August 15, 2003

MEDICAID DRUG REBATE PROGRAM RELEASE #60

For
Participating Drug Manufacturers

PERSONNEL CHANGES

Recently there have been a few personnel changes that are noteworthy.

Judy Allison, longtime member of the Operations staff, has retired. Judy's last day was June 28th. After more than 35 years of federal service, we all wish her the best for a long and happy retirement.

Taking over Judy's responsibilities in the area of receiving and uploading the diskettes is Linda Sapperstein. Linda's phone number is 410-786-3317. If you send your data via overnight delivery, please continue to use the same address/mail stop listed in section O of the Operational Training Guide (OTG). The responsibility for sending out agreements, updating the system with contact changes, and alerting states, via FAX, about new labelers has been assigned to Karen Leshko. Karen is already a member of the Division of State Systems and, for the present, will be splitting her time between duties in the HIPAA area and learning the Operations of the drug rebate program. Karen's phone number is (410) 786-1291 and can be reached via e-mail at kleshko@cms.hhs.gov.

After a 4 month hiatus having bilateral hip replacements, Vince Powell is once again on the scene and back at his duty station. Vince returned to "active" duty on June 30th.

Revised pages to section O of the OTG which reflect the above changes are attached.

OPERATIONAL TRAINING GUIDE REVISIONS

In addition to the above mentioned changes, attached are revised pages (G4, G6-7, G11-14, H4, I2, I7-8, N3, S8) to the OTG. Also, a new page (F10c) has been added to the guide. These pages are being issued to clarify, change, and/or add additional information to the guide. Please share these revisions with staff responsible for drug rebate functions and replace them in your guide.

MDR TECHNICAL QUESTIONS E-MAIL ADDRESS

CMSO has established an e-mail address for your use when technical questions arise. The e-mail address is: MDRtech@cms.hhs.gov. Listed below are some examples of technical questions which can be answered via this e-mail address. Please use this new e-mail address to expedite answers to your technical questions/requests.

- - Request a diskette program (new or replacement)
- - Assistance/questions with the MDR diskette program
- - Errors encountered with the diskette program

OTHER ATTACHMENT

A copy of the current listing of the 90-day Treasury bill auction rates beginning with the period April 22, 2002, is 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/

Wayne Smith
Acting Director
Finance, Systems and Budget Group

2 Attachments

cc:
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid

Multiple Package Size Products and Data Requirements

Baseline Data Fields – 9-digit NDC (same for all package sizes):

1. 1. Drug Category
2. 2. Therapeutic Equivalence Code
3. 3. DESI Indicator
4. 4. Date Entered Market
5. 5. Unit Type
6. 6. FDA Approval Date
7. 7. Drug Type
8. 8. Baseline AMP (for S & I drugs marketed before 10/1/1993)

Baseline Data Fields – 11-digit NDC (unique to each package size):

1. 1. NDC 3
2. 2. UPPS
3. 3. Product Name
4. 4. Termination Date

Quarterly Pricing Data (same for all package sizes):

1. 1. AMP (weighted)
2. 2. BP (for S & I drugs)

Facts regarding multiple package size products:

- As new package sizes are added, pricing data and URAs are back-filled with the information from the oldest marketed package size for uniformity of data.

- Common baseline data fields (shown above) for multiple package size products will be automatically aligned with the information from the oldest marketed package size.

- Pricing changes affect ALL package sizes due to weighting. Changes to Date Entered Market and/or Baseline AMP will cause all package sizes to recalculate.

    - - Individual records for package sizes will not be allowed. There will be one common record for each prodcut and one pricing (history) record for each package size.

DATA EDIT REPORTS
(Before and After the URA Calculations)

B E F O R E . . .

When necessary, edit reports are sent to labelers with an introductory letter explaining what to look for and what to do with data causing "alert" messages, as well as data that actually "rejects." Labelers are asked to make corrections and resubmit the data using the same transmission medium used for the original data submission.

The edit report shows messages for both rejected and alerted records. Records that reject will do so for a number of reasons. If a quarterly pricing record rejects, it would be due to:

- AMP/BP not numeric
- AMP/BP missing
- Product record not on MDRI (NDC does not exist on CMS's file)
- Different package sizes (NDC 3) of a product (NDC 2) with different AMP or BP values.

If a Baseline record rejects, it would be for:

- Field not within specific range (e.g., DESI not between 2 & 6, Unit Type not valid)
- Numeric field not numeric
- Market Date/ FDA Approval Date missing (see explanation below)
- Baseline AMP missing for Market Date < 10-01-93
- Baseline change (Correction Flag = "1") with no match on MDRI
- Baseline addition (Correction Flag = "0"), NDC already exists on MDRI
- Baseline Field(s) (Unit Type, Drug Category, Drug Type, DESI, Therapeutic Equivalent, Market Date, FDA Approval Date) on one package size (NDC 3) not equal to field on established product (NDC 2)

♦ BP greater than AMP

In general, the definition of BP is that it is the lowest price at which a labeler sold its drug for the quarter. Therefore, BP can not be higher than other prices paid. AMP can occasionally be calculated as actually lower than Best Price. (See section F for more information.) In this instance, labelers make the BP **EQUAL TO AMP** (i.e., lower the BP) for the quarter. Again, **this record is NOT rejected**; however, labelers should make a correction prior to or with their next quarter's pricing data submission.

♦ DESI change attempted

CMS breaks both DESI and non-DESI drugs into specific categories. The values of "2", "3", and "4" are used for (non-DESI) drugs that will be covered by the program; values of "5" and "6" are used for (DESI) drugs that are not covered (refer to the Quarterly Pricing Data Definitions in section F for more specifics). All drugs are to be reported to CMS regardless of whether they are DESI drugs or not.

CMS verifies all MDRI records that are designated as DESI (codes "5" or "6") with the FDA. This assures that the DESI indication carried on the MDRI file agrees with the FDA master file. **If labelers attempt to change a DESI code, an alert message will be generated and the change will NOT be made. Labelers are told to change their system's DESI record back to the original value**.

RESERVED

FOR

FUTURE USE

* * * N O T I C E * * *
data edit report

Attached is an edit listing of your latest Product/Pricing data submittal. Please review and follow the instructions below.

1.) Review any messages stating that ***BP*** is greater than ***AMP***. If, in a given quarter, an ***AMP*** computes less than ***BP***, due to large discounts or unusually high level of returns, **BP MUST** be lowered to equal **AMP**. The system has done this automatically. Please correct this record on your file.

2.) There may be **ALERT** messages stating that you attempted to change a **DESI** value. Once baseline data has been established, the **DESI** code can only be changed **UNDER DIRECTION OF THE FDA** and by a CMS Operations analyst. This change **DID NOT** take.

3.) For **PRODUCT DATA MISSING** rejects, it means that the **ENTIRE BASELINE (PRODUCT) RECORD MUST BE** re-reported, as it is **NOT** established on our master file.

4.) For **"REGULAR REJECTS"**, please follow the message. There is probably either an incorrect or unacceptable value.

5.) For **REJECTS** dealing with **Market** and **FDA Approval Dates**, please remember that their inclusion with the Baseline data became mandatory with OBRA'93.

6.) For multiple package size errors, please note that **ONLY Termination Date, Product Name, and Units Per Package Size** fields may be different. All other fields (including AMP and BP) MUST be the same for ALL package sizes of a given product. Follow all multiple package size messages carefully.

REJECT corrections must be submitted using your normal method of data submission. Correcting rejects on the attached listing and returning to us **WILL NOT CORRECT THE ERROR. ALL ERRORS ARE REJECTED BY THE SYSTEM AND MUST BE RESUBMITTED ENTIRELY BY YOU.** ***BP*** corrections (***ALERTS ONLY***) have already been changed on our system and must be duplicated on your system.

Please refer to *Section G,* of your Operations Guide for additional information.
If you have any questions, please refer to section O of your Operations guide for a list of Operations analysts.

Vince Powell, Technical Director
Drug Rebate Operations
CMS/CMSO/FSBG/DSS

*** * A T T E N T I O N R E Q U I R E D * * ***
(NO QUARTERLY PRICING DATA REPORT)

Enclosed is a listing of your drug products for which we did not receive prices for the calendar quarter shown. Unit Rebate Amounts (URAs) equal to zero were reported on the state files; therefore, you will have to calculate URAs and include a ROSI with your payment to each state.

If any of these NDCs have been terminated for more than four quarters, please send us a valid Termination Date. NDCs appearing on this listing either **DO NOT** contain termination dates or have termination dates less than four quarters old. Please remember that prices are due for four quarters ***BEYOND*** the actual quarter of termination or shelf life.

If this report contains 15 or fewer NDCs, please annotate price or termination date corrections and mail to:

Drug Rebate Operations
c/o CMS/CMSO/FSBG/DSS
P.O. Box 26686
Baltimore, Md 21207-0486

ATTN: Christene Holmes
Mail Stop S3-13-15

If there are more than 15 NDCs, please submit price/date corrections ***WITH*** or ***BEFORE*** your next quarterly submission using your ***NORMAL MODE OF SUBMISSION***.

Please **DO NOT FAX** this information to us.

If you have any questions, please refer to the Operations Guide (section O) for a list of Operations analysts.

Thank you,

Vince Powell, Technical Director
Drug Rebate Operations
CMS/CMSO/FSBG/DSS

*** * * A T T E N T I O N R E Q U I R E D * * ***
(NO REBATES - DATA ERRORS)

When OBRA'93 was enacted, values used for Unit Rebate Amount (URA) calculations were changed. For "S" & "I" drugs having a **MARKET DATE** =/> 10-01-90, the 'additional rebate' calculation, for quarters **STARTING WITH 4-93**, is performed using the **CALCULATED** AMP for the **first full quarter** the product was on the market **IN PLACE OF** the BL/AMP. Thus, pricing (BOTH AMP/BP) for the NDCs indicated **FOR THE SPECIFIC QUARTERS REPORTED** on the enclosed report must be reported to us. This may require you to supply prices for an NDC for a quarter **prior to your starting in the rebate program**.

If there are 15 or fewer items for correction, please handwrite corrections on the listing and send it to us at the following address. If there are more than 15 corrections, please use your **NORMAL MODE FOR DATA SUBMISSION.**

Drug Rebate Operations ATTN: Christene Holmes
c/o CMS/CMSO/FSBG/DSS Mailstop S3-13-15
P. O. Box 26686
Baltimore, Md. 21207-0486

Please **DO NOT FAX** this information to us.

If you have any questions, please refer to the Operations Guide (section O) for a list of Operations analysts.

Thank you,

Vince Powell, Technical Director
Drug Rebate Operations
CMS/CMSO/FSBG/DSS

*** * * A T T E N T I O N R E Q U I R E D * * ***
(50/50 REPORT)

Some of your active reported NDCs from the current quarter have been reported to the States as zero, **EVEN THOUGH YOU SUBMITTED YOUR PRICING DATA ON TIME!!** This occurs when the URA for a given NDC for this quarter is calculated to be more than 50% different (+ or -) from last quarter.

Attached is a listing of your NDCs that match this scenario. Enough historical data is included (Baseline AMP, Market Date, Last Quarter AMP/BP, etc.) for you to evaluate the problem and make corrections where applicable. If pricing is correct, **DO NOT NOTIFY US. NEXT QUARTER, CMS WILL REPORT THIS URA TO THE STATES AS A PPA. USE THE CALCULATED URA AT THE FAR RIGHT COLUMN AND COMPUTE TOTAL REBATE OWED FOR THIS NDC TO BE INCLUDED IN YOUR TOTAL REBATE TO THE STATES.** If a correction to AMP or BP is necessary, please recalculate the per unit rebate using the correct pricing and submit your rebate to the States using the CORRECTED URA. Also include a ROSI with your check to each state.

Please submit the same AMP/BP corrections to CMS with or before your next quarterly submission, using your ***NORMAL MODE FOR DATA SUBMISSION***. If there are 15 or fewer corrections to be made, you may wish to annotate them on the listing and return to:

Drug Rebate Operations
c/o CMS/CMSO/FSBG/DSS
P.O. Box 26686
Baltimore, Md. 21207-0486

ATTN: Christene Holmes
Mailstop S3-13-15

Please **DO NOT FAX** this information to us.

If you have any questions, please refer to the Operations Guide (section O) for a list of Operations analysts.

Thank you,

Vince Powell, Technical Director
Drug Rebate Operations
CMS/CMSO/FSBG/DSS

Several values are required to complete the additional URA calculation:

- ◆ Quarterly AMP;
- ◆ Baseline AMP and Baseline CPI-U; and
- ◆ Quarterly CPI-U.

Quarterly CPI-U is always the CPI-U value of the month prior to the quarter being calculated. The Baseline CPI-U value used varies depending on the product's Market Date. A quick reference for Baseline CPI-U is given in the following chart (more information on Baseline values is found further in this section).

Quarter	Market Date	Baseline AMP	Baseline CPI-U
93-4 (4th Qtr. 1993) to present	Greater than 9/30/93	AMP for 1st Qtr. After Market Date	CPI-U for month prior to 1st Qtr. after Market Date
93-4 to present	Greater than 9/30/90; less than 10/1/93	AMP for 1st Qtr. After Market Date	CPI-U for month prior to 1st Qtr. after Market Date
91-1 through 93-3	Greater than 9/30/90; less than 10/1/93	AMP for 1st day of 1st full month on the market	CPI-U for the month before 1st full month
91-1 through present	Equal or less than 09/30/90	90-3 AMP	132.7 (value for 9/90)

Perform the following calculations.

a) a) Baseline AMP/Baseline CPI-U

b) b) Result of "a)" * quarter's CPI-U

c) c) **If result of "b)" is less than AMP**, subtract result from quarter's AMP to get the additional URA.

If result of "b)" is equal to or greater than the quarter's AMP, there is no additional URA to apply.

Total URA for "S" and "I" Drugs

Add any additional URA to the basic URA from step one for the total URA.

INTEREST CALCULATION

The following is an overview of the interest provisions of the Medicaid Drug Rebate program. The rebate agreement requires that interest be paid or credited, when due, by the labeler or the state. For purposes of section V(b) of the National Drug Rebate Agreement, the interest rate, as specified in section 1903(d)(5) of the Act, is used. The interest rate is based on the yield of the weekly 90-day Treasury bill auction rates. The investment yield is considered the bond equivalent rate or the true discount rate.

Auctions of 90-day Treasury bills are generally held each Monday. If Monday is a holiday, the Treasury Department decides whether to hold the auction on the preceding Friday or the following Tuesday. Information on the T-Bill rates is provided to states and labelers in two ways: 1) it is on the Medicaid drug rebate website at www.cms.hhs.gov/Medicaid/drugs/drughmpg.asp and is updated monthly (current month is NOT on the web); and 2) it is included in periodic state and labeler releases.

Interest Due States

1. 1. States are due interest on all unpaid disputed rebate payments that are resolved in the state's favor through dispute resolution. A **dispute** occurs when a labeler disagrees on a specific number of its drug's units reported by the state, and provides detailed written notification of the dispute in writing. A labeler that has not paid for the disputed units that are resolved in the state's favor must pay interest that begins accruing on the 38th calendar day from the date the state receives notification from the labeler as evidenced by the postmark. Interest stops accruing and is calculated up to the postmark date of the labeler's mailed check.

   To avoid paying interest on disputes resolved in the state's favor, CMS encourages labelers to pay for disputed units timely. (See section K of the guide for more information on the dispute program.)

Interest Clarification When Prior Period Adjustments (PPAs) Are Submitted

- • When does interest apply when Prior Period Adjustments (PPAs) are submitted?
    - o Interest applies to disputed or unpaid rebate amounts and late rebate payments.
    - o Interest does not apply to PPAs of unit rebate amounts.
    - o Interest does apply if the rebate amount due from the PPA is not paid timely.
- • When does interest begin accruing on unpaid or disputed rebate payments that were generated due to PPAs?
    - o Interest begins accruing 38 calendar days after the date the state receives the PPA/Unit Rebate Amounts (URAs), included on the current quarterly URA data file.

Interest is applied to disputed or unpaid rebate amounts and late rebate payments. Interest is **not** applied to PPAs of unit rebate amounts or to state utilization adjustments.

PPAs are unit rebate amount changes caused by a correction to a pricing record or a change to a baseline Average Manufacturer Price (AMP) or Market Date submitted by a manufacturer to CMS for Medicaid drug rebate update and inclusion on the next quarterly pricing/product file to the states.

When a baseline AMP or Market Date changes or a pricing record is changed, which causes the recalculation of one or more URAs, the manufacturer may owe an additional rebate to states, which is considered a rebate amount due. Interest cannot be applied when the PPA is initially submitted by CMS to states. Interest may be applied if the rebate amount generated by the PPA is not paid timely. In such a case, it is considered a late rebate payment and interest will begin accruing. Generally, interest starts accruing 38 calendar days from the date the state mails the state invoice to the manufacturers. Since states can't invoice for PPAs, some states have asked when interest would start accruing if a rebate payment, resulting from a PPA, was not paid timely. Interest accrual may be determined based on the postmarked date the state receives the PPA/URAs, which is the same time they receive the current quarterly URAs.

Tolerance Threshold for Interest

If the state determines that its administrative costs to recover interest owed by a labeler exceed the interest amount due, the state may apply up to a $50 tolerance level per labeler to interest payments. Application of this tolerance is optional for states; they may collect or waive interest amounts at or below the tolerance level. In all cases where a state chooses to apply tolerance levels, both the state and the labeler should maintain adequate documentation.

OBTAINING COPIES OF PROGRAM RELEASES

Generally, within a week of issuing a release to either state agencies or drug labelers, CMS uploads the release to the INTERNET.

For states, labelers, and private individuals with access to the Internet, the program releases are available at:

www.cms.hhs.gov/Medicaid/drugs/drughmpg.asp

☞**NOTE:** CMS no longer provides the drug rebate releases for incorporation to the CD-ROM.

The following pages show examples of the text of a state and labeler release.

CMS DRUG REBATE PROGRAM

Area Code 410

OPERATIONS

Tamara Bruce	786-1519
Chris Holmes	786-3328
Karen Leshko	786-1291
Vince Powell (Technical Director)	786-3314
Linda Sapperstein	786-3317
Sue Williams	786-3334

POLICY

Christie Cahee	786-6614
Claire Hardwick	786-6777
Tammi Hessen	786-1025
Chris Hinds	786-4578
Kim Howell	786-6762
Christina Lyon	786-3332
Cindy Pelter	786-1176
Carl Tepper	786-2137
Marge Watchorn	786-4361
Larry Reed/Deirdre Duzor (Co-Directors)	786-3325/786-4626

SYSTEM MAINTENANCE

Kay Alexander	786-0252
Dona Coffman (Technical Director)	786-0260

DISPUTE RESOLUTION PROGRAM

Sue Gaston	786-6918
Tamara Bruce	786-1519
Diane Dunstan	303-844-7040

FAX 786-0390 - Operations/Systems
786-8534 – Policy

WEBSITE www.cms.hhs.gov/medicaid/drugs/drughmpg.asp

CMS DRUG REBATE PROGRAM
PRIMARY FUNCTIONS/CONTACT PERSON

Primary Function	**Contact Person**
Contact Changes (labelers and states)	Karen Leshko Linda Sapperstein
CPI-U Values	Linda Sapperstein
Data Edit Reports	Linda Sapperstein Vince Powell
Data Submission (labelers)	Linda Sapperstein Vince Powell Kay Alexander
Data Submission (states)	Vince Powell
Diskette Installation/Problems	Kay Alexander
Dispute Resolution	Sue Gaston Tamara Bruce
Federal Upper Limits	Cindy Pelter Christie Cahee
HIV/AIDS Drugs	Marge Watchorn
Interest Calculation	Vince Powell Tamara Bruce
Invoice	Sue Williams
Policy Issues (general)	Christie Cahee, Claire Hardwick, Tammi Hessen, Chris Hinds, Kim Howell, Christina Lyon, Cindy Pelter, Carl Tepper, Marge Watchorn
Prior Quarter Adjustment Statement	Sue Williams
Prior Period Adjustments	Vince Powell
Pricing Data/Product Elements	Vince Powell
Reconciliation of State Invoice	Sue Williams
State Tape	Kay Alexander
T-bill Rates	Linda Sapperstein
Training Guide	Sue Williams
VHCA/340B Drug Pricing	Marge Watchorn

Q: I got an invoice from a state and one of the NDCs has a zero URA. Do I ignore that one and just pay for the URAs that have an amount?

A: No. Your responsibility is to pay rebates on all valid NDCs reported to you by a state. If an NDC has zeros in the URA it is due to one of several reasons: 1) You did not report pricing to us on time for this quarter; 2) You reported pricing but it was rejected and you haven't had time to turn around a correction from the edit list; or 3) You reported pricing but when the URA was calculated it was more than 50% higher or more than 50% lower than the last quarter. In case #3, you should have received a 50/50 report showing NDCs that fall into this category. If the pricing you submitted was, in fact, correct, use the URA shown as the very last data element on the 50/50 report for computing the rebate to the state. If the prices you reported are wrong, calculate the URA using correct pricing, use the correct URA for paying the state, and send a correction record to us with your next quarter's pricing submission. (See sections F and G)

WEEKLY U.S. T-BILL DISCOUNT RATE

weekly 90-day treasury bill auction rates

Date of Auction	Discount Rate
04-22-02	1.720
04-29-02	1.760
05-06-02	1.773
05-13-02	1.781
05-20-02	1.760
05-28-02	1.760
06-03-02	1.752
06-10-02	1.752
06-17-02	1.732
06-24-02	1.712
07-01-02	1.719
07-08-02	1.724
07-15-02	1.712
07-22-02	1.692
07-29-02	1.712
08-05-02	1.627
08-12-02	1.659
08-19-02	1.659
08-26-02	1.661
09-03-02	1.639
09-09-02	1.676
09-16-02	1.692
09-23-02	1.639
09-30-02	1.566
10-07-02	1.615
10-15-02	1.659
10-21-02	1.696
10-28-02	1.578
11-04-02	1.433
11-12-02	1.211

Date of Auction	Discount Rate
11-18-02	1.227
11-25-02	1.228
12-02-02	1.231
12-09-02	1.215
12-16-02	1.219
12-23-02	1.207
12-30-02	1.207
01-06-03	1.207
01-13-03	1.199
01-21-03	1.179
01-27-03	1.159
02-03-03	1.175
02-10-03	1.171
02-18-03	1.179
02-24-03	1.195
03-03-03	1.198
03-10-03	1.077
03-17-03	1.137
03-24-03	1.174
03-31-03	1.121
04-07-03	1.158
04-14-03	1.186
04-21-03	1.182
04-28-03	1.141
05-05-03	1.117
05-12-03	1.089
05-20-03	1.040
05-28-03	1.121
06-02-03	1.133
06-09-03	1.024

Date of Auction	Discount Rate
06-16-03	0.854
06-23-03	0.830
06-30-03	0.903
07-07-03	0.907
07-14-03	0.895
07-21-03	0.911
07-28-03	0.964
08-04-03	0.964
08-11-03	0.960
08-18-03	0.964