April 26, 1997

MEDICAID DRUG REBATE PROGRAM

Release Number 67

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

NOTE TO: All State Medicaid Directors

GENERIC SUBSTITUTION LAWS - RESPONSE REQUIRED

The Dispute Resolution Project (DRP), piloted in Boston, has been active for over two years. During this time, many meetings between States and drug companies have taken place and resulted in the resolution of millions of dollars in dispute. As we continue this project, we are constantly updating our procedures, using those tools that work, putting aside those that do not.

To this end, it has become apparent that written documentation specifically targeting drug substitution laws and procedures in each State would be an invaluable asset during these meetings. We are therefore requesting that each State provide, in writing NO LATER THAN MAY 12, 1997, current procedures for drug substitution. As a minimum, the following questions should be answered:

1. On the prescription order for a multisource drug, how must the prescriber indicate:

    a. Substitution of a generic equivalent is allowed;

    b. Substitution of a generic equivalent is NOT allowed;

    c. Substitution of a generic equivalent is at the discretion of the pharmacist; or

    d. Substitution of a generic equivalent is at the discretion of the patient?

2. Do your State's pharmacy laws require pharmacists to dispense brand name drugs if prescribed, regardless of the Federal requirement which limits reimbursement (for brand name drugs in some instances) at the Federal upper limits for multisource drugs?

Please understand that your response will become a permanent part of the DRP documentation package. It is imperative that each State respond, by the due date, and with as much clarity and explanation necessary so that there will be no question regarding each State's substitution laws and procedures. Please mail your response to:

DRP team
Drug Rebate Program/ Medicaid Bureau
P.O. Box 26686
Baltimore, MD 21207-0486

or FAX directly to: DRP team at (410) 786-0390.

If there are any questions regarding this request, please contact Mike Keogh on (410) 786-5910 or Vince Powell on (410) 786-3314.

UTILIZATION TAPE RECORD SPECIFICATION

In the course of furnishing State utilization data to a requesting organization, we discovered that several States are submitting the TOTAL NUMBER OF UNITS data with numbers in the decimal positions even when the units per package size field is a whole number. In one State, we were able to track the occurrence of this event to a specific calendar quarter where the State begin utilizing a microcomputer process to generate their utilization data for submission to HCFA. Their review of the record layout indicated that they had not accounted for the assumed decimal point (V) in their field descriptions. The record description was corrected, and the State is preparing to submit corrected data for the last seven calendar quarters.

It is extremely important that you ensure that State utilization data submitted to HCFA are correct. These data are being used for projects such as ascertaining what States are spending on the treatment of AIDS, projecting future State expenditures, determining the top 200 drugs based on expenditures plus the annual report to the Congress on the operation of the drug rebate program. **Specifications are located on pages F27 - F30 in the Medicaid Drug Rebate Operational Training Guide. That document is now available for download from the Internet website at hcfa.gov in the drug rebate menu.**

MEDICAID COVERAGE OF HELIDAC

Helidac has received FDA approval as a prescription ulcer drug therapy that will utilize a unit-of-use packaging system with combinations to ensure that patients take the medication properly. The packaging system includes 14 separate blister cards (one for each day that the medication is to be taken).

Each of these cards is divided into four quadrants labeled "breakfast," "lunch," "dinner," and "bedtime," and each quadrant contains the proper combination of medications.

Recently, several States have requested clarification on HCFA's reimbursement policy for Helidac. States have flexibility when determining reimbursement for this covered outpatient drug because the product contains a drug that the law allows States to exclude or restrict. Please note that:

States may pay for Helidac as a covered outpatient drug;

States may prior authorize this product to assure that less costly drugs are dispensed;

States may choose to exclude or restrict Helidac because this product contains an over-the-counter product (OTC), bismuth subsalicylate. The law allows States to exclude or restrict from coverage OTCs under section 1927(d)(2) of the Social Security Act.

For medical references or additional questions you may contact Patricia Levy on (410) 786-5917.

OUTSTANDING DISPUTES FOR 1991 AND 1992

Through our ongoing dispute resolution efforts, several States and manufacturers have cited difficulties in resolving remaining disputes from the early years of the program, specifically 1991 and 1992. While the majority of disputes for those years have been resolved, we recognize that in some instances States and manufacturers have encountered difficulty in reaching resolution on those remaining old disputes. Most frequently, States report difficulties in either retrieving 1991 and 1992 data for various reasons, such as archived data or changes to systems over the years. In any event, some States find it understandably prohibitive from a cost perspective to either retrieve or recompile the data.

In the absence of available State data from 1991 and 1992, we suggest the following steps be taken to resolve any outstanding disputes from those years:

Use available data from manufacturers;

Make reasonable utilization estimates for 1991 and 1992 from later data and utilization trends for later years; and

Maintain documentation of resolutions reached.

We believe it is reasonable to expect that all remaining disputes for 1991 and 1992 should be resolved by the end of this calendar year, and we will provide any possible assistance to States and manufacturers to achieve that goal. Additionally, to provide assurance to States which resolve disputes from 1991 and 1992 per the recommendations in this release that States will not be at risk for loss of Federal financial participation (matching funds) for uncollected rebate amounts, we offer to review the resolutions and authorize them. Please contact Mike Keogh on (410) 786-5910 or Vince Powell on (410) 786-3314 for assistance on this or other dispute resolution matters.

CLARIFICATION ON MANUFACTURERS USING MEDICAID REIMBURSEMENT AMOUNTS AS A REASON FOR DISPUTES

In Release Number 27 dated March 5, 1997 to all participating manufacturers, we reiterated our longstanding policy that the level or amount of Medicaid reimbursement is not a factor in calculating rebates. However, we restated our recognition that many manufacturers use the amount of Medicaid reimbursement as one factor in identifying possible units to dispute. We cannot dictate what methods a manufacturer uses to identify disputes and to the extent that the amount of Medicaid reimbursement helps identify erroneous units, then we believe there may be benefit in using that information as a potentially valuable tool. Thus, we believe it is inappropriate for a State to automatically dismiss the possibility that units may be erroneous without further review based simply on the fact that the manufacturer is initially questioning the level of Medicaid reimbursement relative to the units reported. However, as explained in Manufacturer Release 27, if Medicaid paid any portion of a drug claim and the units cannot reasonably be shown to be erroneous, rebates are due on those claims. Conversely, if subsequent review demonstrates that the units should be reduced, then the State must take the appropriate action to reduce the invoiced amount or credit rebates paid on those erroneous units back to the manufacturer.

Taken alone, however, the amount of Medicaid reimbursement is irrelevant to the calculation or payment of rebates under current law and the rebate agreement. Disputes must be settled on the basis of units.

ONGOING DISPUTE RESOLUTION PROJECT MEETINGS

In June, we will be expanding the Dispute Resolution Project (DRP) to the Southern Consortium in Dallas. States in the Southern Consortium will be notified by the Dallas Regional Office (RO) regarding details of the meetings. Also, we will convene another series of meetings in Denver with the Western Consortium States in July and September. Again, States in the Western Consortium will be notified regarding details on those meetings by the Denver RO. We encourage States in those areas to attend the meetings if possible. The respective ROs will provide agendas and the names of the manufacturers who will be participating in the meetings.

REBATE LIABILITY ON HEALTH MAINTENANCE ORGANIZATION FEE FOR SERVICE DRUG CLAIMS

It has come to our attention that at least one manufacturer has disputed all rebate claims from some States on drugs dispensed to HMO-covered Medicaid recipients. We are taking this opportunity to advise States (and manufacturers in our next release) of our policy on this issue. Medicaid rebates are not due on drugs for which payment is included under a capitated program. Rebates are due, however, if a State Medicaid agency reimbursed the pharmacy on a fee-for-service basis for any portion of a drug claim, including Medicaid claims on drugs for HMO-covered Medicaid recipients.

UTILIZATION ADJUSTMENTS FOR PRIOR CALENDAR QUARTERS

Based on complaints and sample State invoices forwarded to HCFA, we are concerned about the need for States to properly prepare and submit utilization adjustments to drug labelers. Per our specifications sent to States in our Dear State Medicaid Director letters and, most recently, in our Medicaid Drug Rebate Operational Training Guide (pages F23 - F24), States must submit utilization changes to the total units reimbursed field and are strongly encouraged to submit utilization related changes to the number of prescriptions and total reimbursement amount fields. **ALL UTILIZATION CHANGES MUST BE REPORTED TO DRUG LABELERS USING A SEPARATE INVOICE PAGE FOR EACH QUARTER IN WHICH CHANGES OCCURRED.**

A utilization adjustment by its very nature cannot pertain to the current quarter, so please ensure that the correct prior quarter is easily discernible on each separate invoice page in order to properly amend the original number(s). State utilization data are used in preparing the annual report to the Congress, in the monitoring of AIDS-related drug expenses and in preparing short and long range budget estimates. Your cooperation and diligence in this area is necessary and appreciated.

NEW LABELERS

The following labelers have entered into drug rebate agreements and will join the rebate program on July 1, 1997:

Pharmascience, Inc. (Labeler Code 51817);

Allscrips Pharmaceuticals, Inc. (Labeler Code 54569);

American Health Packaging (Labeler Code 62584);

SuperGen, Inc. (Labeler Code 62701); and

Ballay Pharmaceuticals (Labeler Code 63162).

LABELER TERMINATIONS

The following labeler is being terminated effective July 1, 1997 for failure to submit pricing data:

Global Source, Inc. (Labeler Code 59618).

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

Harmony Laboratories, Inc. (Labeler Code 52512), and

Lilly Ranbaxy Pharmaceuticals, L.L.C. (Labeler Code 62063).

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 April 21, 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

2 Attachments

cc:

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