

Department of Medical Assistance Service

340B Frequently Asked Questions

What is the 340B Program?

The 340B program is a Drug Pricing Program established by the Veterans Health Care Act of 1992, which is Section 340B of the Public Health Service Act (PHSA). Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes, and qualified hospitals. These providers purchase, dispense and/or administer pharmaceuticals at significantly discounted prices. The significant discount applied to the cost of these drugs makes these drugs ineligible for the Medicaid drug rebate. State Medicaid programs are mandated to ensure that rebates are not claimed on these drugs thereby preventing duplicate discounts for these drugs.

Health Resources and Services Administration (HRSA) is specifically responsible for the enforcement of covered entity compliance with the duplicate discount prohibition. More information regarding eligibility and program logistics can be found on HRSA's website at www.hrsa.gov/opa.

How does a facility enroll in the 340B program?

Entities that are eligible for enrollment into the 340B program can find detailed information about enrollment on the Health Resources and Services Administration's Office of Pharmacy Affairs (OPA) Webpage: www.hrsa.gov/opa.

How does a provider carve-out Medicaid?

If the provider chooses to carve-out, according to HRSA and the 340B Prime Vendor Program (PVP), the 340B drug is dispensed and administered only to non-Medicaid patients. If the provider carves out Medicaid, it cannot dispense drugs purchased under the 340B program to a Medicaid member.

Does the 340B billing requirement apply to Managed Care Organizations?

Yes. Managed Care Organizations must adopt 340B billing policies.

Are contract pharmacies allowed to bill Virginia Medicaid for 340B Drugs?

Contract pharmacies may not submit claims to DMAS Fee-For-Service or Managed Care Plans for drugs purchased through a 340B program. A 340B contract pharmacy MUST carve out Virginia Medicaid pharmacy claims from its 340B operation.

PLAN	BIN	PCN	GROUP	MED 4 HELPLINE	CCC+ HELPLINE
FFS	010900	8263342243	VAMEDICAID	-	-
AETNA	610591	ADV	RX8837	844-270-2365	866-386-2882
ANTHEM	020107	FM	WQWA	833-207-3120	833-235-2027
MCC	016523	63348286	MCCVARX (MED4)	800-424-4518	-
		62282	VAMLTSS (CCC+)	-	800-424-4524
OPTIMA	610011	OHPMCAID	OFC (MED4)	800-643-2273	-
		OHPMCAID	OHCC (CCC+)	-	844-374-9159
UHC	610494	4900	ACUVA	844-284-0149	855-873-3493
VAP	009893	ROIRX	*See Below	855-872-0005	844-838-0711

*VAP Details	
Med4	VAPR4STRD
FAMIS	VAPR4
Expansion	VAPREXP
Kaiser	KPVAPR4

How must claims dispensed with 340B purchased drugs identified during billing?

In order to comply with Federal law, claims must be completed and submitted correctly as mandated by Section 340B(a)(5)(A)(i) prohibiting duplicate discounts. This occurs when the manufacturer gives the provider discounted 340B pricing and also pays DMAS a rebate for the same drug. Manufacturers are not required to pay rebates on a 340B drug if the manufacturer has already provided a discounted price to the provider.

Providers must bill the appropriate code(s) on a claim billed with a 340B purchased drug. **A “UD” or “JG” or “TB” modifier is required for both fee-for-service (FFS) and managed care (MCO) physician administered drug claims and other medical claims. Pharmacy FFS claims require the inclusion of both “08” in field 423-DN, the Basis of Cost Determination field, and “20” in field 420-DK, the Submission Clarification Code. Pharmacy MCO claims require the inclusion of “20” in field 420-DK, the Submission Clarification Code.**

The state will then extract appropriate claims from rebate invoicing and collection.

If the pharmacy does not know at time of dispensing that it is a 340B eligible patient and bills the department their usual and customary rate, how is that resolved when the pharmacy finds out retrospectively that it is a 340B patient and drug?

The pharmacy should void and re-bill the FFS Pharmacy claim using 340B pricing identifying the drug as 340B using the Submission Clarification Code of 20 in field 420-DK and Basis of Cost of 08 in field 423-DN. For MCO claims, the pharmacy should void and re-bill using 340B pricing identifying the drug as 340B using the Submission Clarification Code of 20 in field 420-DK.

Does the 340B billing requirement apply to Medicare Crossover claims?

No, neither the “UD,” “JG,” or “TB” modifier nor the reporting of the AAC for the 340B drug is required.

What is the dispensing fee for 340B purchased drugs?

Currently DMAS’s dispensing fee for all FFS POS and 340B purchased drug pharmacy claims is \$10.65. The provider charge should be the AAC plus the dispensing fee. MCO payment methodology may vary.

Hospital Outpatient EAPG

If we include the “UD,” “JG,” or “TB” modifier with the pharmacy revenue lines, will those drugs continue to be reimbursed? It appears that the drugs are bundled with other procedures.

You will continue to be reimbursed for those drugs but providers participating in the 340B drug discount program must report the “UD,” “JG,” or “TB” modifier. These modifiers indicates that the drug was provided through 340B and should be discounted consistent with reporting of the lowest acquisition costs. Drugs for all providers, whether participating in 340B or not, may not be paid separately. Providers should continue to report the drugs and the appropriate charges on the claims consistent with the current billing policies.

What process should hospital outpatient departments using for drugs that are purchased in a unit/quantity different from the HCPCS unit/quantity required for claim submission?

Medical providers purchasing and dispensing 340B medications as part of a physician administered drug claim must bill the drug using HCPCS units. Appropriate conversion algorithms or systematic conversion to HCPCS units must occur prior to submitting the claim for adjudication.

National Drug Code (NDC)

Hospital providers who administer drug products in **outpatient hospital settings** will be required to include valid NDCs on claims submissions. A valid NDC is defined as a correctly formatted number using the 5-4-2 format, i.e., 5-digits, followed by 4-digits, followed by 2-digits (99999888877). Each NDC must be an **11-digit code** unique to the manufacturer of the specific drug or product administered to the member. If the provider is billing for a compound medication with more than one NDC included in the medication dispensed, each applicable NDC must be submitted as a separate claim line to include both prescription and over-the-counter ingredients. Outpatient hospital claims submitted without a valid NDC will have the revenue code line reduced to a non-covered service line.

DMAS will monitor and edit all outpatient hospital claims to ensure that the pharmacy revenue codes are submitted with an NDC. Claims submitted without the NDC will be **Denied**. Each claim (line) submitted with an N4 qualifier **MUST** have the associated NDC and revenue code billed on that line. Providers participating in the 340B drug discount program must submit each drug line with modifier “UD”, “JG”, or “TB” on the revenue line with the HCPCS/CPT procedure code and NDC for revenue codes 0250 through 0259 and 0636 through 0639. All providers, including those not participating in the 340B discount program, must continue to submit NDC codes for revenue codes 250 through 259 and 636 through 639 and applicable HCPCS/CPT codes for each drug submitted. www.virginiamedicaid.dmas.virginia.gov/wps/myportal/ProviderManual --Discuss with MaryAnn

Fee-for-Service Pharmacy Manual Chapter IV

Pharmacy Reimbursement for Drugs Purchased under the 340B Program

Pharmacies participating in the 340B program established by Section 340B of the Public Health Services Act must notify DMAS regarding their participation. Drugs with discounts generated from participation in this program are not eligible for federal drug rebates and pharmacy claims from 340B providers are not submitted to manufacturers for drug rebates. Pharmacies dispensing drugs purchased under the 340B program must submit **actual acquisition cost (AAC)** for a drug product on FFS claims and will be reimbursed AAC plus a dispensing fee where applicable. 340B entities/providers who are enrolled with DMAS as a provider type other than pharmacy shall charge DMAS no more than their actual acquisition cost for the drug.

NCPDP Prescription Claims Processing 340B Identifier

Pharmacy providers submitting FFS claims through the point-of-sale (POS) for drugs purchased through the 340B program must identify the drug as a 340B purchased drug by populating the Submission Clarification Code (42Ø-DK) field with a value of “20” **and** the Basis of Cost

Determination (42Ø-DN) field with a value of “08”. In addition, the pharmacy must submit their acquisition cost for the drug claim using NCPDP field 409-D9 Ingredient Cost Submitted. For MCO POS pharmacy claims, pharmacy providers must identify the drug as a 340B purchased drug by populating the Submission Clarification Code (42Ø-DK) field with a value of “20.” The following NCPDP denial edits and/or Virginia Medicaid edits may be posted if the claim is not submitted correctly:

- If a FFS Claim is submitted with SCC = 20 and BOC does not equal 08, the claim will deny NCPD EC 85 – Claim Not Processed.
- If a FFS Claim is submitted for BOC = 08 and SCC does not equal 20, the claim will deny NCPD EC 85 – Claim Not Processed.

DMAS Language and requirements concerning the 340B Program

Fee-For-Service Program

Relevant information for Outpatient Pharmacy Services 340B Program may be found in the DMAS Pharmacy Provider Manual Chapter IV, under the section titled Pharmacy Reimbursement for Drugs Purchased Under the 340B Program. This manual may be found at <https://www.virginiamedicaid.dmas.virginia.gov/wps/portal/ProviderManual> by choosing the Pharmacy Manual from the dropdown selection.

Relevant information for Outpatient Hospital Services 340B Program may be found in the DMAS Hospital Provider Manual Chapter IV, under Outpatient Hospital Services. This manual may be found at <https://www.virginiamedicaid.dmas.virginia.gov/wps/portal/ProviderManual> by choosing the Hospital Manual.

Managed Care Contract Language

As set forth in 42 CFR §438.3(s)(3), the Contractor must develop a process and procedure to identify drugs administered under Section 340B of the Public Health Service Act as codified at 42 USC § 256b, as drugs dispensed pursuant to this authority are not eligible for the Medicaid Drug Rebate program. Failure to identify aforementioned 340B drugs on submissions to the Department or its rebate vendor shall be treated as a compliance violation. The Contractor shall identify encounter claims administered under Section 340B in a manner, mutually agreed upon between the Department and the Contractor, that supports an automated solution to identify and remove those encounter claims from Medicaid Drug Rebate processing. If a Contractor engages a Pharmacy Benefit Manager (PBM) to provide outpatient drug services to Medicaid Members, the Contractor shall ensure that the PBM complies with the identification of 340B drugs on encounter claim data in a manner consistent with the NCPDP

standards. This shall include the use of a unique BIN/PCN combination to distinguish Medicaid managed care claims from commercial or other lines of business. Drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies are not covered as part of the DMAS pharmacy benefit.

Med 4.0: <https://dmas.virginia.gov/for-providers/managed-care/medallion-40/more-information/>

CCC Plus: <https://dmas.virginia.gov/for-providers/managed-care/ccc-plus/program-information/>