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Disabled & Elderly Health Programs Group

January 24, 2013

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 162**

For State Technical Contacts

COVERAGE OF BARBITURATES AND BENZODIAZEPINES UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM

Changes Effective January 1, 2013

Except as otherwise specified, Medicare covered Part D drugs generally do not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) of the Social Security Act (the Act). Section 1927(d)(2) of the Act currently specifies that states may exclude from coverage or otherwise restrict barbiturates and benzodiazepines, or their medical uses, for its Medicaid beneficiaries.

With respect to prescriptions dispensed on or after January 1, 2013, section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) amended section 1860D-2(e)(2)(A) of the Act to include Medicare Part D drug coverage of barbiturates "used in the treatment of epilepsy, cancer, or a chronic mental health disorder" and benzodiazepines for all medically accepted indications.

This coverage change will affect Medicaid beneficiaries that also have Medicare (dual eligible beneficiaries). Medicare will be responsible for payment for these drugs as previously indicated for dual eligible individuals as of January 1, 2013. However, a state that covers these drugs under its Medicaid state plan is required to continue covering barbiturates for dual eligible beneficiaries when used for indications Medicare does not cover, as well as any indications listed for non-dual eligible beneficiaries.

Since coverage of benzodiazepines under Medicare Part D is inclusive of all indications, state Medicaid coverage of benzodiazepines would only be for state plan listed uses for non-dual eligible beneficiaries.

A state should examine its current state plan to determine its coverage of barbiturates and benzodiazepines and whether a state plan amendment is warranted. To the extent that the state needs to change its coverage under Medicaid given the amendments to Medicare Part D coverage, the state will need to timely submit a state plan amendment to ensure that Medicaid benefits for dual eligible beneficiaries are appropriate given the changes in the law if it hasn't already done so. Since the Medicare copayment requirement will likely change for dual eligible beneficiaries utilizing these drugs, we also encourage states to notify affected beneficiaries of this financial impact.

Changes Effective January 1, 2014

Effective January 1, 2014, section 2502 of the Affordable Care Act amends section 1927(d)(2) of the Act by removing barbiturates and benzodiazepines from the list of drugs a state Medicaid program may exclude from coverage or otherwise restrict. It also adds section 1927(d)(7) of the Act which explicitly prohibits the exclusion of coverage of barbiturates and benzodiazepines, and their medical uses, under the Medicaid program.

Because these drugs will no longer be restricted or excluded from coverage under Medicaid, they will no longer be excluded from the definition of a covered Part D drug under Medicare Part D. For dual eligible beneficiaries, this means that beginning January 1, 2014, all barbiturates and benzodiazepines that meet the definition of a Part D drug will be covered under Part D, and will no longer be covered under Medicaid. For all other Medicaid beneficiaries, effective January 1, 2014, these drugs are no longer excluded from coverage or otherwise restricted under the Medicaid program.

Given the requirement of section 1927(d)(7) of the Act, a state should examine its state plan to determine its coverage of barbiturates and benzodiazepines. To the extent that the state needs to change its coverage consistent with these Medicaid coverage requirements, it will need to submit a state plan amendment to be effective January 1, 2014, to remove these drugs from exclusion.

For further information, please contact Joe Fine at 410-786-2128.

FURTHER GUIDANCE ON THE OFFICE OF THE INSPECTOR GENERAL (OIG) REPORT: "STATES' COLLECTION OF MEDICAID REBATES FOR PHYSICIAN-ADMINISTERED DRUGS" (OEI-03-09-00410)

Background

The OIG issued a report entitled "States' Collection of Medicaid Rebates for Physician-Administered Drugs" (OEI-03-09-00410, dated June 2011), which determined the compliance of states' participation in the Medicaid drug rebate program for physician-administered drugs and noted that not all states are fully collecting rebates for these drugs. In response to this report, CMS has committed to reiterating the necessary requirements for states to collect rebates for physician-administered drugs. The OIG report can be found at: https://oig.hhs.gov/oei/reports/oei-03-09-00410.pdf.

Section 6002 of the Deficit Reduction Act (DRA) of 2005 requires state Medicaid agencies to provide for the collection of National Drug Codes (NDCs) on all claims for certain physician-administered drugs for the purpose of billing manufacturers for Medicaid drug rebates. Prior to the DRA, physicians' offices, outpatient hospital departments and clinics generally used Healthcare Common Procedure Coding System (HCPCS) codes to bill Medicaid for drugs dispensed to Medicaid patients.

Beginning January 1, 2008, in order for federal financial participation (FFP) to be available for these drugs, state Medicaid agencies must be in compliance with the requirements. These requirements, as set forth at 42 C.F.R. § 447.520, were implemented in a final rule published on July 17, 2007 (72 *Fed. Reg.* 39142).

Under 42 C.F.R. § 447.520, states must require providers to submit NDC and quantity data for single source drugs and also for the 20 multiple source physician-administered drugs with the highest dollar volume in Medicaid.

Top 20 Multiple Source Drugs

We previously published a listing of the top 20 multiple source physician-administered drugs. However, after a thorough search of the limited highest dollar volume Medicaid multiple source drugs, we proposed to stop publishing the list after we found that most of the drugs were low-cost products and would not effectively represent a benefit to the states in rebate collection. Further, we believed the state impact in removing the top 20 listing was minimal, because virtually all states did not limit NDC numbers on claims for only these drugs, but required NDC submission for all physician-administered drugs. For further details, please see http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/State-Prescription-Drug-Resources.html

Billing Requirements

In order to collect manufacturer rebates for physician-administered drugs, states must require that their providers include an NDC number and quantity on the following professional and institutional billing forms: HIPAA 837-P / 837-I for electronic billing and the CMS-1500 / UB-04 for paper claims.

Prior to the Affordable Care Act, states collected the necessary NDC number and quantity information solely for fee-for-service claims. States are now required to ensure that their Managed Care Organizations (MCOs) report the necessary utilization data in order to bill manufacturers for rebates for covered outpatient drugs, except for drugs subject to 340B discounts since there is not a rebate for these drugs. This includes physician-administered drugs.

For individuals covered under both Medicare and Medicaid, when Medicare is primary and Medicaid pays the crossover claim for the co-insurance and/or deductible, the NDCs and corresponding quantity amounts must accompany the claim so that states can bill manufacturers

for rebates. These requirements also apply for both Medicaid fee-for-service and MCO dual eligible individuals.

We will continue to work with states that need assistance with any concerns involving the collection of manufacturer rebates for physician-administered drugs.

For further information, please contact Joe Fine at 410-786-2128.

REPORTING DRUG LINE ITEMS ON THE CMS-64

On a quarterly basis, all states are responsible for reporting their Medicaid drug expenditures, rebates, and offsets on the CMS-64, via the automated Medicaid Budget and Expenditure System/Children's Health Insurance Program Budget and Expenditure System (MBES/CBES).

The line items for Medicaid drug expenditures, rebates, and offsets on the CMS-64 include (fee-for-service (FFS) and managed care organization (MCO)) as follows:

- 7 – Prescribed drugs
- 7A1 – Drug rebate offset – National agreement for FFS 7A2 – Drug rebate offset – State sidebar agreement for FFS (same as state supplemental rebate agreement for FFS)
- 7A3 – MCO – National rebate agreement (effective March 23, 2010 under the Affordable Care Act)
- 7A4 – MCO – State sidebar agreement (same as state supplemental rebate agreement, effective March 23, 2010 under the Affordable Care Act)
- 7A5 – Increased ACA offset – Fee for service – 100% (effective January 1, 2010 under the Affordable Care Act)
- 7A6 – Increased ACA offset – MCO – 100% (effective March 23, 2010 under the Affordable Care Act)

Please note that rebates received under the National Medicaid Drug Rebate Agreement (Lines 7A1 and 7A3) are separate from rebates received under state supplement rebate agreements (Line 7A2 and 7A4). Please do not combine the state supplement rebates with the national rebates when reporting on the CMS-64.

States should also ensure that, when reporting federal financial participation (FFP) for the above drug related line items, the rebates for federal reimbursement are only for rebate-eligible products. In general, rebate-eligible products:

- Meet the definition of covered outpatient drug under section 1927(k)(2) of the Social Security Act;
- Are active in the Medicaid Drug Rebate Program;
- Are not DESI less-than-effective (i.e., DESI Code 5 or 6); and
- Are for manufacturers participating in the Medicaid Drug Rebate Program (MDRP).

For products that are not rebate eligible but states choose to cover these products under their state plan, please report them on line 7 (prescribed drugs) only.

CMS has provided states with access to the Drug Data Reporting for Medicaid (DDR) system to accurately and timely track changes to manufacturer product information and we strongly urge every state to gain access to this system. CMS also continues to notify states of the deletion of manufacturer-reported products that do not meet the definition of covered outpatient drugs.

States should ensure the correct billing and collection of rebates for products that are in the MDRP, bill manufacturers only for products that are in the MDRP, and report timely and accurately on the CMS-64 for the drug provisions.

If you have any questions about rebate eligible products, please email the Division of Pharmacy at MDROperations@cms.hhs.gov.

If you have further questions regarding how to report correctly on the CMS-64, please contact your state CMS's regional financial specialist.

/s/
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