# Commonwealth of Virginia
# Department of Medical Assistance Services (DMAS)
# 340B Frequently Asked Questions

## Background and Policies

### 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.

### What is the impact of Section 340B on the Medicaid Drug Rebate Program and Rebate collection?

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.

### What is the general policy for obtaining rebates on 340B acquired drugs?

DMAS excludes all 340B identified claims from rebate invoicing and collection.

### Do these requirements apply to all drugs/products?

This requirement applies to all 340B purchased drugs and products for outpatient use, both pharmacy and medical (physician/provider administered) claims.

**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) website (www.hrsa.gov/opa).**

**Does DMAS require covered entities (CEs) to carve-out 340B acquired drugs and products dispensed to Virginia Medicaid members?**

No. CEs may choose to carve-in or carve-out 340B acquired drugs and products for Medicaid members. If a CE opts to carve-out, the CE cannot dispense/administer drugs or products purchased under the 340B program to Virginia Medicaid members. If the CE chooses to carve-in, they must notify HRSA of their intent to purchase and dispense 340B drugs to Medicaid members.

**How does a CE carve-out Medicaid?**

Upon enrollment in the 340B Program, a CE must inform HRSA whether it will use 340B drugs for its Medicaid Fee-For-Service (FFS) patients (carve-in), or whether it will purchase drugs for its Medicaid FFS patients through other mechanisms (carve-out). **If the CE chooses to carve-out, it cannot dispense or administer drugs purchased under the 340B program to a Medicaid member**.

**Are contract pharmacies allowed to bill DMAS for 340B Drugs?**

Contract pharmacies may **not** submit claims to DMAS FFS or Managed Care Organizations (MCOs) for drugs purchased under a 340B program. **A 340B contract pharmacy MUST carve out Virginia Medicaid pharmacy claims from its 340B operation.**

**Do I need to identify 340B drugs dispensed to members in Medicaid Managed Care Organizations?**

Yes. The requirement to identify the drug as a 340B drug on the claim applies to Medicaid MCOs.

**Does DMAS seek Medicaid rebates on claims for members that:**

- are dual eligible (Medicare/Medicaid)? Yes, if DMAS pays a portion of the claim, the claim will be submitted for rebates.
- received physician/provider administered drugs? Yes
- are enrolled in Medicaid Managed Care? Yes

**What happens if an internal audit, HRSA audit or drug dispute identifies a duplicate discount has occurred?**

HRSA has stated as part of the Corrective Action Plan that the covered entity must work with the drug manufacturer to repay the duplicate discount billing errors. See https://www.hrsa.gov/opa/updates/2018/may.html

**Can you direct me to DMAS language and requirements concerning the 340B program?**

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://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library and selecting the Pharmacy Manual.

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://vamedicaid.dmas.virginia.gov/pdf_chapter/hospital

## Identification of 340B Drugs and Billing Procedures

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.

*DMAS does not use HRSA's Medicaid Exclusion List to identify claims billed with drugs purchased under the 340B program.*

**How do I submit Pharmacy claims for drugs purchased under the 340B program?**

FFS pharmacy point-of-sale 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.

**Can a DMAS provider enrolled in the 340B federal drug pricing program charge DMAS something other than their 340B actual acquisition cost (AAC)?**

If the CE carves-in all prescriptions, physician/provider administered drugs, and other products into the 340B program for Medicaid, the provider must charge Medicaid no more

than their 340B AAC for the drugs or products. This requirement is applicable to claims billed to the Virginia Medicaid FFS program.

**What is the dispensing fee for 340B purchased drugs?**

$10.65. The provider charge should be the AAC plus the dispensing fee. MCO payment methodology may vary.

**What if our facility is registered as a "carve-in / opt-in" covered entity and bills for a drug that is deemed not eligible through the 340B drug pricing program?**

If the drug is not eligible for 340B pricing, the provider will bill the drug at the usual and customary charge for the drug and should not include the "UD" modifier (and, if billed as a Medicaid primary crossover claim, the "JG" or "TB" modifier) for physician administered drug claims or both the "20" and "08" in fields 420-DN and 423-DN, respectively, for pharmacy claims.

**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.

**How do I submit physician/provider administered claims for drugs purchased under the 340B program?**

Providers must bill the appropriate code(s) on a claim billed with a 340B purchased drug. A **"UD"** (and, if billed as a Medicaid primary crossover claim, the **"JG" or "TB"** modifier) is required for both fee-for-service (FFS) and managed care (MCO) physician administered drug claims and other medical claims.

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

Yes. The Centers for Medicare & Medicaid Services (CMS) established two Healthcare Common Procedure Coding System (HCPCS) Level II modifiers to identify 340B-acquired drugs for Medicare Part B drugs effective January 1, 2018. The revised descriptors for CY 2023 and subsequent years are listed below:

- JG – Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes
- TB – Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities

Reporting of the 340B AAC for the 340B drug is required if Medicaid is primary, however for crossover claims pricing should be at Medicare policy.

**Does the requirement for the UD modifier apply to claims billed to Medicaid when Medicaid is the secondary payer?**

Yes. Providers must include the UD modifier for 340B purchased and administered drugs billed secondary to Medicaid on CMS 1500 and outpatient UB-04 claims.

**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 drugs 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.

**Do I need to include the National Drug Code (NDC) and NDC units for drug products billed on the CMS 1500 or UB-04?**

Yes. Providers who administer drug products in **outpatient hospital settings** must include valid NDCs and NDC units on all drug 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 compounded 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.

## 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.

## Additional Resources

**HRSA Drug Pricing Program FAQs**

**340B Prime Vendor Program FAQs**

**340B Office of Pharmacy Affairs Information System**