DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 90**

For Participating Drug Manufacturers

REPORTING BASELINE DATA FOR DRUGS

We have received frequent inquiries from manufacturers regarding how to either report or obtain baseline data when buying/selling products for resale. We are issuing this guidance to remind manufacturers how baseline data should be reported in the Drug Data Reporting (DDR) system.

Buying a Drug from Another Manufacturer

A manufacturer that buys a drug product from another manufacturer is responsible for obtaining the baseline data of the drug. Under Section 1927(b)(3)(D) of the Social Security Act (the Act), pricing information disclosed by manufacturers or wholesalers may not be disclosed by the Secretary or states, except in limited circumstances. Therefore, the Centers for Medicare & Medicaid (CMS) does not provide the baseline data to the manufacturer purchasing the drug and will not carry over the base date AMP from the selling manufacturer to the buying manufacturer in the DDR system. It is the buying manufacturer's responsibility to obtain the baseline data for the new NDC. This includes obtaining the necessary data to report a base date AMP consistent with section 1927(c)(1)(C) of the Act.

Buying a Drug but Not Changing the NDC

The NDC (in particular the labeler code) on the drug identifies for CMS the manufacturer that is responsible for timely reporting to the DDR system and payment of Medicaid rebates. When a manufacturer buys a drug but does not change the NDC on the product, the manufacturer with the NDC on the product will continue to be responsible for providing pricing data and rebates. Manufacturers should be mindful of this when purchasing drugs from other manufacturers.

Buying a Drug and Changing the NDC

When a manufacturer buys a drug and changes the NDC to its own labeler code, the selling manufacturer is responsible for updating DDR by providing the drug termination date for the selling manufacturer's NDC. The drug termination date in the DDR System, as outlined in the DDR Labeler Data guide, is generally the date when the drug is withdrawn from the market, or the expiration date for the NDC's last lot sold. The selling company is responsible for reporting pricing data on that NDC for 4 quarters beyond the drug termination date.

The buying manufacturer is responsible for reporting pricing data and paying rebates under the new NDC. In addition, the buying manufacturer is responsible for obtaining the baseline data of the drug from the selling manufacturer and reporting that baseline data to CMS. If the buying manufacturer did not obtain this information from the selling manufacturer and needs to obtain the contact information of the selling manufacturer, information regarding participating manufacturer technical contacts can be found on our website at http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html under the Contact Information section.

The manufacturer buying a drug is responsible for entering a purchased product date (PPD) into DDR for the new NDC at the time the drug is reported by that manufacturer in DDR. The PPD is needed in order for CMS to identify when the manufacturer is responsible for reporting pricing and providing rebates for that drug.

Sale of Authorized Generic Drugs

When a company enters into an agreement with a brand product manufacturer to buy and market an authorized generic drug, the buying manufacturer is responsible for obtaining baseline data for the authorized generic drug to ensure accurate reporting to CMS.

To determine if drugs should have the same baseline data, manufacturers may access the FDA Online Label Repository at http://labels.fda.gov/, and enter each drug's NDC to determine if the drugs have the same NDA/ANDA.

If it is determined that incorrect baseline data have been reported to CMS for a drug, we request that manufacturers email RxDrugPolicy@cms.hhs.gov to request a change. Additional questions regarding baseline data should be directed to RxDrugPolicy@cms.hhs.gov.

2012 STATE UTILIZATION DATA FOR BRANDED PRESCRIPTION DRUG FEES

CMS issued its annual reminder to manufacturers to review their data submissions for accuracy for the upcoming Branded Prescription Drug fee year. This can be found on the Medicaid.gov website at (http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Branded-Prescription-Drug.html) under BPD Disputes, titled "CMS Medicaid BPD Guidance to Manufacturers".

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

/s/

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