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Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 178**

For State Technical Contacts

Defining a "Prescribed Drug" and a "Covered Outpatient Drug"

For purposes of Medicaid, there are various terms used in describing a drug. This release provides the legal definition of the terms "prescribed drugs" and "covered outpatient drug" along with some explanation and examples provided. Additionally, the attachment following this release is a visual schematic of how a covered outpatient drug relates to the more general term "prescribed drug."

In the context of a state plan for medical assistance, 42 CFR §440.120 defines "prescribed drugs" that may be covered by a state Medicaid program and claimed on the CMS-64 form for the purposes of claiming Federal Financial Participation (FFP). It is not required that a product meet the definition of a covered outpatient drug in order for it to be eligible for FFP. However, if a product meets the definition of a covered outpatient drug, but the manufacturer of such drug does not have a rebate agreement in effect, that drug is not eligible for FFP and may not be claimed on the CMS-64 form, even though the drug may meet the definition of a prescribed drug.

Prescribed Drugs

We remind states that the regulatory definition for "prescribed drugs" is found at 42 CFR §440.120:

"Prescribed drugs" means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are—

(1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;

(2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

(3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.

Covered Outpatient Drugs

To understand the basis of covered outpatient drugs, it is important to note both the statutory definition at section 1927(k)(2)-(4)) of the Social Security Act, which is codified in regulation at 42 C.F.R. 447.502:

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (4)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act[222] or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations[223]) to such a drug, and (II) 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 Federal Food, Drug, and Cosmetic Act[224]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii)(I) which 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 of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section 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; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 351 of the Public Health Service Act, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) Limiting definition.—The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital 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) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) Nonprescription drugs.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

Based on the legal definitions provided, we emphasize that the definition of "prescribed drugs" includes products that may not be considered drugs:

- For example, if an over-the-counter vitamin was prescribed by a physician in order to treat or prevent a disease, and dispensed by a licensed authorized practitioner to the individual based on that prescription, that vitamin is a "prescribed drug" and may be covered by a state Medicaid plan.
- Similarly, insect repellents that may be used to prevent Zika virus are not drugs per se, but if an insect repellent is prescribed by a physician for a Medicaid beneficiary in order to prevent disease, and dispensed by a licensed authorized practitioner based on that prescription, then it is also a "prescribed drug."
- Extemporaneously compounded prescriptions do not meet the definition of "covered outpatient drug," nor do active pharmaceutical ingredients that may be used in the creation of a compounded prescription. However, compounded prescriptions may meet the definition of "prescribed drugs" and therefore are eligible for FFP.

If a product meets the regulatory definition of “prescribed drug”, it may be covered by a state, and is eligible for FFP. If a state chooses to cover a “prescribed drug”, even if it is not a “covered outpatient drug”, FFP is available. Rebates, however, are only available on a “covered outpatient drug” from manufacturers with a rebate agreement in effect. Expenditures for both “prescribed drugs” and “covered outpatient drugs” should be reported on Line 7 - Prescribed Drugs of the CMS-64 form,

Thus, "covered outpatient drugs" are a subset of prescribed drugs. If a “prescribed drug” is also a “covered outpatient drug, it must be covered by a state Medicaid program, subject to appropriate utilization management techniques. Only those prescribed drugs that are also covered outpatient drugs are eligible for manufacturer rebates when the manufacturer has a rebate agreement in effect.

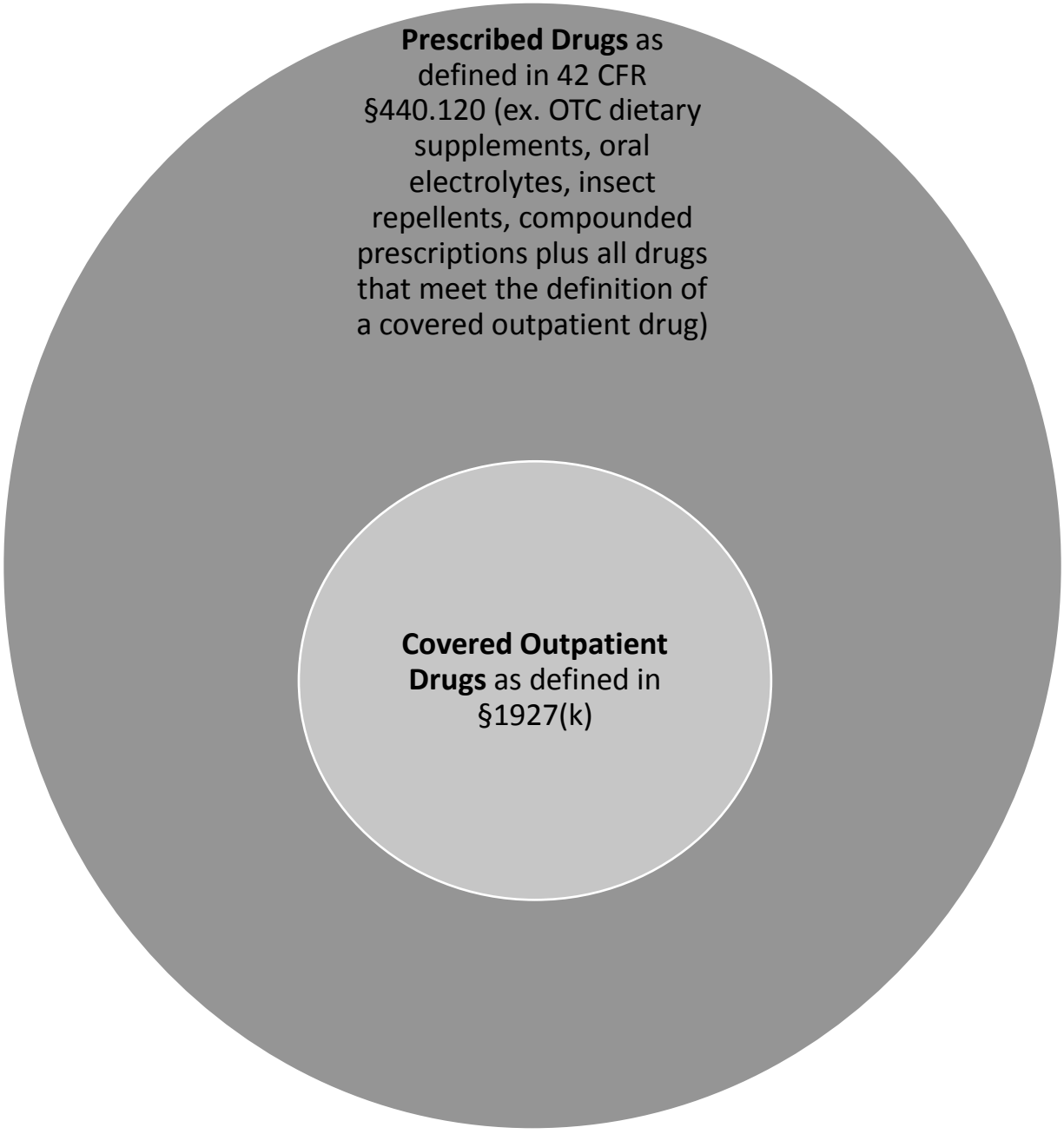
If you have further questions regarding the definition of prescribed drug versus covered outpatient drug, please contact us at rxdrugpolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group

Attachment


Prescribed Drugs as defined in 42 CFR §440.120 (ex. OTC dietary supplements, oral electrolytes, insect repellents, compounded prescriptions plus all drugs that meet the definition of a covered outpatient drug)
Covered Outpatient Drugs as defined in §1927(k)