DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Disabled & Elderly Health Programs Group

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 166**

For State Technical Contacts

2012 STATE UTILIZATION DATA FOR BRANDED PRESCRIPTION DRUG (BPD) FEES

CMS issued its annual reminder to states to review the accuracy of utilization data submissions in order to prepare for the upcoming Branded Prescription Drug fee year calculations. A copy of CMS' guidance to states is available on our website, Medicaid.gov. Go to our BPD page at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Branded-Prescription-Drug.html, look under the BPD Disputes heading, and click on the "CMS Medicaid BPD Guidance to States" link.

If you have any questions, please email us at: mdroperations@cms.hhs.gov, and please include "BPD" in the subject line. :

CLARIFICATION OF POSTMARK DATES FOR PURPOSES OF CALCULATING INTEREST

In accordance with section 1927(b)(1)(A) of the Social Security Act (the Act) and the terms of the National Medicaid Drug Rebate Agreement, manufacturers are required to pay a rebate to each state for all covered outpatient drugs of the manufacturer that were paid for in a quarterly rebate period. This section of the Act also states that such rebate payments are to be paid within 30 days of the manufacturer's receipt of the state invoice. For purposes of calculating interest on late rebate payments, previously issued guidance (e.g., Manufacturer Release #7 and State Release # 29) has noted that manufacturers have 37 calendar days (as evidenced by the postmark by the U.S. Postal Service on the envelope) to pay rebates before interest begins to accrue. We have received various inquiries regarding the "postmark date" that should be used for state invoices received via alternate methods (i.e., other than the traditional paper format received via regular U.S. Postal Service). Therefore, as a follow-up to our release item titled "Clarification on Postmark Dates for Web Invoices" (State Release #154), we believe it would be helpful to provide a list of scenarios that identifies different state invoice transmission methods, along with

the appropriate "postmark date" manufacturers should use when determining when interest begins to accrue:

- If a state sends a paper invoice:

  The postmark date equals the date the postmark is applied to the envelope which may not necessarily be the day that the envelope was mailed. For example, the envelope containing the paper invoice was mailed on 1/13/14; however, the envelope was postmarked 1/15/14. The date when interest begins to accrue is the postmark date 1/15/14.

- If a state sends an email with the invoice attached:
  The date when interest begins to accrue equals the date on which the email was sent. For example, if the email was sent 1/14/14, the date when interest begins to accrue is 1/14/14.

- Secure websites:
  For states that use a secure website (optional), the date when interest begins to accrue equals the date of an email notification that a web invoice is ready to be downloaded; however, these state emails should also include the invoice within the body of the email or, at a minimum, include the information on the number of units paid, by NDC. State email notifications that do not contain unit information (i.e., ones that only link to an invoice) do not meet the minimum invoice requirements; therefore, the date of such an email does not qualify as a postmark date.

- If a state sends an invoice in multiple formats:
  The date when interest begins to accrue equals the date of whichever format is transmitted first.

Note: If a state receives a rebate payment that is missing the postmark date on the envelope, the date of the enclosed payment check should be used to determine if any interest applies.

If you have any questions, please contact MDROperations@cms.hhs.gov.

DESI CODE CORRECTION

The states were previously notified, in State Release #159, dated December 28, 2011, that the Food and Drug Administration (FDA) has determined that NDCs 00574-0159 and 62559-0153 Opium Tincture, USP (Deodorized) are safe and effective, DESI code 2. That statement was incorrect; FDA has not determined that NDCs 00574-0159 and 62559-0153 Opium Tincture, USP (Deodorized) are safe and effective, DESI code 2. FDA does not assign or determine the CMS DESI indicator code. It is CMS that requires the correct CMS DESI indicator code to be reported by the labeler for purposes of the Medicaid Drug Rebate program. FDA has informed us that opium tincture was not reviewed under FDA's DESI review process.

This notification does not address eligibility of the products as covered outpatient drugs. It remains the labelers' responsibility to determine if their product meets the definition of a covered outpatient drug and to report only those products to the Medicaid Drug Rebate program.

If you have any questions, please contact MDROperations@cms.hhs.gov.

PRODUCT DELETIONS

As we previously notified the states in an email on September 17, 2013, labeler 00904 informed us that the following NDCs are non-drug products and, therefore, 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 as a covered outpatient drug.

Date of original notification: 09/17/2013

NDC	Product Name
00904-5311	Magnesium Oxide 400mg tablets
00904-5989	Poison Ivy Wash
00904-7744	Effervescent Denture Cleanser Tablets

As previously notified, several labelers have informed us that the following NDCs are non-drug products and 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 as a covered outpatient drug.

Date of original notification: 12/31/2013

NDC	Product Name
38779- 0013	Fluoxetine HCL
38779- 0015	Bacitracin, USP (Micronized)
38779- 0037	Mineral Oil, NF (Light)
38779- 0043	Progesterone, USP (Micronized)
38779- 0059	Pyrantel Pamoate, USP
38779- 0060	Acacia, NF (Spray Dried)
38779- 0065	Butylated Hydroxytoluene, NF (USP)
38779- 0078	Ketoprofen, USP
38779- 0081	Lidocaine, USP
38779- 0082	Lidocaine Hydrochloride, USP
38779- 0084	Methylcellulose, USP (4000 CPS)
38779- 0085	Methylcellulose, USP (1500 CPS)
38779- 0090	Praziquantel, USP
38779- 0140	Megestrol Acetate, USP (Micronized)
38779- 0159	Reserpine, USP
38779- 0163	Testosterone, USP (Micronized)
38779- 0189	Amitriptyline Hydrochloride, USP
38779- 0204	Chloramphenicol Palmitate, USP
38779- 0234	Isoxsuprine Hydrochloride, USP
38779- 0251	Polyethylene Glycol 400, NF (PEG-8)

38779-0260 Squalane, NF
38779-0264 Benzalkonium Chloride Solution, NF
38779-0268 Trichlormethiazide, USP
38779-0281 Dimenhydrinate, USP
38779-0289 Polyethylene Glycol 3350, NF (PEG-75)
38779-0290 Polyethylene Glycol 8000, NF
38779-0303 Dihydroergotamine Mesylate, USP
38779-0355 Dextromethorphan Hydrobromide, USP
38779-0362 Flurbiprofen, BP
38779-0395 Cyclobenzaprine Hydrochloride, USP
38779-0483 Hypromellose, USP (4000 CPS) Methocel E4m
38779-0495 Acetylcysteine, USP (N-Acetyl-L-Cysteine)
38779-0510 Propylene Glycol, USP
38779-0519 Talc, USP
38779-0526 Polysorbate 80, NF (Tween 80)
38779-0549 Calcium Carbonate, USP (Heavy-Precip.)
38779-0567 Cellulose, NF (Microcrystalline)
38779-0586 Chloroform, ACS
38779-0598 Lugol's Solution USP (Strong Iodine Soln)
38779-0616 Ethanol (Denatured)(Ethyl Alcohol)
38779-0618 Cetyl Alcohol, NF
38779-0659 Bismuth Subcarbonate, USP
38779-0685 Aluminum Chloride, USP
38779-0767 Naloxone Hydrochloride, USP (Dihydrate)
38779-0770 Trimethoprim, USP (Micronized)
38779-0810 Isopropyl Alcohol, USP (Alcohol 99%)
38779-0827 Peppermint Oil
38779-0834 Poloxamer, NF (407) (Pluronic F-127)
38779-0837 Capsaicin (95%) (Natural)
38779-0852 Phenobarbital, USP
38779-0908 Ascorbyl Palmitate, NF
38779-0935 Cold Cream Unscented
38779-0949 Mineral Oil, USP (Heavy)
38779-0955 Acetyl Salicylic Acid, USP
38779-0956 Acetyl-D-Glucosamine
38779-0989 Aminocaproic Acid, USP (6-Animohexanoic)
38779-1030 Benzyl Benzoate, USP
38779-1040 Betaine (Anhydrous)
38779-1046 Bismuth Subgallate, USP
38779-1047 Bismuth Subnitrate, USP
38779-1236 Dibutyl Squarate
38779-1354 Hydroxyurea, USP
38779-1630 Stearyl Alcohol, NF
38779-1698 Diclofenac Sodium, BP
38779-1754 Ketamine Hydrochloride, USP
38779-1764 Apomorphine Hydrochloride, USP

38779- 1855	Seasame Oil
38779- 1877	Stearic Acid
38779- 1966	Glucosamine Hydrochloride
38779- 1980	Gabapentin
38779- 2118	Magnesium Oxide, USP (Heavy) (Powder)
38779- 2256	Clomipramine Hydrochloride
38779- 2258	Medihol Gel Base
38779- 2510	Oral SUSPend
38779- 2511	Oral Syrup
38779- 2512	Oral Mix
38779- 2599	Oral Syrup SF
38779- 2600	Oral Mix SF
38779- 2629	Leuprolide Acetate, USP

Please note that while the products listed above are not eligible for coverage under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage 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.

If you have any questions about rebate eligible products, please contact MDROperations@cms.hhs.gov.

NEW/REINSTATED REBATE AGREEMENTS AND TERMINATED LABELERS

We have created a new webpage on Medicaid.gov to post information on new/reinstated and terminated labelers in lieu of including this information in the state releases going forward. The webpage can be found at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/NewandTerminatedLabelerInformation.html. Please note State Technical Contacts will continue to receive email notifications of new/reinstated rebate agreements as well as terminated labelers.

If you have any questions, please contact MDROperations@cms.hhs.gov.

RETIREMENT NEWS

Larry Reed has decided to retire after 37 years of Federal service effective January 3, 2014. Until the position of Director of the Division of Pharmacy is filled, we are pleased to announce that Kim Howell will serve as Acting Director.

/s/

Barbara Coulter Edwards
Director
Disabled & Elderly Health Programs Group