ISSUED: 12/01/05 REPLACED:

# CHAPTER 37: PHARMACY BENEFITS MANAGEMENT SERVICESSECTION 37.11: PUBLIC HEALTH SERVICES340B DRUG PRICING PROGRAMPAGE(S) 4

### **37.11 PUBLIC HEALTH SERVICES 340B DRUG PRICING PROGRAM**

#### Overview

Introduction	This Section explains the reimbursement methodology for the Public Health services (PHS) 340B Drug Pricing Program that ensures all State Medicaid agencies obtain the full pricing advantages available.
In This Section	This Section contains:
	Public Health Services 340B Program Definitions Pharmacy Eligibility and Enrollment Reimbursement Methodology Contacts

ISSUED: 12/01/05 REPLACED:

## CHAPTER 37: PHARMACY BENEFITS MANAGEMENT SERVICESSECTION 37.11: PUBLIC HEALTH SERVICES340B DRUG PRICING PROGRAMPAGE(S) 4

### **37.11.1 PUBLIC HEALTH SERVICES 340B PROGRAM**

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 (PHS) Act.

In 1990, Congress created the Medicaid Rebate Program to lower the cost of pharmaceuticals reimbursed by state Medicaid programs. The program required drug companies to pay rebates as a precondition to having their drugs covered by Medicaid. As a result of the Medicaid rebate law, many drug companies increased the prices of their products to offset the Medicaid discounts. Other federally and state-supported providers' drug expenses increased significantly because of the companies' changes in pricing strategies and eventually offset any savings realized as part of the Medicaid rebate law.

In order to remedy this situation, Congress enacted the Veterans Health Care Act of 1992. Section 602 of that Act added section 340B to the PHS Act requiring drug companies whose drugs are covered by the Medicaid Program to provide discounts on covered drugs purchased by certain government-supported facilities and/or entities. Significant savings on pharmaceuticals may be seen by those entities that participate in this program

#### **37.11.2 DEFINITIONS**

Actual Acquisition Cost	The covered entity's net payment made to purchase a drug product, after taking into account such items as purchasing allowances, discounts, wholesaler fees and rebates.
Contract Pharmacy	A pharmacy under contract with a covered entity that lacks its own pharmacy whereby the contract pharmacy is authorized to dispense 340B-discounted drugs on behalf of the covered entity in accordance with 1996 Health Resources and Services Administration (HRSA) guidelines (61 FR 43549, August 23, 1996). C ontract pharmacies may also serve as billing agents for covered entities.
Covered Entity	A provider or program that meets the eligibility criteria for participating in the 340B Program as set forth in Section 340B(a)(4) of the PHS Act. C overed entities include eligible disproportionate share hospitals that are owned by or under contract with state or local government, community health centers, migrant health centers, health centers for public housing, health centers for the homeless, AIDS drug assistance programs and other AIDS clinics and programs, black lung clinics, hemophilia treatment centers, native Hawaiian health centers, urban Indian clinics/638 tribal centers, school-based programs, Title X family planning clinics, sexually-transmitted disease clinics, and tuberculosis clinics.

ISSUED: 12/01/05 REPLACED:

## CHAPTER 37: PHARMACY BENEFITS MANAGEMENT SERVICESSECTION 37.11: PUBLIC HEALTH SERVICES340B DRUG PRICING PROGRAMPAGE(S) 4

Dispensing Fee	The fee paid by Medicaid for the professional services provided by a pharmacist when dispensing a prescription, including the \$.10 provider fee assessed for each prescription filled in the State of Louisiana per legislative mandate.
Medicaid Carve-Out	A billing mechanism is available to covered entities that implements the 340B requirement protecting manufacturers from giving a 340B discount and paying a Medicaid rebate on the same drug. If a covered entity elects to implement the Medicaid carve-out option, the covered entity only purchases through the 340B Program covered drugs dispensed to non-Medicaid patients; drugs dispensed to Medicaid patients are purchased outside the 340B Program.
Patient	An individual eligible to receive 340B discounted drugs from a covered entity by virtue of being the covered entity's patient as defined in HRSA's 1996 pa tient definition guideline (61 FR 55156, October 24, 1996).
340B Program	The federal drug discount program established under Section 340B of the PHS Act and administered by the Office of Pharmacy Affairs within HRSA.

### **37.11.3 PHARMACY ELIGIBILITY AND ENROLLMENT**

In order to become eligible to participate in the 340B Program, a facility must submit a request to the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA), Department of Health and Human Services.

Entities must enroll in Louisiana Medicaid in order to bill and receive reimbursement for self-administered drugs purchased through the 340B Program and dispensed to eligible 340B patients.

**Note:** Refer to Section 37.2 Pharmacy Provider Enrollment and Participation Guidelines for additional enrollment and participation information.

### **37.11.4 REIMBURSEMENT METHODOLOGY**

Covered Entity Self-administered drugs that are purchased by a covered entity through the 340B program and dispensed to patients who are covered by Medicaid shall be billed to Medicaid at actual acquisition cost unless the covered entity has implemented the Medicaid carve-out option, in which case such drugs shall be billed in accordance with existing state Medicaid reimbursement methodologies.

Contract Pharmacies In that the covered entity has entered into a contract pharmacy arrangement and the contract pharmacy serves as the covered entity's billing agent, the contract pharmacy

## CHAPTER 37: PHARMACY BENEFITS MANAGEMENT SERVICESSECTION 37.11: PUBLIC HEALTH SERVICES340B DRUG PRICING PROGRAMPAGE(S) 4

shall bill Medicaid at actual acquisition cost under the covered entity's Medicaid pharmacy billing number, unless the covered entity has implemented the Medicaid carveout option, in which case such drugs shall be billed in accordance with existing state Medicaid reimbursement methodologies under the contract pharmacy's Medicaid pharmacy billing number.

**Dispensing Fee** 

The covered entity shall be paid a dispensing fee of \$8.10 for each prescription dispensed to a Medicaid patient, unless the covered entity has implemented the carve-out option, in which case the covered entity shall be paid the state's existing non-340B dispensing fee. With respect to contract pharmacy arrangements in which the contract pharmacy also serves as the covered entity's billing agent, the contract pharmacy shall be paid the \$8.10 dispensing fee on behalf of the covered entity, unless the covered entity elects the Medicaid carve-out, in which case the contract pharmacy shall be paid the state's existing non-340B dispensing fee.

### **37.11.5 CONTACTS**

Any questions regarding the 340B program should be directed to HRSA, Office of Pharmacy Affairs at:

Office of Pharmacy Affairs HSB/HRSA 5600 Fishers Lane Rockville, MD 20857 301-594-4353 800-628-6297 <u>OpaStaff@hrsa.hhs.gov</u> http://www.hrsa.gov/opa

Providers may also contact the LMPBM Section at 225-342-9768.