DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Center for Medicaid and CHIP Services

July 19, 2012

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 160**

For State Technical Contacts

TRANSMISSION OF UTILIZATION DISCREPANCY REPORTS

As a reminder, utilization discrepancy reports are only generated in hard copy format and sent via regular mail for those state utilization files that have been submitted to CMS via TAPE. Once a state begins submitting utilization files using an Electronic File Transfer (EFT) transmission method, the resulting utilization discrepancy reports are electronically transferred back to the state via the same EFT transmission method the state uses to submit its utilization data. Typically, the utilization discrepancy reports that are sent via EFT arrive back to the state within a few days after the state submits its data. However, for the remaining states that have not yet converted to EFT, the hard copy utilization discrepancy reports may take several weeks to arrive by regular mail. In all cases, states are strongly encouraged to review the utilization discrepancy reports to identify errors or problems with their utilization data. As always, any questions regarding the utilization discrepancy reports should be sent to mdroperations@cms.hhs.gov.

REVISION OF CMS FORM R-144 TO INCLUDE "RECORD ID" COLUMN

In accordance with guidance that was previously provided in State Release No. 158 entitled, "Draft Revised State Invoice/Utilization Data File Format to Accommodate Separate MCO and Fee-For-Service Utilization Data Reporting", we notified states via email on December 11, 2011, that CMS had received Office of Management and Budget (OMB) approval via the Paperwork Reduction Act (PRA) process to revise CMS Form R-144 (i.e., the state invoice) and the State Utilization Data file format. Attached is the revised CMS Form R-144, along with an updated utilization data file format and data definitions.

Revised CMS Form R-144

As mentioned in Release No. 158, a new column titled, "Record ID" has been added to the CMS Form R-144 to allow states to separately identify each drug utilization data record on an invoice as either Fee-For-Service (FFS) utilization or Managed Care Organization (MCO) utilization. The addition of the "Record ID" column to the CMS Form R-144 is the only change that was made to this form. While the "Record ID" column will enable states to separate out FFS units from MCO units on their drug rebate invoices, CMS is not mandating that states bill

manufacturers with either one invoice or multiple invoices each quarter. States may choose to include both FFS and MCO units altogether on one invoice, or may opt to submit one invoice containing all FFS units and another containing MCO units. However, regardless of which method states choose, each state invoice should include the new "Record ID".

States had the option to use the revised invoice, including the new "Record ID" field, beginning with the invoices they submitted for fourth quarter 2011 (i.e., the invoices that were sent out in February 2012). Beginning with the second quarter 2012 invoice process (i.e., the invoices that the states submit to labelers in August 2012), states are expected to use the revised invoice format.

Revised Utilization Data Format

The existing "Record ID" column on the State Utilization Data file format has also been revised so that states may separately identify FFS units (i.e., a Record ID of "FFSU") versus MCO units (i.e., a Record ID of "MCOU") when reporting quarterly utilization data to CMS. States had the option to use the updated file format, including the revised "Record ID" field beginning with any utilization submissions they sent to CMS as of January 3, 2012. However, states are expected to use the revised utilization data format for any state utilization data submitted to CMS effective October 1, 2012.

During the transition period (i.e., January 3, 2012 through September 30, 2012), CMS will continue to accept utilization data in the previous format to accommodate those states that need additional time to update their systems; however, please note that once a state has submitted utilization data to CMS in the revised format, the state will be unable to successfully transmit any additional submissions in the previous format, regardless of whether the transition period is over or not.

Because covered outpatient drugs dispensed by an MCO on or after March 23, 2010 (i.e., within the first quarter of 2010) are generally eligible for Medicaid drug rebates, states can use the new "MCOU" Record ID for utilization data submissions with a rebate period equal to first quarter 2010 onward. For all rebate periods earlier than first quarter 2010, utilization data submissions should only reflect the "FFSU" record ID. We are also aware that some states submitted combined MCO units and FFS units in their state utilization data to CMS for all four quarters of 2010 and the first three quarters of 2011. For these states, we encourage them to resubmit previously transmitted utilization data from the first quarter 2010 onward so that MCO and FFS units can be reflected separately.

If you have any questions regarding the revised invoice or state utilization data format, please contact mdroperations@cms.hhs.gov.

PRODUCT DELETIONS

As previously notified on April 9, 2012, the NDCs listed below are over-the-counter medical foods; therefore, the NDCs do not meet the definition of a covered outpatient drug as defined in Section 1927(k)(2) of the Social Security Act and are subsequently no longer eligible for inclusion in the rebate program. The labeler of these products is responsible for paying rebates on the NDCs for any state utilization that occurred prior to April 9th (the date of the notice).

NDC	PRODUCT NAME
00338-9170	Pure Powdered Glutamine
00338-9177	Sympt-X Plain Glutamine Packet
00338-9178	Rapid Release Plain Glutamine

As previously notified on June 27, 2012, CMS has determined that 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. As a result, the products are not eligible for inclusion in the Medicaid Drug Rebate Program or eligible for FFP as a covered outpatient drug. The labeler of these products is responsible for paying rebates on the NDCs for any state utilization that occurred prior to June 27th (the date of the notice).

NDC	PRODUCT NAME
00095-0073	Hylase Wound Gel
43538-0510	Genadur

As previously notified on June 27, 2012, CMS has determined that the following NDCs are over-the-counter dietary supplements; therefore, the NDCs do not meet the definition of a covered outpatient drug as set forth in Section 1927(k)(2) of the Social Security Act. As a result, the products are not eligible for inclusion in the Medicaid Drug Rebate Program or eligible for FFP as a covered outpatient drug. The labeler of these products is responsible for paying rebates on the NDCs for any state utilization that occurred prior to June 27th (the date of the notice).

NDC	PRODUCT NAME
00132-0177	Probiotic Yums
54859-0501	Nutrivit Liquid
54859-0515	Proteinex Liquid
54859-0516	Nephronex Liquid
54859-0715	Proteinex Tablet
54859-0716	Nephronex Caplet

Please note that while the products listed above are not eligible for coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services, EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved state plan.

NEW REBATE AGREEMENTS

Labeler Name: BANNER PHARMACAPS INC.
Optional Effective Date: 05/09/2012
Mandatory Effective Date: 10/01/2012

Labeler Code: 10888
Labeler Name: HALOZYME THERAPEUTICS, INC
Optional Effective Date: 02/03/2012
Mandatory Effective Date: 07/01/2012
Labeler Code: 18657

Labeler Name: INSYS THERAPEUTICS, INC.
Optional Effective Date: 04/10/2012
Mandatory Effective Date: 07/01/2012
Labeler Code: 20482

Labeler Name: SIGMAPHARM LABORATORIES, LLC
Optional Effective Date: 01/27/2012
Mandatory Effective Date: 04/01/2012
Labeler Code: 42794

Labeler Name: GLOUCESTER PHARMACEUTICAL INC.
Optional Effective Date: 01/31/2012
Mandatory Effective Date: 04/01/2012
Labeler Code: 46026

Labeler Name: EDGEMONT PHARMACEUTICALS, LLC
Optional Effective Date: 01/12/2012
Mandatory Effective Date: 04/01/2012
Labeler Code: 49909

Labeler Name: POLYGEN PHARMACEUTICALS, LLC
Optional Effective Date: 02/17/2012
Mandatory Effective Date: 07/01/2012
Labeler Code: 52605

Labeler Name: STI PHARMA, LLC
Optional Effective Date: 06/26/2012
Mandatory Effective Date: 10/01/2012
Labeler Code: 54879

Labeler Name: IMPAX LABORATORIES, INC.
Optional Effective Date: 03/23/2012
Mandatory Effective Date: 07/01/2012
Labeler Code: 64896

Labeler Name: KEDRION BIOPHARMA, INC
Optional Effective Date: 01/26/2012
Mandatory Effective Date: 04/01/2012
Labeler Code: 76179

Labeler Name: INTERNATIONAL MEDICATION SYSTEMS, LTD
Optional Effective Date: 04/19/2012
Mandatory Effective Date: 07/01/2012

Labeler Code: 76329
Labeler Name: CORCEPT THERAPEUTICS INCORPORATED
Optional Effective Date: 04/11/2012
Mandatory Effective Date: 07/01/2012
Labeler Code: 76346

Labeler Name: VIRTUS PHARMACEUTICALS, LLC
Optional Effective Date: 01/31/2012
Mandatory Effective Date: 04/01/2012
Labeler Code: 76439

TERMINATED LABELERS

Labeler Code	Labeler Name	Effective Date
00083	Novartis	07/01/2012
00089	3M Pharmaceuticals	07/01/2012
10768	Perrigo Pharmaceuticals	07/01/2012
12593	Red River Pharma Manufacturing, LLC	07/01/2012
18011	Zerxis Pharma, LLC	04/01/2012
24839	SJ Pharmaceuticals, LLC	07/01/2012
29336	Graceway Pharmaceuticals, LLC	07/01/2012
43351	Allaire Pharmaceuticals, LLC	07/01/2012
45985	Stewart-Jackson Pharmacal, Inc.	07/01/2012
52569	Generamed, Inc.	04/01/2012
53905	Chiron Corporation	07/01/2012
54391	Watson Pharma, Inc.	07/01/2012
59834	Orchidpharma, Inc.	04/01/2012
60598	KOS Pharmaceuticals, Inc.	07/01/2012
62161	Orphan Medical, Inc.	07/01/2012
64682	Collagenex Pharmaceuticals	07/01/2012
65084	McKesson Corp, Rx Pak Division	07/01/2012
67781	Purdue Pharmaceutical Products, L.P.	07/01/2012
68013	Vision Pharma, LLC	07/01/2012
68188	Alliant Pharmaceuticals, Inc.	07/01/2012
68330	Cephazone Pharma, LLC	04/01/2012
68734	Critical Therapeutics (CRTX)	07/01/2012

Please direct your drug rebate data questions to MDROperations@cms.hhs.gov and your drug policy questions to RxDrugPolicy@cms.hhs.gov.

/s/

Barbara Coulter Edwards
Director
Disabled & Elderly Health Programs Group

Attachments