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11	Independent Living Center of Southern California,		
Inc.; Gerald Shapiro, Pharm.D., dba Uptown Pharmacy & Gift Shoppe: Sharon Steep, dba			
	Pharmacy & Gift Shoppe; Sharon Steen, dba Central Pharmacy; and Tran Pharmacy, Inc.,		
13	3 ,		
14	IN THE UNITED STATES	DISTRICT CO	OURT
15 16	CENTRAL DISTRICT OF CALIFORN	IA, WESTERN	N DIVISION
	Independent Living Center of	No. 2:09-CV-0382 CAS (MANx)	
17	Southern California, Inc., et al.,	Date:	November 2, 2009
18	Plaintiffs, 1	Time:	10 a.m.
	-VS	Courtroom:	5
19	DAVID MAXWELL-JOLLY,	Judge:	Hon. Christina A.
20	Director of Department of Health Care Services of State of California,		Snyder
21	Defendant, /		
22	NOTICE OF MOTION TO ENFO	RCE PREL	IMINARY INJUNCTION
23			
24	¹ Plaintiff Managed Pharmacy Care has bee	n voluntarily di	smissed as a party.
25			
26			

1 2 2	AND, ALSO, TO STAY AND PRELIMINARILY ENJOIN IMPLEMENTATION OF PAYMENT CUTS FOR LACK OF PUBLIC NOTICE AS REQUIRED BY 42 C.F.R. 407.205 TABLE OF CONTENTS
3	MEMORANDUM IN SUPPORT OF ORDERS AND STAY 6
5	MEMORANDUM IN SUPPORT OF ORDERS AND STAT
6	PART ONE: ENFORCEMENT OF ORDERS
7	1. The fact that the Director is directed by both (1) Sec. 14105.45 Welf. & Inst. Code and Sec. 134105.455 Welf. & Inst. Code, and (2) California
8	Constitution, article 3.5, to implement the:
- the payment cuts under the U	 generics payment cut of Sec. 14105.45 Welf. & Inst. Code, the payment cuts under the Upper Billing Limit statute of Sec. 14105.45 Welf. & Inst. Code,
10	and is willing to unilaterally without any statute, now cut pharmacy
11	payments by 4% without any Legislative statute at all, requires the
12	Court to take immediate firm action to prevent the Director from violating the amended Injunction of August 18, 2008, and the
	5% injunction of February 27, 20099
14	2. The Supreme Court and other cases have established that an
15	injunction must still be obeyed even if the enjoined party
16	contends the injunction has been mooted. I.e., as long as the injunction is in force, the enjoined party must still obey unless
17	the enjoined party applies to the Court and meets the burden of
	showing the injunction has become moot, and, thereby, obtains
18	an order which modifies or terminates the injunction
19	
20	PART TWO: INJUNCTION AND STAY OF PAYMENT CUTS FOR
21	FAILURE TO GIVE PUBLIC NOTICE REQUIRED BY
22	42 C.F.R. § 407.205
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It must be emphasized that Plaintiffs are only exercising procedural
rights in this motion to seek to stop these insane and life-destroying
payment cuts to Medi-Cal pharmacies. I.e., Plaintiffs are not in this motion seeking to bar the payment cuts on the basis that they violate
the Medicaid rate-setting statute or any provisions of law: only, that as
of today, the Director is still subject to the two outstanding injunctions against him, not to reduce any payments to Medi-Cal pharmacies; plus,
he has not complied procedurally with the public notice requirement
of 42 C.F.R. § 447.205
3. The DHCS cut in payments to pharmacies in the Medi-Cal fee-for-
service and managed care programs, which commenced September 26, 2009, was because First Data Bank changed the standard and
formula for AWP, by which Medi-Cal rates are set, from the
existing standard or formula of 1.25 of WAC, to 1.20 of WAC. This was a change in the "methods and standards" of the
agency (i.e., DHCS) "for setting payment rates" for pharmacy
services, yet, no public notice has been provided as provided by 42 C.F.R. § 447.204
12 0.1 1.6. § 117.20 1
Summary and prayer

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2	Cases
4	Firefighters v. Stotts, 467 U.S. 561 (1984)
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6	Independent Living Center v. Shewry, 543 F.3d 1050 (9th Cir. 201608)
7 8	Independent Living Center v. Shewry, 572 F.3d 644 (9th Cir. 2009). 13
9	<i>Missouri D.S.S. v. Sullivan</i> , 957 F.2d 542 (8th Cir.1992)
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12	700 F.2d 145 (4th Cir. 1983)
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1	TABLE OF AUTHORITIES (Cont.)
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3	42 U.S.C. § 1396(a)
4	42 C.F.R. § 407.205
5	42 C.F.R. § 447.204
7	Welfare & Institutions Code § 14105
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12	42 Code of Federal Regulations, sec. 447-204
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26	NOTICE OF MOTION, AND MOTION, TO ENFORCE ORDERS, AND TO STAY PAYMENT CUTS -iv-

1	TO THE DEFENDANT DAVID MAXWELL-JOLLY, (successor in office to
2	SANDRA SHEWRY), Director of Department of Health Services of the State of
3	California, and his attorneys of record:
4	PLEASE TAKE NOTICE that at 10 a.m. on November 2, 2009, in
5	Courtroom 5 of the above-entitled Court, located at 312 North Spring Street, Los
6	Angeles, California, that each of the plaintiffs Independent Living Center of
7	Southern California, Inc.; Gerald Shapiro, Pharm.D., dba Uptown Pharmacy & Gift
8	Shoppe; Sharon Steen, dba Central Pharmacy; and Tran Pharmacy, Inc., dba Tran
9	Pharmacy, (herein "Plaintiffs"), will move, – and each of the Plaintiffs does hereby
10	move, – for each of the following orders; namely:
1112	(A) for an order which commands the Defendant DAVID MAXWELL-
13	JOLLY, Director of the California Department of Health Care Services ("DHCS"),
13	- who is the successor in office to the prior Director, SANDRA SHEWRY, - and
15	his agents, servants, employees, attorneys, successors, and all those working in
16	concert with him, as follows;
17	- (1) to refrain from implementing, and to stay, § 14105.45 California
18	Welfare & Institutions ("Welf. & Inst.") Code, including (without limitation
19	thereby) refraining from reducing any payments to pharmacies in respect to
20	prescription drugs in the Medi-Cal fee-for-service program, on account of or
21	related to any provision in the aforesaid § 14105.45 Welf. & Inst. Code
22	which was enacted on July 28, 2009 by Assembly Bill X4 5 and filed with
23	the California Secretary of State as Chapter 5, Statutes of 2009-10 Fourth
24	Extraordinary Session;
25	

1	- (2) to refrain from implementing, and to stay, § 14105.455 Welf. &
2	Inst. Code, including (without limitation thereby) refraining from reducing
3	any payments to pharmacies or for prescribed medicines in the Medi-Cal fee-
3	for-service and managed care programs; including without limitation
5	thereby, prescribed over-the-counter medicine, pursuant, related, or to carry
6	out any provision of the aforesaid § 14105.455 Welf. & Inst. Code;
7	- (3) to refrain from reducing any payments to pharmacies in respect to
8	prescription drugs in the Medi-Cal fee-for-service program on account of or
9	related to (A) any markdown or rollback, on or about September 26, 2009, in
10	Average Wholesale Price ("AWP") published by First Databank, Inc. and/or
11	MediSpan or other publishers, arising out of or related to the settlement and
12	or the implementation of the settlement in the First Databank, Inc. and/or
13	MediSpan AWP litigation in the U.S. District Court (D.Mass.) in Boston,
14	Massachusetts, (being Case No. 1:05-CV-11148-PBS, New England
15	Carpenters Health Benefits Fund, et al. v. First Databank, Inc.), (herein, the
16	"First Data Bank case"), or (B) on account of or related to all other
17	markdowns or rollback, or reduction, on or about September 26, 2009, and
18	continuously since the, of AWP by either or both of these pharmaceutical
19	information publishers and/or by other publishers in respect to 18,000 to
20	20,000 or more drug products (including but not limited to drug products
2122	which were the subject of the aforesaid <i>First Data Bank</i> case and/or
23	settlement); and,
2425	- (4) to refrain from reducing any reimbursement or payments to
4 3	

pharmacies for their costs to acquire brand drug products in the Medi-Cal 1 2 fee-for-service or Medi-Cal managed care program, whatsoever or at all, 3 during the pendency of this litigation or until further order of this Court; and, 4 - to refund immediately all the payments the Director has and is withholding 5 under these three new payments cuts which are the subject of the within 6 motions; and, 7 8 - save, unless and until the Defendant MAXWELL-JOLLY, Director of DHCS, or 9 a successor in office, does each and both of the following: 10 FIRST: by a regularly noticed motion, applies to and obtains an order from 11 the above-entitled Court which terminates or amends the existing August 18, 2008 12 preliminary injunction (Document 121 in Case No. 2:08-CV-03315 CAS (MANx), 13 Independent Living Center of Southern California, Inc., et al. v. Shewry, as 14 amended by orders filed August 27, 2008 (Document 124) and September 15, 2008 15 (Document 176), -- (hereinafter, "the amended Order"), and, similarly, also so 16 applies to and obtains an order from the above-entitled Court in the within 17 18 companion case No. 2:09-CV-0382 CAS (MANx), Managed Pharmacy Care et al. 19 v. Maxwell-Jolly, which terminates or amends the existing February 27, 2009 20 preliminary injunction (Docket 34), so as to permit the Defendant to reduce 21 payments to providers in the Medi-Cal fee-for-service pharmacy program, and to 22 permit the Defendant no longer comply with the amended Order in Case No. 2:08-23 CV-03315 CAS (MANx) and with the February 27, 2009 order in Case No. 2:09-24 CV-00382 CAS (MANx). 25

- SECOND, als	so, publishes a public notice, as required by 42 U.S. Code of
Regulations, sec. 447.	205, in respect to each one or any combination of, the three
changes in Statewide	methods and standards for setting and paying Medi-Cal
payment rates for serv	rices, namely:
- the char	nge in Statewide methods and standards, both in the Medi-Cal
fee-for-service	program and also the Medi-Cal managed care program, for
setting and pay	ing Medi-Cal payment amounts, (which are called "Maximum
Allowable Ingre	edient Costs" or "MAIC" rates), for services, which changes
were enacted by	the amendment of § 14105.45 Welf. & Inst. Code on July
28, 2009 by Sec	etion 38 of Assembly Bill X4 5, in respect to both the Medi-
Cal fee-for-serv	vice pharmacy program and the Medi-Cal managed care
pharmacy progr	ram;
- the char	nge in Statewide methods and standards, both in the Medi-Cal
fee-for-service progra	am and also the Medi-Cal managed care program, for setting
and paying Medi-Cal	payment amounts to pharmacy providers, (which are called
"Upper Billing Limit"), which changes were enacted in (new) § 14105.455 Welf. &
Inst. Code on July 28,	2009 by Section 39 of Assembly Bill X4 5, in respect to both
the Medi-Cal fee-for-s	service pharmacy program and the Medi-Cal managed care
pharmacy program;	
- the char	nge in Statewide methods and standards, both in the Medi-Cal
fee-for-service progra	m and also the Medi-Cal managed care program, for setting
and paying Medi-Cal	payment amounts, and the change in payment amounts,

resulting from the markdown by First Databank, Inc. and other pharmacy industry 1 2 publishers, on or about September 26, 2009 and continuing, of the AWP, from any 3 level over 1.20 of Wholesale Average Cost ("WAC"), down to the new level of 4 1.20 of WAC, for 18,000 to 20,000 or more drug products (each of which has a 5 National Drug Code ("NDC"), identification code number; 6 with such public notice shall be published in the form, manner, and in compliance 7 with all provisions of 42 Code of Federal Regulations § 447.205; and, with the Defendant also ordered to email to Plaintiffs' counsel of record, and deliver to each 9 of their offices of record by overnight express, any and all publications which the 10 Defendant does publish, if any, to comply with this Order of the Court; all, without 11 without prejudice to Plaintiffs subsequently filing all other complaints and 12 13 motions, on all other grounds, to obtain the same orders hereinabove specified, or 14 any other orders or relief; which right to sue for such same or other orders, is 15 hereby expressly reserved, and is not waived, by any of the Plaintiffs; and further, 16 that the Director be ordered to refund immediately all the payments the Director has 17 and is withholding under these three new payments cuts which are the subject of 18 the within motions, until he duly publishes a public notice in respect to these three 19 new changes in standards and methods for setting Medicaid payment rates; and, 20 **THIRD**: That the Director, exercising his powers under Sec. 14105, Cal. 21 Welf. & Inst. Code to set all policies and rates and regulations in DHCS both under 22 State law and the Single State Agency provisions of the Medicaid Act and the State 23 Plan filed by California with HHS, take all steps and issue all orders necessary to 24 25

1	all parts of the Medicaid program in California, including both the Medi-Cal fee-
2	for-service program and the Medi-Cal managed care program, to cease at once each
3	of the three practices set forth above, so that no rates are lowered in any part of the
4	Medi-Cal program by reason of Sections 14105.45 and 141-05.455 of Cal. Welf. &
5	Inst. Code, by reason of the AWP markdown, and by reason of failure of the
6	Department to publish any public notice as required by 42 C.F.R. sec. 447.205.
7 8	Further, in making the within motions the Plaintiffs do not intend to waive
9	and do not waive, and reserve, any and all rights of theirs to file new and different
10	lawsuits, motions, or claims for relief respecting any and all of the acts of the
11	Defendant MAXWELL-JOLLY which are the subject of the within motions.
12	These above motions and also the request for stay shall be made and based
13	upon all the papers on file in both the aforesaid cases, this notice of motion, the
14	enclosed Memorandum in support of this motion; the declarations filed this date in
15	the above-entitled case of:
16	- Thu-Hang Tran, Pharm.D.
- Gerald Shapiro, Pharm.D Richard D. Wilson, C.P.A Lynn Rolston	
	- Lynn Rolston
19	- John Cronin
20	and the requests for judicial notice filed herewith and which may be filed in respect
21	to this motion. This motion and also the request for stay shall be made upon all the
22	grounds set forth in the within Memorandum in support of this motion.
23	Dated: October 8, 2009
24	Respectfullyy submitted,
25	

1	LYNN S. CARMAN STANLEY L. FRIEDMAN
2	/s/ Lynn S. Carman
3	/s/ Lynn S. Carman Attorneys for Plaintiffs Independent Living Center of Southern
4	California, Inc., et al.
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26	NOTICE OF MOTION AND MOTION TO ENFORCE ORDERS AND TO STAY PAYMENT CUTS

MEMORANDUM IN SUPPORT OF ORDERS AND STAY

This Court issued its August 18, 2008 preliminary injunction and its amending
orders of August 27, 2008 and Sept. 15, 2008, (herein, "amended Order"), with the
expectation that it be obeyed. The order, with its amendatory orders, specifically
commanded the Director and all those working in concert with her, to refrain, among
other things, from "reducing by ten percent payments under the Medi-Cal fee-for-
service program for prescription drugs provided on or after July 1, 2008."
The State, before the ink was dry on the injunction, violated it by the
Legislature simply enacting a new law, (Assembly Bill 1183 on September 30, 2008)
to "terminate" the 10% reduced payments law but, without let, now reducing Medi-
Cal payments by 5% in the Medi-Cal fee-for-service program, to commence March 1,
2009.
Plaintiffs claimed that the new law clearly violated the 10% injunction because
the Legislature simply did the same thing all over again, with no change, except to
lower the 10% payment cut to a 5% payment cut.
However, the Court on November 17, 2008, denied Petitioner's motion for an
order to enforce the 10% injunction, without prejudice, (i.e., with leave to amend).
(Minutes, November 17, 2009, being Docket No 239).
So Plaintiffs had to file an entirely new suit and prove the same thing,
redundantly, all over again: and the Court also, on February 27, 2008, issued a
preliminary injunction to also enjoin the 5% payment cut of Assembly Bill 1183.

The ink was not dry on that second injunction when the Legislature thrice, and
quadruply, violated the 10% injunction and now the 5% injunction all over again, by
enacting two new pharmacy payment cuts in AB X4 5 on July 28, 2009, - namely,
§ 14105.45 Cal. Welf. & Inst. Code, for the Director to reduce the Maximum
Allowable Ingredient Cost ("MAIC") limit on payments Medi-Cal pharmacies for
certain generic drugs, and a fancy new law, – to wit, § 14105.455 Cal. Welf. & Inst.
Code, (the "Upper Billing Limit law"), to reduce the amounts paid to Medi-Cal
pharmacies by capping payments to be no higher than the best price the pharmacy
gives private insurance companies, (against whom, of course, the pharmacies, not
being allowed to combine, are helpless by the insurers binding together millions of
insureds to fix the price they will pay for pharmacies' services). Accordingly,
pharmacies are forced by adhesion contracts to accept payments from private insurers
which are far less than what Medi-Cal pays them. So, this new MAIC law and the
Upper Billing Limit law are simply two more flagrant, contemptuous, and unlawful
violations of the two preliminary injunctions issued August 18, 2008 and on February
27, 2009, which prohibits the Director from reducing, by any amount, to pharmacies
for prescription drugs in the Medi-Cal fee-for-service program.
Then, on September 26, 2009, the State struck again, in violation of the 10%
and the 5% injunctions. I.e., now, the Director (1) unilaterally reduced payments to
all Medi-Cal pharmacies by 4% or more, on 18,000 to 20,000 brand drug products
which have a National Drug Code identification number, and (2) failed, neglected,

and refused to perform his purely ministerial duty, (under the exclusive powers 1 2 granted him by § 14105 Cal. Welf. & Institution to direct and control the 3 operation of the entire Medicaid program to the end that all parts of it comply 4 with the Medicaid Act), to take all actions necessary to command all parts of the 5 Medi-Cal program, including both fee-for-service and managed care, to refrain from 6 so reducing payments to pharmacies in the Medi-Cal fee-for-service and managed 7 care programs. In other words the Director simply used the happenstance of the First Data 9 Bank 4% AWP markdown, as an "excuse" – because it is no excuse, – to violate the 10 two existing injunctions against him, not to reduce any payments to pharmacies for 11 prescribed medicine in the Medi-Cal fee-for service program. 12 Also, as established by the declaration of Richard D. Wilson, C.P.A., these 13 three new cuts are, cumulatively, a 5% cut in overall payments annually to 14 15 pharmacies in the Medi-Cal program: which is exactly what the Director was enjoined 16 not to implement! 17 Therefore the Plaintiffs are requesting that the Court do what they urged the 18 Court to do back in last November: enforce the 10% injunction, and now, enforce also 19 the 5% injunction, by (1) ordering the Director not to reduce by one penny any of the 20 payments required to be made under the payment statutes which preceded the 10% 21 and the 5% cuts, initially; (2) by ordering the Director to refund, at interest all the 22 pharmacy payments he has been withholding in violation of the two existing 23 24 25

injunctions; and, (3) be ordered to make no more payment cuts in the future again,

2 unless and until the Director first applies to the Court for a finding and order that

exempts the Director from complying with the 10% and the 5% injunctions in the

future.

Conclusion on this point:

Where I have been enjoined by a court of competent jurisdiction, then if I wish to do the acts against which I have been enjoined, I must first apply to the Court to show cause why the injunction should be lifted in the circumstances I claim excuse me from obeying the injunction.

Unless we have this rule, we have no law in California. Only, the federal district court ordering the Director not to reduce payments to pharmacies for prescription drugs, but the Director repeatedly violating the injunctions as if they were never issued, without ever first showing cause to the District Court why the two injunctions should not be lifted for his newest payment cut to pharmacies.

Enough is enough! This Director must at this long last point be finally stopped in his tracks today from violating any more these existing injunctions against him on the subject of not reducing any payments for prescribed medicine in the Medi-Cal feefor-service program.

Otherwise, unless the Court acts in respect to these continued violations of its existing two injunctions, the Director is no different from your ordinary wife-beater, who beats his spouse again and again no matter how many injunctions a court issues to stop him. It is long past time, Plaintiffs say, for the Court to act in this case to enforce its two injunctions which preclude the Director from reducing by one penny

the payments otherwise due to pharmacies in the Medi-Cal fee-for-service program.

1. The Supreme Court and other cases have established that an injunction must still be obeyed even if the enjoined party contends the injunction has been mooted. I.e., as long as the injunction is in force, the enjoined party must still obey unless the enjoined party applies to the Court and meets the burden of showing the injunction has become moot, and, thereby, obtains an order which modifies or terminates the injunction.

See, the most frequently cited case of United States v. Swift, 286 U.S. 106, 119 (1932) on this point. I.e., an enjoined party who believes that an existing injunction has become mooted by subsequent events or by an amendment to existing statutes, must apply to the court for an order to modify or terminate the injunction clause which the enjoined party questions as now being moot; otherwise the enjoined party acts in contempt if the enjoined party commits acts which violate te terms of the order. See, Firefighters v. Stotts, 467 U.S. 561 (1984): an injunction which is still in force must, unless set aside, still be complied with, even if the enjoined party contends that the matter in question has become mooted.

In such an application by a State to modify or terminate an injunction which is still in force, the enjoined State has the burden of proof to show facts that events occurring since the entry of the original injunction justify approval of the modification or termination of the injunction; and if the State fails to prove that changes justify the change, the original injunction may not be disturbed. *Nelson v. Collins* 700 F.2d 145, 147 (4th Cir. 1983).

1 It must be emphasized that Plaintiffs are only exercising procedural rights in this motion to seek to stop these insane and life-destroying payment cuts 2 to Medi-Cal pharmacies. I.e., Plaintiffs are not in this motion seeking to bar the payment cuts on the basis that they violate the Medicaid rate-3 setting statute; only, that as of today, the Director is still subject to the 4 two outstanding injunctions against him, not to reduce any payments to Medi-Cal pharmacies; plus, he has not complied procedurally with the 5 public notice requirement of 42 C.F.R. § 447.205. 6 Plaintiffs contend that at this point they need not file a new substantive 7 complaint to stop these payment cuts. Plaintiffs have two sound procedural grounds for obtaining a court order to stop the cuts; namely, (1) the existence of two hardobtained injunctions which already order him not to make any payment reductions 10 to California pharmacists in respect to prescribed medicine in the fee-for-service 11 program; and (2) 43 C.F.R. § 447.205, which command the Director to publish a 12 public notice in respect to each of these three changes in methods and standards for 13 14 setting payments for Medicaid pharmacy providers in both the Medi-Cal fee-for-15 service and managed care programs. 16 (For the information of the Court and counsel, Plaintiffs' counsel are 17 preparing as fast as they can, new claims for relief based on **substantive** grounds, – 18 such as failure to comply with the Medicaid rate-setting laws and other provisions 19 of federal law. Today, however, we are only addressing **procedural** grounds for the 20 relief requested: i.e., the existence of valid outstanding injunctions which prohibit 21 these payment cuts, and the public notice requirement of 42 C.F.R. § 447.205.) 22 So, Plaintiffs will vigorously object if the Director seeks to turn these 23 procedural requests for relief, into substantive claims for relief which Plaintiffs are 24 25

not seeking today (because the Plaintiffs are going to seek relief on these substantive claims for relief, as soon as we can).² 2 3 SUMMARY AND PRAYER 4 The Plaintiffs respectfully pray the above-entitled Court to (1) order the 5 Director to cease reducing payments to pharmacies who participate in the Medi-Cal 6 fee-for-service program, as long as the 10% amended injunction of August 2008 7 and the 5% injunction of February 2009 remain in place; (2) to refund all the payments the Director is withholding under these three new cuts, (which violate the 9 existing injunctions against the Director doing this!); and (3) order the Director not 10 to make any more cuts in payments to pharmacies in the future, for any reason 11 whatsoever or at all, save and unless the Director first applies to the Court for a 12 finding and order, and receives an order, that for good cause excuses the 13 **Director** from complying any more with the 10% and the 5% injunctions, in 14 respect to such payment cuts in the Medi-Cal fee-for-service pharmacy program. 15 16 PART TWO: INJUNCTION AND STAY OF PAYMENT CUTS FOR FAILURE TO GIVE PUBLIC NOTICE REQUIRED BY 17 42 C.F.R. § 407.205 18 42 Code of Federal Regulations, § 447.205 provides: 19 20 ² Plaintiffs, out of an abundance of caution, have filed herewith a ton of 21 evidence that, should the Director attempt to turn these purely procedural motions of 22 Plaintiffs into a **substantive law** contest instead, – over our objections, – then, Plaintiffs will still overwhelmingly prevail, even were somehow the Defendants to be 23 successful in somehow turning Plaintiffs' purely procedural motions into a substantive law contest, instead. 24 25

1	"447.205 Public notice of changes in Statewide methods and standards for setting payment rates.
2	
3	(a) When notice is required. Except as specified in paragraph(b) of this section, the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services.
4	
5	(b) When notice is not required. Notice is not required if
6	(1) The change is being made to conform to Medicare levels of reimbursement.
7	(2) The change is required by court order; or,
8	(2) The change is required by court order, or,
9	(3) The change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost plus a professional fee.
10	material cost plus a professional fee.
11	(c) Content of notice. The notice must
12	(1) Describe the proposed change in methods and standards.
13	(2) Give an estimate of any expected increase or decrease in annual aggregate expenditures.
14	(3) Explain why the agency is changing its methods and standards.
15	(4) Identify a local agency in each county (such as the social services
16	agency or health department where copies of the proposed changes are available for public review.
17	
18	(5) Give an address where written comments may be sent and reviewed by the public; and,
19	(6) Give an address where written comments may be sent and reviewed by
20	the public;
21	(d) Publication of Notice. The notice must
22	(1) Be published before the effective date of the change, and
23	(2) Appear as a public announcement in one of the following publications:
24	(i) A State register similar to the Federal Register "
25	

1	[46 FR 58680, Dec. 3, 1981; 47 FR 8567, Mar. 1, 1982, as amended by 48 FR 58057, Dec. 19, 1983].
2	* * * *
3	* * * * *
4	2. The DHCS cut in payments to pharmacies in the Medi-Cal fee-for- service and managed care programs, which commenced September
5	26, 2009, was because First Data Bank changed the standard and
6	formula for AWP, by which Medi-Cal rates are set, from the existing standard or formula of 1.25 of WAC, to 1.20 of WAC.
7	This was a change in the "methods and standards" of the
8	agency (i.e., DHCS) "for setting payment rates" for pharmacy services, yet, no public notice has been provided as provided by
9	42 C.F.R. § 447.204.
10	Accordingly a permanent injunction and a stay must be issued immediately,
11	on behalf of the Plaintiffs:
12	- Sharon Steen and Gerald Shapiro, Pharm.D., in their capacity as Medi-Cal fee-for-service providers and as individual members of the public;
131415	- Tran Pharmacy, Inc., dba Tran Pharmacy, in its capacity as corporate member of the public, and as a Medi-Cal fee-for-service and Medi-Cal managed care provider; and,
16	- the Independent Living Center of Southern California, Inc., in its capacity as an independent living center who serves the disabled;
17	to enjoin the Director from reducing payments to pharmacies in both the Medi-Cal
18 19	fee-for-service program and the Medi-Cal managed care program, until the
20	Director first complies with, and publishes a public notice of this cut in provider
21	payments, as specifically required by 42 C.F.R. § 447.205.
22	Note: Each of these Plaintiffs, in the above-listed capacities, have standing
23	under 42 U.S.C. § 1983, (Washington State Health Facilities v. Washington Dept.
24	Soc. Ser., 698 F.2d 964, fn. 4, 965 (9th Cir. 1982). They are also continually injured
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1	by such State action which is preempted, under the Supremacy Clause, by this
2	contrary federal "public notice" regulation. (ILC v. Shewry, No. 09-56422, 9th
3	Cir., July 9, 2009; ILC v. Shewry, 543 F.3d 1050 (9th Cir., 2008).
4	Facts
5	Under the State Plan filed with Centers for Medicare and Medicaid Services
6	("CMS") as required by 42 U.S.C. § 1396(a)(30)(A), the State Plan must:
7 8 9 10	provide such methods and procedures relating to the payment for, care and services available under the plan as may be necessary to assure that payments are consistent with efficiency, economy, and quality of care, and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area.
11	However, in the State Plan filed by DHCS with CMS, the only description of
12	the State's methods and standards for setting payment rates for services, is at pages
13	12-6 of Supplement 2 to Attachment 4.19-B, which on Page 1 states that the
14	method used to establish maximum drug product payments is that payments to
15	pharmacists shall equal the Estimated Acquisition Cost (EAC) of the drug product
16	dispensed, plus a dispensing fee.
17	The EAC for brand drug products is stated on Page 1 to be:
18	the lowest of the Average Wholesale Price (AWP) minus 17
19	percent, or the charges to the general public.
20	and Page 2 states merely that:
21	For purposes of this Supplement 2, the following definitions apply:
22	"Average wholesale price" means the price for a drug product listed in the department's primary reference source.
23	Accordingly, this is the blackest of black boxes: it fails to inform the reader of the
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They did this not merely to be civilized about such a criminal and shocking event, but to act in their best ultimate interests: to enable the System to go on working, for without this adjustment, the System collapses, due to pharmacies going out of business because the 4% cut prevents their being paid sufficient to cover their costs to acquire-and-dispense these 18,000 to 20,000 brand NDCs. But not DHCS, the Medi-Cal fee-for-service agency. Instead, DHCS is pocketing the windfall, and since September 26, 2009, has (1) cut payments 4%, – the amount of the AWP markdown – for pharmacies' costs to acquire brand drugs; even though this new Medi-Cal payment, – reduced by 4% on account of the 4% AWP markdown, – does not cover pharmacies' costs to acquire-and-dispense these brand drugs, and even though no public notice of this significant change in the methods and standards which the Director uses for setting rates for pharmacies in California's Medicaid program, has been published by DHCS as required by the "public notice" regulation, 42 C.F.R. § 447.205, in the Medi-Cal program. **Discussion** It is unanimously held that where an equation for calculating Medicaid provider rates is changed, that a public notice, – specified by 42 Code of Federal Regulations § 447.205, --is required. See, Missouri D.S.S. v. Sullivan, 957 F.2d 542. 544. (8th Cir.1992). Here, in the case at bar, the formula for AWP was changed from 1.25 WAC to 1.20 WAC. Hence, § 447.205 public notice is required in case at bar.

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1	It is unanimously held that where the State does not reveal its methodology
2	in its State Plan, but rather the State Plan operates, – exactly as in case at bar, – as
3	sort of a "black box," then when the State uses a different method, (here, changing
4	from a methodology of setting EAC payment for drug acquisition costs at 1.25 of
5	WAC, to the new methodology of setting EAC payment for drug acquisition costs
6	at only 1.20 of WAC), that such change "may reasonably be construed as a change"
7	in methods and standards. (Missouri D.S.S., 957 F.2d at 544). Hence, § 447.205
8	public notice is required in case at bar.
10	It is unanimously held that where a State "relied on indices to set its
11	adjustment, those indices <u>must be identified and their use explained</u> " in the State
12	Plan, otherwise, a change in the final "number" is "considered a change in methods
13	and standards" within the meaning of § 447.205. See, State v. Shalala, 42 F.3d
14	595, 599, (10th Cir.1994)). Hence, § 447.205 public notice is required in case at
15	bar.
16	Also, subs. (b)(3) of § 447.205 provides no safe harbor at all to the Director
17	in case at bar. This provision provides;
18	(b) When notice is not required. Notice is not required if—(3) The change is
19	based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost
20	plus a reasonable fee.
21	However, the facts are that the wholesalers' and manufacturers prices of
22	brand drugs were the same on September 25, 2009 as they were on the next day,
23	September 26, 2009, when First Data Bank made the one-time 4% markdown on
24	published AWP from a level equal to 1.25 WAC to 1.20 WAC.
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Thus, just as Mae West reminded her audiences that "Goodness had nothing to do with it," so also wholesalers' and manufacturers' prices for brand drugs had nothing to do with the one-time 4% markdown which First Data Bank published, on September 26, 2009, in respect to 18,000 to 20,000 brand drug produces, (each with a National Drug Code identification number). **Conclusions** Accordingly, it is clear that the Director is in violation of the public notice requirement of § 447.205, hence, – by the terms of § 447.205, – may not implement the new 4% cut in payment to pharmacies, which commenced on September 26, 2009 in respect to their costs to acquire brand drugs. Further, – as shall be explained in a separate section below, – the Director must also be affirmatively ordered, preliminary to final determination of this litigation, to command the CEOs of the various Medi-Cal managed care plans, to refrain from cutting pharmacy's payments on account of the 4% AWP markdown of 18,000 to 20,000 brand drugs, until such time as the particular Medi-Cal managed care plan, as the case may be, publishes a public notice, as required by 42 C.F.R. § 447.205 in respect to this change in standards and methods for setting reimbursement for pharmacy acquisition costs in the Medi-Cal program. This request to the Court is made by Plaintiffs, due to the fact that under § 14105 Cal. Welf. & Inst. Code, the Director has exclusive power to set all rules and regulations for DHCS. Then, 42 U.S.C. 1396a(a)(5) and the Single State Agency regulation,

(42 C.F.R. § 431.10), provide that while the Single State Agency in a Medicaid 1 program may delegate functions, (as, for example, to Medi-Cal managed care 2 3 plans) that nevertheless the ultimate power and authority to administer the state's 4 Medicaid program, is always retained and resides in the Single State Agency: here, 5 DHCS, – which agency in turn is exclusively controlled, by the terms of §14105 6 Cal. Welf. & Inst. Code, by the defendant Director. 7 (Thus, 42 C.F.R. § 431.10, subs. (e)(3) provides that: 8 "If other State or local agencies or offices perform services for the Medicaid 9 agency, they must not have the authority to change or disapprove any administrative decision of that agency, or otherwise substitute their judgment 10 for that of the Medicaid agency with respect to the policies, rules, and 11 regulations issued by the Medicaid agency." 12 Hence, if the managed care side of Medi-Cal is to be enjoined from 13 implementing these infamous and insane pharmacy payment reductions, (due to the 14 3 new Medi-Cal cuts which are the subject of this enforcement motion), the 15 feasible way to do it is for the District Court to affirmatively order the Director to 16 stay, and order, each of the various Medi-Cal managed care plans, and their CEOs, 17 to adjust their payments to their managed care pharmacy providers, to offset and 18 neutralize the 4% AWP markdown; all, as the Director is authorized, and has 19 jurisdiction to do, under his Powers Statute, (i.e., § 14105 Cal. Welf. & Inst. 20 Code).3 21 22 ³ Please note that CalOptima, in Orange County, which is the largest Medi-Cal 23 managed care program in the state, has already preceded the Director and the District Court, by voluntarily increasing the pre-September 26, 2009 payments to 24 participating pharmacies, to offset and neutralize the payment cuts to pharmacies that 25

1	INJUNCTION ALSO LIES TO RESTRAIN THE
2	DIRECTOR FROM IMPLEMENTING THE OTHER
2	TWO PHARMACY PAYMENT CUTS, DUE TO FAILURE
3	TO COMPLY WITH THE PUBLIC NOTICE
4	REQUIREMENTS OF 42 C.F.R. § 447.205.
5	Although the Director did post a notice of the other two payments
6	cuts complained of, nevertheless, he failed in each case to comply with
7	§ 447.205 in two of its most important requirements. I.e., the public
8	notice posted in the California Regulatory Notice Register for each of
9	these other two provider payment cuts:
10	(1) failed to explain why DHCS is changing its methods and
11 12	standards, as required by subs. (c)(3) of § 447.204; and,
13	(2) failed to give an estimate, as required by subs. (c)(2), of
14	any expected increase or decrease in annual aggregate expenditures, due
15	due to the payment cut from the new Upper Billing Limit law
16	(§ 14105.455 Cal. Welf. & Inst. Code); and, also, similarly,
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18	otherwise result, to pharmacies, under the one-time, 4%, markdown of AWP by 4%,
19	as of September 26, 2009.
20	See, Declaration of Thu-Hang Tran, Pharm.D., filed herewith, and, the
	Caloptima action report, in respect to which CalOptima, on October 1, 2009, increased the payments to pharmacies in CalOptima, by an amount to offset and
21	neutralize the bombshell 4% markdown of AWP by the First Data Bank publisher, on
22	September 26, 2009.
23	(A copy of the CalOptima action report, to increase the CalOptima rates so as
	to offset and neutralize the reduced payment effect of the marked-down AWP, is
24	attached to this Motion as Exhibit A .)
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26	NOTICE OF MOTION, AND MOTION, TO ENFORCE ORDERS, AND TO STAY PAYMENT CUTS -15-

1	(3) failed to give an estimate, as required by subs. (c)(2), of
2	any expected increase or decrease in annual aggregate expenditures, due
3	due to the payment cut from the new formula for setting MAIC
4	payment limits for generics, (§ 14105.45 Cal. Welf. & Inst. Code).
5	ONE
6	The single page in the Cal. Regulatory Notice Register of August 2009
7	where these two notices appear, is attached to this Memorandum as Exhibit B . ⁴
8	However, not one single reason or explanation is given in the notice in the
9	state's Notice Registry of why the Single State Agency is changing its methods and
11	standards for paying pharmacy providers by (1) now limiting pharmacies to the best
12	price they give to 3d party payers, and, (2) now reducing reimbursement on
13	generics subject to a MAIC limit, downwards to either (A) "average purchase
14	price" (whatever that means) paid by retail pharmacies in California, or (B) what a
15	private contractor calculates shall now be the MAIC rate.
16	Hence the notice violates the "public notice" requirement of 42 C.F.R.
17	§ 447.206, subs. (c)(3), which expressly provides that the notice must explain why
18	the agency is changing its methods and standards for setting provider payment
19	rates.
20	TWO
21	The Register page, (Exhibit B attached to this Motion), lumps the notice of
2223	the Upper Billing Limit law (§ 14105.455 Cal. Welf. & Inst. Code), with the notice
2425	⁴ A copy of the Register page is also at Exhibit C of Plaintiffs' Further RJN.
26	NOTICE OF MOTION, AND MOTION, TO ENFORCE ORDERS, AND TO STAY PAYMENT CUTS -16-

of the new MAIC payment cut, together on one page, (with a third new statute, to 1 2 boot), and then gives an estimate of the total or aggregate of the decrease in 3 expenditures for all three of the statutes, lumped together! 4 But this does not "break out" the expected increase or decrease in annual 5 aggregate expenditures expected under each of these new laws, and instead hides 6 from beneficiaries and providers information intended by the rulemaker to be 7 provided: "... as a procedural protection for providers and beneficiaries and 'a 9 reasonable method for ensuring that rate changes are equitable and conform to statutory mandates." (Shalala, 42 F.3d at 602). (Emphasis supplied.) 10 Conclusion: The notice given by DHCS in the state Notice Register of the 11 Upper Billing Limit statute (§ 14105.455 Cal; Welf. & Inst. Code), and of the new 12 MAIC payment statute (§ 14105.45 Cal. Welf. & Inst. Code), is void, due the 13 complete failure of DHCS to comply with the requirements of § 447.205 that 14 DHCS explain why the agency is changing its methods and standards for setting its 15 Medicaid provider rates, and disclose what the dollar amount of savings or added 16 State expenses will be, under the "significant proposed change in its methods and 17 standards for setting payment rates for services." 18 19 SUMMARY AND PRAYER 20 The notice posted in the state Registry for each of the two Medi-Cal 21 pharmacy provider payment cuts (1) facially violates subs. (c)(3) of § 447.205, for 22 lack of any explanation of why DHCS is changing its methods and standards, and 23 facially violates; (2) facially violates subs. (c)(2) of § 447.205 for failure to give 24 any estimate, in respect to the Upper Billing Limit law of Cal. Welf. & Inst. Code 25

1	§ 14105.455, of any expected increase or decrease in annual aggregate
2	expenditures, and (3) facially violates subs. (c)(2) of § 447.205 for similar failure
3	to give any estimate, in respect to the new MAIC law of Upper Billing Limit law,
4	of § 14105.455 Cal. Welf. & Inst. Code, of any expected increase or decrease in
5	annual aggregate expenditures.
6	Hence in the respectful view of the Plaintiffs, the requested injunctions
7	should be issued against the Director, (1) to order him to cease and refrain from
8	implementing the Upper Billing Limit law, or the new MAIC law, and (2) to order
10	him to direct and ensure that the CEOs of each of the managed care plans in the
11	Medi-Cal managed care program, and these Medi-Cal managed care plans,
12	not implement any of the payment cuts under the Upper Billing Limit law or the
13	new MAIC payment law, until and unless the Director first publishes a public
14	notice in respect to each of these two laws, as is required by subss. (c)(2) and (c)(3)
15	of 42 C.F.R. § 447.205.
16	Dated: October 8, 2009
17	Respectfully submitted,
18	
19	LYNN S. CARMAN STANLEY L. FRIEDMAN
20	By: /s/ Lynn S. Carman
21	Attorneys for Plaintiffs Independent Living Center of Southern California,
22	Inc., et al.
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26	NOTICE OF MOTION, AND MOTION, TO ENFORCE ORDERS, AND TO STAY PAYMENT CUTS, -18