

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF NEW YORK

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PHARMACISTS SOCIETY OF THE :  
STATE OF NEW YORK; NATIONAL :  
ASSOCIATION OF CHAIN DRUG STORES; :  
NATIONAL COMMUNITY PHARMACISTS :  
ASSOCIATION; BLACK ROCK PHARMACY; :  
and MIDDLEPORT FAMILY HEALTH CENTER;

Plaintiffs, :

-against- :

Civil Action No.

DAVID PATERSON, not individually, but :  
Solely in his official capacity as Governor of the :  
State of New York, RICHARD F. DAINES, M.D., :  
not individually, but solely in his official capacity :  
as Commissioner of the New York State :  
Department of Health, DEBORAH BACHRACH, :  
not individually, but in her official capacity as :  
Deputy Commissioner Office of Health Insurance :  
Programs, New York State Department Of Health; :  
THE NEW YORK STATE DEPARTMENT OF :  
HEALTH; and OFFICE OF HEALTH :  
INSURANCE PROGRAMS, NEW YORK :  
STATE DEPARTMENT OF HEALTH, :

COMPLAINT FOR  
INJUNCTIVE AND  
DECLARATORY RELIEF

Defendants. :

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The Pharmacists Society of the State of New York, Inc. ("PSSNY"); the National  
Association of Chain Drug Stores ("NACDS"); National Community Pharmacists Association  
("NCPA"); Black Rock Pharmacy; and Middleport Family Health Center, complain against  
David Paterson, not individually, but solely in his capacity as Governor of the State of New  
York; Richard F. Daines, M.D., not individually, but solely in his capacity as the  
Commissioner, New York State Department of Health' and Deborah Bachrach, not  
individually, but solely in her capacity as Deputy Commissioner, Office of Health Insurance

Programs, New York State Department of Health; New York State Department of Health (“the Department”); and the Office of Health Insurance Programs, allege as follows.

**NATURE OF THE CASE**

1. This Complaint is for injunctive and declaratory relief. It seeks to enjoin the September 26, 2009 four (4) percent, on average, decrease in reimbursement for drug product costs based on Average Wholesale Price (“AWP”) by the State of New York Medicaid Program (the “September 26 reimbursement reduction”). The Court should grant injunctive relief because: (a) Section 1902(a)(30)(A)<sup>1</sup> of the Social Security Act (“Section 30(A)”), preempts implementation of the September 26, 2009 reimbursement reduction because the rates will not comply with the “quality of care” and “access” provisions of Section 30(A); (b) the State 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 September 26, 2009 reimbursement reduction; (c) the State failed to provide public notice of changes to its reimbursement for brand-named and generic drugs as required by federal law; (d) New York violated federal law by making reimbursement payments that are lower than New York’s own best estimates of pharmacies’ actual acquisition costs; and (f) the reimbursement reduction will reduce the quality of care and services delivered to Medicaid beneficiaries in the State of New York and, as such, violates state law. For these reasons, Plaintiffs are entitled to a declaratory judgment that the September 26, 2009 reimbursement reduction violates federal and state law, and injunctive relief.

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<sup>1</sup> Section 30(A) is codified at 42 U.S.C. § 1396a(a)(30)(A).

**JURISDICTION AND VENUE**

2. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1331 because the claims asserted herein arise under the Constitution and the laws of the United States. In addition, this Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

3. 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**

4. PSSNY is a 130-year old association with nearly 3,000 members including pharmacies, pharmacists and technicians located throughout the State. PSSNY is a professional and trade association whose main purpose is to promote the interests of providers of pharmaceutical services within the State of New York. PSSNY also seeks to assure that patients have access to safe and appropriate care, which includes lobbying and otherwise acting to promote reasonable reimbursement for pharmacy services. PSSNY members have standing to bring this action in their own right; the interests at stake are consistent with PSSNY's organizational purpose; and neither the relief requested nor the claims asserted require the participation of such members although several are named plaintiffs herein. Many of PSSNY's members participate in New York's Medicaid program.

5. NACDS is a national association whose members include over 25 pharmacy chains in New York with over 2,100 individual pharmacies within the State. NACDS's mission includes assuring its members are adequately reimbursed by federal and state

healthcare programs and assuring patient access to pharmaceutical care. NACDS members participate in New York's Medicaid program.

6. NCPA is a national association whose members include independent community pharmacies and pharmacists including independent community pharmacists in New York. The nation's independent community pharmacists are small business entrepreneurs and multifaceted healthcare providers who represent a vital part of the United States' healthcare delivery system. NCPA's members are acknowledged by consumers as 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. Many of NCPA's members participate in New York's Medicaid program.

7. Black Rock Pharmacy is a pharmacy licensed in New York located in Buffalo, New York. Black Rock Pharmacy provides services to Medicaid beneficiaries including dispensing prescription drug products subject to the September 26, 2009 reimbursement reduction.

8. Middleport Family Health Center is a pharmacy licensed by New York located in Middleport, New York. Middleport Family Health Center provides services to Medicaid beneficiaries including dispensing prescription drug products subject to the September 26, 2009 reimbursement reduction.

9. David Paterson is named solely in his official capacity as Governor of the State of New York. As Governor, Mr. Paterson has executive responsibility for the Department,

the single state agency responsible for administering the Medicaid Program in the State of New York. N.Y. Soc. Serv. Law §§ 363-a and 364 (2009)

10. Richard F. Daines, M.D. is sued solely in his capacity as Commissioner of the Department. The Department is charged with administering the Medicaid program in New York and the department that will implement the September 26, 2009 reimbursement reduction.

11. Deborah Bachrach is sued solely in her capacity as the Deputy Commissioner of the Department's Office of Health Insurance Programs, the designated medical assistance unit for Medicaid-related activities within the Department and the entity which will implement the September 26, 2009 reimbursement reduction described below.

12. The Department is sued in its capacity as the State of New York department charged with administering the Medicaid program in New York and the department that will implement the September 26, 2009 reimbursement reduction.

13. The Office of Health Insurance Programs is the entity within the Department which will implement the September 26, 2009 reimbursement reduction.

#### **The Medicaid Program**

14. 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 and a Medicaid State Plan which CMS reviews and approves.

15. The New York Medicaid State Plan ("State Plan") is the Department's comprehensive written statement submitted to CMS that describes the nature and scope of the State Medicaid program and gives assurances that the Department will administer the State

Plan in conformity with the specific requirements of the Social Security Act. N.Y. Soc. Serv. Law § 363-a (2009). CMS must approve all amendments to a State Plan before a state may implement “material changes.” 42 C.F.R. § 430.12(c)(1)(i) and (ii). In addition, a State must give public notice of changes in Statewide methods and standards for setting payment rates. 42 C.F.R. § 447.205.

16. 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).

17. 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.*

18. 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. § 447.204.

19. 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 New York’s Medicaid Reimbursement**

20. 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 New York.

21. 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.<sup>2</sup>

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

23. With regard to the second component, New York Medicaid reimbursement for multiple source or brand-named prescription drugs for which no specific upper limit has been set by CMS cannot exceed the lowest of (i) the Estimated Acquisition Cost (“EAC”) of such drug to pharmacies, or (ii) the dispensing pharmacy’s usual and customary price charged to the general public. New York Soc. Serv. § 367-a(9)(b)(ii).

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<sup>2</sup> A reimbursement rate for each individual drug product is set for, and corresponds to, the National Drug Code (“NDC”) for that drug product. A NDC is a unique numerical code that identifies the manufacturer, active ingredients, dosage size, and packaging for a drug product.

24. New York has not made assurances to CMS that the reimbursement cuts that went into effect on September 26, 2009 represents its best estimate of EAC as required by federal law. 42 C.F.R. §447.518.

25. New York also has not certified to the federal government in its State Plan that the reduced reimbursement as of 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.”

#### **The AWP Reductions**

26. First DataBank, Inc. and Medi-Span, clearinghouses of data pertaining to the pharmaceutical industry, publish lists of prescription drugs and the AWP for each prescription drug. New York uses First DataBank and Medi-Span AWP data in calculating its EAC.

27. 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 AWP for 1,442 NDCs. In addition, First DataBank announced it would voluntarily cut the WAC mark-up to 1.20 when setting AWP 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 AWP occurred on September 26, 2009. Medi-Span agreed to do the same.

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

#### **The Department’s Failure To Comply With Federal And State Laws**

29. There is nothing in the administrative record that suggests that New York 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.

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

31. In addition, there is no indication that New York 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.

32. New York must amend its State Plan before implementing “material changes,” including those made to “reflect. . . court decisions” such as the First DataBank case. 42 C.F.R. § 430.12(c).

33. There is no evidence that New York 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.

34. There is no evidence that the new, reduced reimbursement payments were “designed to enlist participation” of sufficient providers of Medicaid, as New York warranted in the state plan.

35. New York 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 New York.

**Harm To Pharmacies And Their Patients**

36. Unless enjoined, the effect of the reimbursement reduction will be catastrophic for Medicaid beneficiaries across New York, 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.

37. 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.

38. Bradley J. Arthur, the owner and operator of Black Rock Pharmacy located in Buffalo, New York, has stated that current reimbursement rates barely cover his acquisition costs. Mr. Arthur stated that he cannot afford to provide medications to Medicaid patients where the reimbursement paid is below the actual cost of acquisition of the drugs. Therefore, Mr. Arthur has stated that, if the September 26, 2009 reimbursement reduction goes into effect, he may not be able to continue his Medicaid pharmacy business, accept new Medicaid patient, and/or fill prescriptions for high cost drugs including AIDS medications and anti-psychotropics for Medicaid patients. In addition, Mr. Arthur may be forced to limit his Pharmacy's business hours and/or layoff employees.

39. Similarly, Stephen L. Giroux, the owner and operator of Middleport Family Health Center located in Middleport, New York, has stated that current reimbursement rates barely cover his acquisition costs. Mr. Giroux stated that he cannot afford to provide medications to Medicaid patients where the reimbursement paid is below the actual cost of acquisition of the drugs. Therefore, Mr. Giroux has stated that, if the September 26, 2009 reimbursement reduction goes into effect, it will significantly affect his ability to continue to provide services to Medicaid patients.

40. **Thus, Medicaid patients may lose access to lifesaving medications.**

41. At various meetings with the Department and the Governor's Office, including one on September 28, 2009, several New York State pharmacy associations proposed that the State change its calculation of EAC to use a Wholesale Acquisition Cost ("WAC") methodology that would not affect quality of care and access to the degree of the pending September 26, 2009 reimbursement reductions and would better reflect the EAC of pharmacies. To date, the State has not implemented any of these alternatives.

42. Pharmacies made every effort, including bringing pharmacy owners to meetings, to alert the Department and the Governor's office to the detrimental effects of the planned September 26, 2009 reimbursement reduction on actual patient access and quality of care. The Plaintiffs regard this lawsuit as a last resort which they sought to avoid. The Governor's office and the Department have left pharmacies with no choice but to sue and seek injunctive relief.

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

#### **COUNT I**

#### **(For an Injunctive Halting the September 26, 2009 Reimbursement Reduction)**

44. Plaintiffs repeat and reallege Paragraphs 1 through 43 as if set forth fully herein.

45. Pursuant to Section 30(A), the State had a duty to consider efficiency, economy, quality, and access when establishing reimbursement rates. 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 by implementing the September 26, 2009 reimbursement reduction because it

has failed to consider or give sufficient weight to the impact of the rate reduction on quality of care or access to care for Medicaid beneficiaries required by Section 30(A), including the relationship of the 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 intended implementation of the September 26, 2009 reimbursement reduction. Finally, it is evident that the new rates 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.

46. Moreover, there is no evidence that the Department has complied with the requirements of federal law to obtain approval of a State Plan amendment prior to implementing the September 26, 2009 reimbursement reduction. There is 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. Finally, there is no evidence that the Department provided any notice to pharmacy providers regarding the reduction to its prescription drug reimbursement rates prior to the propose implementation of the September 26, 2009 reimbursement reduction as required by Federal law.

47. Further, there is no evidence that the Department has complied with state law requirements that it obtain approval for an amendment to the State Plan prior to implementing it or that it make arrangements to obtain or retain such approval of the State Plan, N.Y. Soc. Serv. § 363-a.

48. There is no evidence that the Department has complied with the state law requirement that it develop options to expand coverage, leverage state and federal resources

and take every effort to facilitate the provision of medical assistance prior to implementing the rate cut. N.Y. Const. XVII, § 1 and N.Y. Soc. Serv.

49. There is no evidence that the Department determined that EAC went down by, on average, 4% on September 26, 2009 and no evidence that the Department represented to CMS that this occurred.

50. In short, the Department will act arbitrarily and capriciously, unlawfully and in violation of the Supremacy Clause of the United States Constitution, the Social Welfare Clause of the New York Constitution and its own state laws if it implements the September 26, 2009 reimbursement reduction. Based on the foregoing violations, Plaintiffs have a likelihood of success on the merits.

51. Irreparable harm will occur if the rate cut goes into effect because the members of PSSNY, NACDS, and NCPA and the other named plaintiffs in this matter will be forced to reduce level of services, deny prescriptions to new Medicaid beneficiaries, shut down, reduce service hours, and/or refuse to participate in the Medicaid program and provide services to Medicaid beneficiaries. Plaintiffs will not be able to ascertain lost patients, customers, revenue, and profits. Plaintiffs have no administrative remedy, nor any plain, speedy, or adequate remedy except by this complaint for injunctive relief.

52. 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 reimbursement reduction goes into effect, as well as the inevitable loss of employment if the Pharmacies are forced to close or lay off workers, outweighs little if any monetary loss to the State. This is particularly true, since the current fiscal budget calculated Medicaid prescription drug reimbursements based on the then-current

AWP rate. Accordingly, any reduction in the AWP will not be a harm to the State but rather a windfall.

53. 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 Pharmacies can continue to serve Medicaid beneficiaries.

WHEREFORE, Pharmacies respectfully request that this Court enter an injunction enjoining the State from implementing the September 26, 2009 reimbursement reduction.

**COUNT II**  
**(Declaratory Judgment that the September 26, 2009  
Reimbursement Reduction Violates Federal and State Law)**

54. The Pharmacies repeat and reallege Paragraphs 1 through 53 as if fully set forth herein.

55. An actual controversy exists between the parties concerning whether the reimbursement reduction that took effect on September 26, 2009 violates federal and state law.

56. For the reasons set forth above, the September 26, 2009 reimbursement reduction violates both federal and state law as being preempted by Section 30(A) of the Social Security Act for failing to comply with federal regulations governing the Medicaid program, and being contrary to state law.

WHEREFORE, Pharmacies respectfully request that this Court enter a judgment declaring the reimbursement reduction that took effect on September 26, 2009 is null and void and enjoining the Department from paying reimbursement rates lower than those in effect on

September 25, 2009, and granting such other and further relief as to the Court may seem just and proper.

Dated: New York, New York  
September 29, 2009

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