

ISSUE DATE December 22, 2022	EFFECTIVE DATE January 1, 2023	NUMBER *See below
SUBJECT 340B Drug Pricing Program – Dispensing 340B Purchased Drugs		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

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

*01-22-78	09-22-77	27-22-63	33-22-75
02-22-60	11-22-60	30-22-68	
03-22-59	14-22-60	31-22-81	
08-22-87	24-22-69	32-22-60	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at

<https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

policies and procedures designed to prevent duplicate discounts for 340B-purchased drugs. State Medicaid programs may have different requirements for avoiding duplicate discounts.

DISCUSSION:

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. The MEF includes the State Medicaid Provider Number and the National Provider Identifier (NPI) for 340B covered entities. It is the responsibility of the 340B covered entity to ensure that the information in the HRSA MEF is accurate and up to date. MA providers are required to use the NPI for drug claims billed for MA beneficiaries. The MA Program uses the MEF to identify 340B covered entities that dispense 340B-purchased drugs to MA beneficiaries in both the FFS and managed care delivery systems. MA enrolled providers that are 340B covered entities and are on the MEF may dispense 340B-purchased drugs, other than drugs on the 340B Drug Exclusion list, to MA beneficiaries. The Department will not be invoicing drug manufacturers for Medicaid rebates on these drugs.

HRSA allows 340B covered entities to use contract pharmacies to dispense 340B-purchased drugs. Contract pharmacies generally do not know at the time of dispensing and billing whether a MA beneficiary is eligible for 340B-purchased drugs. The MA Program is unable to identify 340B-purchased drugs dispensed by contract pharmacies, therefore, contract pharmacies must dispense non-340B-purchased drugs to beneficiaries in the FFS and managed care delivery systems. The Department invoices drug manufacturers for Medicaid rebates on these drugs.

MA-enrolled providers that are 340B covered entities located outside the Commonwealth of Pennsylvania (Commonwealth) are required and will continue to be required to dispense non-340B-purchased drugs to MA beneficiaries in the FFS and managed care delivery systems. The Department invoices drug manufacturers for Medicaid rebates on these drugs.

The MA Program has developed a list of drugs for which 340B covered entities 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>. 340B covered entities may not dispense 340B purchased drugs included on the 340B Drug Exclusion List to MA beneficiaries. The Department will be invoicing drug manufacturers for Medicaid rebates on these drugs.

PROCEDURE:

340B covered entities may dispense 340B-purchased drugs to MA beneficiaries when all the following conditions are met:

- The billing provider is a licensed MA enrolled MA provider who can bill for drugs.
- The billing provider is located in the Commonwealth.
- The billing provider's NPI is listed on the HRSA MEF at <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion> with the same NPI as is used on claim.
- The provider dispenses 340B-purchased drugs for MA beneficiaries in both the FFS and managed care delivery systems.
- 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 and 340B covered entities located outside the Commonwealth are required to dispense non-340B-purchased drugs to MA beneficiaries in both the FFS and managed care delivery systems. All drug claims paid to these providers will be invoiced to drug manufacturers for Medicaid rebates.

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.

2023 Pennsylvania Medical Assistance 340B Drug Exclusion List

Trade Name (Chemical Name)	Description	Manufacturer	Labeler Code
Abecma (idecabtagene vicleucel)	Antineoplastic CAR-T Cell Immunotherapy	Celgene/BMS	59572
Breyanzi (lisocabtagene maraleucel)	Antineoplastic CAR-T Cell Immunotherapy	Juno/BMS Company	73153
Carvykti (ciltacabtagene autoleucel)	Antineoplastic CAR-T Cell Immunotherapy	Janssen Biotech	57894
Kymriah (tisagenlecleucel)	Antineoplastic CAR-T Cell Immunotherapy	Novartis	00078
Luxturna (voretigene neparvovec-rzyl)	Retinal Enzyme Replacement	Spark Therapeutics	71394
Tecartus (brexucabtagene autoleucel)	Antineoplastic CAR-T Cell Immunotherapy	Kite Pharma, Inc.	71287
Yescarta (axicabtagene ciloleucel)	Antineoplastic CAR-T Cell Immunotherapy	Kite Pharma, Inc.	71287
Zolgensma (onasemnogene abeparvovec-xioi)	Gene Therapy Agents – SMN Protein Deficiency	Novartis Gene Therapy	71894
Zynteglo (betibeglogene autotemcel)	Gene Therapy Agents – Hematopoietic	Bluebird Bio, Inc.	73554
<i>Last updated January 1, 2023</i>			