



August 23, 2006

MEDICAID DRUG REBATE PROGRAM
RELEASE #75

Bulletin

For Participating Drug Manufacturers



50/50 EDIT REPORT CHANGED TO 400/400 EDIT REPORT

Manufacturer Release #73 stated that the current 50/50 edit would soon be replaced with a revised 400/400 data edit and included a revised cover letter to be sent along with the new 400/400 data edit report. The 400/400 edit went into effect with the processing of second quarter 2006 rebates in early August. Like the 50/50 edit, the new 400/400 edit will generate a report containing NDCs for which no Unit Rebate Amounts (URAs) were calculated for the current quarter as a result of possible pricing errors. Specifically, any NDC included on the report was submitted to CMS with pricing for the current quarter that caused the URA to calculate more than 400% higher or more than 400% lower than the previous quarter. The 50/50 edit is being changed to a 400/400 edit in an effort to reduce the number of zero URAs that are calculated and sent out to the states each quarter. Page G10 of the Operational Training Guide has been updated to reflect this change and is attached to this release.

CHANGES TO CMS FORM R-144 (STATE INVOICE)

States are required to submit a quarterly invoice of utilization data to drug manufacturers that have national rebate agreements with CMS. CMS Form R-144, which is the invoice form used by the states to submit this utilization information to manufacturers, has been revised to include two new columns: the Medicaid Amount Reimbursed column and the Non-Medicaid Amount Reimbursed column. Previously, only one column related to reimbursement was present on the invoice; however, that column did not allow states to differentiate between instances in which both the state and a third party payer each reimbursed a portion of the same claim, and instances in which the state reimbursed the entire claim. As a result, manufacturers would

number of units reimbursed did not correspond to the reimbursement amount included on the form. Therefore, the aforementioned new columns have been added to the invoice to more clearly identify what portion of each Medicaid prescription claim was paid by the State Medicaid Agency and what portion, if any, was paid by another third party. With this revision, CMS anticipates a reduction in the number of Medicaid disputes. Pages F26 and M12 of the Operational Training Guide have been updated to reflect the addition of the two new reimbursement columns and are attached to this release. In addition, pages F16, F23, F25, F27 and F30 of the Operational Training Guide have been revised to reflect this change.

OTHER ATTACHMENTS

Pages F28 and F29 of the Operational Training Guide have been updated to reflect minor changes in the data definitions for the state invoice.

A copy of the current listing of the 91-day Treasury bill auction rates beginning with the period March 7, 2005, is attached.

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

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

Attachments

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

STATE INVOICE

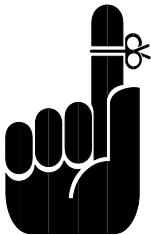
UTILIZATION DATA REPORTING REQUIREMENTS

Statute requires states to report quarterly drug utilization data to labelers participating in the drug rebate program **not later than 60 days** after each rebate period. States are also required to transmit a copy of this quarterly utilization data report to CMS. (Utilization adjustment data for prior rebate periods are discussed later in this section.)

The law requires the Secretary to establish the format for this data submittal. The Secretary delegated the establishment of the reporting format to CMS. In 1991, the former Health Care Financing Administration and State Medicaid agency representatives developed the State Invoice (form CMS-R-144) to report utilization data to labelers. OMB approved the invoice format and CMS mandates its use. This section contains form CMS-R-144, along with the electronic format and definition of each data element required.

For each covered outpatient drug dispensed **AND** PAID FOR BY THE STATE, the invoice specifically requires reporting the following for **EACH** NDC number listed by the state.

- | | |
|-------------------------------------|------------------------------------|
| 1. State Code | 7. Rebate Amount Per Unit |
| 2. Period Covered | 8. Total Units Reimbursed |
| 3. Labeler Code | 9. Total Rebate Amount Claimed |
| 4. Product Code | 10. Number of Prescriptions |
| 5. Package Size Code | 11. Medicaid Amount Reimbursed |
| 6. Product FDA
Registration Name | 12. Non-Medicaid Amount Reimbursed |
| | 13. Total Amount Reimbursed |
| | 14. Correction Record Flag |



Please remember that the utilization data reported on the invoice **MUST** be based on the payment date **NOT** on the date dispensed.

REPORTING UTILIZATION CHANGES



TO LABELERS

States should submit utilization changes to labelers for individual NDCs when there are changes to:

- ◆ the total units reimbursed.

CMS encourages states to send labelers utilization-related changes affecting:

- ◆ the number of prescriptions;
- ◆ the Medicaid amount reimbursed;
- ◆ the Non-Medicaid amount reimbursed; and/or
- ◆ the total reimbursement amount

Changes are reported with current quarter utilization data, **BUT NOT** on the same invoice pages as current quarter data. **STATES SHOULD REPORT UTILIZATION CHANGES TO LABELERS USING A SEPARATE INVOICE PAGE FOR EACH QUARTER CHANGES OCCURRED.** States sending invoice pages representing multiple quarters delay invoice processing.

Delayed invoice processing is also caused by states that use inconsistent utilization change reporting methods. States should initially notify labelers of the method used to report utilization changes. States may completely overlay previously reported data, or may report just the addition or subtraction to previously reported data. Whichever method is chosen, consistency from quarter to quarter is the primary factor. If the state's method of reporting utilization changes is revised, States may use the short form developed by CMS to notify labelers. This form is provided on the following page.

REPORTING UTILIZATION CHANGES (Cont'd.)



TO CMS

States should submit changes to the total units reimbursed, the number of prescriptions, the Medicaid amount reimbursed, the non-Medicaid amount reimbursed, or the total amount reimbursed. These utilization changes should be included on the data tape containing the current quarter utilization.

CMS uses the state correction records as a **replacement** for a record submitted in a prior quarter.

For each correction record sent to CMS, the state should ensure that:

1. The correction flag = "1"; and
2. QYYYY = the calendar quarter and 4-digit year being corrected. (This is never the current calendar quarter/year.)

**MEDICAID DRUG REBATE PROGRAM
RECORD FORMAT
STATE INVOICE/UTILIZATION RECORD
(FORM CMS-R-144)**

Source: State Agencies
Target: CMS and Manufacturers

FIELD	SIZE	POSITION	REMARKS
Record ID	4	1 - 4	Constant of "01"
State Code	2	5 - 6	P.O. Abbreviation
Labeler Code	5	7 - 11	NDC #1
Product Code	4	12 - 15	NDC #2
Package Size Code	2	16 - 17	NDC #3
Period Covered	5	18 - 22	QYYYY
Product FDA Registration Name	10	23 - 32	1 st 10 positions only
**Rebate Amount Per Unit	9	33 - 41	9(5)v9(4)
** Units Reimbursed	14	42 - 55	9(11)v999
** Rebate Amount Claimed	11	56 - 66	9(9)v99
**Number of Prescriptions	7	67 - 73	9(7)
*** M'Caïd Amount Reimb.	12	74 - 85	9(10)v99
*** Non-M'Caïd Amount Reimb.	12	86-97	9(10)v99
**Total Amount Reimbursed	13	98-110	9(11)v99
Correction Flag	1	111-111	See Data Element Definitions
Filler *	19	112-130	For future expansion

* This "filler" is required when states send utilization data to CMS.

** Changed field length size

*** New fields

NOTE: Data elements designated as **ALPHANUMERIC** on the following pages may include numbers, letters, etc. Those designated as **ALPHABETIC** contain letters only.

**MEDICAID DRUG REBATE PROGRAM
STATE INVOICE (FORM CMS-R-144)
DATA DEFINITIONS**

PAGE 1 OF 3

.....
DATA ELEMENT NAME: State Code - Two-character abbreviation for state.
Alphabetic, 2 digits.

.....
DATA ELEMENT NAME: Labeler Code - First segment of National Drug
Code (NDC) that identifies the manufacturer,
labeler, relabeler, packager, repackager or
distributor of the drug. Numeric values only, 5
digit field, right justified, and 0-filled for 4 digit
labeler codes.

.....
DATA ELEMENT NAME: Product Code - Second segment of NDC.
Alphanumeric values, 4 digit field, right justified,
0-filled for 3 digit product codes.

.....
DATA ELEMENT NAME: Package Size Code - Third segment of NDC.
Alphanumeric values, 2 digit field, right justified,
0-filled for 1 digit package size code.

.....
DATA ELEMENT NAME: Period Covered - Calendar quarter and year
covered by data submission. Numeric, 5 digit
field, QYYYY.
Valid Values for Q:
1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid values for YYYY: Four digit calendar year
covered.

.....

**MEDICAID DRUG REBATE PROGRAM
STATE INVOICE (FORM CMS-R-144)
DATA DEFINITIONS**

.....
DATA ELEMENT NAME: Product FDA Registration Name (abbreviated) -
First 10 characters of product name as it appears
on FDA registration form. Alphanumeric values,
10 digits.

.....
DATA ELEMENT NAME: Rebate Amount Per Unit - The CMS calculated
amount (per reported unit type) to be multiplied by
Units Reimbursed by the state during the period
covered. Numeric values, 9 digits: 5 whole
numbers and 4 decimals (assumed).

.....
DATA ELEMENT NAME: Units Reimbursed - The number of units (based on
Unit Type) of the drug (11 digit NDC level)
reimbursed by the state during the period covered.
Numeric values, 14 digits: 11 whole numbers and
3 decimals (assumed).

.....
DATA ELEMENT NAME: Rebate Amount Claimed - The rebate amount the
state agency claims it is owed by the labeler for the
period covered for this (11 digit NDC) drug. It is
calculated by multiplying the units reimbursed by
the rebate amount per unit. Numeric values, 11
digits: 9 whole numbers and 2 decimal places
(assumed).

.....

**MEDICAID DRUG REBATE PROGRAM
STATE INVOICE (FORM CMS-R-144)
DATA DEFINITIONS**

.....

DATA ELEMENT NAME: Number of Prescriptions - The number of prescriptions reimbursed (by the Medicaid program ONLY) to pharmacies for the (11 digit NDC) drug during the period covered. Numeric values, 7 digits, whole numbers only.

.....

DATA ELEMENT NAME: Medicaid Amount Reimbursed - The amount reimbursed (by the Medicaid Program ONLY) to pharmacies for the (11 digit NDC) drug in the period covered. Numeric values, 12 digits: 10 whole numbers and 2 decimals (assumed).

.....

DATA ELEMENT NAME: Non-Medicaid Amount Reimbursed - The amount reimbursed (by NON- Medicaid entities) to pharmacies for the (11 digit NDC) drug in the period covered. Numeric values, 12 digits: 10 whole numbers and 2 decimals (assumed).

.....

DATA ELEMENT NAME: Total Amount Reimbursed - The total amount reimbursed by **BOTH** Medicaid and Non-Medicaid entities to pharmacies for the (11 digit NDC) drug in the period covered (above two fields added together). This total is not reduced or affected by Medicaid rebates paid to the state. This amount represents both the Federal and State reimbursement and is inclusive of dispensing fees. Numeric values, 13 digits: 11 whole numbers and 2 decimals (assumed).

.....

DATA ELEMENT NAME: Correction Flag - Indicates that this record is a correction. Numeric values, 1 digit.
Valid Values: 0 = original record
 1 = correction record

.....

For ALL CPI-U creep calculations beginning with 93-4, the (NEW) values are used. The labeler in this example entered the program in the 4th qtr of 1995 and supplied Baseline data and 95-4 AMP/BP prices on this NDC but did not supply pricing data for the 3rd quarter of 1992. When this report is generated it will show that the AMP from 92-3 is missing and that URAs for this NDC CANNOT be generated by CMS until it is supplied. (Section H of this guide contains a complete discussion of the URA calculation.)

Also, from time to time, a labeler finds that an NDC that should have been coded as “S” or “I” was incorrectly submitted as an “N”, or vice versa. The system will ***not*** allow these changes to be made, so labelers must work with CMS drug rebate operations staff to initiate these changes. Before any change is made, CMS will require documentation from the labeler.

Report 3 is the “400/400 REPORT.” This report contains a list of NDCs for which no URAs were calculated for the current quarter as a result of possible pricing errors. Specifically, each NDC on the 400/400 Report was submitted to CMS with current quarter pricing that caused the URA to calculate more than 400% higher or more than 400% lower than the previous quarter. States do not receive current quarter URAs for any of the NDCs included on this report.

In addition to the NDC, this report contains historical product/pricing information that allows manufacturers to evaluate each URA and make corrections where necessary. If, after reviewing the 400/400 Report, it is determined that the pricing is correct, there is no need to notify CMS. Instead, the manufacturer 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, a review of the 400/400 Report confirms that the AMP and/or BP is incorrect, the manufacturer should calculate the current quarter’s URA based on the correct pricing and use that (corrected) URA when submitting rebates to the states. In addition, the pricing corrections should be submitted to CMS with the next quarterly data submission.

NOTE: The following pages show examples of notices sent to labelers as a result of CMS’s various edit reports.

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
03-07-05	2.767		10-03-05	3.606		05-01-06	4.807
03-14-05	2.792		10-11-05	3.714		05-08-06	4.864
03-21-05	2.859		10-17-05	3.875		05-15-06	4.864
03-28-05	2.839		10-24-05	3.942		05-22-06	4.828
04-04-05	2.792		10-31-05	3.983		05-30-06	4.843
04-11-05	2.767		11-07-05	3.963		06-05-06	4.833
04-18-05	2.864		11-14-05	4.004		06-12-06	4.926
04-25-05	2.941		11-21-05	4.034		06-19-06	4.958
05-02-05	2.931		11-28-05	3.994		06-26-06	5.036
05-09-05	2.911		12-05-05	4.025		07-03-06	5.088
05-16-05	2.859		12-12-05	3.911		07-10-06	5.056
05-23-05	2.957		12-19-05	3.988		07-17-06	5.098
05-31-05	2.998		12-26-05	3.999		07-24-06	5.108
06-06-05	3.029		01-02-06	4.169		07-31-06	5.108
06-13-05	3.039		01-09-06	4.252		08-07-06	5.124
06-20-05	3.029		01-17-06	4.377		08-14-06	5.114
06-27-05	3.147		01-23-06	4.397		08-21-06	5.109
07-05-05	3.214		01-30-06	4.485			
07-11-05	3.204		02-06-06	4.485			
07-18-05	3.292		02-13-06	4.553			
07-25-05	3.420		02-21-06	4.563			
08-01-05	3.477		02-27-06	4.625			
08-08-05	3.539		03-06-06	4.615			
08-15-05	3.549		03-13-06	4.625			
08-22-05	3.539		03-20-06	4.662			
08-29-05	3.575		03-27-06	4.610			
09-06-05	3.513		04-03-06	4.651			
09-12-05	3.529		04-10-06	4.688			
09-19-05	3.575		04-17-06	4.719			
09-26-05	3.518		04-24-06	4.755			

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