



Ohio Department of Medicaid

Ohio Medicaid Enterprise System

340B Reference Guide

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Note: This guide is published as a general reference for 340B Covered Entities that participate in the Ohio Medicaid program. Information contained is subject to change. While every attempt is made to provide the most up-to-date information, providers should work directly with ODM or the applicable Managed Care Entity for any other use, questions, or assistance.

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1. Introduction

This document serves as guidance for providers who participate in the 340B Drug Pricing Program with the Ohio Department of Medicaid (ODM). This guidance applies to covered outpatient drugs dispensed in any setting that are billed in whole or in part to Ohio Medicaid, including Ohio Medicaid Managed Care Entities (MCEs).

2. Definitions and Abbreviations

A **covered entity** is defined as 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.

A **contract pharmacy** is a pharmacy that has a written contract with a 340B covered entity to provide pharmacy services. Contract pharmacies must be registered for the 340B program and be listed as active on the 340B OPAIS Contract Pharmacy Daily Report prior to dispensing 340B drugs. Contract pharmacies are considered non-340B covered entities.

Duplicate discounts occur when a covered entity obtains a 340B discount on a medication and ODM also obtains a discount in the form of a rebate from the manufacturer for the same medication. Duplicate discounts are prohibited in the 340B Drug Pricing Program.

A **340B grantee** is defined as an entity described in section 340B(a)(4)(A)-(K) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4)(A)-(K) that is designated as an active (A)-(K) entity under the health resources and services administration covered entity daily report, and includes any pharmacy under contract with the entity to dispense drugs on behalf of the entity.

AAC: Actual Acquisition Cost

FFS: Fee-for-Service

HRSA: Health Resources and Services Administration

MCE: Managed Care Entity

MEF: Medicaid Exclusion File

NADAC: National Average Drug Acquisition Cost

NCPDP: National Council for Prescription Drug Programs

NPI: National Provider Identifier

OAAC: Ohio Average Acquisition Cost

OAC: Ohio Administrative Code

ODM: Ohio Department of Medicaid

ORC: Ohio Revised Code

WAC: Wholesale Acquisition Cost

3. 340B Background

The 340B Drug Pricing Program was intended to allow covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Manufacturers who offer national rebate agreements are also required to be a part of the 340B Drug Pricing Program.

After enrolling in the 340B program, a covered entity must decide whether it will “carve-in” or “carve-out” its Medicaid fee-for-service (FFS) and managed care patients.

After deciding to “carve-in”, the covered entity is required to notify the Health Resources & Service Administration (HRSA) of their decision so that their Medicaid number and NPI can be listed on the HRSA Medicaid Exclusion File (MEF). This file lists the covered entities’ NPI and lets states and manufacturers know that drugs billed by that NPI number are not eligible for rebates. Covered entities that choose to “carve-out” should not be listed on the HRSA MEF. The HRSA MEF is updated quarterly, and it is the responsibility of the covered entity to ensure that the information on the HRSA MEF is accurate and complete. Covered entities must have mechanisms in place to prevent duplicate discounts.

To prevent duplicate discounts, Ohio Medicaid utilizes both the HRSA MEF and claims-level identifiers to identify 340B claims. Rebate exclusion logic is identified in Section 6, below.

4. Ohio Medicaid Payer Identification

4.1 Pharmacy Benefit:

- Detailed payer identification can be found on the ODM Pharmacy Program Website at: <https://pharmacy.medicaid.ohio.gov>.

4.2 Medical Benefit:

- Detailed payer identification can be found on the ODM Billing Website at: <https://medicaid.ohio.gov/resources-for-providers/billing/billing>.

5. 340B Billing Instructions

Detailed billing instructions and requirements can be found on the ODM Pharmacy Program website and the Single Pharmacy Benefit Manager website.

5.1 Billing Requirements:

- Pharmacy claims: 340B claims must be submitted with a Submission Clarification Code = 20 (NCPDP field 420-DK) and the Basis of Cost Determination = 08 (NCPDP field 423-DN) in accordance with NCPDP standards. This requirement also applies to drug products sourced through the HRSA 340B Rebate Model Pilot Program (or similar models).

- Medical claims: 340B claims must be submitted with appropriate claims-level identifiers when billing for 340B-purchased medications.
 - Modifier -SE must be used for all 340B drug detail lines billed with a HCPCS code (e.g. J- and Q- codes)
 - Ohio Medicaid also recognizes modifiers -JG and -TB when transmitted on Medicare Crossover claims.

5.2 Cost Basis Requirements:

- Fee-for-service pharmacy claims: submitted ingredient cost is the provider's actual acquisition cost (AAC) in accordance with OAC 5160-9-06. For drug products sourced through the HRSA 340B Rebate Model Pilot Program (or similar model), providers must submit the post-rebate (net) acquisition cost.
- All other claim types: submitted ingredient cost is the usual and customary charge that is charged to non-Medicaid members for the same service. See OAC 5160-1-17.2.

5.3 Reimbursement:

- FFS Pharmacy claims: As specified in OAC 5160-9-05.
- Managed Care/SPBM Pharmacy claims:
 - 340B Covered Entities and contract pharmacies: Claims are priced in accordance with ORC 5167.123, plus dispensing fee.
- All other claim types: As specified in the applicable fee schedule or MCE contract.

6. Rebate Exclusion Logic

Ohio Medicaid invoices for rebates on all eligible medications paid in whole or in part by Ohio Medicaid. This includes claims for which Ohio Medicaid is not the primary payer. This also includes providers located in other states who are registered with ODM. For 340B claims, the following logic is used to exclude these claims from rebate invoicing.

6.1 FFS Rebate Exclusion Logic

- FFS Pharmacy claims are excluded from rebate invoicing when both of the following are true:
 - Submission Clarification Code (NCPDP field 420-DK) value of '20' is present on claim
 - Dispensing pharmacy's National Provider Identifier (NPI) is listed on the MEF
- FFS Medical claims are excluded from rebate invoicing when one of the following is true:
 - SE Modifier is present on the drug detail line
 - The billing provider's NPI is listed on the MEF
 - Additionally, claims with a TB or JG modifier that haven't already been excluded due to the above rules will be excluded

6.2 MCE Rebate Exclusion Logic

- MCE Pharmacy claims are excluded from rebate invoicing when one of the following is true:
 - Submission Clarification Code (NCPDP field 420-DK) value of '20' is present on claim
 - Dispensing pharmacy's National Provider Identifier (NPI) is listed on the MEF
- MCE Medical claims are excluded from rebate invoicing when one of the following is true:
 - SE Modifier is present on the drug detail line

- The billing provider's NPI is listed on the MEF
- Additionally, claims with a TB or JG modifier that haven't already been excluded due to the above rules will be excluded

7. Frequently Asked Questions (FAQ)

Do 340B claims need to be identified at the time of dispensing?

Yes, per NCPDP guidance, the value of '20' in the Submission Clarification Code (420-DK) field indicates that, prior to providing service, the pharmacy has determined the product being billed is 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)).

Can a covered entity send batch files to identify 340B claims?

No, since 340B claims need to be identified at the time of dispensing, they cannot be sent as batch files after the fact.

Does Ohio Medicaid allow contract pharmacies for FFS members?

No, contract pharmacies are only permitted when an agreement exists between the contract pharmacy and the state Medicaid agency. Ohio Medicaid currently has no agreements in place (therefore, contract pharmacies are prohibited in FFS).

Does Ohio Medicaid seek rebates for orphan drugs?

Yes, for certain covered entities that are excluded from access to 340B drug pricing when it is used for a rare disease or condition (free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals), Ohio Medicaid will seek drug rebates.

Does Ohio Medicaid seek rebates for MyCare or other dual-eligible claims?

Yes, Ohio Medicaid seeks manufacturer rebates for MyCare Ohio and other dual-eligible claims that Ohio Medicaid pays any portion of.

For drugs that are part of the 340B Rebate Model Pilot Program, what acquisition cost should I use to bill Ohio Medicaid fee-for-service? Are there any additional claim identification requirements under this program?

While the upfront purchase will occur at WAC, the final acquisition cost of a 340B eligible purchase is expected to be the 340B ceiling price, once the rebate is paid. Providers must report the post-rebate (net) cost as the acquisition cost.

Providers must submit a Submission Clarification Code (NCPDP field 420-DK) value of '20' for 340B drugs procured under the 340B Rebate Model Pilot Program, in accordance with NCPDP guidance.

8. Additional Information

Frequently asked questions on the 340B program itself can be found on the HRSA website:

<https://www.hrsa.gov/opa>



340B billing questions for the Ohio Department of Medicaid should be directed to the following:
medicaid_pharmacy@medicaid.ohio.gov.