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

July 13, 2011

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 158**

ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) AND EXCIPIENTS

We are providing further policy clarification regarding APIs and excipients in order to clarify their coverage as pharmacy services when part of a compounded prescription.

As previously explained in State Release # 155 of August 2010, APIs and excipients do not meet the definition of covered outpatient drugs as defined in section 1927(k)(2) of the Social Security Act (the Act). In State Release #155, we stated that these products may be covered in the State plan as incident to another service category (e.g., Home Health, Nursing, or Other Practitioners). We also noted that a list of these products could be found on the Policy & Reimbursement Spotlight Webpage. The guidance in State Release #155 caused concern regarding coverage of these products under State plans, and whether States that removed these products from pharmacy coverage following the issuance of State Release #155 covered these items elsewhere in the State plan. For example, we heard concerns about the removal of APIs used in the treatment of urea cycle disorders. While we believe it was the intent of States to move these items to another service category and not discontinue their coverage, this further clarification will allow States the option to continue to specify such coverage under pharmacy services.

In addition to the possible sources of coverage for APIs and excipients in State plans noted in State Release # 155, there may also be situations where State plans include coverage of products that do not meet the definition of covered outpatient drugs under section 1927(k)(2). Depending on the State plan, these products may also be covered as pharmacy services. In accordance with 42 CFR 440.120, these products may be covered as prescribed drugs according to section 1905(a)(12), when included in an extemporaneously compounded prescription, written by an authorized prescriber and dispensed by an authorized pharmacy provider. If APIs and excipients are covered under the State plan as pharmacy services and billed through the pharmacy point of sale system, these products can be attributed to prescription drugs on the CMS 64 Report as long as they are part of an extemporaneously compounded prescription . The part of the prescription that is an API or excipient is not eligible for rebates, as they are not covered outpatient drugs under section 1927.

The Medicaid agency may wish to reexamine its State plan to assure that it does not preclude coverage of those API or excipients that State wants to cover. While these products may continue to be covered in those parts of the State plan identified in State Release #155, the State may also provide for coverage under the pharmacy section as specified above.

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

DRAFT REVISED STATE INVOICE/UTILIZATION DATA FILE FORMAT TO ACCOMMODATE SEPARATE MCO AND FEE-FOR-SERVICE UTILIZATION DATA REPORTING

As you may be aware, section 2501 of the Affordable Care Act amended section 1927(b) of the Social Security Act to require manufacturers that participate in the Medicaid drug rebate program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid managed care organization (MCO) if the MCO is responsible for coverage of such drugs. In accordance with this provision, manufacturers are responsible for paying rebates on such covered outpatient drugs effective with respect to drugs dispensed by the MCO on or after March 23, 2010 (the date of enactment).

In accordance with this new requirement, CMS expects States to include utilization data reported by each Medicaid MCO on the quarterly rebate invoices to manufacturers, and within the utilization data reports that are submitted to CMS each quarter. Therefore, States are responsible to ensure that, for every covered outpatient drug dispensed to Medicaid MCO enrollees during a quarter, each MCO reports to the State information on the total number of units of each dosage form, strength and package size by 11-digit NDC, the number of prescriptions, the total amount reimbursed, the amount reimbursed under Medicaid, and the amount reimbursed under non-Medicaid.

To facilitate the collection of MCO rebates from manufacturers and the reporting of MCO State utilization data to CMS, we are revising the CMS Form R-144 (i.e. the State invoice/State utilization data file format) to allow States to report MCO utilization data separately from the traditional State Fee-For-Service (FFS) utilization data. Specifically, the column titled "Record ID" on the form States currently use to submit the utilization data to CMS is being revised. The "Record ID" column will allow States to separately identify each drug utilization data record as either FFS utilization or MCO utilization when the utilization data is being submitted as part of a State's quarterly rebate invoice to drug manufacturers, or as part of a State's quarterly drug utilization data submission to CMS. We are currently waiting for Office of Management and Budget (OMB) approval of the revised CMS Form R-144 via the Paperwork Reduction Act (PRA) approval process (i.e. OMB package #0938-0582). Once the revised CMS Form R-144 has been approved, we will notify States and provide additional instructions on when the new utilization data file format should be used for quarterly invoicing and State utilization data submissions.

In the interim, we are providing States with the attached draft utilization data file format and description for review. Please note that States should not use the new format until we receive OMB approval.

If you have questions regarding the submission of State utilization data, please contact the CMS Drug Rebate Operations team at mdroperations@cms.hhs.gov. For questions regarding the new MCO utilization data reporting requirement, please contact rxdrugpolicy@cms.hhs.gov.

NEW DRUG DETERMINATION—DELETIONS FROM MDR

In accordance with the notice published in the Federal Register titled, "Drugs for Human Use: Unapproved and Misbranded Oral Drugs Labeled for Prescription Use and Offered for Relief of Symptoms of Cold, Cough or Allergy; Enforcement Action Dates," States were previously notified that the following active cold, cough and allergy NDCs qualify as unapproved new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, are subject to enforcement action, and should not be marketed without appropriate Food and Drug Administration (FDA) approval (76 Fed. Reg. 11794 (March 3, 2011)). Therefore, in accordance with the notice, we have determined that the NDCs listed below 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.

Please note that the list below may not be an all-inclusive list of the products that are subject to this FDA enforcement action; therefore, we may remove additional oral cough, cold and allergy products at a later time as we are able to identify other NDCs to which this Federal Register Notice applies. Should you become aware of NDCs that you believe are subject to the FDA's Federal Register Notice on unapproved oral, cough, cold and allergy drug products, please send a list of those NDCs to mdroperations@cms.hhs.gov.

NDC	Product Name
00037-0655	RYNA 12 SUSP
00037-0673	RYNA-12 TITRATABLE TABLETS
00037-0692	TUSSI-12D TABS
00037-0693	TUSSI-12D SUSPENSION
00037-1708	RYNA-12X TABLETS
00037-4214	ORGANIDIN NR LIQUID
00037-4312	ORGANIDIN NR TABS
00037-6301	SINA-12X TABLETS
00095-0645	LODRANE 12 D TABLETS
00095-1200	LODRANE 24 EXTENDED RELEASE CAPSULES
00095-1290	LODRANE 24 D EXTENDED RELEASE CAPSULES
00185-1304	CPM 8MG/PSEUDO ER 120MG
00277-0160	DALLERGY TABLETS
00277-0182	DALLERGY CAPLETS
00277-0183	DALLERGY-JR CAPSULES
00485-0054	ED A-HIST TABS
00485-0055	ED A-HIST LIQUID
00485-0071	ED-A-HIST DM
00485-0072	ED-CHLOR-TAN
00485-0074	ED CHLORPED
00603-1066	CARDEC ORAL DROPS 1MG-3.5MG/1ML 30ML
00603-1068	CARDEC DM ORAL DROPS 1MG-3.5MG-3MG/1ML 30ML
00603-1069	CARDEC DM SYRUP 4MG-12.5MG-15MG
00603-1328	IOPHEN NR LIQUID LIQ
00603-1330	IOPHEN-DM NR LIQ
00603-4886	ORGAN-I-NR
00642-0645	TUSSO-DMR
10122-0650	ALLERX DOSEPACK
10122-0702	ALLERX D

10122-0704	ALLERX DOSEPACK DF
10122-0705	ALLERX DOSEPACK PE
11528-0115	TENAR PSE
11528-0120	TENAR DM
13811-0001	Z-DEX PEDIATRIC DROPS
13811-0002	Z-DEX SYRUP
13811-0003	Z-DEX 12D
15370-0006	RU-TUSS DM SYRUP
16477-0130	DONATUSSIN DM SUSPENSION
16477-0132	DONATUSSIN DM SYRUP
16477-0146	DALLERGY PSE TABLET
16477-0819	DALLERGY SYRUP
23359-0003	EXPECTUSS
23359-0011	DOXYTEX
23589-0011	VIRAVAN-P SUSPENSION
23589-0013	VIRAVAN-PDM
24839-0346	RYNEZE LIQUID
28595-0110	SERADEX LA 6-19 MG
28595-0602	ALLRES G
42192-0507	BP 8 COUGH SUSPENSION
50383-0871	CP DEC ORAL DROPS
50383-0873	CP DEC-DM ORAL DROPS
50991-0126	POLY HIST DM
50991-0320	POLY-TUSSIN DM
50991-0412	POLYTAN
50991-0607	ALA-HIST LQ
51991-0131	TRITAL DM LIQUID
51991-0145	COLFED A CAPSULES
51991-0211	DYNATUSS-EX SYRUP
51991-0513	QUARTUSS SYRUP
51991-0534	ALLERGY DN II TABLETS
51991-0591	DURADRYL CHEWABLE TABLETS
51991-0633	GUIADRINE DX LIQUID
54838-0123	GUAIFENESIN-NR LIQUID
54838-0124	GUAIFENESIN DM NR LIQUID
54838-0542	SILDEC PE SYRUP
54838-0544	SILDEC PE-DM SYRUP
58605-0274	BROVEX ADT SUSPENSION
58605-0277	BROVEX PD SUSPENSION
58605-0414	AMBIFED
58605-0415	AMBIFED DM
58809-0303	CARBA-XP
58809-0536	CARBATUSS
58809-0707	CARBATUSS-CL
60258-0220	DEHISTINE SYRUP
60258-0221	CHLOR-MES D LIQUID
60258-0238	CORFEN-DM
60258-0239	DECHLOR DM LIQUID
60258-0240	DE-CHLOR DR LIQUID

60258-0246	CHLORDEX GP
60258-0262	GANI-TUSS DM NR LIQUID
60258-0335	DYPHYLLINE-GG ELIXIR
60258-0371	DY-G LIQUID
60258-0395	NEUTRAHIST PEDIATRIC DROPS
60258-0414	CERON SYRUP
60258-0415	CERON DM SYRUP
60258-0425	PULMARI-GP SYRUP
60258-0426	SIMUC-DM ELIXER
60258-0429	BROMHIST PDX SYRUP
60258-0431	TUSDEC DM SYRUP
60258-0446	BROMHIST DM SYRUP
60258-0760	DIHYDRO-CP
60258-0761	DIHYDRO-GP
60258-0762	DIHYDRO-PE
60575-0619	RESPAHIST 2
63717-0290	NASOHIST DROPS
63717-0291	NASOHIST DM DROPS
63717-0552	CORZALL LIQUID
63717-0554	EXALL LIQUID
63717-0555	EXALL D LIQUID
64376-0530	PCM CHEWABLE TAB
64376-0537	PHENCARB GG SYRUP
64376-0543	BPM 6MG TAB
64376-0544	BPM PSEUDO 6/45MG TAB
64376-0546	PSEUDO CM NF TAB
64376-0707	P CHLOR GG DROPS
64376-0710	PDM GG SYRUP
64376-0711	DEX PC SYRUP
64376-0712	PSEUDO DM GG SYRUP
64376-0714	CPM PSE SYRUP
64376-0716	PSEUDOEPHEDRINE GG SYRUP
64376-0721	PSE BPM LIQUID
64376-0723	PEDIAHIST DM SYRUP
64376-0726	C PHEN DM DROPS
64376-0727	C PHEN DM SYRUP
64376-0728	C PHEN DROPS
64376-0729	C PHEN SYRUP
64376-0733	PSUEDO COUGH LIQUID
64376-0737	DEXPHEN M SOLN
64543-0091	RESCON MX
64543-0096	RESCON TABLETS
64661-0050	J-TAN D SR 100TB
66870-0030	MAXIPHEN ADT
66870-0701	TIME-HIST QD
66992-0146	LUSONAL LIQUID
66992-0230	VAZOBID
68013-0007	BROMPHENIRAMINE TANNATE CHEWABLE 12MG
68013-0014	VISRX DOSE PACK

68032-0191	REME TUSSIN DM
68032-0192	REME HIST DM
68032-0276	GUAIFENESIN 200MG/ PHENYLEPHRINE HYDORCHLORIDE 5 MG SYRUP
68032-0320	SONAHIST DM PEDIATRIC DROPS
68032-0324	BROMPHENIRAMINE MALEATE 1MG DROPS
68032-0325	BROMPHENIRAMINE MALEATE 1MG/PSEUDOEPHEDRINE 7.5 MG DROPS
68032-0326	SONAHIST PEDIATRIC DROPS
68032-0368	RE PHENYLEPHRINE 1.5 MG / GUAIFENESIN 20 MG DROPS
68047-0153	EXEFEN DMX
68047-0160	NOHIST
68047-0167	NOHIST-DMX
68047-0270	CORYZA-DM
68047-0330	SUDAHIST

The FDA has also determined that the following extended release Hyoscyamine products are subject to Federal regulations at 21 CFR 310.502(a)(14), which state that timed-release dosage forms are new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act, and that such drugs require FDA approval before marketing. According to the FDA, these products do not have approved applications; therefore, we previously notified the States that, in light of section 1927(k)(2), the NDCs listed below do not meet the definition of a covered outpatient drug and are not eligible for inclusion in the rebate program.

NDC	**Product Name**
00574-0251	HYOSCYAMINE SULFATE EXTENDED-RELEASE TABLETS
13925-0108	HYOSCYAMINE .375 EXTENDED RELEASE TABLETS
24486-0602	HYOMAX SR
24486-0604	HYOMAX DT
43199-0014	HYOSCYAMINE SULFATE EXTENDED RELEASE TABLETS 0.375 MG
52152-0156	HYOSCYAMINE SR 0.375MG(100) TAB
58177-0017	L-HYOSCYAMINE SULFATE
58177-0237	HYOSCYAMINE .375MG
64125-0110	HYOSCYAMINE SULFATE 0.375 MG ER TABLETS
64543-0112	SYMAX SR
64543-0118	SYMAX DUOTAB
68032-0251	HYOSCYAMINE SULFATE 0.125 MG IR, HYOSCYAMINE SULFATE 0.25 MG SR
68220-0115	LEVBID

The following device products do not meet the definition of a covered outpatient drug as set forth in Section 1927(k)(2) of the Social Security Act. The States were previously notified of these product deletions on June 20, 2011. The device products that are no longer rebate-eligible are as follows:

16781-0189	HYLATOPIC
16781-0197	HYLATOPIC PLUS

DESI CODE CHANGES

As we previously advised you via email, the following products were reported by the labeler with a DESI code of 5 (i.e., less-than-effective/IRS drug for all indications); however, the FDA has determined that the drugs are under an approved application. Therefore, the appropriate DESI code for each of these products is a code 2 (i.e., rebate- eligible):

00496-0716	PRAMOSONE CREAM 1%
00496-0726	PRAMOSONE LOTION 2.5%
00496-0729	PRAMOSONE LOTION 1%
00496-0778	ANALPRAM HC CREAM 1%

As a result, these drugs are eligible for coverage under the Medicaid Drug Rebate Program.

NEW REBATE AGREEMENTS

Labeler Name: HUCKABY PHARMACEUTICALS, INC.
Optional Effective Date: 05/18/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 35501

Labeler Name: BUREL PHARMACEUTICALS
Optional Effective Date: 03/21/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 35573

Labeler Name: ZOGENIX, INC.
Optional Effective Date: 01/31/2011
Mandatory Effective Date: 04/01/2011
Labeler Code: 43376

Labeler Name: DR. REDDY'S LABORATORIES, INC.
Optional Effective Date: 04/18/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 43598

Labeler Name: PHARMAXIS, INC.
Optional Effective Date: 05/09/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 44178

Labeler Name: HUMAN GENOME SCIENCES, INC.
Optional Effective Date: 03/29/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 49401

Labeler Name: ROCHESTER PHARMACEUTICALS
Optional Effective Date: 03/21/2011

Mandatory Effective Date: 07/01/2011
Labeler Code: 49908

Labeler Name: INGENUS PHARMACEUTICALS, LLC
Optional Effective Date: 03/25/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 50742

Labeler Name: NEW AMERICAN THERAPEUTICS
Optional Effective Date: 04/25/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 50816

Labeler Name: WOMEN'S CHOICE PHARMACEUTICALS, LLC
Optional Effective Date: 05/13/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 50967

Labeler Name: VERTEX PHARMACEUTICALS, INC.
Optional Effective Date: 03/14/2011
Mandatory Effective Date: 04/01/2011
Labeler Code: 51167

Labeler Name: TAGI PHARMA, INC
Optional Effective Date: 04/07/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 51224

Labeler Name: LABERTAS PHARMA, INC
Optional Effective Date: 06/15/2011
Mandatory Effective Date: 01001/2011
Labeler Code: 51862

Labeler Name: OPTIMER PHARMACEUTICALS, INC.
Optional Effective Date: 06/22/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 52015

Labeler Name: PARAPRO, LLC
Optional Effective Date: 01/18/2011
Mandatory Effective Date: 04/01/2011
Labeler Code: 52246

Labeler Name: WILSHIRE PHARMACEUTICALS, INC.
Optional Effective Date: 03/09/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 52536
Labeler Name: PEDIATRX, INC.
Optional Effective Date: 03/17/2011

Mandatory Effective Date: 07/01/2011
Labeler Code: 52547

Labeler Name: APO-PHARMA USA, INC.
Optional Effective Date: 04/07/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 52609

Labeler Name: EUSA PHARMA (USA), INC.
Optional Effective Date: 04/27/2011
Mandatory Effective Date: 07/01/2011
Labeler Code: 57902

Labeler Name: BIO PRODUCTS LABORATORY.
Optional Effective Date: 07/01/2011
Mandatory Effective Date: 10/01/2011
Labeler Code: 64208

TERMINATED LABELERS

Labeler Code	Labeler Name	Effective Date
00028	NOVARTIS PHARMACEUTICALS CORPORATION	10/01/2011
00414	PERRIGO PHARMACEUTICALS	07/01/2011
00548	INTERNATIONAL MEDICATION SYSTEMS LTD	04/01/2011
10148	COTHERIX, INC.	07/01/2011
13279	ALLAN PHARMACEUTICAL, LLC	10/01/2011
13436	VERUS	10/01/2011
13453	GRACEWAY PHARMACEUTICALS, LLC	07/01/2011
15330	MYLAN PHARMACEUTICALS, INC.	10/01/2011
15686	MIDLAND HEALTHCARE, LLC	07/01/2011
16887	IPSEN PHARMECEUTICALS, INC.	07/01/2011
19810	BRISTOL-MYERS SQUIBB COMPANY	07/01/2011
49769	KYLEMORE PHARMACEUTICALS LLC	07/01/2011
52769	AMERICAN RED CROSS	04/01/2011
59930	WARRICK PHARMACEUTICALS	07/01/2011
55515	WATSON PHARMA, INC.	10/01/2011
61598	LTC PRODUCTS INC	07/01/2011
62103	BOUDREAUX'S BUTT PASTE	04/01/2011
65234	VALEANT PHARMACEUTICALS NORTH AMERICA	07/01/2011
52604	JONES PHARMA, INCORPORATED	10/01/2011
60237	HOPE PHARMACEUTICALS	10/01/2011
61451	AMERIFIT PHARMA, INC.	10/01/2011
64029	PARKEDATE PHARMACEUTICALS, INC.	10/01/2011
65473	ODYSSEY PHARMACEUTICALS, INC.	10/01/2011
66591	AAI PHARMA	10/01/2011

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.

Barbara Coulter Edwards
Director
Disabled & Elderly Health Programs Group

Attachment

CMS Record Specification
MEDICAID DRUG REBATE DATA
Utilization Record Format
Effective <Implementation Date>

Source: State Agencies
Target: CMS & Manufacturers

Field	Size	Position	Remarks
*Record ID	4	1 – 4	Constant of "FFSU" or "MCOU"
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 Reg. Name	10	23 – 32	Product name as appears on FDA listing form. (1st 10 characters)
Unit Rebate Amount	12	33 – 44	9(5).9(6)
Units Reimbursed	15	45 – 59	9(11).999
Rebate Amount Claimed	12	60 – 71	9(9).99
Number of Prescriptions	8	72 – 79	9(8)
M'Caid Amount Reimb	13	80 – 92	9(10).99
Non-M'Caid Amount Reimb	13	93 - 105	9(10).99
Total Amt Reimbursed	14	106 – 119	9(11).99
*Filler	1	120 – 120	

All fields with decimals require actual decimal
* Change to field

Utilization Field Definitions

Record ID:	Constant “FFSU” or “MCOU”. The FFSU Record ID indicates that the information for this NDC represents a Fee-for-Service Utilization record. The MCOU Record ID indicates that the information for this NDC represents a Managed Care Organization Utilization record. Valid Values: 4Q2009 and earlier = Constant record of FFSU. 1Q2010 and beyond = FFSU & MCOU.
NOTE:	Per the Affordable Care Act, MCO utilization data cannot be reported for periods prior to first quarter 2010.
NOTE:	Beginning with first quarter 2010, CMS will accept one utilization record per NDC per quarter/year combination per record ID type (FFSU vs. MCOU).
State Code:	Two-character post office abbreviation for the state. Alphabetic, 2 digits.
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 zero-filled for 4-digit labeler codes.
Product Code:	Second segment of NDC. Alphanumeric values, 4-digit field, right justified, zero-filled for 3-digit product codes.
Package Size Code:	Third segment of NDC. Alphanumeric values, 2-digit field, right justified, zero-filled for 1-digit package size codes.
Period Covered:	The calendar quarter and year in which the 11-digit NDC was paid for by the State. Numeric, 5-digit field, Q/YYYY 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: 4-digit calendar year covered.

Product FDA Reg. Name:

(Abbreviated) – First 10 characters of product name as approved by the FDA. Alphanumeric values, 10 digits..

Unit Rebate Amount:

The CMS calculated amount (per reported unit type) to be multiplied by Units Reimbursed by the state during the period covered. Numeric values, 12 digits: 5 whole numbers, 6 decimal places, and a decimal point.

Units Reimbursed: The number of FFS or MCO units (based on Unit Type and record ID) of the drug (11-digit NDC level) reimbursed by the state during the period covered. Numeric values, 15 digits: 11 whole numbers, 3 decimal places and a decimal point.

Rebate Amount Claimed:

The rebate amount that the State Agency claims it is owed by the labeler for the period covered for this (11-digit NDC) FFS or MCO drug. It is calculated by multiplying the FFS or MCO units reimbursed by the FFS or MCO rebate amount per unit. Numeric values, 12 digits: 9 whole numbers, 2 decimal places and a decimal point.

Number of Prescriptions:

The number of FFS or MCO prescriptions reimbursed (by the Medicaid Program ONLY) to pharmacies for the (11-digit NDC) drug during the period covered. Numeric values, 8 digits, whole numbers only.

M'caid Amount Reimb:

Medicaid Amount Reimbursed – The amount reimbursed (by the Medicaid Program ONLY) to pharmacies for the (11-digit NDC) FFS or MCO drug in the period covered. Numeric values, 13 digits: 10 whole numbers, 2 decimal places and a decimal point.

Non-M'caid Amount Reimb:

Non-Medicaid Amount Reimbursed – The amount reimbursed (by non-Medicaid entities) to pharmacies for the (11-digit NDC) FFS or MCO drug in the period covered. The Non-Medicaid Amount Reimbursed includes any reimbursement amount for which the state is not eligible for Federal Matching Funds. Numeric values, 13 digits: 10 whole numbers, 2 decimal places and a decimal point.

Total Amount Reimbursed:

The FFS or MCO total amount reimbursed by both Medicaid and non-Medicaid entities to pharmacies for the (11-digit NDC) drug in the period covered (two previous 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, 14 digits: 11 whole numbers, 2 decimal places and a decimal point.

Filler: 1 position filler.

This field previously contained the Correction Flag Indictor which specified whether the record was the first submission (0=original record) or whether it is a correction (1 = correction) to an existing record. The CMS Medicaid Drug Rebate (MDR) system makes the determination: if the record does not exist within the MDR system, it processes as an original; if the record does exist within the MDR system, it processes as a correction.