



Center for Medicaid and CHIP Services

April 23, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 93

For

Participating Drug Manufacturers

**Payment of Medicaid Rebates for Covered Outpatient Orphan Drugs
Dispensed by Certain 340B Entities**

We have received inquiries regarding the release issued by the Health Resources and Services Administration (HRSA) on February 13, 2015, (“February release”) of a list of manufacturers that are not providing discounts to certain 340B entities on drugs that have orphan drug designations (when used for their non-orphan indications). We are providing this information to states so they have a better understanding of our expectations with respect to the collection of Medicaid rebates on these drugs given that we understand that some manufacturers are not providing 340B discounts on these drugs to certain 340B covered entities.

The Affordable Care Act of 2010 added several new categories of entities eligible for participation in the 340B program. The eligible entity types added are free standing cancer hospitals (as discussed in section 340B(a)(4)(M) of the Public Health Service Act (PHSA)), critical access hospitals (as discussed in section 340B(a)(4)(N) of the PHSA) and rural referral centers and sole community hospitals (as discussed in section 340B(a)(4)(O) of the PHSA).

As noted in the February release, HRSA received multiple reports that certain manufacturers are not complying with statutory requirements concerning the inclusion of drugs with orphan designations in the 340B drug pricing program. HRSA has now identified and posted on its website a list of manufacturers that are not offering 340B discount pricing on their orphan drugs (when used for their non-orphan indications) to newly eligible covered entities. This information can be found at:

<http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/manufacturereadlist.html>.

To the extent that these drugs with orphan indications are Medicaid covered outpatient drugs and paid for by Medicaid, states should include the claims for these drugs in their utilization data to

obtain rebates because the covered entities have not received a 340B discount from the manufacturers on this list. The state Medicaid program should not be seeking manufacturer rebates where a covered outpatient drug has been subject to a 340B discount. If a 340B discount price has not been paid for a Medicaid covered outpatient drug, then the drug should be subject to a Medicaid rebate.

CMS is recommending that states work closely with the affected covered entities in their state to develop a plan to identify the orphan drugs of the manufacturers listed on HRSA's website and include the drugs in the Medicaid rebate utilization data. These drugs are subject to a Medicaid rebate whether or not they are used for an orphan drug indication provided the drugs qualify as covered outpatient drugs and are not subject to a 340B discount. States should collect Medicaid rebates from manufacturers in these instances, as the covered entities are unable to purchase the orphan drugs at a 340B discounted price. If you have any questions, please contact CMS at rxdrugpolicy@cms.hhs.gov.

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