Yvette D. Roland (SBN 120311)
Audra L. Thompson (SBN 218479)
DUANE MORRIS LLP
633 West Fifth Street, Suite 4600
Los Angeles, CA 90071
Telephone: 213.689.7400
Facsimile: 213.689.7401
E-Mail: ydroland@duanemorris.com
E-Mail: athompson@duanemorris.com

Frederick R. Ball (*pro hac vice* to be filed)
Nicholas J. Lynn (*pro hac vice* to be filed)
Richard P. Darke (*pro hac vice* to be filed)
Christopher Petelle (*pro hac vice* to be filed)
Duane Morris LLP
190 S. Lasalle Street, Suite 3700
Chicago, IL 60603
Telephone: 312.499-6700
Facsimile: 312.499-1945

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

CV09-7097 VBF (FFMx)

NATIONAL ASSOCIATION OF CHAIN DRUG STORES, and the NATIONAL COMMUNITY PHARMACISTS' ASSOCIATION,

Plaintiffs,

v.

ARNOLD SCHWARZENEGGER, not individually, but solely in his official capacity as Governor of the State of California, DAVID MAXWELL-JOLLY, not individually, but solely in her official capacity as Secretary of the California Department of Health Care Services, and THE CALIFORNIA DEPARTMENT OF HEALTHCARE SERVICES,

Defendants.

Case No.:

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

The National Association of Chain Drug Stores ("NACDS") and the National Community Pharmacists Association ("NCPA") complain against Arnold

Schwarzenegger, not individually, but solely in his capacity as Governor of the State of California, David Maxwell-Jolly, not individually, but solely in his capacity as the Secretary, California Department of Health Care Services, and the California Department of Health Care Services (the "Department") for injunctive and declaratory relief.

This Complaint seeks to enjoin the Defendants from reducing by, on average, slightly more than four percent (4%) Medicaid reimbursement based on Average Wholesale Price ("AWP") for drug products paid to pharmacies for dispensing prescription drugs reimbursed by the State of California's Medicaid program. The Court should grant injunctive relief because: (a) Section 1902(a)(30)(A) of the Social Security Act ("Section 30(A)") preempts these reimbursement cuts because the Department failed to properly consider and abide by the "quality of care" and "access" provisions of Section 30(A); (b) the Department violated federal and state law by failing to obtain approval from the United States Department of Health and Human Services' Centers for Medicare & Medicaid Services ("CMS") before implementing the cuts to reimbursement; (c) the Department violated state law by failing to consult with stakeholders and other interested parties regarding the reimbursement cuts; (d) the Department violated federal law by making reimbursement payments to pharmacies that are lower than the Department's own best estimates of pharmacies' actual acquisition costs; and (e) the reimbursement cuts will reduce the quality of care delivered to Medicaid beneficiaries in California and as such violates state law. Finally, in the past year, this court enjoined similar cuts in reimbursement for the same reasons. For these reasons, which are more thoroughly set forth below, the Pharmacies are entitled to a declaratory judgment that the reimbursement cut violates federal and state law, and injunctive relief.

JURISDICTION AND VENUE

1. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1331. In addition, this Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

2. Venue is appropriate in this jurisdiction pursuant to 28 U.S.C. § 1391 because the persons sued in their official capacity all maintain offices within this District and the State entities are headquartered within, and a substantial part of the events giving rise to these claims occurred in, this District.

PARTIES

3. NACDS is a national association whose members include 20 pharmacy chains in California with over 2,700 individual pharmacies within the State. NACDS's mission includes ensuring its members are adequately reimbursed by federal and state healthcare programs and ensuring patient access to pharmaceutical care. Members of NACDS participate in California's Medicaid program.

4. NCPA is a national association whose members include independent community pharmacies and pharmacists including independent community pharmacists in the state of California. The nation's independent community pharmacists are small business owners and multifaceted healthcare providers who represent a vital part of the United States' healthcare delivery system. NCPA's members are committed to high quality patient care and services and to restoring, maintaining, and promoting the health and well-being of the general public, including Medicaid patients. NCPA represents the professional and proprietary interests of independent community pharmacists, and promotes and defends those interests, including those interests pertaining to federal and state healthcare programs. Members of NCPA participate in California's Medicaid program.

5. Arnold Schwarzenegger is named solely in his official capacity as Governor of the State of California. As Governor, Mr. Schwarzenegger has executive responsibility for the Department, the single state agency responsible for

administering the Medicaid Program in California. See California Welfare and Institutions Code, §§10722, 10740, 14100.0, 10725, 14105, and 14124.5; see also certification of California Attorney General, Attached to California State Plan as Attachment 1.1-A. Relevant sections to the California State Plan are attached as Group Exhibit A.

6. David Maxwell-Jolly is sued solely in his capacity as Secretary of the Department. The Department is charged with administering the Medicaid program in California.

7. The Department is sued in its capacity as the State of California department charged with administering the Medicaid program in California and implementing the September 26, 2009 reimbursement cut.

Laws governing California's Medicaid Program, "Medi-Cal."

8. Medicaid is a joint federal and state program created under Title XIX of the Social Security Act to provide health care to indigent and otherwise disadvantaged Americans. Federal and state government agencies share responsibility for funding the Medicaid program. Each state administers its respective Medicaid program in accordance with federal and state law, as well as a State-authored Medicaid State plan, which the state submits to CMS, and CMS reviews and approves.

9. The California Medicaid State Plan ("State Plan") is the Department's comprehensive written statement that describes the nature and scope of the State Medicaid program and gives assurances that DSHS will administer the State Plan in conformity with the specific requirements of the Social Security Act. CMS must approve all amendments to a State Plan before a state may implement "material changes," including those made to "reflect . . . court decisions." 42 C.F.R. § 430.12(c)(1)(i) and (ii).

10. The Department is required to administer the Medi-Cal program in accordance with Federal Law, as well as in accordance with the California State Plan, applicable State law, and Medi-Cal regulations. 22 C.C.R. § 50004(b) (2009).

11. Pursuant to the State Plan, California agreed to administer the state Medicaid program "in accordance with the provisions of this State plan, the requirements of titles XI and XIX of the Act, and all applicable Federal regulations and other issuances of the Department." See California State Plan, page 1.

12. In order to comply with federal law, a state Medicaid program must comply with the "quality of care" clause of Section 30(A) which provides in pertinent part:

(a) A state plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and 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 . . . .

42 U.S.C. § 1396a(a)(30)(A).

13. A state Medicaid program must also comply with the "access" clause of Section 30(A) which provides in pertinent part:

(a) A state plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments . . . are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Id.

14. For that reason, federal regulations require the Department to offer payments to providers "sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 4407.204.

15. The State Plan, as approved by CMS, affirms that "[the Department's] payments are sufficient to enlist enough providers so that services under the plan are

available to recipients at least to the extent those services are available to the general population." See California State Plan, 4.19(i).

16. Therefore, to demonstrate that reimbursement complies with federal statutes, federal regulations, and the State Plan, and that its reimbursement is not arbitrary and capricious, a State must show that it has evaluated, prior to implementation of new rates and methodologies, that the reimbursement provided complies with the "quality of care" and "access" provisions of Section 30(A), and will ensure enough providers are enlisted so that services under the plan are available to recipients at least to the extent that they are available to the general public.

The Method Used To Calculate California's Medicaid Reimbursement.

17. Retail pharmacies that take part in the Medicaid program dispense prescription drugs and provide related services to patients who are covered by Medicaid. In return, those retail pharmacies apply for, and receive, reimbursement payments from the Department.

18. Reimbursement paid to Medicaid-enrolled pharmacies for drug products and services contains two components: (1) a reasonable dispensing fee meant to compensate a pharmacy for the dispensing costs that it incurs and the associated services that it provides, and (2) reimbursement for the drug product itself.

19. With regard to the first component of reimbursement, California does not provide a reasonable dispensing fee that compensates pharmacies for the dispensing costs that they incur and the related services that they provide.

20. With regard to the second component of reimbursement, the California State Plan provides that California reimburses pharmacies for single source drugs and certain multiple source drugs at a rate of the AWP published by First Databank, minus a discount of 17%. See Cal Wel & Inst Code § 14105.45; Exhibit A, California State Plan, Supplement 2 to Attachment 4.19-b, page 1.

21. California has not made assurances to CMS that the reimbursement that went into effect on September 26, 2009 represents its best estimate of acquisition cost ("EAC") as required by federal law. 42 C.F.R. §447.518.

22. California also has not certified to the federal government in its State Plan that the reduced reimbursement as of the September 26, 2009 is "designed to enlist participation of a sufficient number of providers in the program so that eligible persons can receive the medical care and services included in the plan at least to the extent these are available to the general population." See California State Plan, Attachment 4.19-B, p.1.

The AWP Reductions

23. First DataBank, Inc., a clearinghouse of data pertaining to the pharmaceutical industry, publishes lists of prescription drugs and the AWP for each prescription drug. The Department uses First DataBank AWP data in calculating its EAC.

24. On March 17, 2009, First DataBank entered into a class action settlement agreement ("First DataBank Settlement") in which it agreed to reduce the mark-up to the wholesale average cost ("WAC") from 1.25 to 1.20 when setting AWPs for 1,442 NDCs. In addition, First DataBank announced it would voluntarily cut the WAC mark-up to 1.20 when setting AWPs for thousands of NDCs where the mark-up exceeded 1.20. In effect, First DataBank agreed to reduce its listed AWP for virtually all NDCs by, on average, 4%. These reductions of AWPs occurred on September 26, 2009.

25. The practical effect of First DataBank's reduction of the mark-up to WAC when setting AWPs is that the reimbursement for drug products tied to AWP that the Department pays has been reduced by slightly more than 4%.

26. As a result of the AWP reductions, reimbursement payments will be at virtually the same levels as reimbursement payments that this Court enjoined approximately six months ago, due to violations of the same laws discussed herein.

The Department's Failure To Comply With Federal And State Laws

27. There is nothing in the administrative record that suggests that the State considered or otherwise took into account either the "quality of care" or the "access" provisions of Section 30(A) prior to this reduction of reimbursement payments.

28. Indeed, the plaintiffs have not found any evidence that the State took any steps to determine how the reimbursement reduction would affect compliance with the "quality of care" or "access" provisions of Section 30(A).

29. In addition, there is no indication that the State has received approval from CMS for a State Plan amendment that would allow either for this reduction in actual reimbursement to pharmacies, or in the commensurate reduction in care quality or access.

30. The State has not obtained CMS approval prior to reducing Pharmacies' AWP-based reimbursement by 4%, in violation of federal law. 42 C.F.R. § 430.12(c)

31. There is no evidence that the State provided public notice and the opportunity for public comment prior to the 4% reduction in AWP-based reimbursement, as it is required to do by 42 C.F.R. § 447.205.

32. There is no evidence that the new, reduced reimbursement payments were "designed to enlist participation" of sufficient providers of Medicaid, as the State warranted in the state plan.

33. The State has not made, and cannot make, the required analysis, findings or assurances to CMS that the new reduced reimbursement payments properly reflects the EAC for prescription drugs in the State of Washington.

34. The California Medicaid State Plan requires the Department to set payment pursuant to a very specific methodology:

The methodology utilized by the State Agency in establishing payment rates will be as follows:

(a) The development of an evidentiary base or rate study resulting in the determination of a proposed rate.

(b) To the extent required by State or Federal law or regulations, the presentation of the proposed rate at public hearing to gather public input to the rate determination process.

(c) The determination of a payment rate based on an evidentiary base, including pertinent input from the public.

(d) The establishment of the payment rate through the State Agency's adoption of regulations specifying such rate in the [. . .] Schedule of Maximum Allowances for EPSDT health assessment, or through any other means authorized by State law.

See California State Plan, Attachment 4.19-B, p. 1. There is no evidence the State has complied with these requirements.

Harm To Pharmacies And Their Patients

35. Unless enjoined, the effect of the reimbursement reduction will be catastrophic for Medicaid beneficiaries across Washington, as well as health service providers like the Pharmacies. The 4% AWP cut will result in the reimbursement for many drugs at a level below the Pharmacies' break even cost.

36. The Pharmacies will be forced to take drastic steps if the reimbursement cut goes into effect, including ceasing to fill Medicaid prescriptions and dropping their enrollment in the Medicaid program.

37. Medicaid patients such as those served by members of NACDS and NCPA may lose access to lifesaving drugs.

38. In short, there is real and immediate risk of harm to both the pharmacies and to Medicaid beneficiaries due to the September 26, 2009 reimbursement cut.

COUNT I FOR AN INJUNCTION HALTING THE REIMBURSEMENT CUT

39. The Plaintiffs incorporate Paragraphs 1 – 38 as if set forth fully here.

40. This Court has already recognized that a 10% and 5% reduction in reimbursement rates would both impose irreparable harm upon Medicaid beneficiaries and upon providers such as Pharmacies. *See Independent Living Ctr. Of Southern*

Ca., Inc. v. Shewry, No. CV08-3315 CAS (MANx) (Aug. 18, 2008) and *Managed Pharmacy Care v. Jolly*, 603 F. Supp. 2d 1230 (C.D.C. 2009). This Court enjoined the Department from implementing both a 10% and 5% reduction in Medicaid reimbursement rates on the grounds that the Department had failed to adequately consider the effect such a reduction would have on Medicaid beneficiaries and the availability of Medicaid services through the maintenance of a robust provider network. Id.

41. Pursuant to Section 30(A), the Department had a duty to consider efficiency, economy, quality, and access when establishing reimbursement. It is the state's obligation to develop methods and procedures for assuring that it complies with Section 30(A). Here, the Department acted in violation of the Supremacy Clause of the United States Constitution because it has failed to consider or give sufficient weight to the impact of the reimbursement cut on quality of care or access to care for Medicaid beneficiaries required by Section 30(A), including the relationship of reimbursement payments to provider costs. Additionally, there is no evidence that the Department has complied with the requirements of Section 30(A) prior to its implementation of the September 26, 2009 reimbursement cut. Finally, it is evident that the reimbursement cut will directly result in a failure of the State to comply with the requirements of Section 30(A) because reimbursement will not be sufficient to assure "quality of care" and access.

42. Moreover, there is no evidence that the State has complied with the requirements of federal law, state regulations, or the State Plan to obtain approval of a State Plan amendment prior to this material change in the State's operation of the Medicaid program. 42 C.F.R. § 430.12(c).

43. There is also no evidence that the Department gave adequate public notice or obtained public comment, as it is required to do pursuant to 42 C.F.R. § 447.205.

44. It is also clear that the Department has not taken adequate steps to set payment rates at such a level as to ensure that sufficient providers remain in the program so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 4407.204; See California State Plan, 4.19(i).

45. There is absolutely no evidence that the State made any finding or determination that the four percent (4%) reduction in rates represents the EAC of providers, which is the amount they are obligated to pay providers under Federal law. 42 C.F.R. § 447.518.

46. In short, the Department acted arbitrarily and capriciously, unlawfully and in violation of the Supremacy Clause of the United States Constitution when it reduced reimbursement payments to pharmacies. Based on the foregoing, Plaintiffs are likely to succeed on the merits.

47. Irreparable harm will occur if the reimbursement cut goes into effect because pharmacies, including members of the Plaintiff associations, will be forced to reduce levels of service, deny prescriptions to new Medicaid beneficiaries, shut down, reduce service hours, and/or refuse to take any Medicaid beneficiaries. Plaintiffs have no administrative remedy, nor any plain, speedy, or adequate remedy except by this complaint for injunctive relief.

48. The balance of harms favors entering the injunction because the physical and emotional harm suffered by Medicaid beneficiaries deprived of needed access to quality pharmaceutical products if the cut goes into place, as well as the inevitable loss of employment if the pharmacies are forced to close or lay off workers, outweighs monetary loss to the State. Moreover, the State is receiving additional federal funding, the express purpose of which is to avoid this type of cut.

49. It is in the public interest that the court grant the injunction because it is always in the public interest that State governments comply with federal and state law.

Moreover, it is in the public interest to assure that Plaintiffs' members can continue to serve Medicaid beneficiaries.

WHEREFORE, Plaintiffs respectfully request that this Court enter an injunction enjoining the September 26, 2009 reimbursement cut.

COUNT II FOR DECLARATORY JUDGMENT THAT THE DEPARTMENT HAS VIOLATED 42 C.F.R. § 447.205

50. The Plaintiffs incorporate Paragraphs 1 – 49 as if set forth fully here.

51. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement cut violates 42 C.F.R. § 447.205.

52. 42 C.F.R. § 447.205 requires the Department to provide public notice of any significant proposed change in its methods and standards for setting reimbursement for services and provide an opportunity for public comment.

53. The Department did not provide public notice of the September 26, 2009 reduction in reimbursement as required by 42 C.F.R. § 447.205.

WHEREFORE, Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

COUNT III FOR DECLARATORY JUDGMENT THAT THE DEPARTMENT HAS VIOLATED 42 C.F.R. § 447.204

54. Plaintiffs incorporate Paragraphs 1 – 53 as if set forth fully here.

55. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement cut violates 42 C.F.R. § 447.204.

56. 42 C.F.R. § 447.204, and the California State Plan, require the Department to set payment at such a level as to ensure that sufficient providers remain in the program so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 447.204; See California State Plan, 4.19(i).

57. The proposed reduction in reimbursement will reduce the number of providers in the Medi-Cal program so as to make Medicaid services less available to

Medicaid beneficiaries than they are to the general population, in contravention of Federal Regulations. 42 C.F.R. § 447.204.

WHEREFORE, Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

COUNT IV FOR DECLARATORY JUDGMENT THAT THE DEPARTMENT HAS VIOLATED 42 C.F.R. § 447.518.

58. Plaintiffs incorporate Paragraphs 1 – 57 as if set forth fully here.

59. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement cut violates 42 C.F.R. § 447.518.

60. 42 C.F.R. § 447.518 requires the Department to make assurances to CMS that its proposed payment methodology for prescription drugs reflect the EAC for the drugs. 42 C.F.R. § 447.518. These assurances are based on findings made by the State regarding the EAC for prescription drugs. The State is required to retain and make available to CMS "data, mathematical or statistical computations, comparisons and other pertinent records to support its findings and assurances." 42 C.F.R. § 447.518.

61. There is absolutely no evidence that the State made any finding or determination that the four percent (4%) reduction in reimbursement represents the EAC of providers, which is the amount they are obligated to pay providers under Federal law. 42 C.F.R. § 447.518. Nor is there any evidence the Department has made the required assurances to CMS.

WHEREFORE, Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

COUNT V FOR DECLARATORY JUDGMENT THAT THE DEPARTMENT HAS VIOLATED 22 C.C.R. § 50004(B) (2009).

62. Plaintiffs incorporate Paragraphs 1 – 61 as if set forth fully here.

63. An actual controversy exists between the parties concerning whether the September 26, 2009 reimbursement cut violates 22 C.C.R. § 5000

64. California Regulations require the Department to administer the Medi-Cal program in accordance with Federal Law, as well as in accordance with the California State Plan, applicable State law, and Medi-Cal regulations. 22 C.C.R. § 50004(b) (2009).

65. 42 C.F.R. § 447.204, and the California State Plan, require the Department to set reimbursement at such a level as to ensure that sufficient providers remain in the program so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 447.204; See California State Plan, 4.19(i).

66. 42 C.F.R. § 447.205 requires the Department to provide public notice of any significant proposed change in its methods and standards for setting reimbursement for services and provide an opportunity for public comment.

67. The State previously established, through the methodology set out in the California State Plan, that the current reimbursement payment is the proper one, and certified that fact to CMS in the State Plan. California State Plan Attachment 4.19-B requires the Department to follow a specific methodology in adopting new reimbursement, and the Department has not followed that methodology here.

68. By failing to comply with 42 C.F.R. § 447.204, 42 C.F.R. § 447.205, and California State Plan, 4.19(i), the Department has failed to comply with 22 C.C.R. § 50004(b) (2009), which requires it to administer Medi-Cal in compliance with Federal regulations and the California State Plan.

WHEREFORE, Plaintiffs respectfully request that this Court enter an order declaring that the September 26, 2009 reimbursement cut is invalid.

COUNT VI FOR DECLARATORY JUDGMENT THAT THE SEPTEMBER 26, 2009 RATE CUT VIOLATES FEDERAL AND STATE LAW

69. Plaintiffs incorporate Paragraphs 1 – 68 as if fully set forth here.

70. An actual controversy exists between the parties concerning whether the reimbursement cut resulting from the First Databank Settlement violates federal and state law.

71. For the reasons set forth above, the reimbursement cut violates both federal and state law as being preempted by Section 30(A) of the Social Security Act, contrary to Federal Regulations, contrary to state regulations, and contrary to the Medicaid State Plan.

WHEREFORE, Pharmacies respectfully request that this Court enter a judgment declaring the reimbursement cut unlawful and enter an injunction preventing the Department from implementing the unlawful reimbursement cut.

Dated: September 29, 2009

DUANE MORRIS LLP

By: _____

Yvette D. Roland
Audra L. Thompson
Attorneys for Plaintiffs NATIONAL ASSOCIATION OF CHAIN DRUG STORES, and the NATIONAL COMMUNITY PHARMACISTS' ASSOCIATION
Forge Insurance Company

EXHIBIT A

Revision: HCFA-PM-91-4 (BPD)
AUGUST 1991

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

State/Territory: CALIFORNIA

Citation

42 CFR
430.10

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

Department of Health Services
(Single State Agency)

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

TN No. 92-09
Supersedes TN No.
Approval Date NOV 18 1993
Effective Date JAN 01 1993
HCFA ID: 7982E

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

State California

SECTION 1 SINGLE STATE AGENCY ORGANIZATION

Citation
42 CFR 431.10
AT-79-29

1.1 Designation and Authority

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

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

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

State California

Citation		
42 CFR 447.201 42 CFR 447.204 AT-78-90	4.19(i)	The Medicaid agency's payments are sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
Attachment 1.1-A MEDICAL ASSISTANCE PROGRAM

State of California

ATTORNEY GENERAL'S CERTIFICATION

I certify that:

the Department of Health Services, State of California is the single State agency responsible for:

[X] administering the plan

The legal authority under which the agency administers the plan on a Statewide basis is Welfare and Institutions Code Sections 10722, 10740, and 14100.1, (regulatory authority: 10725, 14105 and 14124.5)

(statutory citations)

[ ] supervising the adminstration of the plan by local political subdivisions.

The legal authority under which the agency supervises the administration of the plan on a Statewide basis is contained in

(statutory citation)

The agency's legal authority to make rules and regulation that are binding on the political subdivision administering the plan is

(statutory citation)

24 May 1984
DATE

Thomas W Warren
Signature

Assistant Attorney General
Title

STATE PLAN UNDER TITLE XIX OF SOCIAL SECURITY ACT
STATE California

The policy of the State Agency is that reimbursement for each of the other types of care or service listed in Section 1905(a) of the Act that are included in the program under the plan will be at the lesser of usual charges or the limits specified in the California Code of Regulations (CCR), Title 22, Division 3, Chapter 3, Article 7 (commencing with Section 51501) and CCR, Title 17, Chapter 4, Subchapter 13, Sections 6800-6874, for EPSDT health assessment services, or as specified by any other means authorized by state law.

The methodology utilized by the State Agency in establishing payment rates will be as follows:

(a) The development of an evidentiary base or rate study resulting in the determination of a proposed rate.

(b) To the extent required by State or Federal law or regulations, the presentation of the proposed rate at public hearing to gather public input to the rate determination process.

(c) The determination of a payment rate based on an evidentiary base, including pertinent input from the public.

(d) The establishment of the payment rate through the State Agency's adoption of regulations specifying such rate in the CCR, Title 22, Division 3, Chapter 3, Article 7 (commencing with Section 51501), and CCR, Title 17, Chapter 4, Subchapter 13, commencing with Section 6868, Schedule of Maximum Allowances for EPSDT health assessment, or through any other means authorized by State law.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR PRESCRIPTION DRUGS

The policy of the State Agency is that reimbursement for Pharmaceutical Services and Prescribed Drugs, as one category of health care or service from among those listed in Section 1905(a) of the Social Security Act that are included in the program under the plan, will be at the provider pharmacy's current charges to the general public, up to the State Agency's limits. The price providers charge to the program shall not exceed that charged to the general public. The pharmacist, to the extent permitted by law, shall dispense the lowest cost, therapeutically equivalent drug product that the pharmacy has in stock, which meets the medical needs of the beneficiary.

The methodology utilized by the State Agency, in compliance with 42 C.F.R. §§ 447.331 and 447.332, in establishing payment rates for Pharmaceutical Services (pharmacy dispensing fees) and Prescribed Drugs (dispensed drug products) to implement the policy is as follows:

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

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

B. The professional fee for dispensing is seven dollars and 25 cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility is eight dollars ($8.00) per dispensed prescription. For the purposes of this paragraph B, "skilled nursing facility" and "intermediate care facility" mean as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

C. For purposes of this Supplement 2, the following definitions apply:

- "Average wholesale price" means the price for a drug product listed in the department's primary price reference source.

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

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

- "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage

form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

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

- "Maximum Allowable Ingredient Cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

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

- "Nonlegend drug" means any drug whose labeling does not contain one or more of the statements required to be a "legend drug".

- "Wholesale Selling Price" (WSP) means the weighted (by unit volume) mean price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor.

D. For purposes of paragraph A, the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in Medi-Cal pharmacy provider bulletins and manuals. The department will update the list of MAICs and establish additional MAICs in accordance with the following:

- The department will base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by the department.

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

E. The federal upper limits of reimbursement, FUL, are initiated by CMS and provided to the State Agency for implementation in the State Medicaid Manual of Instructions. Periodic revisions to Addendum A of Section 6305.3 of the Manual, which is the list of multiple source drugs and the FUL prices, are implemented by the State Agency following notice by CMS of new FUL prices. New FUL prices are implemented within the timeframe required by the CMS notice and as required by applicable California statutes and regulations.

F. Overrides to both the state and federal price ceilings are available only through a state prior approval mechanism. Prior approval is limited to

those cases where the medical necessity of a specific manufacturer's brand of a drug, priced above the ceiling, is adequately demonstrated to a state consultant. The documentation of the approval is linked to the claims payment system assuring correct reimbursement for the brand dispensed. The same system is used for approval and payment for drugs not on the state Medicaid Drug Formulary, known as the Medi-Cal List of Contract Drugs.

G. The Medi-Cal List of Contract Drugs (List), a preferred drug list, is established pursuant to Section 1927 of the Social Security Act with prior authorization required for drugs not included on the List. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations. Prior authorization is applied to certain drug classes, particular drugs, or medically accepted indications for use and doses. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

H. The Medicaid program restricts coverage of certain covered outpatient drugs through the operation of a prior authorization program. The prior authorization process provides for a turn-around response by telephone, fax, or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a 72-hour supply of medications in accordance with the provisions of Section 1927(d)(5) of the Social Security Act.

1. The State Agency believes reimbursement to long-term pharmacy providers to be consistent and reasonable with costs reimbursed to other providers. The State Agency maintains an advisory committee known as the Medi-Cal Contract Drug Advisory Committee in accordance with Federal law.

DRUG REBATE PROGRAM

The State Agency is in compliance with Section 1927 of the Social Security Act. The State Agency reimburses providers of drugs of manufacturers participating in the drug rebate program and is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data to the extent allowed under the Health Insurance Portability and Accountability Act (HIPAA) in order to ensure that the Department is protecting information in accordance with HIPAA. The unit rebate amount is confidential and is not disclosed to anyone not entitled to the information for purposes of rebate contracting, invoicing and verification.

SUPPLEMENTAL REBATE PROGRAM

The State Agency negotiates supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer are separately identified from the federal rebates.

Supplemental rebates received by the State Agency in excess of those required under the national drug rebate agreement are shared with the Federal government on the same percentage basis as applied under the national rebate agreement. CMS has

authorized the State of California to enter into the Medi-Cal Supplemental Drug Rebate Average Manufacturer Price (AMP) Agreement. This supplemental drug rebate agreement was submitted to CMS on December 30, 2005 and has been authorized by CMS. CMS has authorized the State of California to enter into the Medi-Cal Net Cost Supplemental Drug Rebate Agreement. This supplemental drug rebate agreement was submitted to CMS on December 30, 2005 and has been authorized by CMS.
All drugs covered by the program, notwithstanding a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge Valerie Baker Fairbank and the assigned discovery Magistrate Judge is Frederick F. Mumm.

The case number on all documents filed with the Court should read as follows:

CV09- 7097 VBF (FFMx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[X]	**Western Division** **312 N. Spring St., Rm. G-8** **Los Angeles, CA 90012**	[ ]	**Southern Division** **411 West Fourth St., Rm. 1-053** **Santa Ana, CA 92701-4516**	[ ]	**Eastern Division** **3470 Twelfth St., Rm. 134** **Riverside, CA 92501**

Failure to file at the proper location will result in your documents being returned to you.

Yvette D.Roland (SBN 120311)
Audra L. Thompson (SBN 218479)
DUANE MORRIS LLP
633 West Fifth Street, Suite 4600
Los Angeles, CA 90071
Telephone: 213.689.7400; Facsimile: 213.689.7401

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF CHAIN DRUG STORES, and the NATIONAL COMMUNITY PHARMACISTS' ASSOCIATION,

PLAINTIFF(S)

v.

ARNOLD SCHWARZENEGGER, not individually, but solely in his official capacity as Governor of the State of California, DAVID MAXWELL-JOLLY, not individually, but solely in her official capacity as Secretary of the California Department of Health Care Services, and THE CALIFORNIA DEPARTMENT OF HEALTHCARE SERVICES,

DEFENDANT(S).

CASE NUMBER

CV09-7097 VBF (FFMx)

SUMMONS

TO:DEFENDANT(S): ARNOLD SCHWARZENEGGER, not individually, but solely in his official capacity as Governor of the State of California, DAVID MAXWELL-JOLLY, not individually, but solely in her official capacity as Secretary of the California Department of Health Care Services, and THE CALIFORNIA DEPARTMENT OF HEALTHCARE SERVICES,

A lawsuit has been filed against you.

Within 20 days after service of this summons on you (not counting the day you received it), you must serve on the plaintiff an answer to the attached ☒ complaint ☐ _____ amended complaint ☐ counterclaim ☐ cross-claim or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff's attorney, Yvette D. Roland, Duane Morris LLP, whose address is 633 West Fifth Street, Suite 4600, Los Angeles, California 90071. If you fail to do so, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Clerk, U.S. District Court

Dated: 30 SEP 2009

By: _____
Deputy Clerk

(Seal of the Court)

[Use 60 days if the defendant is the United States or a United States agency, or is an officer or employee of the United States. Allowed 60 days by Rule 12(a)(3)].

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
National Association of Chain Drug Stores, and the National Community Pharmacists' Association

DEFENDANTS
Arnold Schwarzenegger, not individually, but solely in his official capacity as Governor of the State of California, David Maxwell-Jolly, not individually, but solely in her official capacity as Secretary of the California Department of Health care Services, and The California Department of Healthcare Services

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)
Yvette D. Roland (SBN 120311); Audra Thompson (SBN 218479)
Duane Morris LLP
633 West Fifth Street, Suite 4600
Los Angeles, CA 90071
Telephone: 213.689.7400

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff ☒ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☐ Yes ☒ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☒ No ☐ **MONEY DEMANDED IN COMPLAINT: $** _____

VI. CAUSE OF ACTION (Cite the U. S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
Complaint for Injunctive and Declaratory Relief pursuant to 28 USC §1331

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☒ 890 Other Statutory Actions
☐ 891 Agricultural Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☐ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
☐ 462 Naturalization Application
☐ 463 Habeas Corpus-Alien Detainee
☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

BANKRUPTCY
☐ 22 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities – Employment
☐ 446 American with Disabilities – Other
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence Habeas Corpus
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus/ Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE / PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R.& Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety /Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
☐ 820 Copyrights
☐ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 61 HIA(1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW 405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609

CV09-7097

FOR OFFICE USE ONLY: Case Number: _____

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☒ No ☐ Yes

If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☒ No ☐ Yes

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)
- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☒ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☒ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles	

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
LOS ANGELES	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ **Date** September 29, 2009

Audra L. Thompson

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3 -1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))