# Admin

## 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 ñ*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 manufacturerôs drugs

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

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

(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 ñwholesale distributor of drugs or a retail pharmacy licensed under State law.

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 ñew drugò(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;

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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.ò

IV. In exchange for state Medicaid coverage of most of a manufacturerôs drugs, ñrebates 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 Programò

## F. Related Policies/Rules

## G. Review/Revision History

| DATES | ACTION |
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## H. References

1. Legal Information Institute. 42 CFR § 447.502 ï 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.**