



# Medicaid and CHIP Managed Care Final Rule (CMS-2390-F)

## Covered Outpatient Drugs

*Center for Medicaid and CHIP Services*



# Background

This final rule is the first update to Medicaid and CHIP managed care regulations in over a decade. The health care delivery landscape has changed and grown substantially since 2002.

- Today, the predominant form of Medicaid is managed care, which are risk-based arrangements for the delivery of Medicaid services
- Many States have expanded managed care in Medicaid to enroll new populations, including seniors and persons with disabilities who need long-term services and supports, and individuals in the new adult eligibility group
- In 1998, 12.6 million (41%) of Medicaid beneficiaries received at least some Medicaid benefits through managed care plans
- In 2013, 45.9 million (73.5%) of Medicaid beneficiaries received at least some Medicaid benefits through managed care (MCOs, PIHPs, PAHPs, PCCMs)

# Goals of the Final Rule

This final rule advances the agency's mission of *better care, smarter spending, and healthier people*

## Key Goals

- To support State efforts to advance **delivery system reform** and **improve the quality of care**
- To strengthen the **beneficiary experience of care** and key beneficiary protections
- To strengthen program integrity by **improving accountability and transparency**
- To **align** key Medicaid and CHIP managed care requirements with other health coverage programs

# Key Dates

- Publication of Final Rule
  - On display at the **Federal Register** on April 25th
  - Published in the **Federal Register** May 6<sup>th</sup> (81 FR 27498)
- Dates of Importance
  - Effective Date is July 5<sup>th</sup>
  - Provisions with implementation date as of July 5th
  - Phased implementation of new provisions primarily over 3 years, starting with the rating period for contracts starting on or after July 1, 2017
  - Compliance with CHIP provisions beginning with the SFY starting on or after July 1, 2018
  - Applicability dates/Relevance of some 2002 provisions

# Resources

- Medicaid.gov – Landing and Managed Care Pages
  - Link to the Final Rule
  - 8 fact sheets and implementation timeframe table
  - Link to the CMS Administrator’s “Medicaid Moving Forward” blog
- ManagedCareRule@cms.hhs.gov to submit questions on the final rule

# SOTA AGENDA

## CMCS Division of Pharmacy

- CMS-2345-FC Applicability to CMS-2390-F and Background Information
- MCOs, PIHPs, or PAHPs that Provide Covered Outpatient Drugs §438.3 (s)<sup>^</sup>
  - Prescription Drug Coverage
  - Managed Care Drug Utilization Data Reporting
  - Exclusion of 340B Drug Utilization Data
  - Drug Utilization Review (DUR)
  - DUR Program Annual Report
  - Prior Authorization Process

<sup>^</sup> For the purposes of this presentation, MCO, PIHP and PAHP are collectively referred to as Managed Care Plans or MCOs.

# Covered Outpatient Drug Rule

## CMS-2345-FC

- NPRM published February 2, 2012.
- Effective date of final rule - April 1, 2016
- CMS sent out a State Medicaid Director's Letter on February 11, 2016 regarding "Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program."

# Covered Outpatient Drug Definition

- CMS-2390-F has incorporated the definitions in §447.502 to covered outpatient drugs in part 438.3(s).
- A drug is considered a Covered Outpatient Drug when the drug may be dispensed only upon prescription and if it meets at least one of the criteria as described in section 1927(k)(2) of the Act.

# Statutory Basis for Pharmacy Provisions of MCO Regulation

## §438.3(s) Requirements for Managed Care Plans that Provide Covered Outpatient Drugs:

- The 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.

# Framework for Medicaid MCO Prescription Drug Coverage

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

- Prescription drug coverage under Medicaid MCOs should demonstrate coverage consistent with the amount, duration, and scope as described by Medicaid Fee-For-Service (FFS).
- MCOs can not have medically necessary criteria for prescription drugs that are more stringent than Medicaid FFS.

# Prescription Drug Coverage

- **§438.3(s)(1)** requires that MCOs and other managed care plans must provide coverage of covered outpatient drugs as specified in the contract.
- Coverage of such drugs must meet the criteria set forth in the definition of covered outpatient drugs at section 1927(k)(2) of the Act.
- If a managed care plan is not contractually obligated to provide coverage of a particular covered outpatient drug, or class of drugs, the state is required to provide the covered outpatient drug through Fee for Service (FFS) that is consistent with the state plan.

# Prescription Drug Coverage

- CMS clarified the specific requirements that either the state, or managed care plan must adopt to ensure the availability of, and access to, equivalent covered outpatient drug services.
  - These requirements are not new to states (§438.210).
  - States may continue to prior authorize drugs consistent with the requirements in 1927(d)(5) and provide drugs for medically accepted indications as defined in the Act at 1927(k)(6).

# Prescription Drug Coverage

## Managed Care Contractual Obligations

- Each state may determine covered outpatient drug coverage either as part of the capitated contractual services or as a carve out.
- A managed care plan that agrees to provide coverage of a subset of covered outpatient drugs under the contract with the state would need to provide coverage of every covered outpatient drug included in the subset when the manufacturer of those drugs entered into a rebate agreement.
- States are required to provide coverage of outpatient drugs that are not included in the managed care plan's contract and the state may meet this obligation through FFS or another delivery system.

# Prescription Drug Coverage

## Managed Care Contractual Obligations

- “Within the scope of the contract” are terms negotiated between the state and the managed care plan to administer the covered outpatient drug benefit to Medicaid enrollees.
- 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 exclude utilization associated with 340B drugs, and operating a drug utilization program (including providing a description of the DUR activities to the state annually).

# Formularies/PDLs

- 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 are covered unless the drug is contractually carved out of the pharmacy benefit.

# Formularies/PDLs

- 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).
- It is incumbent upon the states and managed care plans to address formulary/PDL requirements in their contract documents. Each party must clearly understand their responsibilities and requirements when administering the Medicaid covered outpatient drug benefit.

# Payment

- Payment terms negotiated between a managed care plan and its network pharmacies are outside the scope of this final rule.
- Payments terms are negotiated as part of the contract between the managed care plan and its participating providers.
  - Actual Acquisition Cost (AAC) methodology not required.
  - FULs (Federal Upper Limit) does not apply to MCO
  - National Average Drug Acquisition Cost (NADAC) can be used by, but not mandated.
  - Dispensing fees paid by managed care plans fall under the negotiated contract terms.

# Access and Payment

- **Access –**
  - Each managed care plan must ensure that its enrollees have access to pharmacy services when covered by the Medicaid contract and that the pharmacy network is consistent with the access standards for delivery networks.
  - CMS requires states to ensure that provider payment rates are at levels that help to preserve enrollee access once the pharmacy benefit is transitioning from FFS to managed care plans.
  - Section 438.68 of the MCO Rule stipulates states must establish network adequacy, specifically time and distance standards.

# Managed Care Drug Utilization Data Reporting & Deadlines

- **§438.3(s)(2)** requires implementation of section 1903(m)(2)(A)(xiii)(III) of the Act.
  - Managed care plans submit utilization data under section 1927(b)(2) of the Act within 45 calendar days after the end of each quarterly rebate period. **45 calendar days is the maximum limit. States and managed care organizations may negotiate a different limit.**
    - The 45 calendar day timeframe ensures managed care plan data is included in state utilization data submitted to manufacturers.
    - Utilization data must include, at a minimum, information on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the managed care plan.
- States are required to submit utilization data to manufacturers for rebates **no later than 60 days** after the end of each rebate period (quarter).

# Managed Care Drug Utilization Data Reporting & Deadlines

- In accordance with section 1927(b)(2)(A) of the Act:
  - Manufacturers must pay rebates on drugs dispensed to individuals enrolled in a managed care plan.
  - States and their managed care plans should report their utilization data based upon the quarter in which **the drug was dispensed** (date of service) to the enrollee, as opposed to the quarter in which the managed care plan paid the claim. CMS understands that there are operational issues involved in bringing managed care reporting into compliance with the specification that reporting must be based on the date of dispense.
  - CMS will use its enforcement discretion and **will not** hold states out of compliance with date of dispense reporting as long as states come into compliance by **July 1, 2017**, which is the effective date of this rule (CMS-2390-F).
  - See link for State Release #177 found on the Pharmacy Links page for further information.

# Exclusion of 340B Drug Utilization Data & Reporting

- **§438.3(s)(3)** requires that the managed care plans must have procedures in place to exclude utilization data for drugs subject to discounts under the 340B Drug Pricing Program when states do not require submission of managed care drug claims data from covered entities directly.
- This provision extends to managed care organizations as Section 2501 (c) of the ACA modified section 1927(j)(1) of the Act to specify that covered outpatient drugs **are not subject** to the rebate requirements if such drugs are both subject to discounts under section 340B of the PHS Act and dispensed by HMOs, including Medicaid MCOs.
- Under 438.3(s)(3), managed care plans must exclude 340B drug utilization in their reporting to the states to avoid manufacturers paying duplicate discounts.

# Ways to Identify 340B Drug Claims

States have flexibility to determine with their managed care plans how to identify 340B claims. Please note that all entities play a role in ensuring Medicaid rebates are not paid on 340B drugs.

- States may mandate that their managed care plans require covered entities and their contract pharmacies to use 340B identifiers on either paper or electronic prescriptions.
- Managed care plans may include in their contracts with pharmacy providers billing instructions when identifying 340B claims, such as the use of NCPDP standard modifier - the value of 2Ø in field Submission Clarification Code (42Ø- DK) in the Claim Segment of a Claim Billing (B1) transaction.

# Drug Utilization Review (DUR) Program Requirements

- **Section 438.3(s)(4)** requires managed care plans that provide coverage of covered outpatient drugs to also operate a DUR program that complies with the requirements at 1927(g) of the Act.
- The managed care plans does not have to adopt the same DUR activities that the state's FFS program enacts.
- 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.

# DUR Program Requirements

- The DUR 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.
- **42 CFR 456, Subpart K** further defines the DUR program in three sections:
  - Prospective DUR
  - Retrospective DUR and
  - An Educational Program
- DUR helps to ensure appropriate prescribing of medications and improves the quality of care of the beneficiary.
- States need to ensure MCO contracts beginning July 1, 2017 and thereafter include language on the above DUR requirements.

# DUR Program Annual Report to the State

- **Section 438.3(s)(5)** requires managed care plans to provide a detailed description of its DUR program activities to the state on an annual basis.
- The purpose of the DUR Annual report is to ensure that managed care plans (MCOs, PIHPs and PAHPs) meet the parameters of section 1927(g) of the Act.
- States need to ensure that their MCO contracts beginning July 1, 2017 and thereafter include language on their DUR annual reporting requirements.

# Prior Authorization

- **Section §438.3(s)(6)** stipulates that MCOs conduct the prior authorization process for covered outpatient drugs in accordance with section 1927(d)(5).
  - Prior authorization processes intend to impart cost savings by preventing unnecessary prescribing of medically inappropriate drugs.
  - Managed care plans are required to provide a response to a prior authorization request for a covered outpatient drug by telephone or other telecommunication device within 24 hours of the request and the dispensing of at least a 72 hour supply of a covered outpatient drug in an emergency situation.
- Managed care plans have the flexibility to maintain their own prior authorization procedures in accordance with the standards of section 1927 (d)(5) of the Act.

# Division of Pharmacy Links

- <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/covered-outpatient-drugs-policy.html>.
- <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/program-releases.html>.
- <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/drug-utilization-review.html>.
- <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/program-releases.html>.

# Questions



# Additional Questions?

Please send additional questions to the mailbox dedicated to this rule:

[ManagedCareRule@cms.hhs.gov](mailto:ManagedCareRule@cms.hhs.gov)

While we cannot guarantee individualized responses, inquiries will inform future guidance and presentations