

May 16, 1995



MEDICAID DRUG REBATE PROGRAM Release No. 16

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

NOTE TO: All Participating Drug Manufacturers

MEDICAID DRUG REBATE STAFF RE-LOCATION

Due to a lack of office space at the present location, the Health Care Financing Administration (HCFA) has been renting space in up to 10 buildings throughout the immediate area while a new work site was being built. Based on the completion schedule, it appears that the entire HCFA central office staff will be able to re-locate to this new single site by September 1, 1995.

The HCFA Medicaid drug rebate staff is scheduled to move to the new building complex during the weekend of July 22, 1995. At that time, the telephone exchanges will be converted from 965 and 966 to 786. Therefore, the drug rebate hotline will be reached by calling (410) 786-3249 and the facsimile telephone number will become (410) 786-0390.

Regular drug rebate correspondence and pricing data can continue to be sent to Post Office Box 26686, Baltimore, Maryland 21207.

In those instances where a physical location is needed when shipping via express delivery services, the following **new** address can be used effective July 24, 1995:

Health Care Financing Administration
Medicaid Drug Rebate Program
Mail Stop C-4-16-07
7500 Security Boulevard
Baltimore, Maryland 21244

PROPOSED STATE LEGISLATION ON EQUAL ACCESS TO DISCOUNTS FOR ALL PURCHASERS

Several States have recently introduced legislation which authorizes the State to deny reimbursement for medically necessary drugs if the manufacturers do not offer certain discounts to all purchasers within the State. Generally, the proposed legislation requires a drug manufacturer to give proportionately equal discounts on drugs to all purchasers within the State based on the discounts offered to the most favored purchaser or else Medicaid coverage of that manufacturer's drugs will be denied.

We have recently received several questions as to whether this type of legislation is inconsistent with HCFA's national rebate agreement and under what circumstances a manufacturer can be denied participation in the Medicaid program if it fails to offer the requisite discounts under the State legislation.

State legislation which denies Medicaid beneficiary access to medically necessary drugs of participating manufacturers conflicts with the mandatory coverage provisions of sections 1902(a)(54) and 1927 of the Social Security Act. Section 1902(a)(54) of the Social Security Act requires States to comply with the applicable requirements of section 1927. Section 1927 requires, among other things, that States permit coverage of medically necessary covered outpatient drugs of manufacturers participating in the drug rebate program. Thus, State legislation conflicting with the mandatory coverage provisions of the drug rebate program would not supersede Federal law.

Except for those drugs which may be restricted or excluded under section 1927(d)(2), section 1927(d) provides that the State plan must permit coverage of any covered outpatient drug, regardless of its inclusion in the State formulary under section 1927(d)(4), pursuant to a prior authorization system. Section 1927(d) also provides that a covered outpatient drug must be included in the State formulary if it has a "significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical advantage" over other drugs in the formulary.

Therefore, States cannot impose legislation on manufacturers which denies coverage of their drugs under the Medicaid program contrary to the terms of the statute and the national rebate agreement. If the State legislation is drafted in a way which does not restrict Medicaid coverage of a manufacturer's drugs, then HCFA's rebate agreement would not apply to this type of situation.

REMITTANCE ADVICE REPORT (RAR) IMPLEMENTATION

The Office of Management and Budget (OMB) approved the data collection contained on the RAR through July 1996. However, we are delaying the required use of the RAR until implementation issues are resolved.

For your information, attached is the RAR form with the OMB approval number and the required burden statement.

We are soliciting volunteers to participate in an implementation workgroup to resolve issues rising from labelers' attempts to complete the RAR. HCFA received requests from several labelers for clarification of some of the RAR data fields when certain situations occur. We presented some of the labelers' concerns to the State System Technical Advisory Group (S-TAG). There are conflicting responses among the labelers and States to some of the concerns, and a few new operational concerns and issues arose from speaking with the S-TAG members. The two main issues the implementation workgroup will attempt to resolve pertain to standardizing the process for reporting utilization data changes to the labeler and redeveloping the process for prior period adjustments (unit rebate amount changes) as they pertain to rebate payments.

We plan for the implementation workgroup to consist of ten representatives, five from both the States and labelers (with no more than two systems representatives from each side), and at least three HCFA staff. To assure that the decisions and resolutions of the workgroup result from a proportionate share of labeler input, we are looking for representatives from both innovator and non-innovator companies. We anticipate the workgroup meeting face-to-face for two days with subsequent meetings via teleconference. Details of the workgroup's activities and timetable will be completed once the workgroup members are selected. However, we are hopeful that resolutions of the issues will come quickly to enable a sufficient implementation period and ample time to review feedback once the RAR is in place.

If you are interested in participating in the RAR Implementation Workgroup, please contact Sue Williams at 410-966-5940 or Vince Powell at 410-966-3334 **no later than May 31, 1995.**

TRANSMISSION OF VIRUSES ON DISKETTES

During the past year, we have received drug pricing diskettes that contained computer viruses. This usually occurs when employees import unauthorized software copied or downloaded from a source outside their company. Many viruses remain dormant until pre-programmed dates are reached. At that point they become active, and bad things normally occur.

We are highlighting this area since we cannot process diskettes containing viruses. Current HCFA procedure requires that we shut down the microcomputer where the viruses were discovered and contact HCFA technicians who scan the diskettes to verify the existence of viruses. The offending drug labelers are contacted, made aware of the problem, and encouraged to ensure that their computer hardware and software are scanned and cleaned of any viruses. On several occasions, we were forced to take termination actions against the drug labelers until they were able to provide assurances that their facilities were subsequently cleared of any viruses.

If viruses are discovered on data submitted by any drug company, HCFA personnel will contact the offending company, advise them of the situation and request their pricing data be re-submitted by the required due dates. Repeat offenses will result in termination notices being received by the offending drug companies. Please ensure that your employees are made aware of the consequences of submitting infected diskettes to HCFA.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from July 5, 1994 through May 8, 1995. 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.

REGIONAL OFFICE DRUG REBATE COORDINATORS

Attached is a list of the HCFA Regional Office Coordinators who can be contacted for assistance in resolving rebate disputes. They are trained to act as facilitators in getting the States and drug labelers to communicate with each other and to encourage both parties to share or furnish additional information that will increase the probability of reaching a settlement of the dispute. We strongly recommend that you seek their assistance when you are unable to reach a settlement.

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

4 Attachments

cc:

All Regional Administrators
All Associate Regional Administrators Division of Medicaid