April 25, 2006

MEDICAID DRUG REBATE PROGRAM RELEASE #73

Bulletin

For
Participating Drug Manufacturers

REVISED COVER LETTERS FOR DATA EDIT REPORTS

Effective immediately, cover letters for the various data edit reports are revised. If you receive data edit reports, please take a moment to review the cover letter so that you can better understand the report. The letters are attached to this release as updates to the Operational Training Guide. Please note that although the cover letter for the 50/50 report has been revised to 400/400, we have not yet changed our system to accommodate this revised edit. We expect to have the 400/400 data edit in place in the near future. The revised cover letter is being included in this release so that you have advance notice of the forthcoming data edit change.

BATCH EDIT REPORTS AND THE IMPORTANCE OF MAINTAINING QUARTERLY DATA BACK-UP FILES

We receive frequent inquiries from labelers each quarter regarding the Batch Edit reports that are generated in response to submitted data. In the past, when researching these inquiries, we often needed to review the diskettes or Sterling files that were submitted against the record specifications in order to determine where an error occurred. In our experience, this data review almost always revealed an error on the part of the labeler (e.g., a missing data field or an incorrect data field entry) that resulted in the problem identified on the Batch Edit report. Therefore, when you receive a Batch Edit report, you should thoroughly examine the data that was actually transmitted to CMS (not the data that you currently have in your system) to ascertain the reason for an NDC's inclusion on that report. In order to review your data submission, it is imperative that you maintain a

back-up of the data files that are submitted to CMS each quarter. Specifically, Sterling users should maintain a back-up of their entire quarterly file as it was transmitted to Sterling and diskette users should maintain a back-up of both their product and price files (copy the "prodfile.txt" and "pricfile.txt" from the diskette before mailing to CMS).

Keeping copies of the submitted quarterly files and comparing the data on those files to the record specifications will enable you to resolve many of the issues identified on the Batch Edit reports without contacting CMS. We recommend that you perform such a comparison with your back-up files before contacting us with a question pertaining to the Batch Edit report. In the event that you review your back-up file(s) and still have questions regarding your Batch Edit report, we suggest that you copy and paste the strings of data associated with each NDC in question from your file into an email to MDROperations@cms.hhs.gov.

BACKUP DRUG REBATE LIBRARY

We encourage labelers to maintain a backup library of drug rebate information such as program releases, the Operational Training Guide, letters, etc. Due to our resource limitations, CMS can no longer provide extra copies of these materials. Keeping a backup of these materials will assure that any new staff has access to the current information necessary to perform drug rebate duties. For your convenience, program releases can be found on our CMS's drug rebate website. Please be reminded that these releases often include updates to the Operational Training Guide. Please make sure that these updates are placed in your guide and shared with the appropriate staff.

FDA APPROVAL DATE & MARKET DATE – CHANGE TO CMS PROCESS

FDA Approval Dates and Market Dates that occur prior to 9/30/1990 (the start of the Medicaid Drug Rebate Program) have no bearing on drug rebate operations. Therefore, all existing FDA Approval Date and Market Date data fields less than (earlier than) 09/30/1990 will be changed in CMS's MDR database to 09/30/1990. In addition, new drug product data submitted to CMS with FDA Approval Date and Market Date data fields less than 09/30/1990 will also be changed to 09/30/1990 in CMS's MDR database. These changes to the FDA Approval Date and Market Date data fields will coincide with the 1Q2006 quarterly data processing in April 2006.

In order to align your system with the MDR database, you may choose to make similar changes to your drug rebate database to reflect these edits, however, no rejections, alerts or audits will occur as a result of any changes to the data fields described above that fall into the date parameters specified.

UNIT TYPE EACH: THE UNIT TYPE OF LAST RESORT!

Labelers continue to erroneously report drugs using the Unit Type EACH. Labelers that use the Unit Type EACH incorrectly experience problems when they add package sizes to the original NDC – in many cases, years after the first package size was launched.

When using the Unit Type EACH, decimal quantities are never valid in the Units Per Package Size (UPPS) field because EACH denotes a whole package regardless of the amount of drug (ML, GM, etc.) in the package. The following are the only situations for which it is appropriate for labelers to use the Unit Type EACH:

1. Powder-filled vials, ampules, syringes and packets (same UPPS for multiple packages)
2. Kits containing two or more different items dispensed under one NDC and sold at a single price

There have been other, rare situations brought to CMS's attention that were appropriate to use the Unit Type EACH; however, to avoid the inevitable problems that labelers will be responsible to fix, labelers should contact MDROperations@cms.hhs.gov **before** proceeding with any exception to the abovementioned uses of Unit Type EACH.

Once a labeler inaccurately designates the Unit Type EACH for an NDC and then adds a package size with a different UPPS from the original package size, the weighted AMP cannot be reported as required by the rebate agreement.

RE-USE OF NDCs

It is FDA's policy that an NDC can be re-used after a product has been discontinued for at least five years (21 CFR 207.35(b)(4)(ii)). CMS requests that labelers refrain from re-using NDCs unless they have run out of product codes. Once an NDC has been re-used, the product and pricing history of the original product cannot be maintained in CMS's MDR System.

If the situation arises that requires the re-use of an NDC, we suggest that labelers follow the process outlined below before the re-use of the NDC commences:

Ensure that the original product has been terminated with CMS and discontinued with the FDA and that five years have passed since that discontinue date.

Check to determine when the last utilization of the original product occurred. (http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp#TopOfPage)

Verify that CMS's MDR System pricing is up-to-date for every quarter that the

original product was on the market (i.e., that CMS has all pricing, not only that the labeler's database reflects complete pricing).

Provide notice to CMS Drug Rebate Operations (see section O of the Operational Training Guide for address) that explains the need for re-using the NDC. This notice should also provide the NDC, product name and all package sizes for both the original and the new product, the termination/discontinue date of the original product, and the market date of the new product.

Upon receipt of such notice, CMS Operations staff will verify the information with the FDA, remove the history associated with the original product in CMS's MDR database, and notify the labeler to submit the product and price file (using their designated mode of transmission).

RE-INTRODUCING A PRODUCT TO THE MARKET

When a product is reintroduced to the market, the baseline data remains the same as the original product. Labelers simply have to remove the termination date from the MDR System and begin submitting pricing for the quarter the product was reintroduced. The gap in quarterly pricing does not present a problem.

STATE PHARMACEUTICAL ASSISTANCE PROGRAM (SPAP) EXEMPTION FROM MEDICAID BEST PRICE

The Medicaid statute allows manufacturers participating in the Medicaid Drug Rebate Program to exclude prices to State pharmaceutical assistance programs (SPAPs) from their Medicaid Best Price calculations. CMS has compiled a list of programs that meet the criteria to be considered SPAPs. Please note that this list only includes states that submitted a description of their programs to CMS for review based on the established criteria in CMS' Manufacturer Release #68 (April 1, 2005). The qualification of State-only programs as SPAPs is based on the information provided by the State and may be subject to further review if changes occur within the program. The list can be found on our website at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_Overview.asp#TopOfPage. Questions regarding this may be directed to Marge Watchorn at 410-786-4361.

UPDATES TO THE OPERATIONAL TRAINING GUIDE

The following pages have been revised and attached to this release: G11a and b, G12-14, I2, M10, N3, and O2. Please share these pages with the appropriate staff and replace them in your guide.

OTHER ATTACHMENT

A copy of the current listing of the 91-day Treasury bill auction rates beginning with the period August 9, 2004, is attached.

Please direct any drug rebate questions to MDROPERATIONS@cms.hhs.gov

/s/
Edward C. Gendron
Director
Finance, Systems and Budget Group

10 Attachments

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244

Dear Technical Contact: You recently submitted product and/or pricing data and received an email summarizing that submission. Attached is the Batch Edit Transaction Report which provides additional details to the email you received. This report identifies problems with your data submission, along with a description of the action taken by the MDR System (rejections or alerts/changes). Please review the report and follow the instructions below that pertain to the specific data problems identified on the report.

Alerts and Rejections

BP is greater than AMP: BP must be equal to or less than AMP. If a BP computes higher than AMP (due to large discounts or unusually high levels of returns), BP must be lowered to equal AMP. The MDR System detected this error and automatically made your BP equal to AMP. Please correct this record on your file so that it matches the CMS file.

DESI Change Attempted: Once baseline data has been established, the DESI code can only be changed under direction of the FDA and by a CMS Operations analyst. The MDR System did not allow this change.

Terminated Package Size messages: The CMS file shows a termination date for this package size. If the termination date is incorrect, correct the error using your normal mode of data transmission.

Changes to BASE AMP are not allowed: Pricing adjustments are not allowed beyond 12 quarters from the quarter in which the data were due. The MDR System did not allow this change.

Market Date change rejected since older than 12 quarters: Adjustments to Market Date are not allowed beyond 12 quarters from the quarter in which the data were due. The MDR System did not allow this change.

Earliest Input Market Date Used: You have attempted to change the Market Date on this package size to a date that is different from the initial date entered with the first package size. MDR did not process this change because the Market Date across all package sizes should be equal to the initial date entered with the first package size.

Product Record Does Not Exist in the File: You attempted to submit pricing for an NDC that does not exist in the MDR System. Pricing will not be accepted on this NDC until the entire baseline product record is submitted to CMS using your normal mode of data transmission.

Package Size Data for this Product Does Not Exist: You attempted to submit pricing for a package size that does not exist in the MDR System. Pricing will not be accepted on this package size until the package size data is submitted to CMS using your normal mode of data transmission.

Market Date/FDA Approval Date: Either the Market Date or the FDA Approval Date (or both) for this NDC was missing from your data submission. Both of these dates are required; therefore, submit both dates using your normal mode of data transmission.

Multiple Package messages:

Product Data Messages - For multiple package size products, the only data fields that may contain varied information are the termination date field, the product name field and the units per package size field.

Pricing Data Messages - AMP and BP must be the same for all package sizes.

For any other messages included on your Batch Edit Transaction Report, but not described above please read the message and make the necessary correction using your normal mode of data transmission.

Please correct the errors identified on the attached report and resubmit the data. You may make the corrections now or with the next quarterly submission.

If you have questions regarding this report, please contact MDROPERATIONS@cms.hhs.gov.

Sincerely,

Tamara L. Bruce, Technical Director
Drug Rebate Operations, Division of State Systems

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-13-15
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

Dear Technical Contact:

The attached report, entitled "MISSING PRICING DATA," contains a list of active NDCs for which no pricing was submitted for the quarter specified. As a result, zero Unit Rebate Amounts (URAs) were reported to the states for these NDCs; therefore, you are required to calculate these URAs and include them on the Reconciliation of State Invoice (ROSI) with your quarterly rebate payment to each state. For further information on the ROSI, please refer to section F of the Operational Training Guide.

Many labelers receive this report because they have failed to submit termination dates on NDCs that are no longer active. Termination date is defined as the shelf life of the last lot manufactured or the date that a drug is removed from the market due to safety reasons. Pricing data is due on terminated NDCs for four quarters beyond the termination date.

Under the terms of the rebate agreement, you are required to submit quarterly pricing data on all active NDCs until a termination date (plus four additional quarters of pricing) is received; therefore, you must submit the pricing for the NDCs identified on the attached report and/or submit a termination date with your next quarterly data submission. You also have the option to submit this missing data immediately. Please submit this information using your normal mode of data transmission. Please also note that even if the data in your system looks correct (i.e., does not match what is in the attached report), it does not match the data in CMS's system and requires action on your part.

If you have any questions regarding this report, please contact MDROPERATIONS@cms.hhs.gov.

Sincerely,

Tamara L. Bruce, Technical Director
Drug Rebate Operations
Division of State Systems

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-13-15
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

Dear Technical Contact:

The attached report, entitled "NO REBATES CALCULATED – DATA ERRORS FOUND," contains a list of NDCs for which no Unit Rebate Amounts (URAs) were calculated for single source (S) or innovator multiple source (I) drugs as a result of missing pricing data. Specifically, the report will identify one of two missing pricing error messages.

One error message states, "quarterly AMP missing." When the attached report contains this message, it means that the specified NDC's Average Manufacturer Price (AMP) value was not submitted for the pricing quarter that establishes the Baseline AMP value. In the report, the "pricing quarter" represents the quarter in which the Baseline AMP value is missing and the "period" represents the quarter in which no rebates were calculated because the Baseline AMP value is missing. Because no AMP has been submitted to establish the Baseline AMP for the specified NDCs, no rebates can be calculated for these products. For further information on Baseline AMP, please refer to section H of the Operational Training Guide. In addition to submitting the quarterly AMP to establish the Baseline AMP for the specified NDCs, the corresponding quarterly Best Price (BP) for each drug product must be submitted as well; if not, the data will continue to be rejected.

The other error message states, "No Best Price." When the attached report contains this message, it means that an NDC's BP is missing for the specified period (quarter) and that no rebates were calculated for that particular quarter as a result.

Under the terms of the rebate agreement, you are required to correct the errors identified on the attached report with your next quarterly data submission. You also have the option to submit this missing data immediately. Please submit these corrections using your normal mode of data transmission. Please also note that even if the data in your system looks correct (i.e., does not match what is in the attached report), it does not match the data in CMS's system and requires action on your part.

If you have any questions regarding this report, please contact MDROPERATIONS@cms.hhs.gov.

Sincerely,

Tamara L. Bruce, Technical Director
Drug Rebate Operations
Division of State Systems

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-13-15
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

Dear Technical Contact:

The attached report, entitled "NO REBATES CALCULATED – CURRENT UNIT REBATE AMOUNT > OR < 400% DIFFERENCE," contains a list of NDCs for which no Unit Rebate Amounts (URAs) were calculated for the current quarter as a result of possible pricing errors. Specifically, each NDC on the attached report was submitted to CMS with pricing for this quarter that caused the URA to calculate more than 400% higher or more than 400% lower than the previous quarter. As a result, the CMS Medicaid Drug Rebate (MDR) system identified the prices for these NDCs as possible errors and URAs were not submitted to the states for any of these drug products.

In addition to the NDC, the report contains enough historical product/pricing data (i.e., Baseline AMP, Market Date, AMP and BP for the previous quarter and the current quarter, etc…) for you to evaluate each URA and make corrections where necessary. If you review the attached report and determine that the pricing is correct, there is no need to notify CMS. At that time, you should use the calculated URA found in the last column of the report (entitled "This Quarter Rebate") to compute the total rebate owed to the states for each NDC. After the next quarter's data is processed, CMS will report these URAs to the states as Prior Period Adjustments. If, however, your review of the attached report concludes that the AMP and/or BP is incorrect, please calculate the current quarter's URA based on the correct pricing and use that (corrected) URA when submitting your rebate to the states.

Under the terms of the rebate agreement, you are required to submit accurate pricing to CMS each quarter. Therefore, please review the potential errors identified on the attached report and submit any pricing corrections with your next quarterly data submission. You also have the option to submit pricing corrections immediately. Any corrections must be submitted using your normal mode of data transmission.

If you have any questions regarding this report, please contact MDROPERATIONS@cms.hhs.gov.

Sincerely,

Tamara L. Bruce, Technical Director
Drug Rebate Operations
Division of State Systems

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/medicaiddrugrebateprogram and is updated monthly; and 2) it is included in periodic state and labeler releases. For the complete listing of T-Bill rates, as published by the Treasury Department, go to: www.publicdebt.treas.gov/of/ofaucrt.htm. Then go to Recent Treasury Bill Auction Results Table.

Interest Due States

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 on the ROSI or PQAS. 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.)

MEDICAID DRUG REBATE PROGRAM
STATE AGENCY CONTACT FORM

STATE AGENCY NAME

TECHNICAL CONTACT – Person responsible for sending and receiving data.

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

FAX AREA PHONE NUMBER EXTENSION

EMAIL ADDRESS _____

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY STATE ZIP CODE

PROGRAM POLICY CONTACT – Person responsible for policy decisions.

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY STATE ZIP CODE

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 its website.

The program releases are available at the drug rebate website:

www.cms.hhs.gov/medicaiddrugrebateprogram

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 manufacturer release.

CMS DRUG REBATE PROGRAM

Area Code 410

OPERATIONS

Operational Inquiries	MDROPERATIONS@cms.hhs.gov	
Cindy Bergin	786-1176	cindy.bergin@cms.hhs.gov
Tamara Bruce	786-1519	tamara.bruce@cms.hhs.gov
Chris Holmes	786-3328	christene.holmes@cms.hhs.gov
Karen Leshko	786-1291	karen.leshko@cms.hhs.gov
Sue Williams	786-3334	susan.williams@cms.hhs.gov

DIVISION OF PHARMACY (POLICY)

Kim Howell	786-6762
Madlyn Kruh	786-3239
Bernadette Leeds	786-9463
Christina Lyon	786-3332
Larry Reed (Technical Director)	786-3325
Yolanda Reese	786-9898
Gail Sexton	786-4583
Marge Watchorn	786-4361

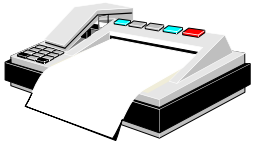
SYSTEM MAINTENANCE

E-mail inquiries to: MDRtech@cms.hhs.gov

DISPUTE RESOLUTION PROGRAM

Sue Gaston	786-6918	susan.gaston@cms.hhs.gov
Tamara Bruce	786-1519	tamara.bruce@cms.hhs.gov
Diane Dunstan	303-844-7040	diane.dunstan@cms.hhs.gov

FAX



786-0390 – Operations
786-5882 or 786-9004 - Policy

WEBSITE www.cms.hhs.gov/medicaiddrugrebateprogram

WEEKLY U.S. T-BILL INVESTMENT RATE

weekly 91-day treasury bill auction rates

Date of Auction	Invest. Rate	Date of Auction	Invest. Rate	Date of Auction	Invest. Rate
08-09-04	1.497	03-07-05	2.767	10-03-05	3.606
08-16-04	1.498	03-14-05	2.792	10-11-05	3.714
08-23-04	1.541	03-21-05	2.859	10-17-05	3.875
08-30-04	1.607	03-28-05	2.839	10-24-05	3.942
09-06-04	1.663	04-04-05	2.792	10-31-05	3.983
09-13-04	1.671	04-11-05	2.767	11-07-05	3.963
09-20-04	1.716	04-18-05	2.864	11-14-05	4.004
09-27-04	1.741	04-25-05	2.941	11-21-05	4.034
10-04-04	1.716	05-02-05	2.931	11-28-05	3.994
10-12-04	1.711	05-09-05	2.911	12-05-05	4.025
10-18-04	1.803	05-16-05	2.859	12-12-05	3.911
10-25-04	1.890	05-23-05	2.957	12-19-05	3.988
11-01-04	1.987	05-31-05	2.998	12-26-05	3.999
11-08-04	2.084	06-06-05	3.029	01-02-06	4.169
11-15-04	2.115	06-13-05	3.039	01-09-06	4.252
11-22-04	2.197	06-20-05	3.029	01-17-06	4.377
11-29-04	2.380	06-27-05	3.147	01-23-06	4.397
12-06-04	2.253	07-05-05	3.214	01-30-06	4.485
12-13-04	2.243	07-11-05	3.204	02-06-06	4.485
12-20-04	2.223	07-18-05	3.292	02-13-06	4.553
12-27-04	2.269	07-25-05	3.420	02-21-06	4.563
01-03-05	2.320	08-01-05	3.477	02-27-06	4.625
01-10-05	2.376	08-08-05	3.539	03-06-06	4.615
01-18-05	2.407	08-15-05	3.549	03-13-06	4.625
01-24-05	2.366	08-22-05	3.539	03-20-06	4.662
01-31-05	2.525	08-29-05	3.575	03-27-06	4.610
02-07-05	2.530	09-06-05	3.513	04-03-06	4.651
02-14-05	2.592	09-12-05	3.529	04-10-06	4.688
02-22-05	2.669	09-19-05	3.575	04-17-06	4.719
02-28-05	2.772	09-26-05	3.518		

TOPICAL INDEX - DRUG LABELER RELEASES 1 - 73