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Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 85**

For Participating Drug Manufacturers

OFFICE OF THE INSPECTOR GENERAL (OIG) REPORT: "STATE MEDICAID POLICIES AND OVERSIGHT ACTIVITIES RELATED TO 340B-PURCHASED DRUGS" (JUNE 2011, OEI 05-09-00321)

This is to inform you that the OIG conducted a study of state Medicaid agencies' policies and oversight activities related to drugs purchased under the 340B Drug Pricing Program, and to highlight those recommendations that pertain directly to state Medicaid agencies. The OIG report can be found at https://oig.hhs.gov/oei/reports/oei-05-09-00321.asp.

In this report, the OIG recommended that CMS direct states to create written 340B policies and inform states about tools they can use to identify claims for 340B purchased drugs. The OIG noted that some states reported that they do not have written 340B policies because they believe that HRSA's 1993 guidance to covered entities to bill at actual acquisition cost (AAC) is in effect. However, HRSA's 2000 guidance withdrew the AAC provision of the 1993 guidance and directed covered entities to follow state guidelines for billing 340B-purchased drugs. The OIG found that 25 states have written policies that direct covered entities to bill at AAC for 340B-purchased drugs. Of the remaining 25 states without written policies, 16 reported that they want covered entities to bill at AAC for 340B-purchased drugs and four had no covered entities that dispense 340B-purchased drugs to Medicaid beneficiaries. The OIG further noted that states that rely on HRSA's old guidance may not be able to enforce their reimbursement policy if they do not have a written policy.

As a follow up to the OIG's recommendations, we encourage your state to:

- Determine if you have clear reimbursement policies for 340B covered entities in your approved state plan.
- If not, develop policies on reimbursement for covered entities that are enrolled in the 340B Drug Pricing Program.

- Submit a state plan amendment consistent with the regulations, including those found at 42 CFR 447.502 and 447.512, to detail how these covered entities are reimbursed.

We believe that states can generally achieve cost savings by paying for 340B purchased drugs. We encourage state Medicaid agencies to work with the covered entities in their states when setting appropriate reimbursement rates for both the ingredient cost and dispensing fees. States should be aware and consider that these covered entities may have additional costs associated with dispensing these drugs compared to a retail pharmacy and also consider those dispensing costs when looking at overall payment to these covered entities.

States are required to invoice manufacturers for rebates for covered outpatient drugs that are not purchased through the 340B program, even when those drugs are purchased by a 340B covered entity. However, states are prohibited from requesting Medicaid rebates on drugs purchased under the 340B program and billed to Medicaid. As noted in the OIG report, states have used a variety of methods to identify 340B claims. States have relied on the Medicaid Exclusion File on the HRSA website at http://opanet.hrsa.gov/opa/CE/CEMedicaidExtract.aspx. This website allows states to identify those covered entities that have reported to HRSA that they will bill Medicaid for drugs purchased through the 340B program. However, the OIG report noted concerns that there may be inaccuracies in that file. HRSA requires 340B covered entities to keep their information up to date in the Medicaid Exclusion File to ensure against duplicate discounts. If states discover discrepancies or have any concerns about the Medicaid Exclusion File, please contact HRSA at OPAexclusion@hrsa.gov. For more information on the Medicaid Exclusion File, HRSA developed a tutorial at http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/medicaidexclusiontutorial.pdf to help states and others understand how to use the file to identify covered entities dispensing 340B-purchased drugs to Medicaid patients.

In addition to the Medicaid Exclusion File, states may choose to use other information in order to identify 340B claims. For example, some states have instructed covered entities to use the National Council for Prescription Drug Plans (NCPDP) Telecommunication Standards to identify 340B claims. More information about the NCPDP standards can be found on that organization's webpage at http://www.ncpdp.org/pdf/340B_Information_Exchange_Reference%20Guide_v1.0.pdf.

Please contact Marge Watchorn at 410-786-4361 for further information.

REBATE CLARIFICATION FOR DRUGS USED IN END STAGE RENAL DISEASE (ESRD) BUNDLED SERVICES

The CMCS Informational Bulletin published on December 30, 2010, (https://www.cms.gov/CMCSBulletins/downloads/12-30-2010-Omnibus-Bulletin.pdf) addressed Medicare's implementation of the End Stage Renal Disease (ESRD) bundled payment system for dates of service on or after January 1, 2011. This guidance responds to questions we have from stakeholders regarding whether rebates are due for drugs used in the ESRD bundled service. As discussed in the original bulletin, the Medicare Improvements for Patients and Providers Act

(MIPPA) required that Medicare-certified ESRD facilities providing outpatient maintenance dialysis services to Medicare beneficiaries receive an all-inclusive bundled payment. This replaced the previous basic case-mix adjusted composite payment system used for the reimbursement of separately billable outpatient ESRD items and services.

As required by MIPPA, renal dialysis facilities are paid a single bundled rate for furnishing renal dialysis services, including most drugs used in the treatment of ESRD, and therefore, such bundled services can no longer be billed separately. The only exception are certain ESRD-related oral drugs (drugs without an injectable form), which are not included in the bundled rate and are separately payable until January 1, 2014. As a result, these bundled renal dialysis drugs and biologicals are no longer eligible for manufacturer rebates. Furthermore, the subsequent cross-over claim for the Medicaid-covered co-insurance requirement will no longer identify the drug information necessary for billing manufacturer rebates and, even if it can be derived from such a billing, should not be used to claim a Medicaid rebate.

The statute also required a 4-year phase-in period and allowed ESRD facilities to decide to make a one-time election to be excluded from this transition period that began in 2011. ESRD facilities that did not elect to receive full payment under Medicare's ESRD Prospective Payment System (PPS), receive a blended payment. For renal dialysis items and services furnished in CY 2011, ESRD facilities under the transition received payment comprised of 25 percent under the ESRD PPS and 75 percent under the basic-case mix adjusted composite rate system. In CY 2012, the percentage is 50 percent under the ESRD PPS and 50 percent under the basic case mix adjusted composite rate. Regardless of whether an ESRD facility elected to be excluded from the one-time election or decided to initially participate in the PPS, all ESRD claims are to be processed as bundled payments, with the exception of certain ESRD related oral drugs which are separately payable until January 1, 2014.

The subsequent cross-over claim for Medicaid-covered co-insurance will be processed by the states. Since this co-insurance is part of a bundled payment, manufacturers are not responsible for rebates. Please note that the rebate exclusion described here is limited to drugs included in the ESRD bundled service payment for dual-eligibles.

For items and services that are not renal dialysis services, we understand that ESRD facilities will be required to place an AY modifier to indicate that an item or service is not ESRD-related, in order to receive separate payment[1]. Items and services without an AY modifier are considered renal dialysis services and therefore, are included in the Medicare bundled payment.

Please contact Joe Fine at 410-786-2128 if you have any questions.

[1] Billing instructions for ESRD payment can be found in Pub. 100-04, Chapter 8. Information regarding usage of the AY modifier for drugs and biologicals can be found in section 60.2.1.1 – Separately Billable ESRD Drugs.

HOW CLOTTING FACTOR (CF) AND EXCLUSIVELY PEDIATRIC (EP) INDICATORS ARE APPLIED IN THE MEDICAID DRUG REBATE (MDR) AND DRUG DATA REPORTING FOR MEDICAID (DDR) SYSTEMS

We are providing additional information on how the clotting factor (CF) and exclusively pediatric (EP) indicators are applied in our systems. Effective January 1, 2010, the Affordable Care Act (ACA) established a new minimum rebate percentage equal to 17.1 percent for the following categories of drugs:

- Drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications

- Clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act

In order to identify CF and EP drugs in the Medicaid Drug Rebate (MDR) system so that the appropriate rebate calculation is performed each quarter, CMS implemented both a CF indicator and an EP indicator in the system. When a drug is either a CF or EP drug, the indicator is activated in MDR at the NDC level and is subsequently transferred to the product information contained in the Drug Data Reporting (DDR) system so that manufacturers and states know which drugs qualify for the minimum 17.1 percent rebate.

When it is determined that a drug is either exclusively pediatric or is a clotting factor, the EP or CF indicator is activated (Y/N flag) in MDR and the minimum 17.1 rebate percentage is applicable for those drugs for the most recent of:

- the quarter in which the labeler's Medicaid drug rebate agreement was optionally effective (i.e., the earliest date states, at their option, can cover the drug);
- the product's Market Date quarter;
- the product's Purchased Product Date quarter (if applicable); or,
- the first quarter 2010 (i.e., the quarter in which the minimum rebate percentage under ACA was effective).

For example, if an NDC of an EP drug product has a Market Date of 5/1/2008, a Purchased Product Date of 6/1/2011 and the labeler code's rebate agreement was optionally effective on 1/1/2007, the most recent quarter is the Purchased Product Date quarter, which is the second quarter of 2011. Therefore, the EP indicator for the NDC would be turned on in MDR as of the Purchased Product Date quarter (i.e., from the beginning of the second quarter 2011).

CF and EP indicators that are turned on in MDR are transferred to the DDR system on a nightly basis and appear on the product screen in that system. In addition, a new feature will be available soon in DDR that will allow state and manufacturer users to generate a current list of all active CF and/or EP drugs in the Medicaid Drug Rebate Program. Users will also have the option to include terminated products to generate a more inclusive list of CF and EP drugs.

Additional information regarding this new feature will be provided in subsequent communications to states and manufacturers.

Please contact MDROperations@cms.hhs.gov if you have any questions.

/s/

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