



Center for Medicaid and CHIP Services

March 26, 2018

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 108

For
Participating Drug Manufacturers

Action Required to Remain in Medicaid Drug Rebate Program: Updated National Drug Rebate Agreement

On March 23, 2018, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register the final notice for the Medicaid National Drug Rebate Agreement (NDRA) [CMS-2397-FN](#) (Final Notice) (83 FR 12770) that announced changes to the NDRA which will be applicable as of the March 23, 2018 publication date. The updated NDRA incorporates legislative and regulatory changes that have occurred since the NDRA was last published on February 21, 1991, and also makes editorial and structural revisions, such as references to the updated Office of Management and Budget (OMB)-approved data collection forms and electronic data reporting. The NDRA reaffirms the manufacturer's responsibilities to correctly and consistently report drug product and pricing data to CMS in a timely manner, and refers to the statutory and regulatory citations for the definitions of single source, innovator multiple source, and non-innovator multiple source drugs.

Manufacturers with existing active NDRAs as of the applicable date of this notice have until September 30, 2018 to complete (including the CMS-367d), sign, and submit the updated NDRA. For manufacturers that do not meet this requirement, the Final Notice served as written notice of good cause to terminate their existing rebate agreement(s) on October 1, 2018, the first day of the full calendar quarter which begins at least six months after the effective date of the updated NDRA. As a courtesy, CMS will send manufacturers email reminders of the compliance deadline.

The Technical Contacts on file for manufacturers who are participating in the Medicaid Drug Rebate Program (MDRP) at the time the updated NDRA was published will be emailed a copy of the updated NDRA for review. Manufacturers with access to the Drug Data Reporting for Medicaid (DDR) system will also be able to obtain a copy of the updated NDRA on the DDR Bulletin Page, which will be available from the NDRA publication date through the compliance date, September 30, 2018, as referenced in the Final Notice.

Manufacturers will need to complete, sign, and submit a separate updated NDRA for each of their labeler codes. The updated NDRA's can be signed electronically and returned to CMS at drugrebateagreement@cms.hhs.gov. Manufacturers are no longer required to mail the original copy of the NDRA to CMS, rather they should retain the original copy of NDRA in their records. Once CMS has received and accepted a manufacturer's updated NDRA(s), the manufacturer will receive confirmation by e-mail, which will include a copy of their executed NDRA(s).

As discussed in the Final Notice, manufacturers that wish to participate in the MDRP are required to report all their covered outpatient drugs to CMS, regardless of labeler code. Therefore, all associated companies of the manufacturer that have covered outpatient drugs must enter into an NDRA in order to comply with the terms of the NDRA, found under section II, Manufacturer's Responsibilities, subsection (a) of the previous NDRA, and in section II, Manufacturer's Responsibilities, subsection (b) of the updated NDRA.

Upon publication of the updated NDRA, only manufacturers that are active in MDRP at the time the updated NDRA is published can sign and return the NDRA. Manufacturers that are not participating in the MDRP at the time will be subject to a new NDRA or reinstatement process that can be found at <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/national-drug-rebate-agreement/index.html>. Requests for a new NDRA or a reinstatement should be sent to drugrebateagreement@cms.hhs.gov.

If you have questions regarding the process of signing an updated NDRA or requesting a new rebate agreement or reinstatement, please contact drugrebateagreement@cms.hhs.gov. All other questions regarding the MDRP or the changes to the updated NDRA can be directed to RxDrugPolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group