Center for Medicaid and CHIP Services

May 2, 2013

MEDICAID DRUG REBATE PROGRAM NOTICE   **Release No. 163**

For State Technical Contacts

USING THE CMS R-144 FORM (THE STATE INVOICE) FORMAT FOR PRIOR PERIOD ADJUSTMENTS

CMS would like to remind states that the CMS R-144 form is the OMB-approved invoice format, and states should generally be using the format as specified below when they submit current quarter invoices or any prior quarter utilization adjustments to labelers:

Record ID
State Code
11-Digit NDC Number
Period Covered
Drug Name
URA
Units Reimbursed
Rebate Amount Claimed
No. of Scripts
Medicaid Amount Reimbursed
Non-Medicaid Amount Reimbursed
Total Amount Reimbursed
Correction Flag (for paper/electronic invoices only)

If you have any questions, please email us at: MDROperations@cms.hhs.gov.

CLARIFICATION ON STATE USE OF CORRECTION FLAGS ON REBATE INVOICES

It was brought to our attention that there is some confusion regarding the use of correction flags on rebate invoices to manufacturers.   Both paper and electronic invoices sent from the states to manufacturers still require the correction flag, as illustrated by the "Correction Flag" column that appears on the OMB-approved invoice form (i.e., the CMS-R-144 form) that was attached to State Release #160. Therefore, please ensure that the correction flag continues to appear on all

rebate invoices to manufacturers. For utilization files submitted to CMS from the states, the correction flag field has been replaced with filler since our MDR system automatically makes the determination as to whether a utilization record is new or a change to previously reported data. For your convenience, both the OMB-approved invoice form and the current utilization data file format are attached to this release.

If you have any questions, please email us at: MDROperations@cms.hhs.gov

NEW EMAIL RESOURCE BOX FOR UTILIZATION DATA-RELATED INQUIRIES

In an effort to better assist our state partners, we have created a new email resource box specifically for handling utilization-related inquiries from the states and their contractors. Effective immediately, you should direct any utilization data file format, discrepancy report or other general utilization data-related questions to MDRUtilization@cms.hhs.gov.

If you have a technical question related to the submission of utilization files via Electronic File Transfer (EFT), please email the CMS IT Service Desk at CMS_IT_Service_Desk@cms.hhs.gov and request that a trouble ticket be opened to the EFT Team so that they can investigate and address your issue.

If you previously sent a utilization data-related email to the MDROperations@cms.hhs.gov email resource box and you have not yet received a response, there is no need to re-submit your inquiry to the MDRUtilization@cms.hhs.gov email resource box as your email will be addressed.

NEW AUTO-GENERATED EMAILS REGARDING SUCCESSFULLY PROCESSED STATE UTILIZATION FILES

You may have noticed that we recently implemented a new feature in our MDR system that automatically notifies a state's Technical Contact (TC) whenever the system has successfully processed one of the state's utilization files. The system generates this email regardless of the state's mode of file submission (i.e., EFT or tape). Therefore, if your state submits a utilization file and your TC doesn't receive a confirmation email from us within one day of that submission, there was an issue processing the file (e.g., the file didn't make it through EFT, the file didn't successfully transmit from EFT to MDR, etc.).

Please contact us at MDRUtilization@cms.hhs.gov if you have submitted a utilization file, but have not received a corresponding confirmation email.

UTILIZATION DATA SUBMISSIONS—REMINDERS

As we enter the final stage in converting states from tape utilization submissions to EFT, we would like to remind you of some potential barriers to successfully submitting your utilization

data via EFT.   While data submission problems often stem from using an incorrect file name (usually due to missing punctuation or characters), use of an obsolete file format or a Record ID value of "UTIL" are also common errors that will result in data rejection (i.e., no confirmation email generated). If you experience difficulty submitting your utilization data, fail to receive a confirmation email when you submit a utilization file, or receive a large Discrepancy Report containing many errors, please first do the following:

1. Double-check your file name to ensure that it adheres to the required EFT naming convention.
2. Ensure that you are using the current utilization file format (which is attached). We have also attached the current data definitions for your reference.
3. Carefully review your Discrepancy Report to assess why your utilization data rejected.

If, after following these steps, you still fail to diagnose the problem, please contact us at MDRUtilization@cms.hhs.gov for assistance.

ADJUSTED/ CORRECTED UTILIZATION FILES

States often submit an initial quarterly utilization data submission to CMS, followed by subsequent submissions that contain adjustments or corrections to that original quarterly data. There is no limit on the number of adjustment/correction files that a state can submit for a particular quarter/year combination; however, please note that each utilization file, whether an original quarterly submission or a subsequent correction/adjustment file should always be reported using the current utilization data file layout that is attached to this release. If the correct file format is not used, the data will be rejected by the Medicaid Drug Rebate (MDR) system.

If you have any questions, please email us at MDRUtilization@cms.hhs.gov.

NEW/REINSTATED REBATE AGREEMENTS

Labeler Name: AMPHASTAR PHARMACEUTICALS, INC.
Optional Effective Date: 10/22/2012
Mandatory Effective Date: 01/01/2013
Labeler Code: 00548

Labeler Name: KEDRION MELVILLE, INC.
Optional Effective Date: 01/18/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 00562

Labeler Name: PHOTOCURE, INC.
Optional Effective Date: 01/07/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 10511

Labeler Name: ROSEMONT PHARMACEUTICALS, LTD.
Optional Effective Date: 10/23/2012
Mandatory Effective Date: 01/01/2013
Labeler Code: 13632

Labeler Name: SUCAMPO PHARMA AMERICAS, LLC
Optional Effective Date: 02/21/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 17350

Labeler Name: SUPERNUS PHARMACEUTICALS, INC.
Optional Effective Date: 01/24/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 17772

Labeler Name: THROMBOGENICS INC.
Optional Effective Date: 01/22/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 24856

Labeler Name: PRESTIUM PHARMA, INC
Optional Effective Date: 11/29/2012
Mandatory Effective Date: 04/01/2013
Labeler Code: 40076

Labeler Name: EXELIXIS, INC.
Optional Effective Date: 02/12/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 42388

Labeler Name: GENBIOPRO, INC.
Optional Effective Date: 01/22/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 43393

Labeler Name: MERZ AESTHETICS, INC.
Optional Effective Date: 03/28/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 46783

Labeler Name: AFAXYS, INC.
Optional Effective Date: 01/17/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 50102

Labeler Name: IGI LABORATORIES, INC.
Optional Effective Date: 12/21/2012
Mandatory Effective Date: 04/01/2013
Labeler Code: 52565

Labeler Name: AMARIN PHARMACEUTICALS IRELAND LTD
Optional Effective Date: 01/16/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 52937

Labeler Name: DUCHESNAY USA, INC.
Optional Effective Date: 04/12/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 55494

Labeler Name: CUTISPHARMA, INC.
Optional Effective Date: 12/19/2012
Mandatory Effective Date: 04/01/2013
Labeler Code: 65628

Labeler Name: BLUEPOINT LABORATORIES
Optional Effective Date: 04/08/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 68001

Labeler Name: NPS PHARMACEUTICALS, INC.
Optional Effective Date: 01/23/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 68875

Labeler Name: BD RX, INC.
Optional Effective Date: 04/18/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 76045

Labeler Name: ARIAD PHARMACEUTICALS, INC.
Optional Effective Date: 01/07/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 76189

Labeler Name: HYPERION THERAPEUTICS
Optional Effective Date: 03/18/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 76325

Labeler Name: W.H. NUTRITIONALS, LLC
Optional Effective Date: 01/07/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 76331

Labeler Name: AEGERION PHARMACEUTICALS, INC.
Optional Effective Date: 01/22/2013
Mandatory Effective Date: 04/01/2013
Labeler Code: 76431

TERMINATED LABELERS

Labeler Code	Labeler Name	Effective Date
00288	FLUORITAB CORPORATION	01/01/2013
10892	LUNSCO, INC	01/01/2013
59702	ATLEY PHARMACEUTICALS INC	01/01/2013
67286	ESP PHARMA, INC.	01/01/2013
16781	ONSET THERAPEUTICS	04/01/2013
00072	WESTWOOD-SQUIBB PHARMACEUTICALS	07/01/2013
00126	COLGATE ORAL PHARMACEUTICALS, INC.	07/01/2013
00276	MISEMER PHARMACEUTICAL, INC.	07/01/2013
12939	MARLOP PHARMACEUTICALS, INC.	07/01/2013
14168	STONEBRIDGE PHARMA LLC	07/01/2013
40042	PHARMAFORCE, INC.	07/01/2013
46129	PALADIN LABS (USA)	07/01/2013
64108	OPTICS LABORATORY, INC.	07/01/2013
64731	INTEGRITY PHARMACEUTICAL CORPORATION	07/01/2013
66479	XANODYNE PHARMACEUTICAL, INC.	07/01/2013
66977	MPM MEDICAL, INC.	07/01/2013
75840	GENPAK SOLUTIONS, LLC	07/01/2013

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