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. 96**

For

Participating Drug Manufacturers

Transition Period Prior to Enforcement of 5i AMP Provisions

The Centers for Medicare & Medicaid Services (CMS) published CMS-2345-FC Covered Outpatient Drugs Final Rule with Comment ("Final Rule") on February 1, 2016 with an effective date of April 1, 2016. This Final Rule addresses key areas of Medicaid drug reimbursement and details changes made to the Medicaid Drug Rebate (MDR) program by the Affordable Care Act. These regulations are codified at 42 CFR 447 Subpart I.

It has come to our attention that drug manufacturers may need additional time to complete system modifications to ensure all necessary changes are operational by the April 1, 2016 effective date for some provisions of the final regulation. In particular, it is our understanding that the greatest challenges for manufacturers relate to the determination of the average manufacturer price (AMP) for inhalation, infusion, instilled, implanted or injectable drugs ("5i drugs") that are not generally dispensed through retail community pharmacies. Specifically, manufacturers assert that the April 1, 2016, effective date does not provide sufficient lead time for them to incorporate and operationalize the changes in the Final Rule into their business policies, procedures, and systems for the 5i AMP calculation.

Given that CMS changed the ratio of retail to nonretail sales for the 5i AMP calculation from the proposed regulation and included the option for manufacturers to use a smoothing methodology, we believe that a transition period prior to enforcement will allow manufacturers additional time to make necessary modifications and test their systems to calculate and report the AMP for 5i drugs in accordance with the requirements established in the Final Rule. Thus, CMS will begin enforcement of the provisions of the Final Rule specific to the calculation of AMP for "5i drugs" on July 1, 2016. The transition period is specific to the provisions which require the identification of 5i drugs consistent with 42 CFR 447.507 and the calculation of AMPs for 5i drugs consistent with 42 CFR 447.504.

Manufacturers are still required to timely report monthly and quarterly AMPs consistent with the requirements of 42 CFR 447.510 as of the effective date of the final rule, but may do so using reasonable assumptions. Furthermore, once manufacturers have completed the necessary modifications to their systems to calculate and report AMP for 5i drugs in accordance with the requirements established in the Final Rule, manufacturers will be responsible for recalculating and restating their monthly and quarterly AMPs back to the effective date of the final rule (April 1, 2016) consistent with the requirements of 42 CFR 447.507 and 42 CFR 447.504.

Manufacturers will have until July 1, 2016 to finalize and operationalize their process and system enhancements needed to comply with the Final Rule provisions specific to identifying 5i drugs consistent with 42 CFR 447.507 and calculating AMPs for 5i drugs consistent with 42 CFR 447.504. In accordance with the National Drug Rebate Agreement, manufacturers are reminded that they must maintain adequate documentation supporting their assumptions.

CMS will be issuing a frequently asked questions document as well as operational guidance to address questions that have been received since the publication of the final rule. However, if you have additional questions regarding the Final Rule or the guidance set forth here, please contact us at rxdrugpolicy@cms.hhs.gov.

/s/
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