183. The court ruled that although the Department of Health Care Services (the Department) had

performed some studies after AB 1183's passage, those post-hoc studies failed to meet the requirements of *Orthopaedic*, 103 F.3d at 1496. It noted that AB 1183 gives the Department no discretion to alter the rate cuts based on the Department's own analysis, and, therefore, the cuts were not "based on" the Department's consideration of the relevant factors, but instead constituted a post-hoc rationalization for a legislative decision that had already been made. Op. at 9-11. Moreover, the district court determined that, although the state Legislative Analyst Office issued a report analyzing the proposed cuts, there was no evidence the legislature actually considered the report before enacting AB 1183. *Id.* at 10 n.8.

We conclude that the district court did not abuse its discretion in concluding that the Hospital Plaintiffs demonstrated a likelihood of success on the merits. Indeed, the Hospital Plaintiffs made a strong showing of such likelihood.

II. Irreparable Harm

The Hospital Plaintiffs must also show a likelihood of irreparable harm. *See Winter*, 129 S.Ct. at 375.

A. Harm

We first address the type of harm we may consider in the irreparable harm analysis. The Department argues that only harm to Medi-Cal beneficiaries is

relevant to this motion, while the Hospital Plaintiffs assert that harm to Medi-Cal service providers is also relevant, and that they need show only the latter type of harm, in this case harm to themselves or their members, in order to obtain injunctive relief. The Hospital Plaintiffs further claim that they or their members will lose considerable revenue between the effective date of AB 1183 and the date their claims can be reviewed on the merits if injunctive relief is denied.

We agree with the Hospital Plaintiffs. In *Independent Living Center v. Shewry* (*ILC*), we held that "a plaintiff seeking injunctive relief under the Supremacy Clause on the basis of federal preemption need not assert a federally created 'right,' in the sense that term has recently been used in suits brought under § 1983, but need only satisfy traditional standing requirements." 543 F.3d 1050, 1058 (9th Cir. 2008). We rejected the contention that federal statutes enacted pursuant to Congress's spending power, such as the one here at issue, are excluded from this principle, *id.* at 1059–62, and concluded that the health care providers in that case (which at that point did not include hospitals) had standing because:

> [A]ccording to their complaint, [they] will be "directly injured, by loss of gross income," when the ten-percent rate reduction takes effect. The Supreme Court "repeatedly has recognized that such [direct economic] injuries establish the threshold requirements" of Article III standing. . . . Moreover, this injury is directly traceable to the Director's implementation of AB 5 [the statute at issue in that case],

> and would certainly be redressed by a favorable decision of this court enjoining the ten-percent rate reduction.

Id. at 1065. Notably, *ILC* did *not* indicate that the service providers had standing to assert the interests of the beneficiary plaintiffs as third parties, as, for example, the medical service providers do in cases concerning the constitutional rights of patients. *See, e.g.*, *Eisenstadt v. Baird*, 405 U.S. 438 (1972). A cause of action based on the Supremacy Clause obviates the need for reliance on third-party rights because the cause of action is one to enforce the proper constitutional structural relationship between the state and federal governments and therefore is not rights-based. In contrast, a case brought to enforce the Due Process or Equal Protection Clauses is rights based, and requires that the rights of *someone* be advanced, even if not the rights of the plaintiffs who have been injured.

Consistent with this understanding, in the various precedents cited throughout the *ILC* opinion in which plaintiffs brought cases directly under the Supremacy Clause, the interests asserted were basically economic, and there was no inquiry into whether the plaintiffs asserting the economic injury were in any sense intended beneficiaries of the federal statute on which the Supremacy Clause cause of action was premised. For example, in *Bud Antle, Inc. v. Barbosa,* one of the cases upon which we relied in *ILC*, we held that employers could sue to enjoin

a California statute as preempted by the National Labor Relations Act (NLRA) "regardless of whether the NLRA conferred a federal 'right' on employers." 45 F.3d 1261, 1271 n.13 (9th Cir. 1994). It was for that very reason that we concluded the § 1983 cases were inapposite, and that *Sanchez v. Johnson*, 416 F.3d 1051 (9th Cir. 2005), did not preclude the plaintiffs' suit. Essentially, the line of cases on which we relied held that private parties could enforce the structural relationship between the federal and state governments so long as they had Article III standing as, essentially, private enforcers of the Supremacy Clause; the specific relationship of those parties to the federal statute on which the Supremacy Clause cause of action is premised does not matter.

Given these underpinnings of *ILC,* there is little basis on which to import an "intended beneficiary" concept back into the case for purposes of determining irreparable injury. Applying this determination to the present motion, it is clear that AB 1183 harms the Hospital Plaintiffs and their members through reductions in Medi-Cal revenue payments.

B. Irreparability of Harm

Having determined that the Hospital Plaintiffs have shown unlawful harm under § (a)(30)(A), we next consider whether the harm is irreparable. Typically,

monetary harm does not constitute irreparable harm. *L.A. Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1202 (9th Cir. 1980). The Hospital Plaintiffs argue that in this case, however, the monetary injury is irreparable because the Eleventh Amendment sovereign immunity of the Department (a branch of the State of California government) bars the Hospital Plaintiffs from ever recovering damages in federal court. The most relevant authority on this issue—though not controlling—supports the Hospital Plaintiffs' argument. *See Kan. Health Care Ass'n v. Kan. Dep't of Soc. & Rehab. Servs.*, 31 F.3d 1536, 1543 (10th Cir. 1994) ("Because the Eleventh Amendment bars a legal remedy in damages . . . the court held that plaintiffs' injury was irreparable. We agree."). We note also that Supreme Court case law and some of our own cases clarify that economic damages are not traditionally considered irreparable *because the injury can later be remedied by a damage award*. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("[I]t seems clear that the temporary loss of income, ultimately to be recovered, does not usually constitute irreparable injury. . . . The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm." (internal quotation omitted)); *Rent-A-Center, Inc. v. Canyon*

Television & Appliance Rental, Inc., 944 F.2d 597, 603 ("It is true that economic injury alone does not support a finding of irreparable harm, *because such injury can be remedied by a damage award.*"(emphasis added)); *Caribbean Marine Servs. Co. v. Baldridge*, 844 F.2d 668, 676 (9th Cir. 1988); *Arcamuzi v. Cont'l Air Lines, Inc.*, 819 F.2d 935, 938 (9th Cir. 1987); *Colo. River Indian Tribes v. Town of Parker*, 776 F.2d 846, 850–51 (9th Cir. 1985); *Goldie's Bookstore, Inc. v. Superior Court*, 739 F.2d 466, 471 (9th Cir. 1984) ("Mere financial injury . . . will not constitute irreparable harm *if adequate compensatory relief will be available in the course of litigation.*" (emphasis added)).

Because the economic injury doctrine rests only on ordinary equity principles precluding injunctive relief where a remedy at law is adequate, it does not apply where, as here, the Hospital Plaintiffs can obtain no remedy in damages against the state because of the Eleventh Amendment. *See Kan. Health Care Ass'n*, 31 F.3d at 1543.[2]

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[2] We observe that, although damages may become available to the Hospital Plaintiffs in state court, persuasive authority suggests that federal courts may consider only what *federal* remedies are available. *See United States v. New York*, 708 F.2d 92, 93–94 (2d Cir. 1983) (per curiam) (holding that "federal courts may consider only the available *federal* legal remedies"). *But see Kan. Health Care Ass'n*, 31 F.3d at 1543 ("Because the Eleventh Amendment bars a legal remedy in damages, *and the court concluded no adequate state administrative remedy*

Considering the relevant authorities, we are persuaded that because the Hospital Plaintiffs and their members will be unable to recover damages against the Department even if they are successful on the merits of their case, they will suffer irreparable harm if the requested injunction is not granted.

III. Equities and the Public Interest

The district court did not reach the question of the equities and the public interest. Although the state argues that these factors weigh in its favor because an injunction will worsen the state's budget crisis, the record reflects that the impact of a stay on the budget crisis will be minimal at most. Further, it is clear that it would not be equitable or in the public's interest to allow the state to continue to violate the requirements of federal law, especially when there are no adequate remedies available to compensate the Hospital Plaintiffs for the irreparable harm that would be caused by the continuing violation. In such circumstances, the interest of preserving the Supremacy Clause is paramount. *See Am. Trucking Ass'n v. City of Los Angeles*, – F.3d –, 2009 WL 723993, at *12 (9th Cir. Mar. 20, 2009)

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existed, the court held that plaintiffs' injury was irreparable. We agree." (emphasis added)). We find the reasoning of *New York* to be more persuasive, and consider *only* prospective federal remedies for the purpose of gauging whether the harm caused to the Hospital Plaintiffs and their members is irreparable.

(considering the public interest represented by "the Constitution's declaration that federal law is to be supreme").

In light of the showing made by the Hospital Plaintiffs in this case, we grant their motion for an order staying the rate cuts in AB 1183 with respect to the specified hospital services pending their appeal to this court of the district court's order denying the motion for preliminary injunction.

MOTION FOR STAY PENDING APPEAL IS GRANTED.