



Center for Medicaid and CHIP Services

June 19, 2013

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 87

**For
Participating Drug Manufacturers**

PRODUCTS IN THE MEDICAID DRUG REBATE PROGRAM THAT ARE NOT LISTED WITH FDA

In Manufacturer Release #84 issued in July 2012, we strongly encouraged all manufacturers to review the Food and Drug Administration's (FDA) comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm> to ensure that all manufacturer NDCs that are in the Medicaid Drug Rebate Program (MDRP) are listed electronically with FDA. As we explained in that release, CMS uses listing information to help verify which drug products are eligible for coverage under the MDRP.

We generated a list of NDCs in the MDRP that are not listed with FDA, by matching the active NDCs at the 11-digit level that are in the first quarter 2013 MDRP drug product data file (<http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html>) against FDA's NSDE file to identify products that have been reported to CMS for inclusion in the MDRP but that are not listed with FDA. The drug products listed in MDRP, sorted by NDC, that are currently not listed with FDA can be found on Medicaid.gov at <http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html>. This list is also available in DDR as an attachment on the "Bulletin" screen.

We believe that it's important that all drugs be listed with FDA. Therefore, we strongly encourage manufacturers to review this list to identify any NDCs under their labeler code(s) which are not currently listed electronically with FDA and list those drugs with FDA promptly. If a review of this list identifies any NDC(s) that you believe should not be included in the MDRP, please contact us immediately at RxDrugPolicy@cms.hhs.gov.

We would like to remind manufacturers that they are responsible for correctly reporting their covered outpatient drugs (CODs) to the MDRP via the Drug Data Reporting for Medicaid (DDR) system. Because the MDRP only covers products that meet the COD definition, CMS is currently reviewing the MDR system to ensure that only products that meet the COD definition are in the rebate program.

If you have any questions or comments regarding this topic, please email us at RxDrugPolicy@cms.hhs.gov.

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