

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.

Do the Fee-for-Service (FFS) 340B billing requirements apply to Managed Care Organizations?

No. Managed Care Organizations (MCOs) are required to identify 340B drugs submitted on encounter claim data in a manner consistent with the NCPDP standards. 340B Covered Entities should consult with the MCO's PBM to determine (refer to Medallion 4 and CCC Plus contract language below).

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

Contract pharmacies may not submit claims to DMAS for drugs purchased through a 340B program. A 340B contract pharmacy MUST carve out Virginia Medicaid pharmacy claims from its 340B operation.

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

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

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” modifier is required for physician administered drug claims and outpatient hospital claims, while pharmacy 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.** 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 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 423DN.

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

No, neither the “UD” 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.

Hospital Outpatient EAPG

If we include the “UD” 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” modifier. The “UD” modifier 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 use 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.

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?

Hospital Manual Chapter IV

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 reduced. 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** 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

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. Said participants must also be listed on the HRSA website, www.hrsa.gov/opa/. 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 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

Effective July 27, 2014, pharmacy providers submitting 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. The following NCPDP denial edits and/or Virginia Medicaid edits may be posted if the claim is not submitted correctly:

- **8R = Submission Clarification Code Not Supported.** (DMAS edit = 1621) The billing provider is not enrolled with Virginia Medicaid as a 340B entity.
- **34 = M/I Submission Clarification Code.** (DMAS edit = 1620)
- **DN = M/I Basis of Cost Determination.** (DMAS edits = 1238, 1620 or 1622)
- **DQ = M/I Usual and Customary Charge.** (DMAS edit = 1623). The submitted acquisition cost is greater than the Virginia Medicaid allowed amount and Submission Clarification Code

= 20 and Basis of Cost = 8, the claim will deny. NOTE: Claims will continue to deny if the acquisition cost is missing or invalid for existing DMAS edit = 0014.

www.viriniamedicaid.dmas.virginia.gov/wps/myportal/ProviderManual

Medallion 4.0 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.

www.dmas.virginia.gov/files/links/5400/Medallion%204.0%20Contract%20SFY21v2.pdf

Commonwealth Coordinated Care Plus 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 DMAS 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.

www.dmas.virginia.gov/files/links/5384/FINAL%20CCC%20Plus%20Contract%20Effective%20July%202020.pdf