Administrative Policy Statement
(MEDICAID)

Policy Name	Policy Number	Date Effective
Medicaid Drug Rebate Program (MDRP) Coverage Rules - AC Reject	**PAD-0099-GA-MCD**	**07/26/2022**

Policy Type			
Medical	**ADMINISTRATIVE**	**Pharmacy**	**Reimbursement**

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A. Subject

Medicaid Drug Rebate Programs (MDRP) agreement requirements, covered outpatient drugs and the AC pharmacy claims reject code

B. Background

This policy serves as guidance for CareSource pharmacy staff on the Medicaid Drug Rebate Program as it relates to the definition of covered outpatient drugs and conditions for claims payment.

C. Definitions

I. Covered Outpatient Drug (COD) - A drug which may be dispensed only upon a prescription and is "*treated as a prescribed drug for the purposes of section 1905(12)"* of the Social Security Act, (with the exception of those defined in paragraphs II and III, Section E. [Conditions of Coverage] below).

II. Medicaid Drug Rebate Program (MDRP) - A program that includes Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers to help offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients.

III. National Drug Rebate Agreement (NDRA) - An agreement entered into by a drug manufacturer with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs.

IV. Section 340B Drug Pricing Program - A discount drug pricing program under Section 340B of the Public Health Service Act that "requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients".

V. Federal Supply Schedule (FSS) - Also known as General Services Administration Schedule (GSA), and Multiple Award Schedule (MAS), is a "long-term governmentwide contract with commercial companies that provides access to millions of commercial products and services at fair and reasonable prices to the government".

VI. National Council for Prescription Drug Programs (NCPDP) Reject Code - A type of reject error code received by a pharmacy upon processing a prescription.

VII. Manufacturer - Any entity that is "engaged in:-

(A) The production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. Such term does not include a "wholesale distributor of drugs or a retail pharmacy licensed under State law."

D. Policy

I. In order for a drug to be eligible for coverage by Medicaid under the Medicaid Drug Rebate Program (MDRP) it has to meet two requirements:

A. It has to **meet the definition of a covered outpatient drug (COD)** under Section 1927 of the Social Security Act which states the requirements for rebate agreements.
B. The **manufacturer must have** entered into and have in effect, on the date of service dispensed, **the following agreements**:
   i. A National Drug Rebate Agreement (NDRA);
   ii. A pricing agreement for the Section 340B Drug Pricing Program administered by the Health Resources and Services Administration; AND
   iii. A master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule (FSS).

II. **AC Reject Code**

a. Pharmacy claims not eligible for reimbursement due to not meeting CMS MDRP requirements will reject at the pharmacy with the following Pharmacy NCPDP Reject Code and Reject Code Description:

AC - Product Not Covered Non-Participating Manufacturer;

Manufacturer is not participating in drug rebate on date of service dispensed.

E. Conditions of Coverage

I. "A drug can only be considered a covered outpatient drug if it:

A. Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;

B. Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the

meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that

it is a "new drug" (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

C. Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw

approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

D. Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

E. Is insulin certified under section 506 of the FFDCA.

II. "A covered outpatient drug <u>does not</u> include:

A. Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;

B. Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph I, Section E. Conditions of Coverage above;

C. Any drug product or biological used for a medical indication which is not a medically accepted indication;

D. Over-the-counter products that are not drugs".

III. "A covered outpatient drug <u>does not</u> include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug):

A. Inpatient Services;

B. Hospice Services;

C. Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;

D. Physician services;

E. Outpatient hospital services;

F. Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;

G. Other laboratory and x-ray services; or

H. Renal dialysis."

IV. In exchange for state Medicaid coverage of most of a manufacturer's drugs, "rebates are paid by these drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program".

F. Related Policies/Rules

G. Review/Revision History

DATES		ACTION
Date Issued	**01/22/2022**	
Date Revised		
Date Effective	**07/26/2022**	
Date Archived		

H. References

1. Legal Information Institute. 42 CFR § 447.502 – Definitions. Retrieved June 8, 2022 from www.law.cornell.edu

2. Social Security. Compilation of The Social Security Laws. Payment for Covered Outpatient Drugs. Retrieved June 7, 2022 from www.ssa.gov

3. Medicaid Drug Rebate Program (MDRP). Retrieved June 8, 2022 from www.medicaid.gov

4. American Hospital Association. Fact Sheet: The 340B Drug Pricing Program. Retrieved June 8, 2022 from www.aha.org

5. U.S. General Services Administration. About GSA Schedule. Retrieved June 8, 2022 from www.gsa.gov

The Administrative Policy Statement detailed above has received due consideration as defined in the Administrative Policy Statement Policy and is approved.