

February 3, 1998

MEDICAID DRUG REBATE PROGRAM

RELEASE #75

TODAY'S NEWS

for State Medicaid Directors

IMPORTANT INFORMATION REGARDING "HALDOL" REBATES

In State Release Number 73 dated December 19, 1997, we outlined the recent resolution for rebates due on McNeil Pharmaceuticals' drug, Haldol, for 1991-1993. In that release, we stated that, as a result of recalculated pricing data for Haldol, "significant additional rebates are due the States." In fact, nationwide, the additional rebate payments exceed \$11 million. However, we recognize that in some cases, the payment amounts are markedly less than what was originally invoiced and this has caused some States concern. To clarify any misunderstanding, we are taking this opportunity to provide further explanation of the recalculation and the effect on rebates.

Most importantly, only Haldol rebates for quarters in the period January 1, 1991 through December 31, 1993 are affected. The manufacturer had previously submitted overstated pricing data for Haldol, which resulted in an inflated unit rebate amount (URA). As a result of discussions between HCFA and McNeil representatives, the manufacturer recalculated and resubmitted pricing data for Haldol in accordance with the rebate agreement and consistent with our guidelines provided to all manufacturers. The recalculated pricing data for Haldol resulted in a reduction in the URAs. Based on the reduced URAs, rebates are less, and in some cases, significantly less than those amounts originally invoiced by the States. Please keep in mind that the original invoiced rebates were based on URAs which were derived from high and incorrectly reported pricing data. Thus, the original invoiced rebate amounts are not valid.

We understand the concern regarding this matter expressed by some States in recent contacts; however, there has been no policy change in the recalculation of rebates. Rather, we have consistently maintained that accurate pricing data must be reported by all

manufacturers and the rebates associated with Haldol sales are dependent on the same factors as all other drugs, specifically, units and URAs. Further, it is important to understand that the rebate payments are appropriate to the extent that the pricing data resubmitted for Haldol withstands any potential review by HCFA or the Office of the Inspector General. The company has been advised that if it is determined by HCFA that the pricing data require further revisions, then, as is the case in all situations of recalculated pricing data for manufacturers, appropriate corrective action may be required by the manufacturer, including paying additional rebates, if necessary.

While most States have indicated relief that the opportunity to resolve Haldol disputes for 1991 - 1993 finally exists, some have expressed reluctance in accepting the rebates from McNeil, citing the fact that rebates are notably less than those previously invoiced. We reiterate, even if the States' utilization data are unchanged from those units included in the original invoice, rebates might be less than those originally invoiced because the URAs are reduced. Once again, the original invoiced rebate amounts are irrelevant to the extent that they were based on incorrect and overstated pricing data.

Therefore, we encourage States to accept the additional Haldol rebate payments due from 1991 - 1993, presuming that there are no changes in the utilization previously reported and with the understanding that McNeil will pay the appropriate interest in accordance with their responsibilities under the rebate program. As we stated in Release 73, we are working toward resolution of the remaining Haldol rebates from 1994 forward and will advise all States accordingly in a future release.

We trust this information clarifies this situation and ask that you direct any Haldol related questions or comments **specifically** to either Mike Keogh or Larry Reed of my staff. Mike can be reached on (410) 786-5910 and Larry can be reached on (410) 786-3325.

NEW LABELERS

The following labelers have entered into drug rebate agreements and are joining the rebate program effective April 1, 1998:

Unigen Pharmaceuticals, Inc. (Labeler Code 62305);
Radford Therapeutics (Labeler Code 63252);
American Pharmaceutical Partners (Labeler Code 63323); and
Endo Pharmaceuticals, Inc. (Labeler Code 63481).

REINSTATED LABELER

SEQUUS Pharmaceuticals, Inc. (Labeler Code 61471) has submitted missing drug prices for all quarters and signed a new rebate agreement. This labeler is reinstated in the drug rebate program effective April 1, 1998.

TERMINATED LABELERS

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

Hall Laboratories (Labeler Code 00417)
Perry Medical Products (Labeler Code 11763)
Bradley Pharmaceuticals, Inc. (Labeler Code 49729)
The Biopractic Group II, Inc. (Labeler Code 57895); and
Glasgow Pharmaceutical Corp. (Labeler Code 60809)

ATTACHMENTS

Copies of the topic index and a listing of the 90-day treasury bill auction rates for the period September 15, 1997 through January 26, 1998 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/

Sally K. Richardson
Director
Center for Medicaid and State Operations

2 Attachments

cc:

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