

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Meyer</i>	DATE <i>1-4-08</i>
--------------------	-----------------------


DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>000328</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>cc: Ms. Forkner, Singleton</i> <i>WJ</i>	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____ <input type="checkbox"/> FOIA DATE DUE _____ <input checked="" type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Miguel</i>	DATE <i>1-4-08</i>
---------------------	-----------------------

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOC NUMBER <i>000328</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>cc: Ms. Forkner, Singleton</i> 	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____ <input type="checkbox"/> FOIA DATE DUE _____ <input checked="" type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations
Disabled and Elderly Health Programs Group (DEHPG)



December 21, 2007

JAN 03 2008

*Log to: Myers
cc: Emma, with
Depts or not?*

Department of Health & Human Services
OFFICE OF THE DIRECTOR

Dear State Medicaid Directors,

The United States District Court for the District of Columbia has issued a preliminary injunction that enjoins CMS from implementing the final rule with comment concerning Average Manufacturer Prices (AMPs) to the extent that it affects Medicaid reimbursement rates for retail pharmacies under the Medicaid program. The order also enjoins CMS from disclosing AMP data to certain individuals or entities, including States or their representatives. A copy of the Order is attached to this letter.

As a result of this preliminary injunction, CMS will not be posting AMPs or Federal Upper Limits (FULs) on our website in late December 2007 despite the schedule we provided for such postings when the final rule with comment was published on July 17, 2007. Consequently, the schedule for States to implement the new FULs will be delayed until further notice. In addition, CMS is suspending the sending of monthly files of AMPs to States.

The preliminary injunction does not affect the use of AMP as defined in the July 17, 2007 final rule with comment for purposes of the Medicaid drug rebate program. Therefore, drug manufacturers will continue to report AMPs in accordance with the provisions of the July 17, 2007 rule and CMS will continue to issue unit rebate amounts (URAs) to the States based on the quarterly manufacturer submissions.

Sincerely,

Gale P. Arden

Gale P. Arden
Director

Attachment

Page 2 - State Medicaid Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Martha Rothery
Director, Health Policy Unit
American Public Human Services Association

Dennis Smith
Director
Center for Medicaid & State Operations

Bill Lasowski
Center for Medicaid & State Operations

David Hoskins
Office of General Council

Winnie Pizzano
Office of External Affairs

Susan McNally
Office of Legislation

Laura Caliguiri
Office of the Secretary

Deirdre Duzor
Director, Division of Pharmacy
Disabled & Elderly Health Programs Group

Larry Reed
Technical Director, Division of Pharmacy
Disabled & Elderly Health Programs Group

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF CHAIN
DRUG STORES *et al.*,

Plaintiffs,

v.

MICHAEL O. LEAVITT, SECRETARY OF
HEALTH AND HUMAN SERVICES *et al.*,

Defendants.

Civil Action No. 1:07cv02017 (RCL)

ORDER

Upon consideration of Plaintiffs' Motion for Preliminary Injunction and Defendants' Opposition thereto, and having conducted a hearing on this matter, the Court finds that:

1. Plaintiffs are likely to succeed on the merits of their claims that Defendants violated the Administrative Procedure Act and acted contrary to law and/or arbitrarily and capriciously in creating its Average Manufacturer Price rule, 72 Fed. Reg. 39142 (July 17, 2007) ("AMP Rule") because the AMP Rule does not comply with either the statutory definition of "average manufacturer price" or the statutory definition of "multiple source drug" as stated by the Court at the hearing on December 14, 2007;
2. Unless enjoined, Defendants' actions are likely to cause Plaintiffs to suffer irreparable harm for which no adequate remedy at law exists as Plaintiffs' members will not be able to recover from the Defendants if the AMP Rule is implemented, and thousands of Plaintiffs' member pharmacies are expected to be forced to reduce hours and services, forced out of the Medicaid program, or forced to close;

3. The harm that will result to Plaintiffs' member pharmacies as a result of Defendants' actions outweighs any harm that may result to Defendants as a result of preliminary injunction; and

4. Issuance of a preliminary injunction will serve the public interest as it is in the public interest for federal departments and agencies to operate in compliance with the law and Medicaid beneficiaries may find access to their retail community pharmacies reduced or eliminated should the injunction not be issued.

Therefore, it is hereby

ORDERED that Plaintiffs' Motion is GRANTED for the reasons stated above and on the record in open court at the conclusion of the hearing on December 14, 2007; and it is further

ORDERED that Defendants United States Department of Health and Human Services ("HHS"), HHS Secretary Leavitt, Centers for Medicare and Medicaid Services ("CMS"), and CMS Acting Administrator Weems, as well as HHS and CMS officers, agents, servants, employees, and attorneys be and hereby are enjoined, until further order of this Court, from:

a. Undertaking any and all action to implement the AMP Rule to the extent such action affects Medicaid reimbursement rates for retail pharmacies under the Medicaid program. Defendants may, however, continue to require drug manufacturers to make AMP calculations and best price calculations under the AMP Rule for purposes of calculating rebates paid to States in the Medicaid program; and

b. Posting any AMP data on a public website or otherwise disclosing any AMP data to any individuals or entities, including but not limited to States and their representatives or agencies, except that Defendants may disclose AMP data within the U.S. Department of Health and Human Services or to the U.S. Department of Justice for their internal use or enforcement activities only.

SO ORDERED.

Signed by Royce C. Lamberth, United States District Judge, on December 19, 2007.