DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid , CHIP, and Survey & Certification

August 11, 2010

MEDICAID DRUG REBATE PROGRAM **Release No. 155**

For State Medicaid Directors

AFFORDABLE CARE ACT OPERATIONAL GUIDANCE & FIRST QUARTER 2010 REBATE INFORMATION

In an effort to expedite this guidance, we previously provided interim guidance via email on May 24, 2010; however, we have since received questions requesting clarification on some of the provisions. Therefore, we have updated the language on the new rebate calculation for Single Source (S)/ Innovator Multiple Source (I) line extension drugs in an oral solid dosage form and on the limit of the rebate amount for S/I drugs under this section. We will continue to provide additional guidance as soon as it becomes available.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (HCERA), P.L. 111-152, together called the Affordable Care Act (ACA). Section 2501 of ACA, as amended by section 1206 of HCERA, include changes to certain Medicaid Drug Rebate (MDR) provisions, effective first quarter 2010. Several of these changes impact the Unit Rebate Amount (URA) calculation for all drugs covered under the MDR Program. Specifically, these sections increase the rebate percentages for S, I, and Non-Innovator (N) drugs and establish new requirements for calculating rebates for reformulated S/I drugs in oral solid dosage form. Additional details about these revised calculations may be found below.

In accordance with the national rebate agreement, labelers are responsible for calculating URAs. However, CMS usually provides States with calculated URAs for use on rebate invoices so that States can verify these URAs with any labeler-adjusted URAs that States may receive. CMS was not able to calculate a URA using the new rebate percentages or requirements for reformulated drugs in time for first quarter 2010 rebate processing. Therefore, until CMS' MDR systems (i.e.,

Drug Data Reporting for Medicaid (DDR) and MDR) are modified to reflect the URA changes implemented by ACA, CMS does not expect to be calculating these URAs.

In order to facilitate the data exchange between CMS and States, CMS did not send updated URAs to States on the first quarter 2010 tapes, along with the usual labeler contact and drug product data files. As a result, State invoices will not contain updated URAs, and labelers remain responsible for calculating these amounts. These uncalculated URAs will also be reflected in DDR beginning with the URAs for the first quarter of 2010 until system modifications are made. (Please note that this does not affect any prior period adjustments (PPAs) which are based on percentages in effect prior to ACA.) Therefore, labelers should update and submit their URAs to States using the OMB-approved Reconciliation of State Invoice (ROSI) form (Form CMS-304) that reflects the ACA amendments beginning with the first quarter 2010 drug rebate reporting period. A copy of the ROSI can be found in the MDR Data Guide for Labelers which is posted on the DDR website.

The URA calculation changes are summarized below:

Changes to the Basic URA Calculation

--Innovator (S/I Drug Category) drugs are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 23.1 percent.

--Innovator (S/I Drug Category) clotting factor drugs for which a separate furnishing payment is made under section 1842(o)(5) of the Social Security Act are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent. A list of these NDCs will be posted and updated in DDR in the near future for State and labeler use.

--Innovator (S/I Drug Category) drugs approved by the Food and Drug Administration (FDA) for exclusively pediatric indications are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent.

--Non-innovator (N Drug Category) drugs are subject to an increase in the minimum rebate percentage used to calculate rebates. To calculate the Basic URA of these products, the product's AMP is now multiplied by 13 percent.

New Rebate Calculation for S/I Line Extension (i.e., New Formulations) Drugs in Oral Solid Dosage Forms

For a drug that is a line extension (new formulation) of an S/I drug that is an oral solid dosage form, the rebate is the amount computed under section 1927 of the Act or, if greater, the product of:

- the AMP for the line extension drug,
- the highest additional rebate for any strength of the original S/I drug, and

- the total number of units of each dosage form and strength of the line extension drug (section 1206 of HCERA, which replaced section 1927(c)(2)(C) as added by section 2501(d) of PPACA).

Limit on Rebate Amount for S/I Drugs

--The total rebate obligation for all innovator drugs (S/I Drug Category) is capped at 100% of AMP.

Labelers are responsible for calculating rebates and URAs in accordance with the statute. CMS is currently working on systems updates and will promptly notify labelers and States when the changes are in place. At that time, States will receive PPAs retroactive, if applicable, to the first quarter 2010.

(Contact: mdroperations@cms.hhs.gov)

LIST OF PEDIATRIC AND CLOTTING FACTOR DRUGS AVAILABLE SOON IN DDR

The Affordable Care Act (ACA) establishes several new rebate calculations for those National Drug Codes (NDCs) covered under the Medicaid Drug Rebate Program, effective January 1, 2010. Under section 2501 of the ACA, most single source and innovator multiple source drugs are subject to a minimum rebate of 23.1 percent. Section 2501(a)(1)(B) of the ACA added a new section 1927(c)(1)(B)(iii) to the Social Security Act (the Act) to require a new minimum rebate of 17.1 percent of the average manufacturer price (AMP), effective January 1, 2010 for a drug approved by the Food and Drug Administration (FDA) exclusively for pediatric indications.

We plan to interpret this provision in accordance with Federal regulations published by the FDA regarding pediatric labeling requirements for prescription drugs, and plan to interpret in light of the FDA labeling and as the indications for pediatric use on the labeling. In accordance with regulations at 21 CFR 201.57, and 21 CFR 201.80, the FDA defines pediatric use for drugs use as for pediatric populations and pediatric patients. The FDA defines pediatric populations and pediatric patients as the pediatric age group from birth to 16 years. Accordingly, we plan to apply the 17.1 percent minimum rebate to those single source or innovator multiple source drugs approved by the FDA exclusively for pediatric indications meeting this FDA definition. Drugs that are not approved, or labeled, exclusively with indications for pediatric use will not qualify for the minimum rebate provisions in section 1927(c)(1)(B)(iii of the Act.

Until CMS's systems can be updated to include an identifier for these drugs and others specified in ACA, we have compiled an initial draft list of those pediatric drugs we have been able to identify that we believe to meet the above-mentioned definition. This list will be posted on the Bulletin Page in the Drug Data Reporting for Medicaid (DDR) application for State and labeler use. Additionally, this list will be posted on the Policy & Reimbursement's Spotlight web page at http://www.cms.gov/Reimbursement/02_Spotlight.asp. If you have concerns or are aware of other drugs that meet the pediatric definition specified above, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov and specify the drug(s) for which you have concerns or that you believe meet this definition as well as supporting documentation, including the FDA labeling, so that CMS can review this and, if appropriate, update the list accordingly.

Additionally, the ACA added a new section 1927(c)(1)(B)(iii) establishing a minimum rebate of 17.1 percent for clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. We expect that when products are included on the list, the minimum rebate of 17.1 percent of AMP will be used as a basis for rebate calculation. CMS has obtained this data from Medicare Part B and will post the list of clotting factor NDCs on the Bulletin Page in DDR for State and labeler use. This list will also be posted on the Policy & Reimbursement's Spotlight web page. If you have any questions or corrections to this list, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov so that we can review this submission and, if appropriate, update the list accordingly.

CMS will issue additional guidance regarding changes to the Medicaid Drug Rebate Program as it becomes available.

REMOVAL OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) AND EXCIPIENTS AS COVERED OUTPATIENT DRUGS

We are providing policy clarification regarding the inclusion of APIs and excipients in the drug rebate program. An API is a bulk drug substance, which is defined by the FDA as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product. 21 C.F.R. § 207.3(a)(4). APIs may be included in extemporaneously compounded prescriptions and may serve as the active drug component in a compounded formulation.

In accordance with the foregoing, APIs do not meet the definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). As such, APIs are not subject to the requirements of the MDR program. In addition, excipient products used in compounds (*e.g.*, aquaphor, petrolatum, etc.) are non-drug products and, as a result, should not be reported to the MDR program. However, FFP may be available for these products if the State plan allows for their coverage as incident to another service category (*e.g.* Home Health, Nursing, Other Practitioner).

To the extent possible, CMS has identified the APIs and excipients that are listed in the MDR system. We are notifying manufacturers that the NDCs do not qualify as covered outpatient drugs and, as a result, will be deleted from the MDR product file of covered outpatient drugs effective January 1, 2011. As with all deletions, we will notify the States regarding the removal of these products. The list of identified API and excipient NDCs can be found on the Policy & Reimbursement's Spotlight Webpage. Please note that this is not a definitive list. If additional API and/or excipient NDCs are identified, please notify MDROperations@cms.hhs.gov to have them removed from the MDR Program.

The State Medicaid agency should also review their State plan to assure that to the extent that it wishes to continue coverage of these products, the plan allows for such coverage. Where the plan does not allow for such coverage, a State plan amendment should be submitted.

If you have any questions, please contact Joseph Fine at 410-786-2128.

BANKRUPTCY FILING BY LABELER CODE 11042 – MIDDLEBROOK PHARMACEUTICAL, INC.

We have recently become aware that labeler code 11042 (Middlebrook Pharmaceutical, Inc.) filed a Chapter 11 Voluntary Petition in the U.S. Bankruptcy Court for the District of Delaware.

When labelers file for bankruptcy, states are expected to protect Medicaid interests related to any rebate payments owed from the affected labelers. To that end, we strongly encourage states to file a proof of claim for any outstanding rebate payments in the bankruptcy proceedings of the abovementioned labelers.

In addition, we are in the process of determining whether this labeler code should be terminated from the Drug Rebate Program as a result of the bankruptcy filing. If a determination is made that the labeler should be terminated, we will notify you of the termination via an email notification.

(Contact: mdroperations@cms.hhs.gov)

UNAPPROVED NEW DRUGS--DELETIONS FROM MDR

The States were previously notified that the FDA has determined that the following active NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval. 73 Fed. Reg. 54831 (September 23, 2008). According to the FDA, these products do not have approved applications; therefore, CMS has determined that the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program. Therefore, they are being deleted from the MDR master file of covered outpatient drugs.

NDC	Product Name
13279-0100	PAPAIN UREA OINTMENT
13279-0101	ALLANFIL 405 OINTMENT
13279-0102	ALLANZYME SPRAY
13279-0103	ALLANFIL SPRAY
51552-0584	PAPAIN POWDER PURIFIED
58177-0804	ETHEZYME PAPAIN UREA DEBRIDING OINTMENT
58177-0816	ETHEZYME 830 PAPAIN-UREA DEBRIDING OINTMENT
58980-0711	KOVIA OINTMENT
58980-0722	KOVIA 6.5 OINTMENT
58980-0765	ZIOX OINTMENT
58980-0776	ZIOX 405 OINTMENT

As a reminder, while these products are not eligible for Medicaid coverage under the MDR Program, they might be eligible for coverage under other Medicaid benefit categories such as home health services or EPSDT services, depending on whether such coverage is consistent with the State plan.

The States were previously notified that the FDA has determined that the following active Exocrine Pancreatic Insufficiency NDCs are unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, subject to enforcement action, and cannot be marketed without appropriate FDA approval. 69 Fed. Reg. 23410 and 72 Fed. Reg. 60860 (April 28, 2004 and October 26, 2007). According to the FDA, these products do not have approved applications; therefore, CMS has determined that the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program. Therefore, they are being deleted from the MDR master file of covered outpatient drugs.

NDC	Product Name
00032-1205	CREON5CAPSULES
00032-1210	CREON10CAPSULES
00032-1220	CREON20CAPSULES
00091-4175	KUTRASE CAPSULES RX
10267-2737	PANCRELIPASE 8,000 TABLETS
39822-9045	PANCRELIPASE 4,500
39822-9100	PANCRELIPASE 10,000
39822-9160	PANCRELIPASE 16,000
39822-9200	PANCRELIPASE 20,000
58177-0028	PANGESTYME MT 16 CAPSULES
58177-0029	PANGESTYME CN 10 (PANCRELIPASE) DELAYED RELEASE CAP
58177-0030	PANGESTYME CN 20 (PANCRELIPASE) DELAYED RELEASE CAP
58177-0031	PANGESTYME EC CAPSULES
58177-0048	PANGESTYME UL 12 CAPSULES
58177-0049	PANGESTYME UL 18 CAPSULES
58177-0050	PANGESTYME UL 20 CAPSULES
58177-0416	PLARETASE
58914-0002	ULTRASE MT 12
58914-0004	ULTRASE MT 20
58914-0018	ULTRASE MT18
58914-0045	ULTRASE MS 4
58914-0111	VIOKASE
58914-0115	VIOKASE 8OZ POWDER
58914-0116	VIOKASE 16000
59767-0001	PANCRECARB MS-8
59767-0002	PANCRECARB MS-4
59767-0003	PANCRECARB MS-16

As a reminder, while these products are not eligible for Medicaid coverage under the MDR Program, they might be eligible for coverage under other Medicaid benefit categories such as home health services or EPSDT services, depending on whether such coverage is consistent with the State plan.

The States were previously notified that FDA has determined that the following active NDCs are unapproved new drugs within the meaning of section 301(a) and (d) and Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d) and 355(a) and the drugs are

misbranded in violation of Section 502(f)(1) of the Act (21 U.S.C. 352(f)(1), subject to enforcement action, and cannot be marketed without appropriate FDA approval. According to the FDA, these products do not have approved applications; therefore, CMS has determined that the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program. Therefore, they are being deleted from the MDR master file of covered outpatient drugs.

As a reminder, while these products are not eligible for Medicaid coverage under the MDR Program, they might be eligible for coverage under other Medicaid benefit categories such as home health services or EPSDT services, depending on whether such coverage is consistent with the State plan.

NDC	Product Name
00603-1314	HYOSCYAMINE SULFATE DROPS (15 ML)
00603-1315	HYOSCYAMINE SULFATE LIQUID (16 OZ)
00603-5141	PHENAZOPYRIDINE HC1 (O.1G) TABLETS
00603-5142	PHENAZOPYRIDINE HC1 (O.2G) TABLETS

(Contact: mdroperations@cms.hhs.gov)

NOTIFICATION OF CHANGES IN DESI CODE

The states were previously notified that the following products were reported by the labeler with a DESI code of 2 (i.e., rebate- eligible); however, the FDA has determined that the drugs are subject to a Federal Register notice dated April 20, 1999 (64 FR 19374) which proposed to withdraw approval of certain New Drug Applications and Abbreviated New Drug Applications for controlled-release nitroglycerin tablets and capsules. Therefore, the appropriate DESI code for each of these products is a code of 5 (i.e., less-than-effective/IRS drug for all indications). As a result, these drugs are no longer eligible for coverage under the MDR Program.

00603-4782	NITROGLYCERIN CAP
49483-0221	NITRO-TIME 2.5MG
49483-0222	NITRO-TIME 6.5MG
49483-0223	NITRO-TIME 9MG
58809-0615	CARBATAB-12

(Contact: mdroperations@cms.hhs.gov)

NEW REBATE AGREEMENTS

Labeler Name:	Baxter Healthcare Corporation
Optional Effective Date:	04/01/2010
Mandatory Effective Date:	04/01/2010
Labeler Code:	00941

Labeler Name:	Actavis Pharma Manufacturing Private Limited
Optional Effective Date:	04/27/2010

Mandatory Effective Date: 07/01/2010
Labeler Code: 14550

Labeler Name: Topco Associates LLC
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 36800

Labeler Name: Allaire Pharmaceuticals, LLC
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 43351

Labeler Name: Amerisource Bergen Drug Corporation
Optional Effective Date: 07/05/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 46122

Labeler Name: Alvogen Inc.
Optional Effective Date: 01/29/2010
Mandatory Effective Date: 04/01/2010
Labeler Code: 47781

Labeler Name: Dyax Corp.
Optional Effective Date: 01/28/2010
Mandatory Effective Date: 04/01/2010
Labeler Code: 47783

Labeler Name: Neurogesx, Inc.
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 49685

Labeler Name: Nautilus Neurosciences, Inc.
Optional Effective Date: 06/08/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 50192

Labeler Name: Leo Pharma Inc.
Optional Effective Date: 02/23/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 50222

Labeler Name: QLT Ophthalmics Inc.
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 50236

Labeler Name: Avpak
Optional Effective Date: 04/30/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 50268

Labeler Name: Wallace Pharmaceuticals
Optional Effective Date: 07/20/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 51525

Labeler Name: Amedra Pharmaceuticals, LLC
Optional Effective Date: 07/20/2010
Mandatory Effective Date: 10/01/2010
Labeler Code: 52054

Labeler Name: Gensavis, LLC
Optional Effective Date: 04/29/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 52304

Labeler Name: Physician Therapeutics LLC
Optional Effective Date: 04/13/2010
Mandatory Effective Date: 07/01/2010
Labeler Code: 68405

TERMINATED LABELERS

Effective 04/01/2010

Labeler Name	Labeler Code
Skin Medica	67402

Effective 07/01/2010

Labeler Name	Labeler Code
Microbix Biosystems, Inc.	24430
Le Vista Inc.	42212
Sage Pharmaceuticals, Inc.	59243
Dabur Pharma US, Inc.	10518

Effective 10/01/2010

Labeler Name	Labeler Code
Beta Dermaceuticals, Inc.	53062

VOLUNTARILY TERMINATED LABELERS

Effective 07/01/2010

Labeler Name	Labeler Code
Blaine Company	00165
Targacept	17205
Topix Pharmaceuticals, Inc.	58211

Effective 10/01/2010

Labeler Name	Labeler Code
Novavax, Inc. (formerly Fielding)	00421

PRODUCT DELETIONS

00904-0985	SYRVITE SYRUP
00145-1504	ZEASORB POWDER
00145-1057	OILATUM CLEANSING BAR
37205-0110	MAGNESIUM CITRATE
37205-0113	DAIRY DIGEST SUPP
37205-0114	DAIRY DIGEST SUPPLEMENT ULTRA
37205-0301	NATURAL VEGETABLE POWDER LAXATIVE
37205-0303	NATURAL VEGETABLE POWDER ORANGE
37205-0347	NATURAL VEGETABLE POWDER LAXATIVE
37205-0362	CITRATE OF MAG LO SODIUM
37205-0366	NATURAL VEGETABLE POWDER SUG-FREE
37205-0480	FIBER SUPPLEMENT 12.3OZ SF
37205-0606	CRANBERRY TAB 50
45802-0357	IMPROVED SALINE MIST 45ML
49614-0134	MAGNESIUM CITRATE LEMON
49614-0135	MAGNESIUM CITRATE CHERRY
49614-0227	FIBER SUPPLEMENT 12.3OZ SF
49614-0345	FIBER LAX 13OZ ORANGE ORIGINAL
49614-0347	FIBER LAX 10OZ ORANGE SMOOTH
49614-0350	FIBER CAPLETS 625MG 90
49614-0366	FIBER LAX 10OX SF ORG SMOOTH
49614-0388	DAIRY DIGESTIVE 32
63717-0099	ICAR-C TABLETS
63717-0102	ICAR PEDIATRIC SUSPENSION
63717-0103	ICAR PEDIATRIC CHEWABLE TABLET

As a reminder, while these products are not eligible for Medicaid coverage under the MDR Program, they might be eligible for coverage under other Medicaid benefit categories such as home health services or EPSDT services, depending on whether such coverage is consistent with the State plan.

UPCOMING MODIFICATIONS TO THE STATE UTILIZATION DISCREPANCY ERROR AND ALERT REPORT

In an effort to improve both the quality and the processing of the state utilization data, we will soon be changing some of the error and alert edits included on the utilization discrepancy report. In addition, the format of the discrepancy report is being changed to consolidate it and to make it more straightforward for states. Please note that these changes will NOT require the States to make any change to the current file structure used to submit utilization data to CMS/MDR. The revised list of discrepancy report error and alert messages is attached, along with an example of the new format for the report and some additional utilization data process information that will be implemented.

(Contact: mdroperations@cms.hhs.gov)

CHANGE TO THE DISPUTE RESOLUTION PROGRAM

CMS is in the process of replacing the Central Office Dispute Resolution Program (DRP) Team Lead, who recently retired. Therefore, as DRP issues arise for which a State and/or labeler would like to request CMS's assistance, please follow the established practice of contacting the appropriate Regional Office DRP Coordinator. The contacts may be found on the web at: www.cms.gov/MedicaidDrugRebateDispR/Downloads/rodrpcoordinators.pdf

The Denver Regional Office's DRP/Drug Coordinator continues to serve as the Lead RO for DRP issues and should be copied on all dispute-related communications to other Regional Office DRP Coordinators.

Please direct your drug rebate data questions to mdroperations@cms.hhs.gov and your drug policy questions to the Division of Pharmacy at RxDrugPolicy@cms.hhs.gov .

Rick Friedman /s/ for

Penny R. Thompson
Acting Director
Data and Systems Group

Attachments

cc:
Regional Administrator

Error and Alert Messages on the Utilization Discrepancy Report

The first page of each State Utilization Discrepancy reports lists the possible Error or Alert messages included on the report, along with their descriptions. Here is the list of all Error and Alert messages as of June 2010:

Error Messages:

INVALID STATE CODE	The two-letter state abbreviation given does not match the 56 state abbreviations residing in the tables file.
INVALID QUARTER AND/OR YEAR	The quarter submitted is not numeric or is not in the range from 1 to 4, or and/or the year submitted is not numeric or is not greater than 1990.
LABELER CODE IS NOT IN MDRP	The labeler code (NDC1) submitted does not participate in the rebate program.

Note: Labeler code has never been in the program.

LABELER CODE HAS BEEN TERMINATED FOR MORE THAN FOUR QUARTERS

The submitted labeler code has been terminated for more than four quarters. Pharmacy providers should no longer be submitting claims for this labeler code.

Note: Labelers are generally terminated the first day of a quarter; therefore, the quarter in which the labeler is terminated would be considered the 'first quarter after termination'.

Example: labeler terminated 4/1/2010; first quarter would be 2/2010, the last quarter to report would be 1/2011; Data submitted for quarters 2/2011 and after would qualify for this edit.

INVALID FIELD VALUE

The indicated field name has one of the following errors:

1. The value is not numeric.
2. The value is not zero padded.
3. The value contains a sign.

Edit Applies to the following fields:

- Unit Rebate Amount
- Units Reimbursed
- Rebate Amount Claimed
- Number of Prescriptions
- Medicaid Amount Reimbursed
- Non-Medicaid Amount Reimbursed, and
- Total Amount Reimbursed

POSITIVE (INTEGER/VALUE) ONLY — The indicated field name must be greater than zero.

Edit Applies to the following fields:

- Units Reimbursed
- Number of Prescriptions

Medicaid Amount Reimbursed, and
Total Amount Reimbursed

NDC REMOVED FROM PROGRAM — The quarter/year combination submitted for this record is equal to or after the quarter in which the submitted NDC was deleted from the Drug Rebate Program.

TOT REIMB NOT EQUAL TO MEDICAID/NON-MEDICAID

The amount supplied by the state for Medicaid amount reimbursed and non-Medicaid amount reimbursed must sum to the amount supplied by the state for the total amount reimbursed.

Note:

For data submitted for quarters prior to the 4q2007, the submission of the Medicaid Amount Reimbursed and Non-Medicaid Amount Reimbursed fields is optional. However, if a state chooses to submit these new fields as part of a submission for a quarter prior to 4q2007, the sum of the fields must be equal to the amount in the total amount reimbursed field.

DUPLICATE RECORD SUBMISSION – RE-SUBMISSION MAY BE REQUIRED

CMS will accept one utilization record per NDC per quarter. Please review the accepted record and submit a replacement record if necessary.

Notes: On a single tape/submission more than one unique NDC, quarter and year was submitted.

NDC'S DESI INDICATES A LESS-THAN-EFFECTIVE DRUG

The quarter/year combination submitted for this record is equal to or after the quarter in which the specified NDC's DESI Code was changed to a Code of "5" or "6"; therefore, the NDC for this product is not rebate-eligible for the submitted periods.

Notes: NDC's DESI value is "5" or "6" AND -

DESI changed at some time during or prior to the qtr/year of submitted utilization qtr/year value.

Example: 3/2005 utilization qtr/year, a DESI changed to a 5 or 6 during or prior to 6/30/2005 would qualify the record for this error.

Note: If DESI value was always a "5" or "6" this Error does not apply.

Alert Messages:

QTR/YEAR EQUALS 1ST QTR OF LABELER'S PARTICIPATION IN MDRP

The quarter/year combination submitted for this record is equal to the first quarter in which the submitted labeler code was effective in the Drug Rebate Program; however, the labeler code may not have been active for that entire quarter. Please review this utilization to ensure that it occurred on or after the labeler's optional effective date. If such a review reveals that some or all of the utilization occurred prior to the labeler's optional effective date, then the affected units should be adjusted accordingly.

Note: Qtr/Year of data being submitted is within the first quarters of the labeler's rebate agreement OPTIONAL effective date.

Example: 2/2009 quarter would convert to 4/1/2009; then determine if Labeler's optional effective date is within that quarter (example: between 4/1/2009 and 6/30/2009

LABELER CODE WAS TERMINATED WITHIN LAST FOUR QUARTERS

The reported labeler code was terminated within the previous four quarters. Please review the utilization to ensure the date of service occurred prior to the labeler's termination effective date

Edit:

Labelers are generally terminated the first day of a quarter; therefore, the quarter in which the labeler is terminated would be considered the "first quarter after termination date".

Example: labeler terminated 4/1/2010, the first quarter after termination would be 2/2010 and the last quarter to report utilization for labeler would be 1/2011. Data could be submitted 4/1/2010 thru 3/31/2011).

RECORD DELETED SINCE ALL FIELDS ARE 0

The input record had 0 values for all the numeric fields which include Rebate Amount per Unit, Total Units Reimbursed, Total Rebate Amount Claimed, Number of Prescriptions, Medicaid Reimbursement Amount, Non-Medicaid Reimbursement Amount, and Total Reimbursement Amount. As a result, the existing record for this NDC for this quarter was deleted from the MDR State utilization database.

ALL fields (below) submitted with a value of Zero:

Rebate Amount per Unit
Total Units Reimbursed
Total Rebate Amount Claimed
Number of Prescriptions
Medicaid Reimbursement Amount
Non-Medicaid Reimbursement Amount, and
Total Reimbursement Amount

PRODUCT NOT FOUND ON FILE

The labeler code (NDC1) and product code (NDC2) combination on the record supplied by the state does not match a record in the Medicaid drug rebate (MDR) system. State should contact the labeler to ensure the product is a rebate-eligible drug and not a coding error and/or DESI 5/6 drug

---

PACKAGE SIZE NOT FOUND ON FILE

The labeler code (NDC), product code (NDC2), and package size code (NDC3) combination on the record supplied by the state does not match a record in the Medicaid drug rebate (MDR) system. State should contact the labeler to ensure the product is a rebate-eligible drug and not a coding error and/or DESI 5 / 6 drug

---

URA DOES NOT MATCH CMS URA

URA supplied by the state does not match the CMS- calculated URA

Processing (relational) requirements:

In addition to the specific Error and Alert Messages identified on the first page of the State Utilization Discrepancy reports, the following edits also apply:

1) The following fields must be greater than zero when submitting an initial/new record. If not, the record will reject:

   Units Reimbursed
   Number of Prescriptions
   Medicaid Amount Reimbursed
   Total Amount Reimbursed

2) In order to delete an existing utilization record, ALL the following fields must be zero AND the record must exist.

   Units Reimbursed
   Rebate Amount Claimed
   Number of Prescriptions
   Medicaid Amount Reimbursed
   Non-Medicaid Amount Reimbursed
   Total Amount Reimbursed

3) When are zeroes allowed in the following fields? When a state wishes to change one of the following fields, enter the new value in the field to be changed then zeroes are allowed to be entered in the other fields. Please note that utilization records for NDC1/2/3 and quarter/year must already exist within the database in order to do this.

   Units Reimbursed
   Rebate Amount Claimed
   Number of Prescriptions
   Medicaid Amount Reimbursed
   Non-Medicaid Amount Reimbursed
   Total Amount Reimbursed

4) For all periods prior to 4Q2007, the Medicaid and Non-Medicaid Amount Reimbursed fields are optional. For all periods after 4Q2007, the Medicaid Amount Reimbursed field is required and the Non-Medicaid Amount Reimbursed field is optional.

5) If submitted, the number submitted for Medicaid Amount Reimbursed and the number submitted for Non-Medicaid Amount Reimbursed must sum to the number submitted for Total Reimbursement Amount.

State Utilization Submission

The next several pages represent the single file/report that the states will receive explaining the outcome of the data they submitted. If the data they submitted contains no errors and no alerts for all quarters/years on the file, they will simply receive the first two pages (describing the error and alert message) and the last page (Summary).

States are still allowed to submit multiple quarters/years data on a single file.

EXAMPLE OF NEW FORMAT

RECEIVED DATE: MM/DD/CCYY HH:MM:SST
STATE: XX

MEDICAID DRUG REBATE
STATE UTILIZATION DISCREPANCY REPORT
ERROR MESSAGES

ERROR RECORDS WILL BE REJECTED

ERRORS:	DESCRIPTION:
INVALID STATE CODE	The two letter state abbreviation given is not a valid state abbreviation
INVALID QUARTER AND/OR YEAR	The submitted quarter is not numeric or is not in the range from 1 to 4 or and/or the year submitted is not numeric or is not greater than 1990
LABELER CODE IS NOT IN MDRP	The labeler code (NDC1) submitted does not participate in the rebate program
LABELER CODE HAS BEEN TERMINATED FOR MORE THAN FOUR QUARTERS	The submitted labeler code has been terminated for more than four quarters. Pharmacy providers should no longer be submitting claims for this labeler code.
INVALID FIELD VALUE	The indicated field name has one of the following errors: 1. The value is not numeric. 2. The value is not zero padded. 3. The value contains a sign.
POSITIVE (INTEGER/VALUE) ONLY	The indicated field name must be greater than zero
NDC REMOVED FROM PROGRAM	The quarter/year combination submitted for this record is equal to or after the quarter in which the submitted NDC was deleted from the Drug Rebate Program
TOT REIMB NOT EQUAL TO MEDICAID/NON-MEDICAID	The amount supplied by the state for Medicaid amount reimbursed and non-Medicaid amount reimbursed must sum to the amount supplied by the state for the total amount reimbursed
DUPLICATE RECORD SUBMISSION – RE-SUBMISSION MAY BE REQUIRED	CMS will accept one utilization record per NDC per quarter. Please review the accepted record and submit a replacement record if necessary.
NDC'S DESI INDICATES A LESS-THAN-EFFECTIVE DRUG	The quarter/year combination submitted for this record is equal to or after the quarter in which the specified NDC's DESI Code was changed to a Code of "5" or "6"; therefore, the NDC for this product is not rebate-eligible for the submitted periods.

RECEIVED DATE: MM/DD/CCYY HH:MM:SST
STATE: XX

MEDICAID DRUG REBATE
STATE UTILIZATION DISCREPANCY REPORT
ALERT MESSAGES

ALERTED RECORDS WILL BE ACCEPTED

ALERTS:	DESCRIPTION:
QTR/YEAR EQUALS 1ST QTR OF LABELER'S PARTICIPATION IN MDRP	The quarter/year combination submitted for this record is equal to the first quarter in which the submitted labeler code was effective in the Drug Rebate Program; however, the labeler code may not have been active for that entire quarter. Please review this utilization to ensure that it occurred on or after the labeler's optional effective date. If such a review reveals that some or all of the utilization occurred prior to the labeler's optional effective date, then the affected units should be adjusted accordingly.
LABELER CODE WAS TERMINATED WITHIN LAST FOUR QUARTERS	The reported labeler code was terminated within the previous four quarters. Please review the utilization to ensure the date of service occurred prior to the labeler's termination effective date
RECORD DELETED SINCE ALL FIELDS ARE 0	The input record had 0 values for all the numeric fields which include Rebate Amount per Unit, Total Units Reimbursed, Total Rebate Amount Claimed, Number of Prescriptions, Medicaid Reimbursement Amount, Non-Medicaid Reimbursement Amount, and Total Reimbursement Amount. As a result, the existing record for this NDC for this quarter was deleted from the MDR State utilization database.
PRODUCT NOT FOUND ON FILE	The labeler code (NDC1) and product code (NDC2) combination on the record supplied by the state does not match a record in the Medicaid drug rebate (MDR) system. State should contact the labeler to ensure the product is a rebate-eligible drug and not a coding error and/or DESI 5/6 drug
PACKAGE SIZE NOT FOUND ON FILE	The labeler code (NDC), product code (NDC2), and package size code (NDC3) combination on the record supplied by the state does not match a record in the Medicaid drug rebate (MDR) system. State should contact the labeler to ensure the product is a rebate-eligible drug and not a coding error and/or DESI 5 / 6 drug
URA DOES NOT MATCH CMS URA	URA supplied by the state does not match the CMS calculated URA

RECEIVED DATE: MM/DD/CCYY HH:MM:SST MEDICAID DRUG REBATE
STATE: XX STATE UTILIZATION DISCREPANCY REPORT

NDC1	NDC2	NDC2	QYYYY	FIELD NAME	FIELD VALUE	TYPE	MESSAGE
----------12345					1234	12 11991	NDC1
12345	ERROR			LABELER CODE IS TERMIANTED			
12345	1234	12	21993	TOT MCAID/NON-MCAID	0000000000251	ERROR	TOT REIMB NOT EQUL TO MCAID/NONMCAID
12345	7894	01	21998	NDC3	01	ALERT	PACKAGE SIZE NOT FOUND
98989	3465	01	11999	URA NOT MATCH CMS URA	00000002421	ALERT	URA DOES NOT MATCH CMS URA
99677	0178	01	31999	ALL NUMERIC FIELDS	0	ALERT	RECORD DELETED SINCE ALL FIELDS ARE 0
88855	0323	10	12008	NDC1/NDC2/NDC3	88855/0323/10	ERROR	NDC REMOVED FROM PROGRAM

.

.

RECEIVED DATE: MM/DD/CCYY HH:MM:SST MEDICAID DRUG REBATE
STATE: XX STATE UTILIZATION DISCREPANCY REPORT

NDC1	NDC2	NDC2	QYYYY	FIELD NAME	FIELD VALUE	TYPE	MESSAGE
----------12345					1234	12 11991	NDC1
12345	ERROR			LABELER CODE IS TERMIANTED			
12345	1234	12	21993	TOT MCAID/NON-MCAID	0000000000251	ERROR	TOT REIMB NOT EQUL TO MCAID/NONMCAID
12345	7894	01	21998	NDC3	01	ALERT	PACKAGE SIZE NOT FOUND
98989	3465	01	11999	URA NOT MATCH CMS URA	00000002421	ALERT	URA DOES NOT MATCH CMS URA
99677	0178	01	31999	ALL NUMERIC FIELDS	0	ALERT	RECORD DELETED SINCE ALL FIELDS ARE 0
88855	0323	10	12008	NDC1/NDC2/NDC3	88855/0323/10	ERROR	NDC REMOVED FROM PROGRAM

.
.
.
.
.

TOPICAL INDEX – STATE RELEASES 1 - 155

TOPIC	RELEASE #
1A Drug Listing	11
Active Pharmaceutical Ingredient & Excipient Removal	155
Additional Copies of Releases to SMDs	40
Adjustment Code for Forms CMS-304 & CMS-304a	57, 145
Affordable Care Act (ACA)	155
Allscrips Pharmaceuticals, Inc.	65, 68, 69
AMP Recalculations	107, 109, 110. 112, 140, 148, 149, 150
AMP to states	142
Monthly AMP Methodology (Manufacturer Assumptions)	146
Bankruptcy - Drug Labelers	19, 61, 68, 151
Best Price	
Effect of Sales to HMOs, etc.	137
To DSH Covered Entities	36
Under MPDIMA of 2003	128
Betaseron - Coverage & Reimbursement	38, 40
Bulk Transfer/Buy-Out of Major Pharm. Assets	54, 55
Calphron	76, 79
Caverject Coverage	55
Closure During Federal Furloughs	57
Compendia	70, 141
Confidential Information Release	17
Constant Disputes by Drug Labelers	23
Contact Information	65, 92
CPI-U Information	09, 102, 147
Database Backup Files	140
Dataset Name Changes on Quarterly Rebate Tapes	41
Deficit Reduction Act of 2005 (DRA)	144
Deleted Products-No Termination Date	139
Depot Prices-TRRx	137
DESI Code Change	137, 140, 142, 144, 145, 146, 148, 149, 150, 151
Dipyridamole Issue	26
Dispute Resolution:	
Definition	19
E-Mail Address/Contacts	128, 155
Issues	55, 65, 71, 86, 108
Meetings	138, 140, 143, 145, 147
Process Stages	45
State Invoicing	152
Transfer of Function	121
Web Site	122
Workgroup Survey Results	42
Dispute Resolution Meetings	59, 151
Drug Category Change	61, 76
Drug Efficacy Study & Implementation (DESI):	
Change Effective Date	20
Change Schedule	18

TOPICAL INDEX – STATE RELEASES 1 - 155

TOPIC	RELEASE #
Effective Date Revisions	23, 24
(State Role In) DESI Process	148
DRUGDEX, a new compendium	70
Drug Emporium, Inc. Effective Date	65
Duplicate Discount/Rebate Mechanism Implementation	33
Effective Date(s) of Rebate Agreements	97
E-mail Address (Operations)	140
Enteral Nutritional Products - Coverage	30
Enteral Products	19
Eon Labs Product	117
Experimental Drugs - Coverage	43
Failure of Manufacturers to Notify States of Disputes or Pay Rebates	63
FDA/MDRI Data Match	107, 115
FDA Federal Register Notices	148, 149
Generic Substitution Laws	67
Goldline OTC Vitamin	102
Haldol Rebates	73, 75, 148
Heparin/Saline Flush Syringes & Other Non-Drug Products	132, 134, 136
Herceptin: Genentech New Product	85
HIPAA – Prescription Numbers	124
Hotline	53
HRSA Notice Published/Exclusion File	98, 101, 106
HRSA – NPI	144
Improper Rebate Withholding/Interest Implications	114
Index for Drug Rebate Notes	31
Information Sharing	57
Interest Calculation under Section V(b)	29, 88, 98
Interest:	
Failure to Pay	65
When PPAs are Submitted	121
Internet:	
Home Page/New Webpage Address	61, 85, 105, 117, 140
Prescription Reimbursement Information	123
Pharmacy Plus Demonstrations	123
Invoices:	
CMS R-144 (State Invoice) – Changes	143, 145, 146, 147, 149
Correct Labeler Address	36
Format	03
Incomplete Drug Labeler Data	18
Incorrect Invoicing	26
Remittance Advice Report Survey	35
Submission	19
Submitting for Multiple Quarters	36
Submitting to Drug Labelers	28
Labeler Contact File Changes	26, 32, 128, 132, 152
Lovenox Prefilled Syringes	91
LTE/IRS Drugs	26

TOPIC	RELEASE #
Magnetic Media	
New Address for Shipping (Effective 6/1/95)	52
Rejections	15
Shipments	15, 23
Specification Revisions	14, 72, 73
Manufacturer Information Record Specification	20
Manufacturer Name & Address Contact Info Diskette	27
MDR Technical E-mail Address	124, 137
Medicaid Drug Rebate Data Guide for States	146
Medical Supplies & Devices	03, 16, 26
Metric Conversion/Rounding	18
MMA of 2003	128, 130
Multiple Package Size-Pricing Inconsistency	123
New Drug Determinations—Deletions from MDR	149, 150, 151
New Drug Products	41
New Rebate Agreement Status	23
Non-Drug Products Coverage	132, 134
(Non-Drug) Product Deletions	138, 139, 140, 142, 143, 144, 145, 146, 148, 149, 150, 151
Novartis Rounding All URAs Back to 1991	117
OBRA '93	40
OIG Reports/Reviews	120, 140
Ortho Evra Replacement Patch	134
Overpayments Due to AMP Recalculations	57, 107
Personnel:	
Changes	53, 124, 130, 139, 142
Relocation	52, 83
PHS Drug Pricing Program	44
Physician Administered Drugs	151
Point-of-Sale System (POS) in Pharmacies	85
Policy E-Mail Address	113, 117
Prior Authorization	55
Prior Period Adjustments	14, 16, 60, 87
Prior Period Adjustments - Eli Lilly & Company	37
Prior Quarter Adjustment Statement (PQAS) Approval	60
Proposed Discount Equal Access Legislation	51
Publication of Drug Rebate Regulations CMS-2175-FC	126
Publication of Drug Rebate Regulations MB-46-P	55
Quarterly Prices, Late Submission	33
Quarterly Reporting - Form CMS-64.r	40
Quarterly Tape Submission to CMS	60, 72, 130
Quarterly Update File	14
Questions and Answers	65
Re-activated NDCs	145
Rebate Agreements:	
Start Date Procedures	102

TOPIC	RELEASE #
Separate/Supplemental	102
Rebate/Reimbursement Issues	64, 113
Rebates:	
Calculation Formula	07
Drugs Purchased Through the FSS	113
Less than Administrative Costs	40
Nonpayment	94
Partial Payments	55
Remittance/Check Address	30
Reconciliation of State Invoice (ROSI) Approval	60
Recordkeeping Regulations	129
Regulation (CMS-2175-F)	136
Regulation (CMS-2238-FC)	
Preliminary Injunction	148
Rejection of State Records Matching LTE Drugs	41
Remittance Advice Report/Workgroup	48, 52, 53, 56
Rescission of Termination for Novopharm USA	39
S-TAG (Systems Technical Advisory Group)	85
Separate Rebate Agreements with Manufacturers	38, 113
Special Advisory Group	16
Special Study – Anti-Load Viral/AIDS Drugs	102
Standard Summary Record Format	13
State Application of the FUL Program	48
State Contact Information	23, 26, 41, 98
State Coverage:	
LTE & IRS Drugs	40
Unit-Dose Drugs	19
State Data Validation Edits	33
State Hearing Process	44
State Invoices Containing Universal Product Codes	51
State Notification Method Change	148
State Pharmacy Assistance Programs	
Exemption From Medicaid Best Price	140
Revised Criteria	124
State Plan Amendment Requirement	47
State Quarterly URA Tape	
Labeler Contact Information	134
Mailing	133
State Responsibility - Terminated Drugs	19
State Utilization Data Study (SUDS)	33
T-bill Rates	83, 86, 132, 149, 150, 151
Technical Contact E-mail Address	140
Termination Date (NDC)	79
Terminated/Deleted Records	44
Termination From Program	55
Therapeutic Equivalency Code	64
Timely Receipt of Tapes/Notices of Mailing	45

TOPIC	RELEASE #
Tolerance Threshold Clarification	
For Interest	48
Rebate Amount Adjustments	44
Training Guide Obsolete	145
TRICARE Retail Pharmacy Benefit Plan	152
Unapproved Drugs—Deletions from DDR	151
Unit-Dose Packaging	15
Unit Per Package Size	03
Change for Boehringer Ingelheim Product	123
Unit Rebate Amount (URA):	
Additional Amounts in 3/1998 File	85
Edits	43
Erroneous Amounts	51
First-Time Reporting on State Tape	132
Incorrect Amounts for 1Q98	79, 80
Invoice when the Amount is Zero	44
New Rounding Method	98, 100, 101, 106
Recalculations	111
Unit Type:	
Changes and Prior Period Adjustments	43
Conversion Date Changed	34
Revisions	32, 83
UPPS Less Than 1.0	19
UPPS Used for Calculating Utilization	61
Use of Information from Outside Sources	48
Utilization Adjustments for Prior Calendar Quarters	67, 72
Receipt	29, 31
Utilization Data:	
Changes to Labelers	57
Corrections/Problems	18, 51, 72
Late Submission	18
Record Format	08, 13, 72, 147, 149
Set Naming Requirements	19
Tapes/Confirmation Letter	19, 30, 40, 45, 58, 72, 82
Transmitting Corrections/Adjustments to CMS	16, 40, 72
Utilization Discrepancy Report	139
Utilization Tape Record Specification	67, 72, 73, 98, 105
Vaccine:	
Deletions	26
Exclusions	19, 23
Policy Clarification	25
Viagra Coverage	81
Vitasert	64
Warrick Pharmaceuticals (Sodium Chloride Solution)	98
Xenical Coverage	97
Y2K	72, 87