

March 4, 1997

MEDICAID DRUG REBATE PROGRAM

Release Number 66

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

NOTE TO: All State Medicaid Directors

RIGHT OF STATES TO FILE AS CREDITORS TO DRUG COMPANY BANKRUPTCIES

Recently, a State Medicaid agency (SMA) filed a claim in the bankruptcy proceeding initiated by Vanguard Labs, Inc. The claim was objected to by the attorney for the debtor, Vanguard Labs, on grounds that the debt is not enforceable against the debtors.

SMA's should continue to file as creditors as soon as bankruptcies become known when there are unpaid rebates due and payable by the bankrupt entity. It needs to be made clear that participating drug companies are required to pay states a rebate amount per the drug rebate provisions of the statute at 42 U.S.C. 1396r-8, where it specifies that a manufacturer must enter into a rebate agreement in order for payment to be made available for its drugs under the Medicaid program. A manufacturer which participates in the program is required to give each state a rebate based, in part, on the volume of its products that were paid for by the state on behalf of the state's Medicaid recipients. States should be prepared to submit documentation to provide a basis for their rebate claims.

SMA's may have to confer with their own attorneys to ensure that the claim is specific, contains adequate documentation and explains the basis for the debtor claim.

REVISION TO INSTRUCTIONS FOR FORM HCFA-304 (RECONCILIATION OF STATE INVOICE (ROSI))

In our original instructions there was an exception to the requirement for completion of the ROSI. That exception being that if there are no zero rebate per unit (RPU) amounts reported on the State's invoice, and the labeler is remitting, in full, the rebate amount claimed for the current quarter utilization, there is no requirement to complete and submit a ROSI report.

Because there are several reasons why a State invoice may contain zeros in the RPU field, some of which are not the fault of the labeler, we have expanded the exception for completion and submission of the ROSI. The following list shows the circumstances under which the ROSI is and is not required.

1. Labeler is NOT paying, in full, the rebate amount due for the current quarter utilization, i.e., the labeler is disputing any units invoiced.

ROSI IS REQUIRED

2. State invoice contains zeros in the RPU field because no dollar figure has been made available via the HCFA tape (due to the labeler's lack of data submittal), AND the labeler is remitting the rebate amount due, in full, for the current quarter utilization.

ROSI IS REQUIRED

3. State invoice contains zeros in the RPU field where a dollar figure has been made available via the HCFA tape, AND the labeler is remitting the rebate amount due, in full, for the current quarter utilization. (In lieu of the ROSI, a copy of the State invoice must be returned with the full remittance. Labelers may optionally pen/ink the RPU field on the invoice copy, however, it is not a requirement.)

NO ROSI REQUIRED

4. State invoice contains zeros in the RPU field due to HCFA data edits, AND the labeler is remitting the rebate amount due, in full, for the current quarter utilization. (The labeler must make pen/ink changes to a copy of the State invoice and return it with the full remittance.)

NO ROSI REQUIRED

5. State invoice contains **no** zeros in the RPU field, AND the labeler is remitting, in full, the rebate amount due for the current quarter. (In lieu of the ROSI, a copy of the State invoice must be returned with the full remittance.)

NO ROSI REQUIRED

NOTE: Labelers have the option of always completing/submitting the ROSI regardless of the circumstances listed above.

The above revisions to the ROSI instructions are effective immediately and incorporated into the Medicaid Drug Rebate Operational Training Guide with the issuance of this release.

UPDATES TO THE MEDICAID DRUG REBATE OPERATIONAL TRAINING GUIDE

This is our first update to the operational training guide. Below is a list of those pages which should be replaced in your guide and the reason for the page revision. Please keep your guide updated to assure that your program is operating under the most recent instructions and guidelines. You may continue to direct your comments/suggestions on the guide to Sue Williams (410-786-3334) or Vince Powell (410-786-3314).

<u>PAGE</u>	<u>REVISION</u>
F7a	New form style.
F11b	Revised example; addition of omitted calculation step.
F14	Typographical error corrected.
F32 - F32a	Revised instructions for ROSI form (Page F32a is new).
F38 - F40	Revised instructions for ROSI form (Pages F39-F40 - pagination only).
G11 - G14	Revised to further clarify instructions.
M3 - M6	New form style.
M7	New form style; additions to option 2.
M10 - M11	New form style; rebate contact added.
O6	New coordinator for Kansas City Regional Office.
P3	Correction to Best Price definition.
Q2	AMP acronym corrected.
R2-R3	Page references revised.

LABELER TERMINATIONS

The following labelers have requested to be terminated from the Medicaid Drug Rebate Program effective April 1, 1997.

Stolle Health and Nutrition (Labeler Code 41701), and

Novo Nordisk Pharmaceuticals, Incorporated (Labeler Code 61874).

NEW LABELERS

The following labelers signed rebate agreements and will begin their participation in the Medicaid Drug Rebate program effective April 1, 1997.

Digestive Care, Inc. (Labeler Code 59767);

Andrx Pharmaceuticals, Inc. (Labeler Code 62037);

Vivus, Inc. (Labeler Code 62541);

Care Technologies, Inc. (Labeler Code 62653);

Brightstone Pharma, Inc. (Labeler Code 62939); and

Nnodum Corporation (Labeler Code 63044).

Retroactive Effective Date

Agouron Pharmaceuticals, Incorporated (Labeler Code 63010) is joining the drug rebate program retroactive to January 1, 1997 due to the possibility that their original rebate agreement was submitted but lost in transit.

ATTACHMENTS

Copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of July 1, 1996 through March 3, 1997 are attached.

Please remember to direct your drug rebate questions to a staff member listed in section O of the Medicaid Drug Rebate Operational Training Guide.

/s/

Judith D. Moore
Acting Director
Medicaid Bureau

3 Attachments

cc:

All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid