DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 98**

For

Participating Drug Manufacturers

DRUG CATEGORY NARROW EXCEPTION GUIDANCE

In the Medicaid Program's Covered Outpatient Drug final rule with comment (CMS-2345-FC) ("Final Rule"), 81 FR 5170 (Feb. 1, 2016) at https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf, the Centers for Medicare & Medicaid Services (CMS) indicated that we plan to issue guidance regarding a narrow exception related to Drug Category.

As discussed in the Final Rule, in limited circumstances, certain drugs approved under a new drug application (NDA) might be more appropriately treated as if they were approved under an abbreviated new drug application (ANDA) and classified as noninnovator multiple source drugs. 81 FR 5191. Such drugs would thereby qualify for the narrow exception to the rule that drugs marketed under NDAs (including section 505(b)(2) NDAs), other than ANDAs, should be classified as either single source or innovator multiple source drugs. The goal of this guidance is to ensure that drugs that are or were required to be marketed under an original new drug application for technical reasons and that otherwise meet the definition of a non-innovator multiple source drug may be classified as such for MDR program purposes. If a manufacturer believes that a drug marketed under an NDA should qualify for the narrow exception, the manufacturer should submit materials to CMS demonstrating the basis of how the drug might be subject to the narrow exception to classify the drug as a noninnovator multiple source drug. Therefore, the following information is intended to assist manufacturers in determining the type of materials that should be submitted to CMS to demonstrate whether a drug marketed under an NDA, other than an ANDA, might fit the narrow exception to be classified as a noninnovator multiple source drug.

As discussed in the Final Rule, examples of drugs with NDA approvals which might be more appropriately treated as if they were approved under an ANDA and classified as noninnovator multiple source drugs are as follows:

- Certain parenteral drugs in plastic immediate containers, for which FDA required that an NDA be filed;

- Certain drugs approved under a paper NDA prior to the enactment of the Hatch-Waxman Amendments of 1984; and,
- Certain drugs approved under certain types of literature-based 505(b)(2) NDA approvals after the Hatch-Waxman Amendments of 1984.

The narrow exception will not be granted under the following circumstances:

- Drugs marketed under NDAs that were not approved under either the paper NDA process prior to 1984 or under certain types of literature based 505(b)(2) approvals, other than certain parenteral drugs in plastic immediate containers, for which FDA required that an NDA be filed; or,
- Drugs that received patent protection or statutory exclusivity, regardless of whether the protection or exclusivity is currently in effect.

Consistent with the MDR program, the determination as to whether the narrow exception applies for the classification of the drug will depend on the drug itself and NDA at issue, not the active ingredient in the drug. If a manufacturer has previously reported a drug marketed under an NDA as a noninnovator multiple source drug, that manufacturer is responsible for submitting materials to demonstrate how its drug might be subject to the narrow exception to be classified as a noninnovator multiple source drug. CMS will review these materials and confirm in writing that the narrow exception does apply to the drug, or state that the narrow exception does not apply. Where a Drug Category change is needed, CMS will provide instructions to the manufacturer detailing the process to implement that Drug Category change. Please note that manufacturers may not rely upon previous communications from CMS regarding Drug Category reporting that were provided prior to the publication of the Final Rule to justify their classification of a drug marketed under an NDA as a noninnovator multiple source drug.

Types of Possible Supporting Information:

If a manufacturer believes that one or more of its drugs qualifies for the narrow exception, the manufacturer should send a request for consideration to CMS at RxDrugPolicy@cms.hhs.gov with the title "Request for Narrow Exception Consideration." Examples of information that may accompany a request include the following:

- A copy of the Food and Drug Administration (FDA) approval letter for the NDA;
- Written communication, such as but not limited to letters or emails, provided by FDA to the manufacturer that would support the manufacturer's position;
- Information that indicates the drug never received patent protection or market exclusivity;
- Information about the reference drug, if any, that may have been used for the approval of the drug for which the manufacturer is seeking the narrow exception;
- Information about past or current therapeutic equivalents, if any, for the drug;
- Dates pertaining to the submission of the NDA to FDA and the subsequent approval of the drug, other than those dates that may have been provided in the FDA approval letter, and dates of approval of other drugs that may have significance to the manufacturer's request.

Manufacturers may submit additional pertinent information not mentioned above and CMS will consider that information.

Timeline for Exemption:

As stated in Final Rule, for drugs that are marketed under an NDA and are currently reported to the MDR program as noninnovator multiple source drugs, manufacturers will have four quarters after the effective date of the final rule, April 1, 2016, to submit materials to CMS demonstrating why the narrow exception should apply. 81 FR 5192. Therefore, all materials submitted to CMS to demonstrate how a drug might fit the narrow exception must be received by March 31, 2017. Please note that a manufacturer's submission of any or all of the information suggested above does not guarantee that an exception will be granted for the drug. Although CMS has allowed manufacturers four quarters to submit materials seeking approval for the narrow exception and to come into compliance before taking administrative action, drugs that are improperly reported as noninnovator multiple source drugs after March 31, 2017 may be subject to administrative action and the time period for administrative compliance does not relieve manufacturers of other potential liability.

Drugs reported to the MDR program for the first time on or after the effective date of Final Rule (i.e., April 1, 2016) as being marketed under an NDA should be reported and certified to CMS as single source or innovator multiple source drugs. If a manufacturer believes that a drug should qualify for the narrow exception, the manufacturer should submit materials as described above to CMS within one year of initially reporting the drug to the MDR program. This narrow one-year exception request window will also apply to reactivated drugs (i.e., drugs that were previously terminated by a manufacturer but the termination date is subsequently removed or changed to a future date). Manufacturers will have one year from the date on which a drug's Reactivation Date is certified to submit a narrow exception request along with all relevant materials. Until such time that CMS has completed its review of the submitted materials and provided confirmation in writing that the narrow exception does apply, manufacturers should report a drug approved under an NDA as single source or innovator multiple source, as applicable, in the MDR program.

If you have any questions regarding this release, please contact CMS at RxDrugPolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group