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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

MANAGED PHARMACY CARE, a California corporation; INDEPENDENT LIVING CENTER OF SOUTHERN CALIFORNIA, INC., a California corporation; GERALD SHAPIRO, Pharm.D., doing business as Uptown Pharmacy & Gift Shoppe; SHARON STEEN, doing business as Central Pharmacy; and TRAN PHARMACY, INC., a California corporation, Plaintiffs, **v.** **DAVID MAXWELL-JOLLY, Director of Department of Health Care Services of the State of California,,** Defendants.	CV09-0382-CAS (MANx) **DEFENDANT'S MOTION TO ALTER OR AMEND, AND CLARIFY ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF** Date: April 6, 2009 Time: 10:00 a.m. Courtroom: 5 Judge The Honorable Christina A. Snyder Trial Date TBA Action Filed: 1/16/2009

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INTRODUCTION

As this Court is aware, there have been a flurry of lawsuits filed as a result of the Medi-Cal payment reductions. Plaintiffs filed their Motion for Preliminary Injunction on February 2, 2009. Oral argument was held on February 23, 2009. The Court granted the preliminary injunction on February 27, 2009. Defendant now files this Motion to Alter or Amend, and Clarify the Order on the grounds listed below.

ARGUMENT

I. THIS COURT IS AUTHORIZED TO ALTER, AMEND OR VACATE ITS ORDER GRANTING PLAINTIFFS' REQUEST FOR PRELIMINARY INJUNCTION DATED FEBRUARY 27, 2009

Rules 6 and 59(e) of the Federal Rules of Civil Procedure provide that this Court, on motion by a party, may alter, amend or vacate a judgment. Alter or amend means "a substantive change of mind by the court." *Miller v. Transamerican Press, Inc.*, 709 F.2d 524, 527 (9th Cir. 1983). In addition, this Court may reconsider, vacate or set aside its judgment. *Ortiz v. Gaston County Dyeing Machine Co.*, 277 F.3d 594, 597, n. 1 (1st Cir. 2002); *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 502 (5th Cir. 2000); *Turner v. Burlington Northern Santa Fe R.R. Co.*, 338 F.3d 1058, 1063 (9th Cir. 2003).

The district court has considerable discretion in considering a rule 59(e) motion. The grounds for a motion to alter, amend or vacate are, generally, (1) to correct "manifest error of law or fact upon which the judgment is based," (2) "newly discovered or previously unavailable evidence," (3) to prevent "manifest injustice," and (4) an intervening change in the "controlling law." *Turner v. Burlington*, 338 F.3d at 1058, 1063. Finally, challenging the district court's analysis of evidence is proper pursuant to a rule 59(e) motion. *Tipati v. Henman,* 845 F.2d 205, 206, n. 1 (9th Cir. 1988).

In the matter at hand, the Court committed manifest error of law or fact in the Order granting Plaintiffs' request for preliminary injunction by: (1) finding that the

California Legislature had a duty to consider "any of the relevant factors" prior to the implementation of AB 1183, see Order, 9:2-3; 10:1-3;12:23-24; (2) finding that the Legislature did not consider any of the said relevant factors, *see* Order, 10:7-28; 12:14-18; and (3) improperly analyzing the evidence regarding the aggregate amount of Medi-Cal reimbursement for all drugs, including multi-source drugs.

II. THE COURT COMMITTED MANIFEST ERROR OF LAW OR FACT BY FINDING THAT THE LEGISLATURE HAD A DUTY TO CONSIDER ANY OF THE RELEVANT FACTORS

The Order granting Plaintiffs' request for preliminary injunction dated February 27, 2009, establishes a new judicial rule that a state Medicaid agency cannot implement a reimbursement change mandated by its state Legislature, even if the state Medicaid agency has conducted a formal rate analysis or study and determined that the reimbursement change fully complies with federal Medicaid law, if the Legislature did not in fact consider the "relevant factors" prior to passing the statute, see Order, 9:2-3; 10:1-3;12:23-24. Defendant has been unable to find any previous court decision invalidating a statutorily mandated Medicaid provider payment change solely on the basis that a state legislature failed to conduct the access and/or the efficiency, economy, and quality of care (EEQ) analysis pursuant to 42 U.S.C. § 1396a(a)(30)(A) (hereinafter § (a)(30)(A)), especially when the state agency has done an analysis and determined that the payment change complies with federal law.

In fact, a review of the Order itself supports Defendant's contention. In discussing the Ninth Circuit ruling in *Orthopaedic*, this Court cited the following conclusion from the Ninth Circuit:

> [T]he **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 costs studies, its own or

> others', that provide reliable data as the basis for its rate setting.

See Order, 7:11-19; emphasis added.

> The Order goes on to state,
> 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.

See Order, 8:3-6; emphasis added.

Further, the Ninth Circuit in *Orthopaedic II/III* stated, "the Department of Health Services of the State of California, is the state agency responsible for the administration of California's version of Medicaid, the Medi-Cal program." *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 at 1493. The Ninth Circuit went on further to state that "California's state plan requires the Department to develop an evidentiary base or rate study . . .," *Orthopaedic Hospital*, 103 F.3d at 1494, and concluding with "the state plan **also allows the legislature to adjust the rates** so long as the requirements of 42 C.F.R. Part 447 are met." *Id*, emphasis added.

Inexplicably, this Court then concluded that the Legislature has a duty to consider these same factors, in direct contravention to the findings in both *Orthopaedic II/III* and *Sanchez*. This Court erroneously concluded that "Orthopaedic II/III [held] that the body responsible for rate setting must consider the relevant factors contemporaneously with the adoption of the rates," *see* Order, 12:14-16.

There is nothing in federal Medicaid law supporting the proposition that for a state law regarding Medicaid reimbursement to be valid, the state legislature[1] must analyze or otherwise consider the access or EEQ criteria in some manner, and must

[1] As noted by this court, "the body responsible for the rate setting."

do so "contemporaneously with the adoption of the rates." Moreover, the Order is unclear on what would be sufficient for the Legislature to have adequately considered.

If there is a legal obligation in § (a)(30)(A) to conduct a study, analysis, or give some sort of consideration of "EEQ" in making rate changes, the federal Medicaid law is clear that any such obligation would not be on a state's legislature, but rather on a state's single state agency.

Specifically, 42 United States Code § 1396a(a)(5) provides that a State Plan must "provide for the establishment or designation of a single state agency to administer or to supervise the administration of the plan." Federal regulations implementing this statute specify that it is the "single state agency" that is to "administer or supervise the administration of the plan." Thus, if § (a)(30)(A) requires a state to do a study or analysis before a change in reimbursement is implemented, then that responsibility would be on the single state agency. In California, the single state agency is the Department, not the Legislature.

The Department's position is supported by both statute and case law. In *Orthopaedic*, the Ninth Circuit held that the requirements of section § (a)(30)(A) are "more flexible" than the requirements of the repealed federal statute commonly known as the Boren Amendment, which required cost based rates for hospitals and nursing facilities.

However, the federal Medicaid law was clear that the responsibility for doing the required findings was that of the single state agency. Federal regulations implementing the Boren Amendment specified that it was the responsibility of the state agency to make findings that payment rates were reasonable and adequate as required by the Boren Amendment. *See* 42 CFR § 447.253(b). *In Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498 (1990), the Supreme Court specifically indicated that under the Boren Amendment, state Medicaid agencies were responsible for doing the required findings. (*Wilder*, 496 U.S. at p. 514, n. 11,

discussing the federal regulations, including a quote of Federal Register language stating that it is the "explicit statutory responsibility of the state agency to make its findings.")

In *Folden v. Washington State DSHS*, 981 F.3d 1054 (9th Cir. 1992), the district court in the underlying case 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. *Folden* noted that states were 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 payment rates meet the substantive requirements of the Boren Amendment. *Folden*, 981 F.3d. at 1057.

Therefore, this Court committed manifest error of law or fact in the Order granting Plaintiffs' request for preliminary injunction when it concluded that the Legislature had a duty to consider "any of the relevant factors" prior to the implementation of AB 1183, even though the single state agency (Department) that is responsible for the administration of the Medi-Cal program conducted an analysis and determined the five percent payment reduction of AB 1183 complied with § a(30)(A).

III. THE COURT COMMITTED MANIFEST ERROR OF LAW OR FACT BY CONCLUDING THAT THE LEGISLATURE FAILED TO HOLD ANY PUBLIC OR LEGISLATIVE HEARINGS PRIOR TO THE ENACTMENT OF AB 1183

Plaintiffs made it very clear in their Motion for Preliminary Injunction that this is a "Supremacy Clause preemption case," (*see* Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, 2:11), therefore not raising any claim that a public process violation is at issue. The focus of the Supremacy Clause argument in this case was that AB 1183 was an obstacle to the Congressional intent of § a(30)(A), a funding statute. Understandably, Defendant did not believe it was necessary to dispute Plaintiffs' misleading legislative history of AB 1183 in its

written opposition since this was a "Supremacy Clause preemption case." However, at oral argument, Defendant did dispute Plaintiffs' misleading public process characterization. Defendant requested that the Court take judicial notice of the legislative digest of AB 1183 and noted that AB 1183 had gone through the Legislative Budget Conference committee. As this Court is aware, this is a significant case with significant issues and the importance of having an accurate record should not be minimized.

This Court, nonetheless, committed manifest error of law or fact by accepting Plaintiffs' inaccurate argument that the legislative history of AB 1183 demonstrates that the Legislature "did not in fact consider the relevant factors prior to passing AB 1183," *see* Order, 10:4-28, 11:1-2, and disregarding Defendant's oral argument on this issue.

As argued previously, the Legislature does not have the duty to consider what the Court has termed the "relevant factors" prior to enacting AB 1183. But even assuming that it did, Plaintiffs have misled this Court to believe that the "relevant factors" could not have been considered as demonstrated by the legislative history. Specifically, the Order cites Plaintiffs' contention, in part, that:

> [o]n 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 . . . by the Senate . . and was immediately passed by the Assembly before 2:08 a.m. of September 16, 2008 . . . .

See Order, 10:21-27; emphasis added.

Contrary to what the Plaintiffs' counsel has led this Court to believe, the provisions that were included in AB 1183, and enacted into law in September 2008, did not magically appear in a few days. Rather, there were multiple hearings beginning in May 2008 related to proposals to modify the 10% payment reductions

mandated by Assembly Bill 5 (*see* Decl. of Katie Trueworthy, a true and correct copy attached as Ex. A to Defendant's Request for Judicial Notice filed concurrently herewith, *see* Legislative Counsel's Digest on AB 1183, a true and correct copy attached as Ex. B to Defendant's Request for Judicial Notice filed concurrently herewith.)

Clearly, as demonstrated by Ms. Trueworthy's accurate review of the legislative history of AB 1183, Plaintiffs' characterization of a midnight passage was misleading. As stated by Ms. Trueworthy, the Department's Deputy Director for Legislative and Governmental Affairs:

> Although AB 1183 became the vehicle for the rate reductions, the Senate proposal and theAssembly proposal was released on May 30, 2008 in public hearings held by the Senate Budget Committee and the Assembly Budget Committee. Between May 2008 and September 2008, I am personally aware of DHCS employees providing information, technical assistance, and responses to numerous inquiries to legislative staff members concerning the various 5% and 1% rate cuts that were included in AB 1183. On May 30, 2008, I personally attended and observed portions of both the Assembly and Senate proceedings. These hearings were well attended by members of the public, lobbyists, governmental employees, and other stakeholders.

See, Trueworthy Decl., ¶ 5, attached hereto as Ex. B.

Therefore, this Court committed a manifest error of law or fact by accepting Plaintiffs' misleading and inaccurate argument that the legislative history of AB 1183 demonstrated that the Legislature "did not in fact consider the relevant factors prior to passing AB 1183," *see* Order, 10:4-28, 11:1-2.

IV. THE COURT COMMITTED MANIFEST ERROR OF LAW OR FACT BY FINDING IRREPARABLE HARM RELATED TO MULTI-SOURCE DRUGS

The Order needs to be altered or clarified in regard to the irreparable harm allegedly caused by AB 1183 in relation to multi-source drugs. The evidence

presented by the Department demonstrated that even after the five percent payment reduction of AB 1183, the aggregate Medi-Cal reimbursement for multi-source drugs was 107% to 137% of pharmacy costs. (*See*, Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction, Ex. A-A, AB 1183 Analysis, pp. 8-12; Ex. C, Gorospe Decl., ¶¶ 9, 22.)

> The Order focused on single source drugs. As stated in the Order:
>
> 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 Order, 16:6-10; emphasis added.

If the Court concludes that anything less than 100 percent reimbursement of pharmacy costs causes irreparable harm as a result of potential equal access issues, the flip side of that conclusion is that anything above 100 percent reimbursement does not cause irreparable harm. Therefore, as demonstrated by the evidence presented by the Department, multi-source drugs should not be included in the Order. The Order's passing reference to the Wilson declaration that "with regard to generic drugs . . . 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" (*see* Order, 13:18, 14:1-2), is not be enough to overcome the fact that Plaintiffs' reimbursement for multi-source drugs was 107% to 137% of pharmacy costs.

Moreover, if compensation of at least 100% of costs does not cause irreparable harm, the Court's Order should be modified to only enjoin anything more than a 3% payment reduction for single source drugs.

Therefore, the Court committed manifest error of law or fact by grouping

single-source and multi-source drugs together in its conclusion on irreparable harm. If the Court is not inclined to alter or amend the Order on the basis that the Legislature does not have the duty to conduct the analysis, the Order needs to be altered so that the multi-source drugs are not affected by the injunction, or at the very least clarified as to why irreparable harm is shown as to AB 1183's effect on reimbursement for multi-source drugs. Additionally, the Order should be altered to only enjoin a payment reduction that exceeds 3% on single source drugs.

CONCLUSION

Defendant respectfully requests that the Motion to Alter or Amend, and Clarify the Court's Order granting Plaintiffs' request for preliminary injunction dated February 27, 2009, be granted.

Dated: March 13, 2009

Respectfully submitted,

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DECLARATION OF SERVICE BY OVERNIGHT COURIER

Case Name: **Managed Pharmacy Care, et al. v. Maxwell-Jolly, D., et al.**

No.: **2:09-cv-00382-CAS-MAN**

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter; my business address is: 300 South Spring Street, Suite 1702, Los Angeles, CA 90013.

On March 13, 2009, I served the attached **DEFENDANT'S MOTION TO ALTER OR AMEND, AND CLARIFY ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THREOF** by transmitting a true copy via electronic mail. In addition, I placed a true copy thereof enclosed in a sealed envelope, in the internal mail system of the Office of the Attorney General, for overnight delivery, addressed as follows:

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Stanley L. Friedman
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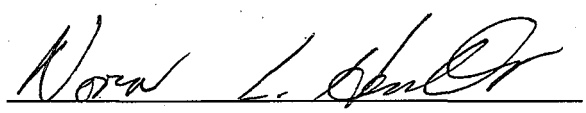
Los Angeles, Ca 90071-1631

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on March 13, 2009, at Los Angeles, California.

Norma L. Herrera-Orr
Declarant


Signature

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