



# 340B Drug Discount Program Provider Manual



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## **Section 1 Background**

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. The 340B Drug Pricing Program is a federal program managed by the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs. Section 340B requires drug manufacturers to provide outpatient drugs to eligible health care centers, clinics and hospitals (termed "covered entities") at a significantly reduced price. The purpose of the 340B Program is to enable these entities to stretch scarce federal resources, reach more eligible patients and provide more comprehensive services.

#### Section 340B applies to the following provider types;

- Health Centers including Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers
- Ryan HIV/AIDS Program Grantees
- Hospitals including Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals
- Specialized Clinics including Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics

A complete list of eligible entities can be found at: https://www.hrsa.gov/opa/eligibility-and-registration/index.html

## **Section 2 DVHA 340B Policy**

While it is not required, providers may choose to carve in Medicaid beneficiaries to their 340B drug discount program. DVHA does not allow contract pharmacies to enroll in the 340b Medicaid drug program.

Effective April 1, 2018, the Department of Vermont Health Access (DVHA) has changed its payment methodology for drugs acquired through the 340B drug pricing program. Incorporating the 340B payment methodology in State Plan is required by the Center for Medicare and Medicaid Services (CMS) based on the Covered Outpatient Drug Final Rule (81 FR 5170).

Payment for drugs dispensed by pharmacies, including specialty drugs, purchased through the federal 340B program by 340B covered entities will be at the 340B actual acquisition cost, not to exceed the 340B ceiling price, plus the professional dispensing fee (PDF). Where applicable, the Professional Dispensing Fee for a retail community, institutional or long-term care pharmacy is \$11.13, and the Professional Dispensing Fee for Specialty Pharmacies dispensing Specialty Drugs including but not limited to biologics and limited distribution drugs is \$17.03.

Payment for physician administered drugs, including specialty physician administered drugs, purchased through the federal 340B program by 340B covered entities will be at the 340B actual acquisition cost, not to exceed the 340B ceiling price.

Payment for drugs dispensed by pharmacies and purchased outside of the 340B program by 340B covered entities is defined in State Plan. This payment schedule can be found in the Pharmacy Provider Manual via this link: <a href="http://dvha.vermont.gov/for-providers/2dvha-pharmacy-provider-manual-updates-cmg-07-11-17-final2.pdf">http://dvha.vermont.gov/for-providers/2dvha-pharmacy-provider-manual-updates-cmg-07-11-17-final2.pdf</a>.

### **Section 3 Enrollment Process**

#### Providers must:

- Enroll with the office of Pharmacy Affairs <a href="https://www.hrsa.gov/opa/index.html">https://www.hrsa.gov/opa/index.html</a>
- Ensure HRSA accurately represents the proper Medicaid Exclusion status.
  - This ensures that Medicaid does not seek federal rebate on 340B discounted drugs
- Complete DVHA 340B provider enrollment addendum available at <a href="http://vtmedicaid.com/#/forms">http://vtmedicaid.com/#/forms</a> (select Form Type "340B Drug Program Enrollment")
- Complete Gainwell Covered Entity Informational Form
  - Available at <a href="http://www.vtmedicaid.com/downloads/forms.html">http://www.vtmedicaid.com/downloads/forms.html</a> (select Form Type "340B Drug Program Enrollment")
  - Covered entity must assign an individual contact to establish communications between the Gainwell reconciliation team and the covered entity.
  - Entity must provide a full list of both owned and/or contracted pharmacies and prescribers
  - DVHA will verify the entities status on the HRSA website prior to implementation and at least quarterly thereafter.
  - o Form should be emailed to VT-340B@gainwelltechnologies.com

#### **Section 4 Reconciliation Process**

- 1. Each covered entity will receive a "Monthly 340B Utilization File" in Excel format. This file will contain all drug claims when billed at the POS level or if any of the following modifiers are present on the claim, UD, JD or TB. The modifiers are used when you bill for physician administered outpatient drugs. It does exclude all drug claims in which VT Medicaid is not the primary payer.
- 2. Covered entity indicates which claims are eligible for 340B pricing.
- 3. For those that are eligible the Covered entity indicates the 340B Acquisition cost as of the date of service.
- 4. The Covered Entity will then return File back to Gainwell.
- 5. Gainwell calculates the refund needed to Medicaid based on the acquisition cost as compared to the Medicaid paid amount.
- 6. Payment is due 30 days of invoice mailing.