December 21, 1994

MEDICAID DRUG REBATE PROGRAM Release No. 14

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

NOTE TO: All Participating Drug Manufacturers

STAGES OF THE DISPUTE RESOLUTION PROCESS

Stages of the Dispute Resolution Process (Attachment A), has been designed to provide general guidelines and time-limits associated with the dispute resolution process. We still stress the importance of open communication between both parties and keeping the Regional Office Drug Payment Coordinators involved.

EFFECT OF ADMINISTRATIVE FEES ON AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE

Recently, we have received numerous inquiries from various manufacturers or their representatives requesting guidance on whether administrative fees paid to buyers of covered outpatient drugs have any effect on AMP and/or best price calculations. We consider administrative fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program, to be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP, and best price.

Except for the explicitly listed exclusions in the rebate agreement and in section 1927 of the Social Security Act, and, in accordance with sections I(a) and I(d) of the rebate agreement, AMP and best price data "... must be adjusted by the Manufacturer if ... other arrangements subsequently adjust the prices actually realized." Thus, we consider any price adjustment which ultimately affects the price actually realized by the manufacturer as "other arrangements" and, as required by the rebate agreement, included in the calculations of AMP and best price.

Please remember that any prices which are nominal in amount, that is, less than 10% of the AMP in the same quarter for which the AMP is computed, are excluded from the best price calculation. Therefore, if any arrangement results in prices which are nominal, those sales and prices do not affect best price and must be excluded by the manufacturer.

NOTICE TO HCFA OF REVISED AVERAGE MANUFACTURER PRICE (AMP) CALCULATION METHODOLOGY

Several drug labelers have notified HCFA of their intent to recalculate the AMPs for selected drug products. In those situations where you plan to submit revised AMPs and are changing the method by which you calculate the AMPs, contact HCFA prior to submitting revised AMPs to explain why you are recalculating the AMPs, the magnitude of the changes, the rationale being used, documentation to support the changes and whether these changes will affect your AMPs both retroactively and prospectively. HCFA will review this documentation and decide whether the proposed change conforms to the statute and the manufacturer's agreement. Do not submit any recalculated AMPs until notified to do so by HCFA. All documentation should be submitted to:

Medicaid Drug Rebate Program
P.O. Box 26686
Baltimore, MD 21207-0486

UNIQUE MEDICAID FACTORS TO BE CONSIDERED BY DRUG LABELERS IN REBATE DISPUTES

From the beginning of this program, HCFA has called upon the expertise of State Medicaid officials in trying to solve problems that occur periodically. This group of State officials referred to as the Pharmacy Technical Advisory Group (P-TAG) have provided information and help on numerous occasions. Recently, the members of the P-TAG developed a list of factors unique to State Medicaid drug programs that may help to reduce the number of rebate disputes by promoting a better understanding by the drug companies.

These factors include:

oMedicaid data includes nursing home dispensing data. Possibly, that information may not be included in manufacturer marketing data;

oRegional marketing data of manufacturers may fail to take into account any border pharmacies, chain drug store distribution systems or regional and national buying groups;

oPrescription limits (e.g., 3 per month) can result in large quantities dispensed per prescription, legitimately;

oIngredients of compounded prescriptions billed by NDC may be claimed for rebates;

oThe total amount reimbursed for prescriptions is not a reliable indicator of units dispensed since copayments, third party liability and sale pricing (loss leaders) can all reduce the total amount reimbursed;

oTopical prescriptions do not always represent one tube per prescription;

oState front end claim edits for maximum quantities must be known by manufacturers since without them, unusual quantities may appear on claims;

oDrugs the manufacturer may not consider outpatient drugs may be claimed for rebate when separate drug claims were generated and paid by the States (e.g. injectables);

oOutside data sources may not be infallible as to accuracy;

oSales data may fail to reflect all sales to wholesalers or individual manufacturer's return/substitution policies may not be reflected in sales data but do affect actual inventory at the pharmacy;

oConflicts regarding billing units still exist between the States, HCFA, First DataBank and MediSpan. This has caused a certain amount of under/over reporting by States;

oManufacturers need to explain why an NDC is not valid (e.g. expired product);

oManufacturers should know the States' unit dose policies and how they might impact rebate claims;

oMedicaid population as a percent of total State population is not a reliable indicator of Medicaid drug utilization;

oAll States have a period of time, sometimes up to a year, from the date of service of a claim in which it can be submitted for payment; (e.g. Manufacturer sales in a quarter may not be indicative of Medicaid claims paid in a quarter); **and**

oThe rebate invoices you receive from States are reflective of the claims **paid** during that calendar quarter **not** the number of claims dispensed to Medicaid patients.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from January 3, 1994 through December 19, 1994. These rates are to be used to calculate interest owed States on overdue rebates.

TOPIC INDEX

For your convenience, also attached is a topic index of all items covered in prior releases.

Please continue to contact us with your drug rebate questions by using the Drug Rebate hotline at (410) 966-3249.

Sally K. Richardson
Director
Medicaid Bureau

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

Attachment A

THE MEDICAID DRUG REBATE PROGRAM
AND THE
STAGES OF THE DISPUTE RESOLUTION PROCESS

DISPUTE RESOLUTION PROCESS:

BEGINS:When the Manufacturer notifies State of disputed data, no later than 38 days after State utilization data is sent.

ENDS:When dispute is resolved and Manufacturer or State settles all disputed money amounts, including interest.

PHASE I: Exchange of Data Time Period:

Phase I of the process falls after the State receives the manufacturer's dispute and involves a period for both parties to seek resolution of dispute through exchange of information and informal negotiations. (The resolution of inconsistencies and the exchange of data should occur by the 38th day after State sends the utilization data.)

WHEN:	THEN:
By 60 days after the end of the quarter, State sends utilization data (invoice) to manufacturer. Manufacturer has 38 Days After Receipt of State Utilization Data (Invoice) to:	
A.Mfr. edits State data & resolves data incon-sistencies with State	Mfr. distinguishes between data inconsistencies & disputes by examining such items as: -unit types, -units dispensed matches amount paid, -NDC numbers match Mfr. numbers, -incorrect decimal position. NOTE: This process can be initiated through telephone contact with State. If State gives written or telephone confirmation, resolution is recorded by the manufacturer. However, if this resolution has not been completed by the 38th day after State sends utilization data, the dispute resolution process applies.
B.Mfr. Agrees with invoice	Mfr. pays full rebate--process ends.
C.Mfr. considers cost effectiveness	Items that would have been disputed may be resolved if Mfr. considers it not cost effective to dispute.

WHEN:	THEN:
D.Mfr. pays partial rebate & disputes some data by NDC, the reason why data	Mfr. submits documentation necessary to identify, are disputed (written notice of dispute & check must be postmarked by the 37th day after the State data are sent. Interest starts on disputed portion of invoice effective 38 calendar days from the date the State mails the State utilization data.
Within 90 days after receipt of manufacturer's dispute:	
E.State contacts Mfr. to discuss, by NDC number, items disputed & reason	State contacts Mfr. by telephone to discuss dispute. State presents report of preliminary response to dispute resolution.
Within 150 days after receipt of manufacturer's dispute:	
F.State takes steps to resolve questionable data -Data of historical trends.	State provides: -Zip-code level data, (Manufacturer requests-Pharmacy level data, OR additional supportive-Opt to conduct sampling documentation from State) of pharmacy claims,
Note: Type of data provided	by State must match type of data requested by Mfr.
F.1.Both parties unable to resolve differences	-Mfr. requests State to perform random sample of pharmacies,
-State requests Mfr. to	validate data used by third party for the purpose for which the manufacturer supplied it.

NOTE: States will ensure any exchange of data protects the confidentiality requirements of section 1927(b)(3)(D) of the Social Security Act. In the case of pharmacy level data, the State may request the Mfr. supply its data if confidentiality laws prevent State release of information.

Within 240 days after receipt of manufacturer's dispute:

WHEN:	THEN:
G.State considers cost effectivessness	If the exchange of information fails to remove dispute, and the disputed amount is BOTH -under $10,000 per Mfr.'s labeler code, AND -under $1,000 per product code of Mfr.'s labeler code (at 9-digit NDC level) the State may choose to cease the dispute process. NOTE: State maintains discretion to enter into the dispute process in cases that fall below these thresholds.
H.State/Mfr. complete good faith negotiations	Settlement can be made on: -State utilization data, (State should document incorrect data) OR -Valid documentation that other data was acceptable.
I.State/Mfr. unable to reach agreement.	The formal review processes are considered in Phase II of the Dispute Resolution Process.The State and Mfr. must proceed to Phase II - Formal Review Process

PHASE II: Formal Review

Phase II of the process is initiated when the dispute is not resolved and when all steps in Phase I have been completed. A State or a manufacturer may proceed to phase II if either party has not fulfilled its obligations under a step in the first phase of the process.

Within 30 days from the end of Phase I process the State must schedule a hearing that must be conducted no later than one year from the 240th day after the State receives manufacturer's dispute. The State and Manufacturer may continue to attempt to settle disputes before the hearing is conducted by considering the settlement options described below.

WHEN:	THEN:
A. Mediation Review-Process in which mediator assists parties in reaching their own settlement but does not have authority to make a binding decision	-Both parties sign agreement to mediate, -Request for mediation prepared with brief statement of dispute, +Both parties agree on how to share mediation expense, +Qualified mediator selected, +Both parties agree on mediator, +Mediator will have no financial or personal interest in result of mediation,
+Agreement reached, +Both parties sign +Agreement states +Amount in dispute paid +Mfr./State records	settlement agreement, settlement & payment of mediation expense, plus interest due, documented,
+Agreement not reached, +Both parties declare in +Parties pursue Binding	writing that mediation ended, Arbitration or State Hearing.

WHEN:	THEN:
B. Non-Binding Arbitration-Both parties agree to Process in which each party participate in arbitration presents its case at an by submitting an informal informal hearing to a request to the other party, neutral party-Parties agree on share of arbitration fee, -Both parties agree on arbitrator-Decision reached & -Agreement states settlement -Final decision subject to -Amount in dispute paid -Mfr./State records -Agreement not reached, -Parties agree on share of -Parties pursue Binding	settlement agreed by both parties, and payment of fees, confirmation at a higher State Agency level, including interest, documented, arbitration fee, Arbitration or State Hearing.

WHEN:	THEN:
C. Binding Arbitration-Both parties agree to Process in which a dispute participate in arbitration, is submitted to one or more-Both parties agree on impartial persons for a arbitrator or panel, final and binding decision +Arbitrator could be -Settlement agreed by both parties, -Award submitted by arbitrator stating relief and -If arbitration panel consists of more than one arbitrator the majority decision is binding.	+Arbitrator could be panel of individuals agreed to by the State agency & Manufacturer, independent arbitration association.e.g., American Arbitration Association, arbitration fees,

WHEN:	THEN:
D. Upon request by either party for a hearing, an administrative review would be conducted by an impartial individual or panel as a hearing officer to facilitate settlement. This review would occur while State Hearing is being scheduled. If agreement reached, State hearing would be cancelled.	Administrative Review-State requests date for State hearing, Administrative Review scheduled prior to hearing, Hearing officer appointed for Administrative Review, appointed or hired-Settlement reached at administrative review level, +Amount of rebate paid plus interest. +Settlement documented, date+Request for State hearing cancelled Agreement not reached at Administrative Review level, +Parties proceed to a State hearing which was scheduled prior to Admin. Review.

State Hearing must be conducted no later than one year from the 240th day after State receives Manufacturer's dispute.

E. State will make its State hearing mechanism as defined in the statute and State law-	State Hearing -Hearing Held available-Decision rendered -Dispute resolved -Rebates+interest pd. -Records documented

OPTIONAL ALTERNATIVES

The following option falls outside of the dispute resolution process, however, the National Rebate Agreement provides the following as an alternative States may pursue after receipt of manufacturers written dispute.

WHEN:	THEN:
Mfr. & State unable to resolve dispute	State may schedule an administrative hearing or tentatively schedule a hearing.
Mfr. & State agree on resolution. Mfr. pays rebate due but not interest due.	State tracks interest due and follows up with Mfr. Interest starts accruing on unpaid interest.

Phase I of the Dispute Resolution Process describes the type of data Manufacturers may request and States may provide in an attempt to resolve a dispute. Excluded from this level of the dispute process would be audits, i.e, fraudulent claims and claims level data requests. An audit may be pursued at any time throughout the dispute resolution process.

WHEN:	THEN:
CLAIMS DATA AUDITS	
-Manufacturer requests-State, with appropriate audit of State utilization Manufacturer input, develops data mutually agreeable audit procedures	
-Manufacturer requests pharmacy-State agrees to audit claims level data pharmacy -State has independent third party audit pharmacy -Payment for audit determined between parties.	
-Audit indicates either State-Adjustments to rebates utilization was greater made or less than previously-Dispute ends specified or information inaccurate	
-After audit performed,-Dispute still exists State and Manufacturer still-Proceed to Phase II in dispute	