

December 19, 1997

**MEDICAID DRUG REBATE PROGRAM**

**Release Number 73**

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

**NOTE TO: All State Medicaid Directors**

**ADDITIONAL REBATE PAYMENTS FROM McNEIL PHARMACEUTICALS FOR HALDOL**

Based on agreement with McNeil Pharmaceuticals (labeler 00045), the company has recalculated pricing data for HALDOL for the period 1991 - 1993, consistent with our guidance to other manufacturers. As a result, significant additional rebates are due the states. McNeil is attempting to complete the processing and payment of these additional amounts by the end of December 1997, or shortly thereafter. Please be advised the company will be sending spreadsheets to each state explaining the additional payments based on the revised pricing data and the reported state utilization. Subsequently, McNeil will pay the appropriate interest upon the states' agreement with and acceptance of the additional amounts.

Further, McNeil is aware that the recalculation is subject to possible review by the Office of the Inspector General. As is the case with all pricing data provided to HCFA for the Medicaid drug rebate program, if HCFA determines that the recalculation requires revision, the company will be required to take appropriate corrective action. We encourage the states to work with McNeil in accepting these additional payments and, with the subsequent receipt of applicable interest, to finally reach closure for the disputed rebates on HALDOL for the period 1991 - 1993. Further discussions are underway with McNeil to reach resolution on the remaining HALDOL rebates for 1994 and forward. We will advise all states when an agreement is reached.

We appreciate the considerable effort McNeil has made in processing the recalculation and payment of the additional amounts and for the states' significant efforts in processing and reconciling these payments. We particularly appreciate the states' patience as we worked toward settlement of these longstanding disputes.

**DRUG LABELERS**

**CHAPTER 11 BANKRUPTCY**

We received information to indicate that on November 12, 1997, both Solopak Medical Products, Incorporated (Labeler Code 59747) and Solopak Pharmaceuticals, Incorporated (Labeler Code 39769) filed for Chapter 11 (reorganization) bankruptcy in the United States Bankruptcy Court, Southern District of Florida. The case number is 97-35655 and the attorney representing these drug labelers is Paul Steven Singerman, Esquire, 200 S. Biscayne Boulevard, Suite 3410, Miami, Florida 33131. Claims for unpaid rebates can be mailed to: Clerk, U.S. Bankruptcy Court, 51 SW 1 Avenue, Room 1517, Miami, Florida 33130.

**Terminations**

The following labelers are being voluntarily terminated effective April 1, 1998:

American Urologicals, Incorporated (Labeler Code 00539); and

F.A. Mitchell Company, Incorporated (Labeler Code 10770).

Ion Labs, Incorporated (Labeler Code 55532) of Pinellas Park, Florida is being terminated effective April 1, 1998 for failure to provide pricing data. This is the second time that this drug labeler was enrolled and subsequently terminated.

**CHANGE TO THE ELECTRONIC RECORD SPECIFICATIONS FOR INVOICES, THE RECONCILIATION OF STATE INVOICE (ROSI) AND THE PRIOR QUARTER ADJUSTMENT STATEMENT (PQAS)**

Enclosed are replacement pages **F27, F28, F41, F42, F44, F65, F66** and **F68** for the Medicaid Drug Rebate Operational Training Guide. These changes are necessary to expand to four positions the year in the invoice **Period Covered** field and the **Quarter Covered** field for both the HCFA Forms 304 (ROSI) and 304a (PQAS) and to expand the report creation date field to eight positions. This change is effective for all electronic transmissions of the ROSI or PQAS created by drug labelers on or after **July 1, 1998**. The change to the electronic invoice record will be effective for invoices created on or after **January 1, 1999**.

**NEW RECORD SPECIFICATIONS FOR HCFA DATA**

Included with this release are the revised specifications for data maintained by HCFA which can be downloaded from the HCFA website at [www.hcfa.gov](http://www.hcfa.gov) or purchased via the HCFA Public Use File (PUF) facility on either magnetic tape or data cartridge. The changes for these data will be effective on or about June 1, 1998.. Questions can be referred to Al Beachley at (410) 786-3276.

**OTHER ATTACHMENTS**

Copies of the topic index and a listing of the 90-day treasury bill auction rates for the period of September 15, 1997 through December 15, 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 or in State release #53.

/s/

Sally K. Richardson  
Director  
Center for Medicaid and State Operations

4 Attachments

cc:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

**HCFA RECORD SPECIFICATION  
 MEDICAID DRUG UTILIZATION DATA  
 PUBLIC USE FILE NO. 1**

<b>Field</b>	<b>Size</b>	<b>Position</b>	<b>Remarks</b>
State Code	2	1 - 2	P.O. Abbreviation
Labeler Code	5	3 - 7	NDC #1
Product Code	4	8 - 11	NDC #2
Package Size	2	12 - 13	NDC #3
Period Covered	5	14 - 18	YYYYQ (Yr/Qtr)
Prd. FDA Reg. Name	10	19 - 28	Abbr. Product Name
Total Units Reimbursed	13	29 - 41	9999999999V999
No. of Prescriptions	6	42 - 47	999999
Total Reimb. Amount	11	48 - 58	9999999999V99

**HCFA RECORD SPECIFICATION  
 MEDICAID DRUG PRODUCT DATA  
 PUBLIC USE FILE NO. 3**

<b>Field</b>	<b>Size</b>	<b>Position</b>	<b>Remarks</b>
Labeler Name	39	1 - 39	Company Associated w/ NDC #1
Labeler Code	5	40 - 44	NDC #1
Product Code	4	45 - 48	NDC #2
Package Size	2	49 - 50	NDC #3
Drug Category	1	51 - 51	See Data Element Definitions
DESI Indicator	1	52 - 52	See Data Element Definitions
Drug Type Indicator	1	53 - 53	See Data Element Definitions
Termination Date	8	54 - 61	MMDDYYYY
Unit Type	3	62 - 64	See Data Element Definitions
Units Per Pkg Size	10	65 - 74	9999999V999
FDA Approval Date	8	75 - 82	MMDDYYYY
Date Entered Market	8	83 - 90	MMDDYYYY
Product Name	63	91 - 153	FDA Registration Name
Filler	2	154 - 155	