



TEXAS  
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# **Texas Vendor Drug Program Pharmacy Provider Procedure Manual**

**340B Resources**

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[www.txvendordrug.com/about/policy/manual](http://www.txvendordrug.com/about/policy/manual)

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# 1 About 340B Drug Pricing Program

Section 340B of the Public Health Services Act requires drug manufacturers to provide outpatient drugs to Health Resources Services Administration (HRSA) eligible healthcare organizations or covered entities at significantly reduced prices. This program enables covered entities to purchase drugs at a discounted price and use the remaining funds to provide services to more eligible patients and to provide more comprehensive services. This policy also allows insurers, including Medicaid programs, to share in the savings generated by the 340B Program. Refer to the "340B Drug Pricing Program" at [www.hrsa.gov/opa/](http://www.hrsa.gov/opa/).

## 1.1 Participation

To participate in the 340B Drug Pricing Program, eligible healthcare organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. When HRSA enrolls a covered entity, that organization is assigned a 340B identification number. Drug manufacturers use this number to verify that organization is allowed to purchase 340B discounted drugs. Covered entities must designate with HRSA whether 340B discounted drugs will be used to bill Medicaid.

HRSA does not specify how covered entities should implement the 340B Program. If they comply with all 340B Program requirements, they have flexibility in implementing the 340B Program.

Most covered entities choose one or more of the following options to provide outpatient drugs to their patients:

- In-house Pharmacy, in which the covered entity owns drugs, pharmacy and license; purchases drugs; is fiscally responsible for the pharmacy; and pays pharmacy staff.
- Contract Pharmacy Services, in which the covered entity owns drugs; purchases drugs; pays (or arranges for patients to pay) dispensing fees to one or more contract pharmacies; and contracts with pharmacy to provide pharmacy services.
- Provider/In-House Dispensing, in which the covered entity owns drugs; employs providers licensed in the state to dispense; holds a license for dispensing for the participating providers; and is fiscally responsible for operating and dispensing costs.

## 1.2 Annual HRSA Recertification

HRSA requires 340B covered entities to annually recertify their eligibility to remain in the 340B Drug Pricing Program and continue purchasing covered outpatient drugs at discounted 340B prices. When recertifying, please be sure that both the entity's National Provider Identifier (NPI) and Texas-issued Medicaid vendor number are included in the HRSA database. If the covered entity is sharing the 340B savings with Medicaid (both fee-for-service and managed care) please ensure that the covered entity has answered 'YES' to the Medicaid Billing question 'Will you bill Medicaid for drugs purchased at 340B prices' and verify that the entity is also listed on the HRSA quarterly 'Medicaid Exclusion' file.

## 2 Pharmacy Provider Enrollment

### 2.1 Vendor Drug Program

The Texas Medicaid Pharmacy Provider Enrollment Application requires applicants to indicate their sources for pharmaceutical products. Covered entities participating in the HRSA 340B Drug Pricing Program are required to identify in the proper field of the application to denote that the entity is eligible to purchase products under through the HRSA 340B program. Download the **Texas Medicaid Pharmacy Provider Enrollment Application** from the "Enrollment Forms" page at [www.txvendordrug.com/providers/enrollment-forms](http://www.txvendordrug.com/providers/enrollment-forms) to enroll with VDP.

Once contracted, it is the responsibility of the covered entity to ensure the information submitted in their application remains current, including the names of pharmacists working at the pharmacy. Refer to the "Pharmacy Enrollment and Support" section of the Contact Information chapter of the PPPM for submitting updates to the original application.

### 2.2 Texas Medicaid and Healthcare Partnership

Providers cannot be enrolled in Texas Medicaid if their licenses are due to expire within 30 days. Generally, to be eligible to participate in Texas Medicaid, a provider must:

- Enroll in Medicare.
- Complete the TMHP enrollment process by submitting a paper Texas Medicaid Enrollment Application or by submitting an electronic application via the Online Provider Enrollment Portal (PEP).
- Submit a signed Texas HHS Medicaid Provider Agreement.

- Pay an application fee as required of institutional providers (42 CFR Section 455.460).
- List all the Texas-issued Medicaid vendor number(s) and NPIs with HRSA and make their Medicaid exclusion known.

Refer to the "Texas Medicaid and Healthcare Partnership" section of the Contact Information chapter of the PPPM for provider enrollment information.

## **3 Pharmacy Claim Submission**

### **3.1 Pharmacy Claims**

Pharmacies of eligible entities participating in the 340B Drug Pricing Program must identify all outpatient pharmacy claims filled with 340B stock for 340B-eligible people in all programs by submitting a value of "2Ø" ("34ØB / Disproportionate Share Pricing/Public Health Service") in the "Submission Clarification Code" field (42Ø-DK).

### **3.2 Contracted Pharmacies**

Many 340B covered entities elect to dispense 340B drugs to patients through contract pharmacy services, an arrangement in which the 340B covered entity signs a contract with a pharmacy to provide these prescription services. A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy or pharmacies. A single covered entity that has more than one 340B eligible site at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract. All contracted pharmacies must be listed in the HRSA's Office of Pharmacy Affairs (OPA) Contracted Pharmacies Database, associated with the covered entity. The covered entity is responsible for compliance of their contract pharmacy arrangement(s) and must maintain ownership of the 340B drugs.

A "ship to, bill to" procedure can be used by which the covered entity purchases the drug; the manufacturer/wholesaler bills the covered entity for the drug that it purchased and ships the drug directly to the contract pharmacy.

#### **3.2.1 Guidelines for Contract Pharmacy Services**

Guidelines that govern the operation and compliance of contract pharmacies can be found at "Notice Regarding 340B Drug Pricing Program — Contract Pharmacy Services, Final Notice." Federal Register 75 (March 5, 2010): 10272-10279. Refer

to the Federal Register at [www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf](http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf).

### 3.2.2 Responsibilities

Covered entities are responsible for ensuring compliance of their contract pharmacy arrangement(s) with all 340B Program requirements to prevent diversion and duplicate discounts.

### 3.2.3 HRSA Audit Requirements

All covered entities are required to maintain auditable records and are expected to conduct annual audits of contract pharmacies performed by an independent outside auditor to fulfill their ongoing obligation of compliance. To the extent that any compliance activity or audit performed by a covered entity indicates that there has been a violation of 340B Program requirements, such finding should be disclosed to HRSA along with the covered entity's plan to address the violation.

## 3.3 Claims Submission from a Contract Pharmacy

A pharmacy may not know at point-of-sale if a claim qualifies as a 340B claim. At the point the pharmacy is notified or discovers that the claim qualifies as a 340B claim, the original claim must be reversed and the claim resubmitted as a 340B claim with the correct "Submission Clarification Code" value (refer to Pharmacy Claim Submission, section 3 above). If the claim has not been corrected to include the correct "Submission Clarification Code" value, the pharmacy and the eligible entity are at risk for duplicate discounts.

# 4 Pharmacy Reimbursement

## 4.1 Fee-For-Service Medicaid, CSHCN, HTW, and KHC

Effective June 1, 2016, the reimbursement methodology for calculating the ingredient cost of pharmacy claims paid to eligible health care organizations is based on the Wholesale Acquisition Cost (WAC):

- Human Immunodeficiency Virus (HIV) products
  - ▶ WAC minus 40 percent
- Hemophilia products
  - ▶ WAC minus 32 percent

- Brands and generics
  - ▶ WAC minus 57 percent

New drugs are added to the formulary at WAC minus 23.1 percent for 6 months. This methodology is not all inclusive and some products may be priced manually.

## 4.2 Medicaid Managed Care

Medicaid managed care organizations (MCO) implemented their own 340B reimbursement methodologies on December 1, 2014. Pharmacy staff should contact the MCO in question for specific processes. Refer to the "Managed Care" section of the Contact Information chapter of the PPPM for contacting the specific MCO.

Medicaid managed care organizations have been notified of the eligible entity's requirement to submit a value of "2Ø" in the "Submission Clarification Code" field (42Ø-DK) for pharmacy claims to denote claims filled with stock purchased through the 340B program.

- A 340B covered entity seeking to use 340B stock in Medicaid managed care must contract with the MCO as a 340B pharmacy and accept the payment terms of their "shared-savings" model:
- If the 340B covered entity does not accept the terms of an MCO's shared savings model for the reimbursement of 340B-purchased drugs, then the covered entity may choose to contract with the MCO as a retail pharmacy.
- If the covered entity contracts with an MCO as a retail pharmacy, the entity cannot use 340B purchased drugs.
- If a pharmacy is not contracted as a 340B pharmacy in their network, MCOs may deny claims submitted with a value of "2Ø" in the "Submission Clarification Code" field (42Ø-DK) as the pharmacy should not have utilized 340B stock.

An MCO cannot require one of its network pharmacy providers to submit its actual acquisition cost (AAC) on outpatient drugs and biological products purchased through the 340B program, consistent with UMCM Chapter 2.2, "Pharmacy Claims Manual."

## 5 Clinician-Administered Drug Claim Submission

Beginning September 1, 2015, all eligible organizations and covered entities that are enrolled in the federal 340B Drug Pricing Program to purchase 340B discounted drugs must use modifier "U8" when submitting claims for 340B clinician-administered drugs. Non-compliance with this requirement may jeopardize a covered entity's 340B status with HRSA. This modifier requirement for 340B clinician-administered drugs applies for Medicaid fee-for-service claims submitted to TMHP and Medicaid managed care claims submitted to the patient's managed care organization.

It is the responsibility of the covered entity to correctly submit claims filled with 340B stock for 340B-eligible patients to ensure rebates are not collected for these drugs.

For all clinician-administered drug claims, all Texas Medicaid providers must submit a rebate-eligible National Drug Code (NDC) and modifier "U8" for professional or outpatient claims, including Medicare crossover claims submitted to TMHP, with a clinician-administered drug-related Healthcare Common Procedure Coding System (HCPCS). Texas Medicaid defines clinician-administered drugs as physician-administered drugs for procedure codes listed on the Texas NDC-to-HCPCS Crosswalk ("crosswalk").

The NDC is an 11-digit number on the package or container from which the medication is administered. Providers must enter modifier "N4" in front of the NDC code on all claim forms. The "NDC Quantity" and the "NDC Unit of Measure" must be entered on all professional or outpatient claims that are submitted to TMHP. TMHP edits medical claims against the crosswalk, which identifies relationships between rebate-eligible NDC and HCPCS codes. All claims with a HCPCS code listed on the crosswalk require a corresponding NDC.

To review the crosswalk and drug labeler directory, refer to [www.txvendordrug.com/formulary/formulary/clinician-administered-drugs](http://www.txvendordrug.com/formulary/formulary/clinician-administered-drugs)

If a provider believes that NDCs are missing for a specific HCPCS procedure code, the provider can submit an email to [vdp-cad@hpsc.state.tx.us](mailto:vdp-cad@hpsc.state.tx.us) requesting an update to the crosswalk. The email should include the procedure code(s) and corresponding NDCs that are believed to be missing.

For more information related to submission of medical claims, call the TMHP Contact Center at 1-800-925-9126.



## 6 Drug Rebates

All outpatient pharmacy and clinician-administered drug claims for all state-administered drug rebate programs are sent to the VDP Drug Rebate System for invoicing.

VDP invoices drug manufacturers for all claims, not excluded because of the 340B program, where the state has paid any amount of money, including co-pay, co-insurance, or any other payment type. Claims or amounts paid for dual eligible patients, either directly by the state or through a Medicaid MCO, are also invoiced.

### 6.1 Pharmacy Rebates

Outpatient pharmacy drug claims submitted with a date of service on or after January 1, 2014, will only be excluded from the drug rebate system invoicing process if they are submitted with a "20" in Submission Clarification Code (Field 420-DK). It is the responsibility of the covered entity and their contracted pharmacies to correctly report claims filled with 340B stock for 340B-eligible patients to ensure rebates are not collected for these drugs.

### 6.2 Clinician-Administered Drug Rebates

For outpatient clinician-administered drug claims, Texas HHS uses the modifier "U8" on claims and encounters, as well as HRSA's Office of Pharmacy Affairs (OPA) Medicaid Exclusion file to identify Texas providers that have been added or deleted. Refer to the "Medicaid Exclusion File" at [www.340bopais.hrsa.gov/medicaidexclusionfiles](http://www.340bopais.hrsa.gov/medicaidexclusionfiles).

For claims and encounters with a paid date on or after April 1, 2017, only medical claims and encounters with the U8 in the modifier field will be excluded from Texas HHS's rebate invoicing. Texas invoices drug manufacturers for all other claims where the state has paid any amount of money, including co-pays, co-insurance, capitated rates, or any other payment type. Claims or amounts paid for people that are dual eligible, either directly by the state or through a Medicaid managed care health plan, are also invoiced.

## 7 Responsibilities

Covered entities/contracted pharmacies:

- Correctly reporting claims filled with 340B stock for 340B-eligible patients to ensure rebates are not collected for these drugs

- Working with the drug manufacturer to resolve disputes when either traditional or managed care claims are not indicated appropriately with SCC “20” or “U8” modifiers and HHSC invoices for rebates

MCOs and pharmacy benefit managers:

- Maintain shared-savings model
- Passing the submission clarification code “20” or “U8” modifier in encounter data to HHSC
- It is not their responsibility to oversee covered entities or the contracted pharmacy to ensure rebates are not collected.

HHSC does not approve alternative arrangements for preventing duplicate discounts. The automated drug rebate system relies on the submitted code or modifier to identify claims excluded from the rebate invoicing process.