

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
340B DRUG PRICING PROGRAM – DISPENSING 340B PURCHASED DRUGS

**Proposed Effective Date: July 1, 2023**

**PURPOSE:**

The purpose of this bulletin is to inform providers of:

1. The procedures for dispensing 340B Drug Pricing Program (340B-purchased drugs) to Medical Assistance (MA) Program beneficiaries.
2. The implementation of the MA Program's 340B Drug Exclusion List.

**SCOPE:**

This bulletin applies to MA providers that are 340B covered entities and pharmacies enrolled in MA and providing MA covered drugs in the Fee-for-Service (FFS) and/or the managed care delivery system(s).

**BACKGROUND:**

Under the Federal Drug Rebate Program states are required to invoice manufacturers for Medicaid drug rebates for MA covered drugs dispensed to MA beneficiaries. 42 U.S.C. § 1396r-8(b)(2). 340B-purchased drugs dispensed to MA beneficiaries do not qualify for Medicaid rebates. 42 U.S.C. § 256b(a)(5)(A)(i). State Medicaid agencies are expected to have policies and procedures designed to prevent the MA Program from invoicing for drug rebates for 340B-purchased drugs.

According to the U.S. Department of Health & Human Services Health Resources & Services Administration (HRSA), 340B covered entities have the option to dispense either 340B-purchased drugs ("carve in") or non-340B-purchased drugs ("carve out") to MA beneficiaries. HRSA developed the 340B Medicaid Exclusion File (MEF) to facilitate the prevention of duplicate discounts that could result when a drug is discounted under the 340B Drug Pricing Program and subject to a Medicaid rebate. The 340B MEF lists all 340B covered entities that have informed HRSA that they will dispense 340B-purchased drugs to MA FFS beneficiaries. HRSA provided no resource for identifying 340B providers when dispensed to MA managed care beneficiaries. Therefore, the MA Program has used the MEF to identify drug claims paid to 340B covered entities and prevent duplicate discounts in FFS programs for more than 25 years and in managed care programs since 2010.

HRSA allows 340B covered entities to use contract pharmacies to dispense 340B-purchased drugs. Contract pharmacies are not included on the MEF. MA has never removed drug claims paid by FFS or MA managed care organizations (MCOs) to contract pharmacies from the drug rebate process because the MA Program has had no way to identify contract pharmacies or when a contract pharmacy dispenses 340B purchased drugs.

## **DISCUSSION:**

The MA Program hosted workgroup meetings with 340B covered entities and contract pharmacies to identify a process to notify the MA Program when a drug purchased under the 340B program is dispensed to an MA beneficiary in the managed care delivery system. The National Council for Prescription Drug Programs (NCPDP) claim format used by pharmacies includes a field that can be used to indicate the drug dispensed was purchased under the 340B program. Professional and institutional outpatient 837 claim formats used by dispensing prescribers include modifier values that can be used to indicate the drug dispensed was purchased under the 340B program. Beginning July 1, 2023, all claims billed to MA managed care organizations (MCOs) for 340B purchased drugs dispensed to MA MCO beneficiaries must include the 340B claim indicator or modifier. When the 340B indicator or modifier is included on MCO paid drug claims, the MA Program will not invoice drug manufacturers for Medicaid rebates on these drugs.

The MA Program has developed a list of drugs for which 340B covered entities and contract pharmacies may only dispense non-340B-purchased drugs to MA beneficiaries. This list, referred to as the 340B Drug Exclusion List, applies to both the FFS and managed care delivery systems. The list is available on the Department's website at <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/340B.aspx>. The Department will invoice drug manufacturers for Medicaid rebates on these drugs.

The MA Program will continue to use the MEF to identify 340B purchased drug claims paid by the FFS delivery system to 340B covered entities. The Department will not invoice drug manufacturers for Medicaid rebates on these drugs.

## **PROCEDURE:**

### **340B covered entities may dispense 340B-purchased drugs to MA beneficiaries in the FFS DELIVERY SYSTEM when all the following conditions are met:**

- The billing provider is a licensed MA enrolled provider who can bill for drugs.
- The billing provider's NPI is listed on the HRSA MEF at <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion> and is the same NPI used on the claim.
- The 340B covered entity will work with the drug manufacturers to resolve duplicate discounts if the NPI of the billing provider is not listed on the MEF.
- The drug is not included on the MA Program's 340B Drug Exclusion List at <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/340B.aspx>.

MA enrolled contract pharmacies are required to dispense non-340B purchased drugs to MA beneficiaries in the FFS delivery system. The Department will invoice drug manufacturers for Medicaid rebates for all drug claims paid to these providers.

### **340B covered entities may dispense 340B-purchased drugs to MA beneficiaries in the MANAGED CARE DELIVERY SYSTEM when all the following conditions are met:**

- The billing provider is a licensed MA enrolled provider who can bill for drugs.
- The drug is not included on the MA Program's 340B Drug Exclusion List at <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/340B.aspx>.
- The billing provider identifies claims filled with 340B-purchased drugs as follows:
  - For 340B covered entities' in-house pharmacies, include the NCPDP Telecommunication Standard's 340B indicator code on all applicable drug claims.
  - For 340B covered entities non-pharmacy providers, by including the 837 Institutional and 837 Professional format modifiers of "JG", "UD", or "TB" on all applicable drug claims.
- The 340B covered entity will work with the drug manufacturers to resolve duplicate discounts for claims that do not include the appropriate 340B claim identifiers.
- The 340B covered entity ensures that 340B claim identifiers are included only on claims for 340B purchased drugs.

**Contract pharmacies may dispense 340B-purchased drugs to MA beneficiaries in the MANAGED CARE DELIVERY SYSTEM when all of the following conditions are met:**

- The billing provider is a licensed MA enrolled provider who can bill for drugs.
- The drug is not included on the MA Program's 340B Drug Exclusion List at <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/340B.aspx>.
- The 340B covered entity contracted with the pharmacy will confirm 340B eligibility for all drug claims submitted to MA MCOs and notify the billing provider.
- The billing provider identifies 340B-purchased drug claims by including the NCPDP Telecommunication Standard's 340B indicator code on all applicable drug claims.
- The 340B covered entity will work with the drug manufacturers to resolve duplicate discounts for claims that do not include the appropriate 340B claim identifiers.
- The 340B covered entity ensures that 340B claim identifiers are included only on claims for 340B purchased drugs.

**RESOURCES:**

Information for 340B Covered Entities

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/340B.aspx>

HRSA Medicaid Exclusion File

<https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion>

The MA Program National Council for Prescription Drug Programs' (NCPDP) Processor Identification Number (BIN), Processor Control Number (PCN), and group numbers for both FFS and the MA MCOs

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/340B.aspx>

**OBSOLETE:**

MA Bulletin 99-13-08, titled, "340B Drug Pricing Program Provider Requirements and Billing Instructions – Pharmacy Services," issued May 16, 2013.