May 13, 2005

MEDICAID DRUG REBATE PROGRAM **RELEASE #137**

For State Medicaid Directors

DEPOT PRICES – TRICARE RETAIL PHARMACY BENEFIT PLAN

We have received numerous inquires from manufacturers requesting guidance regarding the treatment of transactions under the Department of Defense's (DoD) TRICARE Retail Pharmacy Benefit Plan (TRRx) and whether refunds provided to DoD should be included in the calculation of the Medicaid average manufacturer price (AMP) and best price (BP), as well as the Medicare average sales price (ASP). This release provides guidance concerning AMP and BP calculations. In regard to guidance concerning Medicare, CMS will post a new question and answer to the ASP frequently asked questions section of the ASP web site. This web site can be found at http://www.cms.hhs.gov/providers/drugs/asp.asp.

In May 2004, the TRICARE Management Activity restructured its pharmaceutical benefit program by removing the pharmacy benefit from TRICARE regional managed care contracts and placing it under a separate contract with a pharmacy benefit manager. DoD, with the concurrence of the Department of Veterans Affairs (VA) considers these transactions as DoD "depot" sales that qualify for Federal Ceiling Prices under the Veterans Health Care Act of 1992.

The Medicaid Drug Rebate Program, as set forth in the relevant statutes and the Medicaid Rebate Agreement, specifically excludes DoD and depot prices from the BP calculation. The VA has determined that TRRx meets the requirements of depot as defined in 38 U.S.C. 8126(h)(3). We see no reason to disagree with that determination for purposes of the Medicaid Drug Rebate Program. Accordingly, since depot sales are excluded from BP

calculations under section 1927(c)(1)(C), TRRx sales, including refunds (rebates) provided for TRRx beneficiaries, should be excluded from the calculation of BP. Similarly, in light of our conclusion, TRRx sales, as well as refunds (rebates), for the TRRx program should be excluded from AMP calculations.

CHANGE IN DRUG COVERAGE STATUS/DESI CODE CHANGE

States were previously informed, via a state fax that went out on April 6, 2005, of several products for which the DESI codes were reported incorrectly. Those products are as follows:

00496-0716 Pramosone Cream 1%
00496-0717 Pramosone Cream 2.5%
00496-0726 Pramosone Lotion 2.5%
00496-0729 Pramosone Lotion 1%
00496-0763 Pramosone Ointment 1%
00496-0777 Pramosone Ointment 2.5%

Although the labeler of these products provided a DESI Code 2 (safe and effective) for each NDC, the FDA has determined that these drugs are less-than-effective, or a DESI Code 5.

Please be aware that these drugs **will no longer be eligible for Federal financial participation or rebate billing beyond June 30, 2005**. If your system can process an immediate change, please do so. The 1Q2005 CMS tape will reflect the DESI Code 5 status.

Questions concerning this notice can be referred to an Operations Team member (see page O2 of the Operations Training Guide).

NON-DRUG DELETIONS FROM MDR

In accordance with previously released state faxes and as part of our continuing effort to remove non-drug items from the Medicaid Drug Rebate (MDR) system, the following products were deleted from the MDR Master file of covered outpatient drugs **effective April 1, 2005**. The products are as follows:

00517-2802-25	Sodium Chloride Injection, USP 0.9%
00517-2810-25	Sodium Chloride Injection, USP 0.9%
64054-0902-03	Sodium Chloride 0.9% 2 ml Fill In 3 ml SYR
64054-0903-02	Sodium Chloride 0.9% 3 ml Fill In 12 ml SY
64054-0903-03	Sodium Chloride 0.9% 1 ml Fill In 3 ml SYR
64054-0903-06	Sodium Chloride 0.9% 3 ml Fill In 6 ml SYR
64054-0903-12	Normal Saline IV Flush Syringe 3 ml Fill/12 ml Syringe
64054-0905-02	Sodium Chloride 0.9% 5 ml Fill In 12 ml SY
64054-0905-06	Sodium Chloride 0.9% 5 ml Fill In 6 ml SYR
64054-0910-02	Sodium Chloride 0.9% 19 ml Fill In S

Also **effective April 1, 2005**, the following non-drug product codes (all package sizes) will be deleted from the MDR Master file:

Labeler Code: 53303

0000	0012	0030	0082	0141
0006	0019	0070	0090	0142
0010	0022	0080	0100	0143
0011	0024	0081	0140	0144

Labeler Code: 00615

0369	0421	0587	0669	0686	0687	0692	0697	0870	3569	3594	4537
4560	4572	4574	4581	4584	4585	4586	4587	5517	5520	5522	5524
5528	5560	5561	5562	5563	5565	5567	5570	5571			

In addition, the following non-drug items will be deleted from the MDR Master file of covered outpatient drugs **effective July 1, 2005**:

52735-0694-12	Blood Glucose Strips
52735-0695-01	Blood Glucose Meter, Value Pak
52735-0851-00	Glucose Tabs, Orange
52735-0851-12	Glucose Tabs, Orange
52735-0852-00	Glucose Tabs, Raspberry
52735-0852-12	Glucose Tabs, Raspberry

The abovementioned products were not approved as prescription drugs by the Food and Drug Administration (FDA) under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act and therefore, do not meet the definition of covered outpatient drugs as defined in Section 1927(k)(2) of the Social Security Act.

USE OF MDRTECH@cms.hhs.gov

Please **do not** use MDRTECH@cms.hhs.gov for operational inquiries. Using this email address for this purpose delays our response to you. This email address is limited to requests for a replacement URA tape, technical inquiries regarding the URA tape, and state utilization tape errors/questions.

Operational questions should be directed to an operational analyst listed on page O2 of the Drug Rebate Operational Training Guide. Phone numbers and email addresses are provided on that page for your convenience.

UPDATED PAGES FOR THE OPERATIONAL TRAINING GUIDE

Attached is a revised page O2 for the operational training guide which reflects new email addresses for the operations staff and new policy staff members. Also, section S (Q&As) has been revised. A new section S is attached. Please share theses pages with the necessary staff and replace them in your guide.

THE EFFECTS OF SALES TO HEALTH MAINTENANCE ORGANIZATIONS (HMOs) AND TO OTHER ENTITIES PURCHASING DRUGS FOR DIRECT CONSUMER SALES OR DISTRIBUTION ON THE CALCULATION OF BEST PRICE (*REPACKAGER ISSUE*)

As a result of several inquires from manufacturers and the Office of Inspector General's (OIG) conclusion in Report No. A-06-00-0056: Medicaid Drug Rebates - Sales to Repackagers Excluded from Best Price Determination (March 27, 2001) that there are instances where manufacturers excluded sales to repackagers that are HMOs from their best price determinations, we are reiterating our policy requiring the inclusion of sales to HMOs and other entities purchasing drugs for direct consumer sales or distribution in the calculation of best price.

As previously explained in Releases No. 29 and 47, section 1927(c)(1)(C)(i) of the Social Security Act (the Act) specifies that best price is the lowest price available from the manufacturers to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity within the United States. Sections 1927(c)(1)(C)(i)(I)-(IV) of the Act list specific exclusions from the best price calculation. Under these provisions and section 1927(j)(3), it is clear that sales to organized health care settings such as HMOs must be included in best price. The best price provisions in the statute contemplate the inclusion of sales to HMOs without regard to special packaging or labeling.

The Medicaid Drug Rebate Program Manufacturers Releases No. 29 and 47 were issued to reiterate our existing policy regarding the inclusion of sales to HMOs in the calculation of best price, not to implement new policy. Specifically, Program Manufacturer Release No. 29 (June 1997), "Additional Guidance on Average Manufacturer Price (AMP) Calculations" was issued to assist manufacturers in determining the appropriateness of the AMP calculations or proposed calculations and Release No. 47 (July 2000), "The Effect of Sales to Health Maintenance Organizations and Other Entities Purchasing Drugs for Direct Consumer Sales or Distribution on the Calculation of Best Price" was issued to reiterate the existing policy that drug sales to an HMO should not be omitted from a manufacturer's best price calculation on the basis that the purchaser is a drug repackager. Releases No. 29 and 47 did not supersede requirements or change obligations in the rebate agreement or in section 1927 of the Act. Further, no new requirements were imposed on manufacturers and no action was necessary by manufacturers that were not revising or recalculating pricing data.

It is our position that those sales to entities that repackage/relabel under the purchaser's NDC are to be included in best price if that entity also is an HMO or other non-excluded entity. Therefore, if applicable, the best price calculation for quarters prior to the issuance of Release No. 47 (July 2000), as well as any quarter thereafter, must be adjusted to include those sales to other entities who repackage/relabel (inclusive of private label agreements) under the purchaser's NDC and are HMOs. Additionally, the payment of additional rebates may be due.

As with all pricing data submitted under the Medicaid drug rebate program, if CMS, the Office of Inspector General, or another authorized government agency reviews a manufacturer's pricing data and determines that adjustments or revisions are necessary, irrespective of the quarter, the manufacturer is bound to comply with that determination. Therefore, this determination requiring revised best price pricing data in connection with the repackager issue is not subject to the 3-year timeframe limitation regarding pricing revisions, established January 1, 2004. Consequently, manufacturers will be required to report revisions to best price for a period in excess of 12 quarters prior to the quarter in which the data were due.

NEW LABELERS

Labeler Name/Labeler Code	Mandatory Coverage Date	Optional Coverage Date
Cornerstone Biopharma, Inc. (labeler code 10122)	07/01/2005	04/26/2005
Cotherix, Inc. (labeler code 10148)	07/01/2005	04/14/2005
GTx, Inc. (labeler code 11399)	07/01/2005	03/18/2005
Richmond Pharmaceuticals, Inc. (labeler code 54738)	07/01/2005	02/14/2005
Viro Pharma, Inc. (labeler code 66593)	07/01/2005	04/18/2005
Varsity Laboratories (labeler code 67537)	07/01/2005	04/06/2005
Dava Pharmaceuticals, Inc. (labeler code 68774)	07/01/2005	03/14/2005

REINSTATED LABELERS

Gemini Pharmaceuticals, Inc. (labeler code 51645) has signed a new rebate agreement. Due to special circumstances, this reinstated labeler is permitted an optional coverage effective date of 02/12/2005. The mandatory coverage effective date is 07/01/2005.

OHM Laboratories, Inc. (labeler code 51660) has signed a new rebate agreement with a mandatory coverage effective date of 07/01/2005. There is no optional coverage date for this reinstated labeler.

Contact information for new/reinstated labelers is attached for your convenience.

TERMINATED LABELERS

The following labeler code is being voluntarily terminated effective April 1, 2005:

Ranbaxy Laboratories, Inc., (labeler code 10631).

The following labeler codes are being voluntarily terminated effective July 1, 2005:

Niche Pharmaceuticals (labeler code 59016); and
Aslung Pharmaceutical, L.P. (labeler code 65271).

The following labeler codes are being terminated effective July 1, 2005:

Steris Laboratories (labeler code 00402;
Berlex Laboratories (labeler code 11994;
Jerome Stevens Pharmaceuticals, Inc. (labeler code 50564;
Speywood Pharmaceuticals, Inc. (labeler code 55688);
Elge, Inc. (labeler code 58298);
Kiel Laboratories, Inc. (labeler code 59063);
AM2PAT, Inc., (labeler code 64054); and
Morepen Max, Inc. (labeler code 67836).

OTHER ATTACHMENT

A copy of the current listing of the 91-day treasury bill auction rates beginning with the period January 12, 2004, 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/

Edward C. Gendron
Director
Finance, Systems and Budget Group

4 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

CMS DRUG REBATE PROGRAM

Area Code 410

OPERATIONS

Cindy Bergin	786-1176	cynthia.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
Vince Powell (Technical Director)	786-3314	vincent.powell@cms.hhs.gov
Sue Williams	786-3334	susan.williams@cms.hhs.gov

POLICY

Kim Howell	786-6762
Madlyn Kruh	786-3239
Bernadette Leeds	786-9463
Christina Lyon	786-3332
Katiuscia Potier	786-1947
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
786-8534 - Policy

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

(FREQUENTLY ASKED)

QUESTIONS

AND

ANSWERS

In this section we have accumulated a list of questions we get from telephone calls, conferences, e-mails and letters. Our goal is to offer complete, concise and to-the-point answers in plain English. If you have a question, whether you are new to drug rebate or are an "old timer" in the program, it may be best that you refer to this section with your question before calling or writing the drug rebate staff. This could save you time and give you a clearer understanding of your current problem. It is our attempt in this FAQ section to amass answers to common problems that affect all users, both new and experienced.

We anticipate this section to be an ever-expanding list of questions and answers, so watch for future updates to the operations guide; your question may be included next!

* * * PLEASE NOTE * * *

In order to make this (FAQ) section an easier document to use, we have divided it into Labeler (Section S-L) and State (Section S-S) groups, each having their own page numbers. Because of their generalness, there are some questions that fall under both sections.

LABELER

FAQS

S-L1

Q1: Who do I contact regarding drug rebate questions?

A1: Whether your questions are related to policy or operations, you can find a listing of drug rebate personnel (both operations and policy) in section O of your OTG. This section provides a list of drug rebate functions and the staff members responsible for those areas. Also provided are staff telephone numbers and e-mail addresses, operations and policy fax numbers, addresses, and the website for the drug rebate homepage.

Q2: I am new to the Drug Rebate Program. What am I expected to send in, when, how, to whom and where?

A2: After you, or a company representative, submits a signed copy of the rebate agreement, Baseline and initial pricing data is to be submitted on all outpatient drug products during the month following the quarter in which your agreement was postmarked. If, for example, your agreement was postmarked somewhere between January 1 and March 31, this data is due during the month of April. If your agreement was signed between April 1 and June 30, it is due during July, etc.

You are expected to submit Baseline data on ALL products having NDCs that are FDA-approved drugs and are billable as outpatient drugs. Baseline data is the product information that includes FDA Approval Date, Market Date, DESI code, etc. The required data elements are described in the data dictionary, which is part of the agreement package sent to you originally. This data dictionary can also be found in the OTG sent to you after we received your signed agreement. Pricing data for the quarter you became effective is also due at this time. (See section F for computation of AMP and BP)

If you are sending your data through the regular mail please send it to:

CMS/CMSO
Drug Rebate Program
P.O. Box 26686
Baltimore, MD 21207-0486

If you are sending your data overnight delivery please send it to:

CMS/CMSO
Drug Rebate Program
Mail Stop S3-18-03
7500 Security Blvd.
Baltimore, MD 21244

Q3. My company purchased a drug product from another drug company. We will be selling it under our labeler code. At the same time, it will be sold under the old labeler code until the old supply of packaging runs out. How is this handled and who is responsible for what?

A3: This is a two-part question, so let's break it down and show who is responsible for which and when responsibility for paying rebates ends for the originating company and begins for the new company.

As long as there is a supply of this product available for sale under the old NDC at the pharmacist level, the company holding title to it (the old NDC) is responsible for reporting pricing data. They are to submit (to CMS) the termination date (shelf life of the last lot sold under the old number) of the old NDC as soon as they have it. After sales under the old number have stopped, the calculated AMP (and, BP if needed) is to be reported to CMS for up to 4 quarters beyond termination date. This company is also responsible for receiving invoices and paying rebates. If the selling company and buying company work out a situation where the buying company will submit quarterly data, process invoices and pay rebates, that is O.K.; however, invoices will still go to the original company and, if the new company pays states for that NDC only, ROSI forms will have to be generated and sent by BOTH old and new companies to each state each quarter this process exists. Once the product is no longer sold under the old NDC, the calculated pricing for the last quarter sold is to be submitted to CMS each quarter until four quarters past Termination date. At that point, reporting of prices stops.

When the new company begins selling the product under the new NDC, product (baseline) data is to be submitted to CMS following the NDA. In other words, product (baseline) information for the NEW NDC is to be EXACTLY the same as the OLD NDC. Also, based on OBRA'93 rules, if

the product is an "S" or "I", and the Market Date is greater than (newer) 09-30-1990, a pricing record for the quarter after Market Date is due to us with the

product (baseline) data. For a better explanation, please see section "H" of the Operations Guide and especially page 5.

After the product data (baseline) has been established for the new NDC, quarterly pricing is due, just like any other product.

Q4. I have been in your program for almost six months and, as yet, have not received a check from you for the number of my products that have been sold. When do I start receiving rebates for signing up in the drug rebate program?

A4: There seems to be some confusion as to whom pays whom. When you signed the agreement, **YOU** agreed to pay rebates to states based on the amount of your drugs they reimbursed pharmacies for, on behalf of Medicaid Recipients. You were sent a report after last quarter, telling you that product/pricing data had not been submitted and was overdue. If this data (please see section **F** of your Operations Guide) is not submitted along with the pricing for this quarter, it would mean that you have not submitted data for two consecutive quarters and would, therefore, be sent a letter stating that labeler termination process was underway and that you would have 45 days to submit everything that was missing to avoid being put out of the drug rebate program.

Please refer to both sections **F** (Program Requirements) and **S** (FAQS). This is covered in detail in both sections.

Q5: What drugs can states restrict or deny coverage for? I understand that there are drugs that a state can restrict or exclude from coverage even though I have been led to believe that ALL my drugs will be covered by the states when I sign the CMS Medicaid Drug Rebate Agreement.

A5: The following drugs, by their class or designation of medical uses, may be restricted or excluded from coverage by any state.

- Drugs, when used for anorexia, weight loss or weight gain
- Drugs, when used to promote fertility
- Drugs, when used for cosmetic purposes or hair growth

- Drugs, when used for symptomatic relief of cough or colds
- Drugs, when used to promote smoking cessation

- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- Nonprescription drugs
- Covered outpatient drugs, which the manufacturer seeks to require as a condition of sale, that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Barbiturates
- Benzodiazepines

Q6: My prices didn't change this quarter. Do I still have to send them to CMS?

A6: Quarterly pricing is due to us within 30 days after the end of each quarter. Whether your prices changed is not an issue. Your calculated AMP is based on specific sales only, with discounts, charge backs, returns, etc., included to bring the gross dollars down to net dollars which is divided by total units sold. Because of the mix of sales, discounts, etc., even if your sales prices do not change, it is quite possible that your calculated AMP will change. Also, for those products where BP is included, BP is based on the lowest price you SOLD the product for during the quarter, NOT the lowest price you offered it for sale. You may have several contracts where you sell a product for different prices. The company you sell to with the lowest price doesn't buy any product this quarter, but the second best does. That changes your BP for the quarter. (See section F)

Q7: We have a new drug that has a Market Date as the last (working) day of the quarter and have no sales listed for that quarter, yet you require pricing information. What do I send you?

A7: In this case, use the selling price as the AMP (BP also, if required) to satisfy the requirements of the system. There will be no rebate requests from states as there were no actual sales. (See section F)

Q8: I had no sales in this quarter for an NDC. Should I report zeros for prices or not report any data this quarter for the drug?

A8: Pricing is due to us every quarter on every active NDC ("active" means that the NDC has no termination date or the termination date is less than 4 quarters past the reporting quarter). Therefore, no sales does **not** mean no reporting or zero reporting. For any quarter, if you had no sales or if your AMP calculated to a minus figure due to adjustments, discounts, etc., go to the last quarter when a valid AMP was calculated and report that AMP for this quarter. (See section F)

Q9: I sent pricing for a new product this quarter but it rejected because I didn't send baseline data. This is an "N" drug and doesn't require baseline data. What should I do?

A9: Baseline (product identification) data is required for <u>every product</u> you sell under your labeler code that is classified as an outpatient drug. Sometimes there is some confusion between baseline data and baseline AMP. <u>Baseline AMP</u> is a field that is required for all "S" and "I" products having a Market Date less than 10-01-1993. <u>Baseline data</u> is the information we need to identify each product and includes such elements as Drug Type, Drug Category, DESI code, Unit Type, etc. (See section F)

Q10: I have several package sizes of my product and sent pricing based on the sales of each one. You sent me an edit list stating that my pricing was incorrect and that you were using my highest AMP and lowest BP for ALL sizes. What gives?

A10: When you have more than one package size of the same product (same strength and unit type), pricing is calculated slightly different from products having only one package size. Your AMP calculation is:

> Total units sold of ALL package sizes (adjusted for returns, chargebacks, etc.) ÷ into the total net sales dollars (adjusted for discounts, breakage rebate, etc.,) for ALL package sizes.

This gives you a "weighted" AMP for the product (9-digit NDC) that is to be reported for ALL package sizes (11-digit NDC) of the product. BP is not calculated or weighted. Instead, it is the lowest price per unit the

product sold for during the quarter regardless of package size. The same (lowest) BP is reported for all package sizes of the same product. Remember this rule: Price by 9-digit, report by 11-digit. (See section F)

Q11: I have a new package size of a product that just came on the market last quarter. I supplied Baseline data to you but some of it was rejected. For example, you wouldn't let me use the new market date for this package. Why not?

A11: Even though you are required to report all product information by 11-digit NDC, pricing and MOST baseline information must be the same for all package sizes of a product (9-digit NDC), with the exception of Units Per Package Size (UPPS), Termination Date, and Product Name. The redesigned system will not allow reporting of different values in any of the other fields. (See section F)

Q12: Since CMS changed the way it rounds the URA, and does so only for new or PPA records, I have a question regarding how this will work when reporting new package sizes of old products. Since the new package size must have all quarters of pricing completed back to the Market Date of the oldest size, wouldn't that cause the new package size to have its old rebates calculated and, thus, have different values than the already existing package sizes?

A12: No. The new package size will have the same URA values as the existing package sizes. When you submit information for a new package size, the system allows for specific information to be entered from your data, such as: NDC3, UPPS, and Product Name. All other information is taken from the already existing product. Since the inception of our new software system, pricing is maintained on a product level (9-digit NDC) only. That means that the integrity of the URA from the old package sizes is maintained for all new package sizes.

Q13: 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 NDCs that have an amount?

A13: 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% different (+ or -) 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 field on the 50/50 report for computing the total product rebate for each state. If any prices you reported are wrong, calculate the URA using correct pricing, use the correct URA for paying the states, and send a correction record to us with your next quarter's pricing submission for each incorrect price. (See sections F and G)

Q14: I have a product that came on the market in May, 2000. It is an "I" drug, thus, it requires a Baseline AMP and (every quarter) Best Price. When I submitted the product record, I included the Baseline AMP. Now, I have calculated the URA for all quarters since the product came on the market and the first 2 quarters match; however, since the 4th quarter, 2000, my URA is different from yours. I have followed the URA calculation in the Operations Guide, but cannot get my URAs to match those computed by CMS. HELP !!!

A14: There are two quick observations. 1) ALL "S" and "I" products having a Market Date of 10-01-1993 or GREATER do NOT have Baseline AMP reported for them, and 2) your question suggests that your product's price is going up pretty quickly if the "creep" calculation is already involved.

Check to make sure you are calculating your AMP correctly. With that being said, the Baseline AMP you filled in with your initial product record to us is **ignored by the system**. Check your calculated AMP for the July, 2000 quarter to see if it is different from the Baseline AMP you are using in your URA calculation. If it is, perform the calculation again using the July quarterly AMP in place of the Baseline AMP and see if your URA and ours are now in agreement. If the two figures STILL don't agree, make sure you are using the CPI-U value from June, 2000. If that still doesn't work, try a new calculator. By the way, the reason your URA calculation for the first 2 quarters this product was on the market matched ours was because for the first two quarters (Market Date quarter plus the next quarter) only the first part of the URA calculation is performed (AMP * 15.1% or AMP – BP, whichever is greater). There was no CPI-U creep involved.

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Many people still get confused over the changes OBRA'93 made to the values used in the CPI-U creep portion of the URA calculation. Beginning with the 4th quarter 1993 and forward, when the CPI-U CREEP calculation is performed for **ALL "S" and "I"** products having a **Market Date equal to 10-01-1990 or**

GREATER, the **CPI-U creep** portion of the URA calculation uses the calculated **AMP** from the **quarter AFTER Market Date *IN PLACE OF*** the **Baseline AMP** and the **CPI-U value** from the **month PRIOR to the calculated AMP** quarter ***IN PLACE OF*** the **Baseline CPI-U**. That does not mean that **YOU** physically include this value in the Baseline AMP field. It simply means that you **USE** this value **IN PLACE OF THE *BASELINE AMP*** when doing the **CPI-U creep** portion of the URA calculation. (See section H)

Q15: If my company sells a product to another company are we responsible for reporting prices and/or paying rebates? If so, for how long?

A15: There are actually two answers depending on the sale and how the product will be sold by the new company.

First and foremost, any products sold under your company's NDC are the responsibility of your company for reporting prices and product changes and, ultimately, paying rebates. If an agreement is worked out between the two companies where the new company will supply pricing/product information, so be it. However, if the pricing comes to CMS late or does not come in, CMS will hold the owner of the labeler code responsible. Likewise, all invoices, edit reports, etc., will be sent to the holder of the labeler code. If the new company continues to sell the product under the old NDC, this practice continues.

If the new company starts packaging and selling the product under its labeler code, all responsibility for reporting and paying under the new NDC, now completely falls with the new company. At this point, one last thing must be done with products under the old NDC. The Termination Date last date the product can be dispensed from the shelf) field must be updated on the CMS MDRI Master file, via your quarterly reporting. Also remember, when a product terminates, pricing is due to CMS for 4 quarters beyond the termination date. You continue to calculate prices quarter after quarter until the last quarter the product is sold. From that point on, use the calculated prices from the last quarter sold until and including the 4th quarter after the termination date. Once that 4th quarter has past, stop reporting prices. (See section F)

Q16: I have a product that is going to be discontinued. What do I send you as termination date; the date we stopped making it or the date we stopped selling it?

A16: Neither. Termination Date equals one of two dates:

1. Date product was removed from pharmacy shelves; or
2. Date of shelf life (last day it can be dispensed) of last lot sold.

It doesn't matter when a company stops making or selling a product. The Termination Date is equal to the last day the product may be dispensed. (See section F)

Q17: I sent termination dates on several of my products last quarter but CMS is still asking for pricing data for these NDCs. Why, and what price do I send since there are no longer sales of these products?

A17: Pricing data for terminated products must continue to be sent to CMS for 4 quarters **beyond** the termination date. This is necessary because Medicaid law states that pharmacies have up to one year to submit reimbursement claims to the state. The pricing data you should submit for the 4 quarters beyond the termination date is the calculated pricing from the last quarter of sales. (See section F)

Q18: Am I under obligation to pay a state invoice even if it is 2 or 3 months late? I am told that I have 37 days after postmark of a state invoice to pay or be subject to interest payments, yet, states constantly send their invoices long after the "60 days past the end of the quarter" timeframe they are supposed to meet.

A18: Section 1927(b)(2) of the Act does, in fact, require a state to submit invoice data to labelers within 60 days after the end of a quarter. There is no provision in the law to relieve labelers from the requirement to pay rebates regardless of when the invoice is received. Of course, the labeler's 37-day clock never begins until the postmark of the invoice, thus relieving the labeler of paying prior to 90 days past the end of the quarter.
(See section F)

Q19: I am new to the program and have submitted pricing to you as required under section 1927 of the Act and have started getting my first state invoices. The URA field on the invoices is showing that I owe about 100 times more in rebate than I sold the product for. Why are these invoices coming to me with these extremely high rebate amounts due?

A19: Check the pricing data you sent to us. Are you submitting prices based on **ONE** of your Unit Type or on the whole package? Please remember that when you submit your Baseline data for a product you include a Unit Type that is equal to the lowest dispensable unit of the product (TAB, ML, etc.). **ALL AMP and BP** pricing is to reflect **ONE UNIT** of the **UNIT TYPE**. If your pricing looks correct, contact one of the drug rebate staff for assistance. (See section F).

Q20: I have signed the Drug Rebate Agreement and would like to report some of my drugs so they may be covered for Medicaid. What do I need to do?

A20: If you are to be a labeler active in the drug rebate program, **ALL** of your FDA-approved drugs that can be billed as outpatient **MUST** be reported to CMS and be covered in our program. You **CANNOT** pick and choose which drugs will be covered and which will not. Also, it makes no difference whether your drugs are **Rx, OTC or a mixture**, they **ALL** are to be reported as part of your drug file and have pricing included each quarter.

STATE

FAQS

Q1: Who do I contact regarding drug rebate questions?

A1: Whether your questions are related to policy or operations, you can find a listing of drug rebate personnel (both operations and policy) in section O of your OTG. This section provides a list of drug rebate functions and the staff members responsible for those areas. Also provided are staff telephone numbers and e-mail addresses, operations and policy fax numbers, addresses, and the website for the drug rebate homepage.

Q2: What drugs can states restrict or deny coverage for? I understand that there are drugs that a state can restrict or exclude from coverage even though I thought that ALL drugs must be covered by the states when a labeler signs the CMS Medicaid Drug Rebate Agreement.

A2: The following drugs, by their class or designation of medical uses, may be restricted or excluded from coverage by any state.

- Drugs, when used for anorexia, weight loss or weight gain
- Drugs, when used to promote fertility
- Drugs, when used for cosmetic purposes or hair growth
- Drugs, when used for symptomatic relief of cough or colds
- Drugs, when used to promote smoking cessation
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- Nonprescription drugs
- Covered outpatient drugs, which the manufacturer seeks to require as a condition of sale, that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Barbiturates
- Benzodiazepines

Q3: I am new to the state and don't know much about the drug rebate program. I understand that CMS sends a URA file to us each quarter. What is it? What's on it? How often and on which dates do we get it?

A3: Each quarter, labelers active in the drug rebate program, submit specific pricing data on their drug products plus add new drug products that have been sold by them during the pricing quarter. CMS calculates a Unit Rebate Amount (URA;

aka RPU & RAPU) for each of these reported drugs and includes that information on a file to each state every (calendar) quarter. Additional information on new products (whether they be "new" or new to this labeler) is also included. This file contains information used by states: 1) To assure that they are paying for valid drugs [drugs not on our file are considered non-valid; DESI drugs – DESI indicator other than 2, 3 or 4 and drugs that are past their shelf life are considered non-valid], 2) To get the Unit Rebate Amount to include on labeler invoices and 3) To update already-existing and add new product information to the state master labeler file.

There is a second data set on this file. It is the labeler name and address file. It is an entirely new file each quarter and is to be overlaid on the old file to assure that the most current labeler Invoice name and address is used when mailing each invoice.

Labelers are required by law to submit their product/pricing data to CMS within 30 days after the end of each calendar quarter. Within 37 days after the end of each calendar quarter CMS "shuts down" the MDR Master file. A series of programs are executed that do all the end of quarter processing, including URA calculations, PPA generation, product record updates and producing specific quarterly reports, some of which go to labelers, reporting on specific problems with their data. When this processing is complete, the quarterly files are mailed to the states. They are generally in the mail by the 10th or 11th of the month (40 days + or -) after the end of each calendar quarter.

Q4: Can CMS send my quarterly file to me via UPS or some other overnight carrier? I can give you our account number so it can be billed directly to the state.

A4: Sorry, but this cannot be done. The files are generated by the computer operations group. They have specific instructions on generating mailing labels and packaging the files for delivery to the CMS central mailroom for regular USPS pick up. For us to "upset the applecart", shall we say, by pulling one or two files from the mix would cause a lot of undo confusion and would create, at the least, a longer lead time for mailing the majority of the files and could lead to mishandling of these files and possible errors in mailing them.

Q5: I got my quarterly file and some of the NDCs contain zeros in the URA field. Should I still include these on my invoices?

A5: Yes. ANY utilization for ANY NDCs that match the quarterly file from CMS should be submitted to the proper labeler for rebate. If there are zeros in the URA field it is because the labeler either:

- Did not supply pricing for the NDC this quarter;
- Supplied pricing data but it was rejected (by us) and the labeler did not have enough time to resubmit the corrected data before we shut the system down for quarterly processing; or,
- Supplied pricing data but when the URA was calculated it fell outside the parameters of the 50/50 edit.

(See section F)

Q6: I prefer to use my FirstData Bank (FDB) file for information on each labeler. Is there a down side to doing this?

A6: Several. Your FDB file serves a valuable purpose in your everyday Medicaid processing. This file, however, does NOT necessarily contain all of the correct data for running your Drug Rebate System. The CMS quarterly file contains information on ALL active NDCs reported to us by the labelers. It also contains the official CMS values for each field.

If, for example, the labeler submits baseline data for a new product and the DESI code INCORRECTLY contains a value of "2," where it should have a value of "5," and it gets onto the CMS file, the state is covered for ALL prescriptions it pays for until CMS corrects the mistake. If, however, the CMS file contains the CORRECT value of "5" and the FDB file contains the INCORECT value of "2" and the state uses the FDB value, the state is NOT covered for FFP and CMS will NOT suggest to the labeler that they make a rebate payment to the state for all prescriptions the state paid for while using the incorrect value. There are several DESI values on the FDB file. There are also several Termination Dates, including an obsolete date, which CMS doesn't even recognize. Remember, when in doubt about whose data are correct, CMS's data always takes precedence.

(See section G)

Q7: Do I have to wait for the CMS file before sending my invoices out? I generally have my utilization calculations done and my invoices ready long before the 45 days after the end of the quarter when the CMS file gets here.

A7: No, you do not have to wait for the quarterly CMS file to send out your invoices. HOWEVER, this means that ALL of your invoices must go out with zeros in the URA field and thus, the amount owed the state field, as well. This also means that you are having the labeler calculate every URA for every NDC on their file. This could delay their rebate check to you. Also, do you EVER use the CMS file? If you do not use it for supplying URA values, do you match it to your file to make sure your NDCs are active and accurate? (See section G)

Q8: I sent my invoice to labeler "X", but they didn't pay for the NDCs that they said weren't on the CMS file. What can I do?

A8: First, you should always use the CMS file. The quarterly file CMS sends contains one record for every ACTIVE NDC on our MDR Master file. If you have paid for an NDC that is NOT on our file you should have checked to make sure it was correct. If you paid a pharmacy for utilization on an invalid NDC, you may have to go back to the pharmacy to recoup your funds. (See section G)

WEEKLY U.S. T-BILL INVESTMENT RATE

weekly 91-day treasury bill auction rates

Date of Auction	Invest. Rate
01-12-04	0.887
01-20-04	0.891
01-26-04	0.907
02-02-04	0.939
02-09-04	0.939
02-17-04	0.931
02-23-04	0.947
03-01-04	0.957
03-08-04	0.945
03-15-04	0.961
03-22-04	0.945
03-29-04	0.961
04-05-04	0.945
04-12-04	0.929
04-19-04	0.949
04-26-04	0.985
05-03-04	1.001
05-10-04	1.078
05-17-04	1.058
05-24-04	1.066
05-31-04	1.150
06-07-04	1.251
06-14-04	1.413
06-21-04	1.336
06-28-04	1.381
07-05-04	1.344
07-12-04	1.336
07-19-04	1.352
07-26-04	1.449
08-02-04	1.490

Date of Auction	Invest. Rate
08-09-04	1.497
08-16-04	1.498
08-23-04	1.541
08-30-04	1.607
09-06-04	1.663
09-13-04	1.671
09-20-04	1.716
09-27-04	1.741
10-04-04	1.716
10-12-04	1.711
10-18-04	1.803
10-25-04	1.890
11-01-04	1.987
11-08-04	2.084
11-15-04	2.115
11-22-04	2.197
11-29-04	2.380
12-06-04	2.253
12-13-04	2.243
12-20-04	2.223
12-27-04	2.269
01-03-05	2.320
01-10-05	2.376
01-18-05	2.407
01-24-05	2.366
01-31-05	2.525
02-07-05	2.530
02-14-05	2.592
02-22-05	2.669
02-28-05	2.772

Date of Auction	Invest. Rate
03-07-05	2.767
03-14-05	2.792
03-21-05	2.859
03-28-05	2.839
04-04-05	2.792
04-11-05	2.767
04-18-05	2.864
04-25-05	2.941
05-02-05	2.931
05-09-05	2.911

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