NEW YORK STATE | Department of Health | Office of Health Insurance Programs

CMS Medicaid and CHIP Managed Care Final Rule

Monica M. Toohey
Supervising PPh. NYS DOH

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CMS Medicaid and CHIP Managed Care Final Rule Pharmacy Overview

Purpose:

- To review and clarify areas pertaining to the Covered Outpatient Drugs (COD) within the CMS Final Rule with the Managed Care Plans.
- To update MC contracts to ensure compliance.

Framework for Medicaid Managed Care Prescription Coverage

In accordance with sections 1902 and 1903 of the Social Security Act (the Act):

- To review and clarify areas pertaining to the Covered Outpatient Drugs (COD) within the CMS Final Rule with the Managed Care Plans.
- To update MC contracts to ensure compliance.

Statutory Basis for Pharmacy Provisions of Managed Care Regulatory Changes

- The proposed managed care standards are based primarily on section 1903(m)(2)(A)(xiii) of the Act which provides, in part, that covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the (rebate) agreement entered into under section 1927.

- Section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

§ 1927 Requirements for Managed Care Plans that Provide Covered Outpatient Drugs

Covered Outpatient Definition 1927 (k) (2)-(4):

- Those drugs which are treated as a prescribed drug for the purposes of section 1905(12) of the act, a drug which may be dispensed only upon a prescription and:
  - Are approved for safety & effectiveness as a prescription drug under the Federal Food Drug & Cosmetic Act;
  - Was commercially used or sold in the US before date of the enactment of the Drug Amendments of 1962 and has not been the subject of a final determination by the Secretary that it is a “new drug” or an action brought by the Secretary or for which the secretary has determined there is compelling justification for its medical need. https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/default.htm and;
- A biological Product, other than a vaccine
- Insulin

§ 1927 Requirements for Managed Care Plans that Provide Covered Outpatient Drugs

The term does not include;

- Inpatient Hospital Services
- Any such drug or product for which an NDC is not required by the FDA
- The following outpatient services <u>when payment for such are included in a bundled rate for the service and not as direct reimbursement for the drug:</u>
  - ✓ Hospice Services*
  - ✓ Dental Services, except drugs*
  - ✓ Physician Services*
  - ✓ Outpatient Hospital services*
  - ✓ Nursing Facility Services & Services provided by an Intermediate Care Facility for the Mentally Retarded*
  - ✓ Other Laboratory & X-Ray Services*
  - ✓ Renal Dialysis*

NYS Medicaid FFS provides direct reimbursement for some or all of the drugs in these settings, and therefore these drugs are considered Covered Outpatient Drugs.

- "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.

§ 1927 Requirements for Managed Care Plans that Provide Covered Outpatient Drugs

Medicaid contracts with MCOs must meet the requirements of section 1927 of the Act when providing coverage of covered outpatient drugs.

- **Requirements for Rebate agreement-** Managed care plans are subject to the same rebate required by the agreement entered into under section 1927 (a) as the State is subject to.
  - **Medicaid FFS Formulary- https://www.emedny.org/info/formfile.aspx**
- **Limitations on Coverage of Drugs-** May exclude or restrict coverage of a covered outpatient drug if:
  - it is not for a medically accepted indication (k)(6);
  - not a rebate signer (a)(1) & (a)(4) or;
  - with respect to the treatment of a specific disease or condition for an identified population (if any) only if the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion (d)(4).

§ 1927 Requirements for Managed Care Plans that Provide Covered Outpatient Drugs

States can determine coverage of the following excludable drugs or classes of drugs, or their medical uses, subject to State Plan approval (NYS Medicaid approved coverage, if applicable, is noted):

- ✓ Agents when used for anorexia, weight loss, weight gain **– NONE**
- ✓ Agents when used to promote fertility **– NONE**
- ✓ Agents when used for the symptomatic relief cough and colds: **SOME - benzonatate only**
- ✓ Prescription vitamins and mineral products, except prenatal vitamins and fluoride: **SOME - select B Vitamins (niacin, pyridoxine, thiamine, cyanocobalamin); Folic Acid; Vitamin K; Vitamin D (ergocalciferol, cholecalciferol); Iron (including polysaccharide iron complex); Iodine**
- ✓ Nonprescription drugs: **SOME – select allergy, asthma and sinus products; analgesics; cough and cold preparations; digestive products; insulin; feminine products; topical products, minerals and vitamin combinations**
- ✓ Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee – **NONE**
- ✓ Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a medical condition, other than sexual or erectile dysfunction for which the agents have been approved by the FDA. –**Adcirca, Revatio- PDE-5 Inhibitors for PAH**

https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-179.pdf

§ 1927 Requirements for Managed Care Plans that Provide Covered Outpatient Drugs

Drug Utilization Review-

- Conduct a drug use review program described in (g)(2) & section 1903(i)(10)(B), for covered outpatient drugs in order to assure that prescriptions:
    - (i) are appropriate;
    - (ii) are medically necessary and;
    - (iii) are not likely to result in adverse medical results.
- The program shall be designed to educate physicians and pharmacists to identify and reduce:
    - the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as;
    - potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.
- This also includes a DUR annual report (g)(3)(d)

§438.3(s) Prescription Drug Coverage

The managed care plan's contract must ensure that:

- The managed care plan's drugs are covered outpatient drugs in accordance with section 1927(k)(2) of the Act and meet the standards for coverage under section 1927 of the Act;
- The managed care plan reports drug utilization data to the states to enable billing for Medicaid drug rebates;
- The managed care plan has procedures in place to allow for the exclusion of utilization data from rebate invoicing for covered outpatient drugs that are subject to 340B discounts;
- The managed care plan operates a drug utilization program that complies with the requirements of section 1927(g) of the Act, provides a description of the DUR activities to the state on an annual basis, and conducts a prior authorization program, when applicable, consistent with the minimum requirements set forth at section 1927(d)(5) of the Act.

§438.3(s) Prescription Drug Coverage Continued

- **438.3(s)(1)-**the MCO must provide coverage of covered outpatient drugs (as defined in section 1927(k)(2) of the Act) as specified in the contract and in a manner that meets the standards for coverage of such drugs imposed by section 1927 of the Act.
    - 1927(k)(2)- those drugs treated as prescribed drugs which may be dispensed on a prescription, with exceptions.

- **438.3(s)(2)-** MCOs must report drug utilization data necessary for the state to submit utilization data under section 1927(b)(2) of the Act and within 45 calendar days after the end of each quarterly rebate period to ensure that MCO data is included in utilization data submitted by states to manufacturers. Such utilization information must include, at a minimum, information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO.

- **438.3(s)(3)-** The MCO must have procedures in place to allow for the exclusion of utilization data from rebate invoicing for drugs subject to discounts under the 340B Drug Pricing Program. Encounter data for 340B drug claims shall be tagged as 340B in accordance with SDOH requirements. The contractor or its designee must ensure that all 340B entities and/or pharmacies have their 340B drug claims identified properly – either upon original submission or through adjustments – no later than 45 days after the end of each quarterly rebate period.
    - https://www.health.ny.gov/health_care/medicaid/program/update/2016/dec16_mu.pdf

§438.3(s) Prescription Drug Coverage Continued

- **438.3(s)(4)-** The MCOs must operate a DUR program that is consistent with the standards in section 1927(g) of the Act; this standard means that the DUR program operated by the MCO would be compliant with section 1927(g) of the Act if it were operated by the state in fulfilling its obligations under section 1927 of the Act. This can also be found under 42 CFR part 456, subpart K.
  - Section 1927(g)(1)(A) of the Act requires that the state's DUR program assures that prescriptions are: appropriate; medically necessary; and not likely to result in adverse medical results.
  - 42 CFR 456, Subpart K further defines the DUR program in three sections: Prospective DUR, Retrospective DUR and an Educational Program.
- **438.3(s)(5)-** The MCO would have to provide a detailed description of its DUR program activities to the state on an annual basis. The purpose of the report is to ensure that the parameters of section 1927(g) of the Act are being met by the MCO's DUR program, as proposed under paragraph 438.3(s)(4).
- **438.3(s)(6)-** The MCO must conduct a prior authorization process for covered outpatient drugs in accordance with section 1927(d)(5) of the Act; authority under section 1902(a)(4) of the Act. The MCO would provide a response to a request for prior authorization for a covered outpatient drug by telephone or other telecommunication device within 24 hours of the request and dispense a 72 hour supply of a covered outpatient drug in an emergency situation.

Additional Items of Note:

- **§438.10 (i)-** The MCOs and PCCM entities provide their medication formularies electronically or on paper, if requested. The formulary must display all covered medications, both generic and brand name, and have the tier of each medication. Additionally, the MCO formulary drug lists must be made available on the MCO's and or if applicable the entity's Web site in a machine readable file and format as specified by the Secretary.

- **§438.210 (d)(3)-** The MCO's, in accordance with SSA 1927(d)(5)(A) must ensure all covered outpatient drug authorization decisions be provided by telephone or other telecommunications device within 24 hours of a request for authorization. Authorization and noticing requirements was provided to plans in separate guidance.

Summary

- When within the scope of the contract, drug coverage must meet the standards in 1927 of the Act, including reporting of drug utilization data to enable billing of rebates, procedures in place to allow for the exclusion of utilization data from rebate invoicing for drugs subject to discounts under the 340B Drug Pricing Program, and operating a drug utilization program (including providing a description of the DUR activities to the state annually).
- Managed care plans have the flexibility to maintain their own preferred drug lists (PDLs) or formularies and apply their own utilization management practices (i.e. quantity limits and days supply) in accordance with the requirements of section 1927 of the Act.
- Managed care plans need to ensure all covered outpatient drugs (formulary and non-formulary) are covered in accordance with the requirements of section 1927 of the Act.
- If the managed care plan's formulary or PDL does not include a covered outpatient drug that is otherwise covered by the state plan, access to the off-formulary covered outpatient drug must be aligned with the prior authorization requirements at 1927(d)(5).
- Managed care plans are subject to the same rebate required by the agreement entered into under section 1927 (a) as the State is subject to and Managed care must submit utilization data under section 1927(b)(2) of the Act within 45 calendar days after the end of each quarterly rebate period.

Resources

- § 1927- https://www.ssa.gov/OP_Home/ssact/title19/1927.htm
- Medicaid & CHIP Managed Care Final Rule- https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered
- § 1903- https://www.ssa.gov/OP_Home/ssact/title19/1903.htm
- CMS Medicaid & CHIP Managed Care Final Rule Covered Outpatient Drug Presentation- https://www.medicaid.gov/medicaid/managed-care/downloads/mco-cod-presentation.pdf

Questions

Please submit questions to:

PPNO@health.ny.gov