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11
12 IN THE UNITED STATES DISTRICT COURT
13 FOR THE CENTRAL DISTRICT OF CALIFORNIA
14 WESTERN DIVISION

15 MANAGED PHARMACY CARE, a
California corporation; INDEPENDENT
16 LIVING CENTER OF SOUTHERN
CALIFORNIA, INC., a California
17 corporation; GERALD SHAPIRO,
Pharm.D., doing business as Uptown
18 Pharmacy & Gift Shoppe; SHARON
STEEN, doing business as Central
19 Pharmacy; and TRAN PHARMACY,
INC., a California corporation,

20
21 Plaintiffs,

22 v.

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

25 Defendant.
26
27
28

CV09-0382-CAS (MANx)

**DEFENDANT'S OPPOSITION
TO PLAINTIFFS' MOTION
FOR PRELIMINARY
INJUNCTION**

Date:

Time:

Courtroom:

Judge:

The Honorable
Christina A. Snyder

Trial Date: TBA

Action Filed: 1/16/2009

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INTRODUCTION

On September 20, 2008, the Governor signed into law AB 1183, a 5%
payment reduction to pharmacies and other service providers participating in the

1 Medi-Cal fee for services program. AB 1183 is effective on March 1, 2009. This
2 bill included various amendments and additions to the California Welfare and
3 Institutions Code (W&I). AB 1183 enacted new W&I section 14105.191 and
4 amended W&I section 14105.19 to provide that the 10% reduction in payments for
5 various services covered under the Medi-Cal program, including payments to
6 pharmacies, imposed by AB 5, would end on March 1, 2009. Instead of the 10%
7 payment reduction, new section W&I 14105.191 provides for a 5% payment
8 reduction for some services, effective March 1, 2009.

9 As this Court is aware, there have been a flurry of lawsuits filed as a result of
10 the Medi-Cal payment reductions. In a lawsuit pending in this Court contesting
11 AB 5 [hereinafter *ILC* AB 5]^{1/}, this court granted Plaintiffs' third motion for
12 preliminary injunction to prevent Defendant (hereinafter Department) from
13 enforcing the 10% payment reduction. The injunction was granted after Plaintiffs
14 appealed this Court's denial of Plaintiffs' first motion for preliminary injunction.
15 The initial denial was based on this Court's ruling that Plaintiffs could not bring
16 suit under the *Shaw*^{2/} Supremacy Clause doctrine. In other words, the issue was
17 whether Plaintiffs' claim of preemption should be dismissed at the initial pleading
18 stage. The Ninth Circuit ruled it should not.^{3/}

19 It is worth repeating that the only issue in front of the Ninth Circuit in *ILC*
20 AB5 was "whether *ILC* may maintain a valid cause of action to enjoin
21 implementation of AB 5 on the basis of federal preemption." *Independent Living*
22 *Center*, 543 F. 3d. at 1055. As will be shown in the Department's opposition: (1)
23 Plaintiffs have failed to meet their burden that the 5% payment reduction is an

24
25 1. *Independent Living Center of Southern California et al., v. Sandra Shewry et al.*, Case
26 no., CV 08-3315 CAS (MANx).

27 2. *Shaw v. Delta Airlines, Inc.*, 463 U.S. 85 (1983).

28 3. *Independent Living Center of Southern California et al., v. Sandra Shewry et al.* 543
F.3d 1050 (9th Cir. 2008).

1 “obstacle” to the accomplishment of 42 U.S.C. §1396a(a)(30)(A); and (2)
2 Plaintiffs have failed to establish a strong likelihood of success on the merits and
3 irreparable harm. Therefore their motion for preliminary injunction must be
4 denied.

5 STATUTORY BACKGROUND

6 Congress created the Medicaid program in 1965 as a purely voluntary
7 program in which states could elect to receive federal funds in exchange for
8 providing medical services to certain individuals statutorily defined as “needy.”
9 See generally 42 U.S.C. §§ 1396 et seq.; *Wilder v. Virginia Hosp. Ass’n*, 496 U.S.
10 498, 502 (1990). States use federal Medicaid funds to reimburse a portion of the
11 expenditures incurred by service providers. In exchange for federal funding, states
12 must meet certain statutory and regulatory conditions. See *Schweiker v. Gray*
13 *Panthers*, 453 U.S. 34, 37 (1981). If a state is unable or unwilling to satisfy these
14 conditions, it may (i) voluntarily withdraw from the Medicaid program, (ii) seek a
15 waiver from the Secretary of the U.S. Department of Health and Human Services,
16 which administers the Medicaid program, see, e.g., 42 U.S.C. § 1396n, or (iii) risk
17 federal penalties, including the withholding of some or all of its federal funding.
18 See *id.*, § 1396c.

19 The most significant rule requirement for federal Medicaid funding is that
20 states submit for federal approval a “plan for medical assistance.” 42 U.S.C.
21 § 1396a(a). The State Plan contains a comprehensive statement of the nature and
22 scope of the state’s Medicaid program, and includes the state’s scheme for
23 reimbursing service providers. See *Wilder*, 496 U.S. at 502. As codified, section
24 1396a(a) of the Medicaid Act includes 71 sub-parts describing the procedural and
25 substantive requirements for State Plans. See 42 U.S.C. §§ 1396a(a)(1)-(71).
26 Plaintiffs’ allegations center on subpart section 1396a(a)(30)(A). The full text
27 follows:

28 42 U.S.C. § 1396a(a):

1 A State plan for medical assistance must, (30)(A) provide such
2 methods and procedures relating to the utilization of, and the
3 payment for, care and services available under the plan (including
4 but not limited to utilization review plans as provided for in
5 section 1396b(i)(4) of this title) as may be necessary to safeguard
6 against unnecessary utilization of such care and services and to
7 assure that payments are consistent with efficiency, economy, and
8 quality of care and are sufficient to enlist enough providers so
9 that care and services are available under the plan at least to the
10 extent that such care and services are available to the general
11 population in the geographic area.

12 A state must obtain federal approval of its Medicaid Plan, *see* 42 U.S.C. §
13 1316(a), and must submit for federal approval a proposed State Plan amendment
14 whenever the state intends to make a significant change to its practices or
15 procedures. *See* 42 C.F.R. § 430.12. Proposed amendments to a State Plan must
16 be submitted by the last day of the fiscal quarter in which the change occurs. *See*
17 42 C.F.R. §§ 430.20(b)(2), 447.256. So long as the proposed amendment is timely
18 submitted, a state need not wait for federal approval before the policy change takes
19 effect. If the federal government rejects part or all of a state's proposed State Plan
20 or any amendment to that Plan, the state may be disqualified from receiving some
21 or all of its federal Medicaid funds. *See* 42 U.S.C. § 1396c. Similarly, if a state
22 fails to timely submit a proposed Plan or amendment, or if its actual practices
23 deviate from the scheme set forth in its Plan, it risks losing its federal funding. *See*
24 *id.*

25 By its terms, the Social Security Act, which includes the federal Medicaid
26 Act, does not itself confer a cause of action, and whether a particular statute is
27 judicially enforceable is dependent on whether it confers "rights" that are
28 enforceable under 42 U.S.C. §1983. *Edelman v. Jordan*, 415 U.S. 651, 673-674
(1974), *Maine v. Thiboutot*, 448 U.S. 1, 7 (1980). Thus the Medicaid Act, itself,
provides no recourse or remedy for private individuals or entities to challenge a
State's Plan or to assert that a state's actual practices deviate from that Plan. *See*
Wilder, 496 U.S. at 521. That is why the Supreme Court in *Wilder* evaluated in
some detail whether the particular Medicaid statute in that case conferred

1 enforceable “rights” under section 1983. Otherwise, Congress provided only one
2 mechanism to address state violations of the statute and accompanying
3 regulations: termination of some or all of the state’s federal Medicaid funding
4 following an administrative process. *See id.*; 42 U.S.C. § 1396c. These penalties
5 are not mandatory. The Center for Medicare & Medicaid Services (hereinafter
6 CMS), the federal agency within the U.S. Department of Health and Human
7 Services that administers the Medicaid program, has the power to impose, refuse
8 to impose, reduce, or rescind these financial penalties in its administrative
9 discretion. *See generally Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981). In
10 addition, states may seek a waiver from CMS to excuse what might otherwise be
11 deemed a statutory violation. *See, e.g.*, 42 U.S.C. § 1396n(f). Disputes between a
12 state and CMS over the adequacy of a State Plan, amendment, or the state
13 practices and procedures pursuant thereto, need not result in the termination of
14 federal funds, and often do not.

15 Since the enactment of the Medicaid Act in 1965, Congress has expressly
16 considered how much discretion to afford states in setting reimbursement rates,
17 and whether to immunize states from private challenges to the rates they set.
18 During this early period, federal regulators retained primary authority for
19 determining whether a state’s reimbursement rates satisfied federal requirements.
20 But in 1981, Congress passed what became known as the Boren Amendment,
21 which transferred primary rate-setting authority from federal regulators to the
22 states. The Boren Amendment required a State Plan to provide for payments. In
23 so doing, Congress intended to give states more flexibility in how they set rates
24 and manage costs, and to discourage challenges from providers. *Evergreen*
25 *Presbyterian Ministries Inc. v. Hood*, 235 F.3d 908, 919 n.12 (5th Cir. 2000).

26 The Supreme Court nonetheless held that providers had rights under the
27 Boren Amendment pursuant to section 1983 to challenge the adequacy of a state’s
28 reimbursement rates under the Medicaid statute. *See Wilder*, 496 U.S. at 502-03.

1 In response to *Wilder*, Congress repealed the Boren Amendment in 1997.
2 (Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4712(c), 111 Stat. 509
3 (1997)). By repealing the Boren Amendment, Congress sought not only to reverse
4 *Wilder* but to preclude any providers from challenging rates under the Medicaid
5 Act. See FN 8 to this Opposition.

6 ARGUMENT

7 I

8 AB 1183 DOES NOT PRESENT AN OBSTACLE TO THE 9 ACCOMPLISHMENT OF 42 U.S.C. § 1396a(a)(30)(A)

10 Plaintiffs' Supremacy Clause claim is based on alleged federal conflict
11 preemption. In order to establish a strong likelihood of success on the merits in a
12 conflict preemption action, the Plaintiffs must show that "compliance with both
13 federal and state regulations is a physical impossibility," or that "state law stands
14 as an obstacle to the accomplishment and execution of the full purposes and
15 objectives of Congress." *Pacific Gas & Elec. Co. v. State Energy Comm'n*, 461
16 U.S. 190, 204 (1983). Thus, Plaintiffs have the burden of proving that it is not
17 possible for the Department to comply with both AB 1183 and 42 U.S.C. § 1396a
18 § (a)(30)(A) (hereinafter § (a)(30)(A)), or that AB 1183 stands as an obstacle to
19 the enforcement of § (a)(30)(A). The district court's task, in turn, is to analyze
20 whether the Plaintiffs have met that burden.

21 Courts have long held that in policy areas like health care that traditionally
22 have been occupied by the states, courts should be reluctant to find preemption
23 unless the evidence of Congressional intent is compelling. See *Hillsborough*
24 *County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715-18 (1985);
25 *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Plaintiffs, therefore,
26 have the burden of submitting evidence that gives rise to a "clear" and "manifest"
27 inference that Congress intended to displace a law in the state's traditional sphere
28 of discretion. *Rice*, 331 U.S. at 230. Further, any ambiguities must be construed

1 against finding preemption, and courts should narrowly interpret the scope of
 2 Congress's "intended invalidation of state law" whenever possible. *Medtronic*
 3 *Inc., v. Lohr*, 518 U.S. 470, 485 (1996). "When considering preemption, no matter
 4 which type, 'the purpose of Congress is the ultimate touchstone.'" *Ting v. AT&T*,
 5 319 F.3d 1126, 1136 (9th Cir. 2003), citing *Cipollohne v. Liggett Group, Inc.*, 505
 6 U.S. 504, 516 (1992).

7 And when, as here, a plaintiff seeks to enjoin a government agency, "his
 8 case must contend with the well-established rule that the Government has
 9 traditionally been granted the widest latitude in the dispatch of its own internal
 10 affairs." *Rizzo v. Goode*, 423 U.S. 362, 378-79 (1976). This "well-established
 11 rule" bars federal courts from interfering with non-federal government operations
 12 in the absence of facts showing an immediate threat of substantial injury.

13 *Hodgers-Durkin*, 199 F.3d 1037, 1042-43 (9th Cir. 1999); *Midgett v. Tri-County*
 14 *Metropolitan Transp. Dist. of Oregon*, 254 F.3d 846, 850 (9th Cir. 2001).

15 Plaintiffs' claim must fail as a matter of law. Plaintiffs bear the burden of
 16 demonstrating that the payment reduction of AB 1183 poses an "obstacle" so great
 17 to Congressional purpose that Congress must have impliedly intended to preempt
 18 it. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *Jimeno v. Mobil Oil. Corp.*, 66
 19 F.3d 1514, 1526 n.6 (9th Cir. 1995).⁴

20 First, the Medicaid Act creates no substantive limitations regarding
 21 Medicaid rates that are capable of being violated and therefore an "obstacle" to
 22 Congress's purpose, but merely sets policy objectives that are not judicially
 23 enforceable. By its terms, § (a)(30)(A) merely governs the content of the State
 24 Medicaid Plans, and requires that they "provide such methods and procedures" to
 25 "assure that payments [to providers] are consistent with efficiency, economy, and
 26

27 4. Courts recognize other doctrines to determine Congressional intent, such as express
 28 preemption, field preemption, and impossibility preemption, *see generally English v. General*
Electric Co., 496 U.S. 72 (1990).

1 quality of care and are sufficient to enlist enough providers so that care and
2 services are available under the plan at least to the extent that such care and
3 services are available to the general population in the geographic area [equal
4 access].”

5 To the extent that § (a)(30)(A) could be construed as having significance
6 beyond the mere contents of a State Plan, which the Department disputes, it does
7 not mandate that the state pay any set minimum, or that the State, for example,
8 cover a given providers’ costs. *See Evergreen*, 235 F.3d at 929; *Folden v.*
9 *Washington State Department of Social and Health Services*, 744 F.Supp. 1507,
10 1523-24 (W.D. Wash. 1990). Ultimately, state policymakers and the federal
11 agency that regulates them must strike the appropriate balance.

12 Even if the state’s rates fall short of federal requirements, which is not the
13 case here, there is no “obstacle” to Congressional purpose, when Congress
14 expressly contemplated such shortcomings and established a detailed regulatory
15 regime to deal with them. Congress expected that some states might at times strike
16 the wrong balance between beneficiary services and cost controls, as plaintiffs
17 allege in this case. *See Sanchez*, 416 F.3d at 1059-60. However, Congress did not
18 intend to presumptively preempt states from enacting such laws and regulations.
19 Instead, Congress established a “complementary administrative framework” to
20 deal with them. *New York Dept. of Social Services v. Dublino*, 413 U.S. 405, 421
21 (1973).

22 An injunction should not issue where the court’s order itself would present
23 an “obstacle” to Congress’s purpose. Ultimately, the “purpose of Congress is the
24 ultimate touchstone” under the preemption doctrine. *Retail Clerks Int’l Ass’n*
25 *Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963). Plaintiffs bear the burden
26 of proof, *see Jimeno*, 66 F.3d at 1526 n.6, which on this motion requires them to
27 produce at least some evidence of Congressional intent in support of preemption.

28 Plaintiffs’ burden is particularly onerous in this case because they must

1 overcome both the judicially recognized presumption against preemption in cases
2 involving health, safety, and welfare and the legislative history relating to the
3 repeal of the Boren Amendment which suggests that Congress's intent was to
4 foreclose provider suits rather than permit them. The legislative history confirms
5 that, rather than advancing Congress's intent, an order granting an injunction in
6 this case would undermine, rather than effectuate, Congressional intent.
7 Accordingly, the Court should dismiss Plaintiffs' challenge to the adequacy of
8 rates under the Medicaid Act as a matter of law.

9 As the Court is aware, there are three components to a preliminary
10 injunction: (1) Plaintiffs need to establish a strong likelihood of success on the
11 merits; (2) the balance of irreparable harm favors Plaintiffs; and (3) that the public
12 interest favors granting the injunction. *See Aleknagik Natives Ltd. v. Andrus*, 648
13 F.2d 496, 501 (9th Cir. 1980).

14 Under an alternative test, a preliminary injunction may issue upon a clear
15 showing of either: (1) probable success on the merits and possible irreparable
16 injury; or, (2) sufficiently serious questions going to the merits to make them fair
17 ground for litigation, and a balance of hardships that tips decidedly toward the
18 party requesting the preliminary relief. *Benda v. Grand Lodge of Int'l Ass'n*, 584
19 F.2d 308, 314-315 (9th Cir. 1978). In order to be entitled to an injunction,
20 Plaintiffs must make a showing that they face a real or immediate threat of
21 substantial or irreparable injury. *Hodgers-Durgin*, 199 F.3d at 1042.

22 Moreover, any injunction that prevents implementation of a state statute,
23 whether a TRO, preliminary injunction, or permanent injunction, *per se* inflicts
24 irreparable injury to the public interest. As the court stated in *Coalition for*
25 *Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997), "a state suffers
26 irreparable injury whenever an enactment of its people or their representatives is
27
28

enjoined."^{5/} Because an injunction against lawfully-enacted state legislation constitutes irreparable harm to the State and the public, *per se*, the district court must weigh the harm to the State against whatever showing the Plaintiffs made as to their threatened harm.

II

THE DEPARTMENT HAS CONDUCTED A REASONABLY PRINCIPLED ANALYSIS AND CONCLUDED THAT REIMBURSEMENT PURSUANT TO AB 1183 WILL COMPLY WITH 42 U.S.C. SECTION 1396a(a)(30)(A)

Under the Boren Amendment, judicial review was "limited to a determination of whether the state action is arbitrary and capricious or contrary to law." *Folden*, 744 F. Supp. at 1525. The Boren Amendment imposed a much stricter requirement on the kind of analysis States must conduct. It expressly required rates to be "reasonable and adequate" to "meet" efficient and economically operated provider costs, and expressly required states to make "findings" that such rates were reasonable and adequate. However, even the Boren Amendment did not require a formal rate study or written findings.

In *Folden v. Washington State DSHS*, 981 F. 3d 1054 (9th Cir. 1992), the district court correctly noted that the procedural requirements of the federal regulation are satisfied if the state agency has engaged in a bona fide fact-finding process. The district court noted that the states are free to create their own methods of arriving at the required findings and that the findings process does not require any special studies or written findings. It is sufficient if the state agency has considered, on the basis of some reasonably principled analysis, whether its

5. As *Coalition for Economic Equity* further explained: "Balancing the equities, we are persuaded that the State has demonstrated the clear possibility of irreparable injury to its citizens if a stay of the mandate is granted; it is clear that a state suffers irreparable injury whenever an enactment of its people or their representatives is enjoined. See *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345 (1977) (Rehnquist, J., in chambers) ("It also seems to me that any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury."); see also *Campbell v. Wood*, 20 F.3d 1050, 1051 (9th Cir. 1994).

1 payment rates meet the substantive requirements of the Boren Amendment. *Id.* at
2 1057.

3 In this case, the state agency has gone even beyond what was required under
4 the stricter Boren Amendment by not only doing a reasonably principled analysis,
5 but incorporating it into a formal written Analysis of Pharmacy Reimbursement
6 under AB 1183. *See* Douglas Decl., ¶11; Ex. A-A, AB 1183 Analysis.

7 It is public knowledge that the State is experiencing an unprecedented
8 financial crisis, with a projected budget deficit of over \$40 billion. *See* Douglas
9 Decl. ¶ 13 Ex. A. In times of unprecedented fiscal and budgetary crisis,
10 policymakers must exercise their judgment to balance competing federal
11 objectives in the best interests of Medi-Cal patients and the residents of California.
12 Congress afforded California "substantial discretion" to do so. *Alexander v.*
13 *Choate*, 469 U.S. 287, 303 (1985); 42 U.S.C. § 1396a(a)(18). According to
14 policymakers, the rate reductions promote efficiency within the Medi-Cal system;
15 enhance the long-term fiscal health of the program; and avoid far more painful
16 cuts to the program (such as cutting optional services or restricting eligibility) that
17 could curtail care for current beneficiaries. *See* Exhibit A-A, AB 1183 Analysis.
18 As noted in the Department's AB 1183 analysis:

19 The Legislature had other alternatives for reducing spending in
20 the Medi-Cal program, which would have had a much more
21 negative impact on Medi-Cal recipients. For example, the
22 Legislature could have eliminated Medi-Cal coverage for
23 various optional services, that states are not required by federal
24 law to cover. These optional services include, but are not
25 limited to, prescription drugs, adult day health care services
26 and adult dental services. For example, the Medi-Cal program
27 currently pays pharmacies approximately \$2.9 billion annually
28 for drugs. Thus, the state could have achieved much greater
budgetary savings by simply eliminating Medi-Cal coverage of
prescription drugs. The Legislature could have also achieved
greater savings by imposing stricter eligibility requirements,
that would have eliminated Medi-Cal coverage altogether for
some recipients. In an effort to achieve some reduction in
Medi-Cal expenditures in the State's Budget, the Legislature
and Governor chose moderate provider payment reductions,
rather than many measures that could have had a detrimental
impact on many Medi-Cal recipients.

1 See Douglas Decl. Ex. A; Exhibit A-A, AB 1183 Analysis, p. 4.

2 Instead of paying pharmacies approximately \$3.2 billion annually (\$2.9
3 billion for drugs), the Medi-Cal program will be paying them approximately \$3
4 billion annually (\$2.75 billion for drugs). See Douglas Decl. Ex. A ¶ 10. The
5 analysis further concluded that Medi-Cal reimbursement would comply with all
6 applicable requirements related to the “efficiency, economy, and quality of care”
7 (hereinafter EEQ) provision. See Douglas Decl. Ex. A, pp. 3-10. The Analysis
8 concluded that reduced reimbursement pursuant to AB 1183 will compensate a
9 higher portion of pharmacy costs even above the “range of reasonableness”
10 required by the stricter Boren Amendment. *Id.* at 5-10. The analysis concluded
11 that recipients should continue to have sufficient access to Medi-Cal covered
12 drugs and other pharmacy services when the 5% payment reduction is
13 implemented on March 1, 2009. See Ex. A-A, AB 1183 Analysis, pp. 10-12.
14 Thus, “the payment reduction results in more efficient and economic
15 administration of the program while assuring that the interests of Medi-Cal
16 recipients are maintained.” *Id.* at p. 5.

17 The analysis determined that recipients should continue to have sufficient
18 access to Medi-Cal covered drugs and other pharmacy services when the 5%
19 payment reduction is implemented on March 1, 2009. See Ex. A-A, AB 1183
20 Analysis, pp. 10-14; Ex. C, Gorospe Decl., ¶¶ 5-10; Ex. D, Flores Decl., ¶¶ 4-7.

21 This Court’s ruling granting the third preliminary injunction in *ILC AB5*
22 held that “when *the State of California* seeks to modify reimbursement rates for
23 health care services provided under the Medi-Cal program, it must consider
24 efficiency, economy, quality of care, and equality of access, as well as the effect of
25 providers’ costs on those relevant statutory factors.”^{6/} The Department thoroughly
26 considered EEQ and access, and as noted in the Analysis:

27
28 6. The Department does not concede that it must conduct a written analysis of EEQ prior
to a payment reduction, or of the effect of provider’s costs.

1 After a 5% payment reduction is implemented on March 1,
2 2009, Medi-Cal reimbursement paid to pharmacies will comply
3 with title 42, United States Code, section 1396a(a)(30)(A). The
4 available data indicates that Medi-Cal recipients will continue
5 to have sufficient access to pharmacy services as required by
6 federal law. Reimbursement will be below applicable federal
7 upper payment limits. The 5% payment reduction will result in
8 more efficient and economical Medi-Cal coverage. It will not
9 have any negative impact for Medi-Cal recipients. Finally, the
10 Department determined that Medi-Cal reimbursement will in
11 the aggregate compensate pharmacy drug costs at a level that is
12 well above the "range of reasonableness" that was acceptable
13 under the repealed Boren Amendment. Thus, reimbursement
14 will be sufficient under the more flexible requirements of
15 section 1396a(a)(30)(A).

16 See Ex. A-A, AB 1183 Analysis, pp. 12-13.

17 In part, the analysis relied on the Myers and Stauffer survey of dispensing
18 and acquisition costs of pharmaceuticals in California. See Exhibit A-A. On
19 pages 5-10 of the analysis report, the effect of the 5% payment reduction is
20 analyzed to determine the aggregate Medi-Cal reimbursement for various drugs.
21 The aggregate Medi-Cal reimbursement for all drugs is 103% of pharmacy costs
22 after the 5% payment reduction. This is significantly higher than the acceptable
23 range of reasonableness under the repealed Boren Amendment which was 85%-
24 95% ; the aggregate Medi-Cal reimbursement for all single source drugs is 98-
25 99% of pharmacy costs after the 5% payment reduction; the aggregate Medi-Cal
26 reimbursement for multi-source drugs ranges from 107% to 137% of pharmacy
27 costs after the 5% payment reduction. See Ex. A-A, AB 1183 Analysis, pp. 8-12;
28 Ex. C, Gorospe Decl., ¶¶ 9, 22.

29 Since a detailed analysis of EEQ was performed by the Department,
30 Plaintiffs cannot establish a strong likelihood of success on the merits. As a result,
31 this Court does not need to address the second component of a preliminary
32 injunction request, irreparable harm. *Global Horizons, Inc., v. United States DOL*,
33 510 F.3d. 1054, 1058 (9th Cir. 2007).

34 However, even if Plaintiffs' allegations of irreparable harm were
35 considered, the conclusion of potential harm would be speculative at best.

1 Speculative injury does not constitute irreparable injury sufficient to warrant
 2 granting a preliminary injunction. *Goldie's Bookstore Inc., v. Super Ct.*, 739 F.2d
 3 466, 472 (9th Cir. 1984). Plaintiffs must do more than merely allege imminent
 4 harm sufficient to establish standing; they must demonstrate immediate threatened
 5 injury as a prerequisite to preliminary injunctive relief. *L.A. Mem'l Coliseum*
 6 *Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1201 (9th Cir. 1980).

7 The declarations submitted by Plaintiffs, the majority of whom are Medi-
 8 Cal providers, run the gamut on how their businesses allegedly will be affected by
 9 the 5% payment reduction. Much of the speculative injury mirrors what was
 10 asserted in *ILC AB5*. As alleged, some Plaintiffs may stop providing Medi-Cal
 11 services, others will stop, and all allege that their profitability will be adversely
 12 impacted by AB 1183. However, their proposed testimony is speculative and
 13 disputable. *See* Ex. C, Gorospe Decl., ¶¶ 11-23; Ex. C-A. All of them also
 14 speculate as to how Medi-Cal beneficiaries would be harmed in some fashion.
 15 Declarant David Medina takes it a step further by stating, "I may cut the business
 16 hours of the pharmacy or layoff employees to remain a profitable business." *See*
 17 Medina Decl. 11:26-28. However, as the Supreme Court has stated:

18 [T]he temporary loss of income, ultimately to be recovered,
 19 does not usually constitute irreparable injury. . .mere injuries,
 20 however substantial, in terms of money, time and energy
 necessarily expended. . .are not enough.

21 *Sampson v. Murray*, 415 U.S. 61, 90 (1974).

22 More importantly, however, the Department's analysis demonstrates that
 23 Medi-Cal reimbursement after a 5% reduction will compensate pharmacy costs at
 24 levels that exceed the "range of reasonableness" that was acceptable under the
 25 stricter Boren Amendment. *See* Ex. A-A, AB 1183 Analysis, pp. 5-10.
 26 Furthermore, the Department evaluated data during the time the 10% reduction of
 27 AB 5 was in place from July 1, 2008 through August 17, 2008, and found no
 28 negative impact on pharmacy participation. *See* Ex. A-A, AB 1183 Analysis, p. 5-

1 10, Ex. A-A(D)-(G). In other words, pharmacists are not going to shutter their
2 businesses. *See* Ex. A-A, AB 1183 Analysis, p. 13, Ex. A-A(D)-(G); *See* Ex. C,
3 Gorospe Decl. ¶ 10; Ex. D, Flores Decl., ¶¶ 4-7; Ex. A-A.

4 In the aggregate, an extremely high percentage of pharmacy costs will be
5 compensated and the more efficient pharmacies should be able to obtain a
6 substantial profit from providing services under the Medi-Cal program. *See* Ex.
7 A-A, AB 1183 Analysis, p. 10; *See* Ex. C, Gorospe Decl. ¶ 17.

8 The third and final component of a preliminary injunction, if applicable, is
9 whether the public interest favors granting the injunction. As noted earlier, federal
10 courts should not interfere with non-federal government operations in the absence
11 of facts showing an immediate threat of substantial injury. *Hodgers-Durgin*, 199
12 F.3d at 1042-43; *Midgett*, 254 F.3d at 850.

13 The State is in the midst of an unprecedented fiscal and budgetary crisis.
14 The Legislature must exercise its judgment to balance the competing federal
15 objectives in the best interests of Medi-Cal patients and the residents of California.
16 Congress afforded California "substantial discretion" to do so. *Alexander*, 469
17 U.S. at 303, (internal quotations omitted).

18 At the end of the day, and as argued above, Plaintiffs have failed to meet
19 their burden of proving a conflict between AB 1183 and § (a)(30)(A)
20 demonstrating that the payment reduction of AB 1183 poses an "obstacle."
21 Plaintiffs cannot establish a strong likelihood of success on the merits. The
22 Department has conducted a detailed analysis on the payment reduction and found
23 that reimbursement under AB 1183 will comply with both the EEQ and access
24 provision of § (a)(30)(A). Plaintiffs' irreparable harm contention is speculative at
25 best and the public interest does not favor granting the injunction.

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III

CONGRESSIONAL INTENT UNDER 42 U.S.C. SECTION 1396a(a)(30)(A) DOES NOT CONFER AN INDIVIDUAL RIGHT TO SUE⁷

As noted previously, § (a)(30)(A) requires state Medicaid agencies to submit to CMS a State Plan that provides that “payments are consistent with efficiency, economy, and quality of care” and that there is sufficient access to providers for services. Upon approval of the State Plan, a state is eligible to receive federal funds to operate the program. If a state operates its Medicaid program in violation of its state plan or federal law, CMS may decline federal funding for such services. 42 U.S.C. § 1396c. Thus, the statutory remedy intended by Congress for any alleged violation of § (a)(30)(A) is the withholding of federal funds, not judicial enforcement.

In *Sanchez v. Johnson*, 416 F.3d 1051, the court held that Congress did not intend a judicial remedy for alleged violations of § (a)(30)(A)’s efficiency, economy, and quality of care provisions. The court specifically found that:

Section 30(A) is concerned with a number of competing interests. It requires a State to “provide such methods and procedures . . . to assure that payments are consistent with efficiency, economy, and quality of care.” The most efficient and economical system of providing care may be one that benefits taxpayers to the detriment of medical providers and recipients; likewise, the provision of “quality” care — whatever standard may be implied by such a nebulous term — is likely to conflict with the goals of efficiency and economy. The tension between these statutory objectives supports the conclusion that § 30(A) is concerned with overall methodology rather than conferring individually enforceable rights on individual Medicaid recipients. [¶] . . . *The language of § 30(A) is . . . ill-suited to judicial remedy; the interpretation and balancing of the statute’s indeterminate and competing goals*

7. The Department anticipates that Plaintiffs will argue the Department is collaterally estopped from addressing this issue pursuant to *Independent Living Center of Southern California et al., v. Sandra Shewry et al.*, 543 F.3d 1050 (9th Cir. 2008), although the facts in the instant matter are substantially different. Indeed, 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.” The Department does not concede that 42 U.S.C. §1396a(a)(30)(A) confers an individual right to sue.

1 *would involve making policy decisions for which this court has*
 2 *little expertise and even less authority.*

3 *Id.* at 1059-1060. Emphasis added.

4 Thus, the Ninth Circuit recognized the administrative, statutory remedy
 5 intended by Congress and acknowledged that Congress did not intend judicial
 6 enforcement for alleged violations of § (a)(30)(A)'s provisions, by finding that
 7 they are "ill-suited to judicial remedy."

8 In 2007, the Ninth Circuit reaffirmed *Sanchez's* interpretation of
 9 § (a)(30)(A) as involving a "policy decision for which [a] court has little expertise
 10 and even less authority," and further stated that attempting to enforce § (a)(30)(A)
 11 "would require a court to account for numerous, largely unquantifiable variables."
 12 *Ball v. Rodgers*, 492 F.3d 1094, 1115 (9th Cir. 2007).

13 The above interpretation of Congressional intent finds support in
 14 Congress's express statement concerning the Social Security Act, which includes
 15 § (a)(30)(A). In enacting the Balanced Budget Act of 1997, Congress explicitly
 16 stated its intent that § 1396a should not be judicially enforced, when it repealed
 17 the Boren Amendment, which applied to hospitals and nursing facilities.^{8/}

18
 19 8. The history of the repeal of the Boren Amendment illustrates Congressional intent that
 20 §(a)(30)(A) not be judicially enforced. Unlike §(a)(30)(A), the Boren Amendment expressly
 21 mentioned provider costs and expressly required states to establish reasonable cost based rates for
 22 hospitals and nursing facilities. In *Wilder v. Virginia Hospital Association*, 496 U.S. 498, the
 23 Supreme Court undertook a lengthy analysis to determine whether providers had a "right" under the
 24 Boren Amendment that would be enforceable under 42 U.S.C. § 1983, and held that the Boren
 25 Amendment did create such a "right" for providers. If providers could have simply filed an action
 26 for alleged preemption based on the Supremacy Clause, there would have been no reason for the
 27 Supreme Court to have evaluated in detail whether the Boren Amendment created such enforceable
 28 "rights" for providers. It is well-settled that the Social Security Act, which includes the Medicaid
 statutes, does not itself create a cause of action for anyone to challenge a state's compliance with its
 provisions, and whether such a provision is judicially enforceable is dependent on whether Congress
 intended to confer a "right" that is enforceable pursuant to 42 U.S.C. §1983. (*Edelman v. Jordan*,
 415 U.S. 651, 673-674 (1974), *Maine v. Thiboutot*, 448 U.S. 1, 7 (1980), *Wilder v. Virginia Hosp.*
Ass'n, 496 U.S. 498, and *Blessing v. Freestone*, 520 U.S. 329 (1997)). The Social Security Act does
 not itself create a cause of action because there is no expression of Congressional intent in the Act

1 Plaintiffs are attempting to have this Court undercut decades of federal
 2 jurisprudence to say that, merely by claiming to be suing under the Supremacy
 3 Clause instead of § 1983, a party can obtain a remedy in federal court against a
 4 state agency for non-compliance with a provision of the Medicaid Act, when
 5 Congress has clearly, expressly, and unequivocally stated otherwise.

6 Congress's clear purpose would be thwarted if parties were successful in
 7 suing a state for violating § (a)(30)(A)'s provisions. With the Boren
 8 Amendment's repeal, there is no federal Medicaid statute requiring that
 9 reimbursement rates be set based on provider costs. Interpreting § (a)(30)(A) as
 10 establishing a reasonable cost based reimbursement standard that providers or
 11 others could judicially enforce would nullify Congress's intent in repealing the
 12 Boren Amendment. This would be true regardless of the vehicle used in framing
 13 the complaint, whether it is §1983 or the Supremacy Clause.

14 IV

15 **THE STATE RETAINS SOVEREIGN IMMUNITY AND PLAINTIFFS'** 16 **LAWSUIT IS BARRED BY THE ELEVENTH AMENDMENT**

17 The State retains sovereign immunity under the United States Constitution
 18 against the relief Plaintiffs seek because the protection of a conferred federal right
 19 is not involved. The Eleventh Amendment reaffirmed that states have sovereign

20
 21 itself that it be judicially enforced. Thus, on that basis alone, the Social Security Act fails the four-
 22 part test for whether a federal statute creates an implied right of action, as set forth in *Cort v. Ash*,
 23 422 U.S. 66 (1975). Even though the Social Security Act itself contains no indication of
 24 Congressional intent that the Act be judicially enforced, Congress expressly stated its intent in 42
 25 U.S.C. §1983, that lawsuits may be filed seeking to enforce "rights" contained in the Social Security
 26 Act. *Wilder*, 496 U.S. at p. 509, n. 9. But whether a federal statute creates an implied right of action
 27 or whether it can be enforced under 42 U.S.C. §1983 "overlap in one meaningful respect - in either
 28 case [the Court] must first determine whether Congress intended to create a federal right." *Gonzaga*
v. Doe, 536 U.S. 273, 283 (2002). Furthermore, if a federal statute creates no "rights" enforceable
 under 42 U.S.C. § 1983, then "[t]he question *whether Congress intended to create a private right*
of action [is] definitively answered in the negative. *Id.* at p. 284, quoting *Touche Ross & Co. v.*
Redington, 442 U.S. 560, 576 (1979) (emphasis added). Therefore, as *Gonzaga* held, if a federal
 statute does not create a "right" for plaintiffs, then there is *no basis for a private suit*, whether under
 §1983 or under an implied right of action. *Id.* (emphasis added).

1 immunity against federal court lawsuits seeking relief based on alleged violations
2 of federal law. *Edelman v. Jordan*, 415 U.S. 651, 662-663; *Pennhurst State*
3 *School & Hosp. v. Halderman*, 465 U.S. 88, 100 (1984); and *Alden v. Maine*, 527
4 U.S. 706 (1999).

5 However, the Supreme Court has carved out a very narrow exception for
6 lawsuits seeking prospective injunctive relief against state officials in their official
7 capacity, for the purpose of remedying an ongoing violation of federal law and for
8 the purpose of protecting federal rights. *Ex parte Young*, 209 U.S. 123 (1908).

9 As the Ninth Circuit held in *Sanchez*, § (a)(30)(A) does not create a
10 judicially enforceable "right" for providers or recipients. The Supremacy Clause
11 "is not a source of any federal rights." Rather, it "secure[s] federal rights by
12 according them priority whenever they come in conflict with state law." *Chapman*
13 *v. Houston Welfare Rights Organization*, 441 U.S. 600, 613 (1979).

14 Each state is a sovereign power within the federal system, and sovereignty
15 signifies that a state may not be amenable to suit without that state's consent.
16 *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 54 (1996). The United States
17 Supreme Court has consistently reaffirmed that "federal jurisdiction over suits
18 against unconsenting States was not contemplated by the Constitution when
19 establishing the judicial power of the United States." *Id.* (citations and internal
20 quotation marks omitted). This rule is based on the principle that any attempt to
21 assert federal jurisdiction over a State in a private action brought without the
22 State's consent is barred because sovereign immunity protects against "the
23 indignity of subjecting a State to the coercive process of judicial tribunals at the
24 instance of private parties." *Puerto Rico Aqueduct and Sewer Authority v. Metcalf*
25 *& Eddy, Inc.*, 506 U.S. 139 (1993) (internal quotation marks omitted).

26 Plaintiffs' remedy in the instant matter is to recover money against the State
27 for funds above the 5% payment reduction. The Eleventh Amendment bars a
28 lawsuit when relief must be paid from public funds in the state treasury. The

1 Supreme Court explained:

2 [W]hen the action is in essence one for the recovery of money
3 from the state, the state is the real, substantial party in interest
4 and is entitled to invoke its sovereign immunity from suit even
5 though individual officials are nominal defendants.

6 *Ford Motor Co. v. Dep't of Treasury*, 323 U.S. 459, 464 (1945).

7 A central objective of the Eleventh Amendment is to prevent federal court
8 judgments that must be paid directly out of state funds. *Hess v. Port Authority*
9 *Trans-Hudson Corp.* 513 U.S. 30, 48 (1994); *Quern v. Jordan*, 440 U.S. 332, 337
10 (1979). Any such payment constitutes damages against the state prohibited by the
11 Eleventh Amendment. Therefore, merely labeling the requested relief as
12 prospective is insufficient to invoke *Ex parte Young*.

13 Although the *Ex parte Young* doctrine allows injunctive relief that might
14 have an ancillary effect on a state treasury, it does not allow an award for
15 monetary relief that is the practical equivalent of money damages, even if this
16 relief is characterized as equitable. *Edelman*, 415 U.S. at 666-668. In *Edelman*,
17 the Supreme Court made clear that the doctrine of *Ex parte Young* permits suits for
18 prospective injunctive relief only, and that the Eleventh Amendment prevents a
19 federal court from awarding relief that will be paid out of the state treasury, even if
20 the suit is brought against a state officer rather than the state itself. *Id.* The
21 primary purpose driving this lawsuit is to obtain funds from the State above the
22 5% payment reduction. The effect of any grant of relief in this case is beyond just
23 an ancillary effect on the state treasury.

24 Furthermore, as noted earlier, prospective injunctive relief for Plaintiffs
25 pursuant to *Ex parte Young* is not available for a violation of § 1396a(a)(30)(A)
26 because their federal "rights" are not involved. See *Edelman v. Jordan*, 415 U.S.
27 651.

28 In the event that Plaintiffs' Supremacy Clause challenge is upheld, the
Department did not act arbitrarily and capriciously. The Department is acting in

1 accordance with its obligations under state and federal law and the State Plan. It is
 2 exactly this absence of wrongful conduct on the part of the Department that
 3 distinguishes the facts of this case from cases that allowed lawsuits to proceed
 4 against state officials even with substantial ancillary effects on the state treasury.
 5 *See e.g. Milliken v. Bradley*, 433 U.S. 267, 289-290 (1977) (wrongful conduct was
 6 violation of duty to desegregate). Thus, the *Ex parte Young* doctrine has no
 7 application here, and the Eleventh Amendment bars this action from proceeding
 8 against the Department.

9 In summary, the State retains sovereign immunity against any judicial relief,
 10 including prospective injunctive relief, for alleged violation of section
 11 § (a)(30)(A).

12 V

13 THE SEPARATION OF POWERS DOCTRINE BARS THIS COURT 14 FROM GRANTING THE REQUESTED RELIEF

15 Pursuant to the of separation of powers doctrine, a court may not issue
 16 mandate to compel appropriations. Only the legislature may appropriate funds.
 17 *Hopkins v. Saunders*, 93 F.3d 522, 527 (8th Cir. 1996) (citing *Dover Elevator Co. v.*
 18 *Arkansas State Univ.*, 64 F.3d 442, 447 (8th Cir. 1995); CAL. CONST., art. III, § 3.

19 Granting Plaintiffs' preliminary injunction motion would require this Court
 20 to legislate and therefore violate the separation of powers doctrine. Neither a
 21 court nor an executive agency is permitted to revise or rewrite law to force a
 22 constitutional interpretation. This rule applies even in the case of a facial
 23 challenge.⁹

24 It is clear Plaintiffs will attempt to dispute any payment reduction and is
 25 asking this Court to step into the shoes of the Legislature to determine the amount

26
 27 9. "The canon of construction that a court should strive to interpret a statute in a way that
 28 will avoid an unconstitutional construction . . . is "not a license for the judiciary to rewrite the
 language enacted by the legislature." *Chapman v. United States* (1991) 500 U.S. 453, 464 (quoting
U.S. v. Monsanto, 491 U.S. 600, 611 (1989)).

1 of any payment reduction which violates the Separation of Powers Doctrine.
 2 Granting Plaintiffs' preliminary injunction motion prevents the Legislature from
 3 doing its job at a time that is unprecedented given the fiscal and budgetary crisis
 4 facing the State.

5 VI

6 PLAINTIFFS LACK PRUDENTIAL STANDING

7 There are prudential rules of standing that "apart from Article III's
 8 minimum requirements, serve to limit the role of the courts in resolving public
 9 disputes." *Warth v. Seldin*, 422 U.S. 490, 500 (1975).^{10/}

10 In summary plaintiffs in this case are health care providers who have no
 11 "rights" under the federal law they seek to enforce. Therefore, they fail to meet
 12 the prudential rules of federal court standing.

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26 10. As the Supreme Court later explained the prudential rules of standing, the "judiciary
 27 seeks to avoid deciding questions of broad social import where no individual rights would be
 28 vindicated." *Gladstone Realtors v. Village of Bellwood*, 441 U.S. 91, 99-100 (1979). It is essential
 for standing that plaintiffs have been injured "by conduct that violates someone's . . . rights." *Id.* at
 103. n.9.

CONCLUSION

The Department respectfully requests that Plaintiffs' motion for preliminary injunction be denied.


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Respectfully submitted,

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