DOCUMENT HISTORY

STATUS	DOCUMENT REVISION	EFFECTIVE DATE	DESCRIPTION
Baseline	1.0	7/1/2023	Initial version, EOHHS Medicaid Managed Care Manual Chapter 2.1, 340 B Policies and Procedures
Revision			

Purpose

The purpose of this Policy is to outline the procedures for 340B claims submission and responsibilities of Medicaid Managed Care Organizations (MCOs) to ensure that 340B Drug Pricing Program claims are coded, submitted and reported accurately to the Executive Office of Health and Human Services (EOHHS) to prevent duplicative discounts, in accordance with the *Contract Between The State of Rhode Island Executive Office of Health and Human Services and Medicaid Managed Care Services Organization.* The MCO must meet all Contractual, State and Federal requirements for submitting 340B billing claims.

Policy

The Medicaid Drug Rebate Program and the 340B Drug Pricing Program both require drug manufacturers to provide discounts on their products covered entities and Medicaid Managed Care Organizations. Under the Medicaid Drug Rebate Program, discounts are provided in the form of rebates from drug manufacturers on covered outpatient drugs paid for by state Medicaid programs. Under participation in the 340B Drug Pricing Program, drug manufacturers are required to sell drugs to participating providers at a significantly reduced price to covered entities, as defined in Section 340B(a)(4) of the Public Health Service Act. States may not claim a Drug Rebate for a drug that was purchased under the 340B Drug Pricing Program. This is known as the prohibition on duplicate discounts and ensures that drug manufacturers are not paying two separate discounts on the same drug.

In accordance with the *Contract Between The State of Rhode Island Executive Office of Health and Human Services and Medicaid Managed Care Services Organization*, for reports described in Section 2.12.03.02.01, MCOs are required to "establish procedures to clearly identify utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from these reports to enable EOHHS to accurately bill for the rebate."

This policy sets forth 340B policy requirements for the MCOs to provide oversight of covered entities contracted with the MCO to ensure accurate reporting of 340B claims. MCOs are responsible for ensuring adherence with the procedures for billing and reporting 340B claims by covered entities. MCOs will conduct oversight of covered entities, as described herein and may be subject to penalties for non-compliance of covered entities as described in Section IV of this policy.

Definitions

Actual Acquisition Cost (AAC) – In accordance with 42 CFR, Section 447.502, actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Contract Pharmacy – A pharmacy that is contracted with the MCO and, in accordance with HRSA guidelines, contracts with a covered entity to dispense 340B drugs to eligible patients on the covered entity's behalf. Contract pharmacies must register for the 340B Program and be listed on the 340B OPAIS prior to dispensing 340B drugs on a covered entity's behalf. Covered entity owns and purchases drugs.

Covered Entity – As used herein, in accordance with 42 CFR, Section 10.3, means an entity that is listed within section 340B(a)(4) of the Public Health Service Act (PHSA), meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database.

In-House Pharmacy – Covered entity (see definition of Covered Entity herein) owns drugs, pharmacy, and pharmacy license. Covered entity has responsibility for drug purchases; fiscal responsibility for pharmacy and drug dispensing.

MCO – Medicaid Managed Care Organization contracted with EOHHS under the *Contract Between the State of Rhode Island Executive Office of Health and Human Services and Medicaid Managed Care Services Organization*.

Physician Administered Drugs – Drugs dispensed by licensed covered entity (see definition of Covered Entity herein) providers. Covered entity owns drugs and employs providers licensed to dispense drugs in the State, in accordance with the 340B Drug Pricing Program.

Section 1: Covered Entity Procedures

To participate in the 340B Drug Pricing Program, eligible covered entities must register and be enrolled with the 340B Program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that drug manufacturers verify before allowing a covered entity to purchase a 340B-eligible drug at a discounted price.

The following section outlines the procedural requirements for submission of 340B Drug Pricing Program claims by covered entities.

A covered entity may dispense drugs that were purchased at 340B discounted prices to Medicaid managed care beneficiaries through three dispensing methods: 1) in-house pharmacies; 2) physician-administered drugs; or 3) contract pharmacies.

A. In-House Pharmacy

Covered entities with in-house pharmacies must comply with the coding and billing requirements detailed below.

For all applicable 340B drug products, in-house pharmacies must identify claims as follows:

- In field '420- DK' (Submission Clarification Code), a value of '20' must be included indicating that the pharmacy has determined the drug products submitted to the MCO/MCO Pharmacy Benefit Manager (PBM) were purchased pursuant to rights available under Section 340B of the Public Health Act of 1992 including sub-ceiling purchases authorized by Section 340B (a) (10) and those made through the Prime Vendor Program (Section 340B (a) (8)).
- The ingredient cost must be billed at the actual acquisition cost (AAC).

B. Physician Administered Drugs

Covered entities must comply with the coding and billing requirements detailed below for physician administered drugs that were purchased at 340B discounted prices.

Physician administered 340B drugs must be billed:

- Using a "UD" modifier, in addition to the corresponding Healthcare Common Procedure Coding System (HCPCS) and National Drug Code (NDC), on a CMS 1500 Health Insurance Claim Form or Uniform Billing (UB04) Form, in order to identify a 340B purchased drug.
- The ingredient cost must be billed at the actual acquisition cost (AAC).

C. Contract Pharmacies

Covered entities must ensure compliance with the coding requirements detailed below for its contract pharmacies.

For all applicable 340B drug products, contract pharmacies must identify claims as follows:

- In field '420- DK' (Submission Clarification Code), a value of '20' must be included indicating that the contract pharmacy has determined the drug products submitted to the MCO/PBM were purchased pursuant to rights available under Section 340B of the Public Health Act of 1992 including sub-ceiling purchases authorized by Section 340B (a) (10) and those made through the Prime Vendor Program (Section 340B (a) (8)).
- The ingredient cost must be billed at the actual acquisition cost (AAC).

Section 2: MCO Responsibilities

The MCO must identify utilization data for covered outpatient drugs that are subject to discounts under the 340B Drug Pricing Program, dispensed by covered entities. MCOs must ensure covered entities contracted with MCOs are accurately reporting 340B claims. MCOs are responsible for ensuring adherence with the procedures for billing and reporting 340B claims by covered entities. The MCO will conduct oversight of covered entities, as described herein and may be subject to penalties for non-compliance of covered entities as described in Section IV of this policy.

The MCO must have policies and procedures in place to ensure covered entities are adhering to the claims coding, billing and reporting procedures described herein. The MCO will submit its policies and procedures to RI EOHHS, at least annually, or as requested by EOHHS.

The MCO must report identified 340B claims data to EOHHS on Encounter Data submissions utilizing the indicators described herein.

The MCO must, no less than annually, conduct audits of 340B covered entities contracted with the MCO to ensure all contractual obligations are met and in compliance with the Plan's policies and procedures and those described herein. The MCO must submit audit results to EOHHS annually or upon request by EOHHS Compliance.

Section 3: EOHHS Responsibilities

Preventing duplicate discounts is a significant issue confronting state Medicaid programs regarding participating 340B covered entities. To ensure 340B and Drug Rebate Program integrity, EOHHS will annually or upon request:

- Review and approve the MCO 340B Program Policies and Procedures;
- Review MCO annual internal audits of covered entities/340B providers contracted with MCO. Based on audit results received from MCO, EOHHS Compliance may request a corrective action plan from the MCO;
- Review 340B claims submitted through Encounter Data Reporting; and/or
- Conduct, at minimum, an annual audit of MCO 340B claims data, processes and procedures.

Section 4: Non-Compliance with 340B Requirements

The following section outlines the consequences that EOHHS may impose if the MCO fails to meet the Contractual 340B Reporting and Monitoring Requirements described herein. The MCO is considered non-compliant with 340B reporting/claiming requirements if it is determined that a claim for a drug that was purchased at the 340B discounted price and dispensed by a covered entity did not include the appropriate indicators descried in Section 1 when reported to EOHHS.

Disciplinary Actions

If it is determined the MCO knowingly and/or repeatedly failed to submit 340B data to EOHHS, EOHHS at its discretion, may impose disciplinary actions up to and including a warning letter, MCO Board of Directors notification, imposing Corrective Action and/or suspension of enrollment, in accordance with EOHHS and the MCO contract Section 3.07.04.03 (Managed Care Core Contracts), and 42 CFR 438.700(b)(4) and 42 CFR 438.702 .

I. Warning (Level 1)

- EOHHS will issue the MCO a warning letter via email stating that the MCO has failed to comply with submission of 340B data via Encounter Data Reporting.
- The warning letter will indicate where the MCO has failed to meet a 340B identification and/or reporting requirement. EOHHS will specify the area of deficiency.
- The MCO has up to one (1) business days after receipt of warning notification from EOHHS to acknowledge receipt of notification.
- If the MCO believes they have met the 340B identification and/or reporting requirements and that the warning was incorrectly imposed, the MCO may provide written documentation to the EOHHS Managed Care Director, no later than) five (5) business days after date of warning letter refuting the warning with an evidentiary rationale.

- If, after internal review, EOHHS agrees and finds that the warning was incorrectly imposed on the MCO, EOHHS will provide written acknowledgement within five (5) business days of the retraction. Retraction of warning will be documented and filed with the Medicaid Managed Care Team.
- If, after internal review, EOHHS does not agree the warning was incorrectly imposed, EOHHS will notify the MCO, in writing, within five (5) business days, that the warning remains in effect.
- The MCO then has ten (10) business days after notification from EOHHS stating the warning notification remains in place to submit the requested information to EOHHS.

- The MCO will receive one (1) warning letter accompanied by one (1) opportunity to submit the corrected late, inaccurate/inadequate data report. If the MCO fails to correct or submit, within ten (10) business days, EOHHS will notify the MCO's Board of Directors of the MCO's failure to timely respond to EOHHS' request.
- If the MCO is in agreement with the imposed issue(s) of non-compliance:
  - The MCO must submit the required corrected submissions to the Medicaid Managed Care Compliance Officer, Medicaid Deputy Director, and Medicaid Managed Care Director within ten (10) business days.
  - EOHHS will review submitted corrections for accuracy. EOHHS will notify the MCO of either approval or rejection of the MCO submission within fourteen (14) business days.
- Failure to comply with the Warning will result in Disciplinary Action (Level II) and imposition of a Corrective Action.

II. Disciplinary Action - Corrective Action (Level 2)

- If the MCO fails to correct documented inadequacies and/or continues to be non-compliant with contractually required 340B identification and/or reporting, EOHHS, at its discretion, will impose an immediate corrective action be implemented by MCO.
- MCO will be required to submit a corrective action plan (CAP)* to address root cause, immediate and long-term remediation processes to mitigate continued non-compliance with these requirements inclusive of mitigation timeline, no later than fourteen (14) business days from notification by EOHHS.
  - *in accordance with EOHHS/MCO Corrective Action Plan process,

EOHHS will review and respond to MCO's submitted corrective action plan within fourteen (14) business days.

- If the CAP is not approved by EOHHS, the MCO will resubmit the CAP with required provide corrections within five (5) business days.
- The approved CAP, dependent on the severity of the non-compliance issue as determined by EOHHS, must be implemented by MCO no later than thirty (30) business days and no more than ninety (90) business days.
- The CAP will be considered closed when EOHHS is satisfied that all remediation actions are achieved. At the discretion of EOHHS, continued reporting of remediation actions will be required at intervals determined by EOHHS.
- EOHHS will notify the MCO, in writing, that the CAP and associated activities have been successfully concluded.

III. Additional Disciplinary Actions

If, EOHHS determines, either through audit or reporting, that the MCO continues to be non-compliant with the documenting, monitoring or reporting of 340B claims data, further disciplinary actions may be imposed.

These actions include, but are not limited to, a second Corrective Action and/or other actions deemed appropriate by EOHHS.

EOHHS retains the authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in 42 CFR 438.700, as well as any additional areas of noncompliance. As set forth in 42 CFR 438.710(a), EOHHS will provide the Contractor written notice thirty (30) days prior to imposing any intermediate sanction. The notice will include the basis for the sanction and any available appeal rights.

IV. CMS Sanction (Level 3)

- As outlined under 42 CFR 438.704 (b)(3), if an MCO provides EOHHS or CMS false or materially misleading information or false statements in reports, CMS may sanction the MCO.
- EOHHS shall provide documentation to the MCO where they have breached reporting requirements related to falsifying data reports.
- The MCO will have the opportunity to provide written explanation to deny the alleged falsification.

- EOHHS will be required to report findings to CMS.
- CMS will assess the violation and recommend to EOHHS if a financial penalty or denial of payment is warranted and the effective date of sanction will begin against the MCO.

MCO Requirements for Documenting, Monitoring and Reporting 340B Claims Data
Version 1

Policy Owner:	Director, Medicaid Managed Care	
Policy Reviewers:	Medicaid Managed Care, Compliance, Data Analytics	
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