

CMS Upcoming Exclusions from the Medicaid Drug Rebate Program

On August 20, CMS notified drug manufacturers of some products classified as "not listed" on the Food and Drug Administration (FDA)'s [National Drug Code database](#) that these products will no longer be eligible for the Medicaid drug rebate program. **This policy will go into effect on September 30.**

From: CMS MDROperations

Sent: Wednesday, August 20, 2014 11:22 AM

To: CMS MDROperations

Subject: Upcoming Potential Product Deletions from the Medicaid Drug Rebate Program

Importance: High

Dear State Technical Contact,

In accordance with State Release #164, we have been working with manufacturers to ensure that all NDCs that are in the Medicaid Drug Rebate (MDR) program are electronically listed with the Food and Drug Administration (FDA). CMS uses listing information included in the FDA's comprehensive NDC Structured Product Labeling (SPL) Data Elements (NSDE) file to help verify which products are eligible for coverage under the MDR program. The NSDE file is available at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm>.

On August 20, 2014, we notified manufacturers with products on the "not listed" NDC file that we will be deleting all not listed NDCs from the MDR program as of September 30, 2014. For a preliminary idea of the scope of this deletion exercise, please review the most current not listed NDC file on Medicaid.gov at

<http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html>. If you are concerned about the potential deletion of any of these products, please contact us by September 15, 2014 at mdroperations@cms.hhs.gov with the specific NDC(s) and an explanation regarding the impact that the deletion of the NDC(s) will have on your state's Medicaid program.

Over the next few weeks, CMS will continue to perform a daily match of MDR's product data against FDA's data. Any NDCs that are listed with the FDA prior to September 30, 2014, will remain in the MDR program. We will be sending states a formal deletion notification on September 30, 2014, that will include a list of all NDCs to be removed from state MDR systems. After September 30, 2014, CMS will continue to perform daily file comparisons to see if any of the recently deleted NDCs match the FDA file. When a deleted NDC's listing has been confirmed, CMS may restore the NDC in the MDR program and will notify the manufacturer and states accordingly.

For Medicaid policy-related questions about listing, please contact the Division of Pharmacy at RxDrugPolicy@cms.hhs.gov.

Sincerely,
Division of Pharmacy, CMCS, CMS