

340B Drug Pricing Program Overview

Overview:

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 Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices allowing them to reach more eligible recipients and provide these recipients with more comprehensive services.

Eligible health care organizations/covered entities are defined in statute and include Health Resources and Services Administration (HRSA) supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.

To participate in the 340B Program, eligible organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs.

Medicaid Drug Rebates and 340B Pricing:

The Agency is authorized, through Florida Statutes, to negotiate supplemental rebates with drug manufacturers for prescription drugs dispensed to Medicaid recipients. The Agency contracts with a vendor for drug rebate administration including calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

Since manufacturers give large drug purchase discounts to 340B entities, state Medicaid programs must exempt outpatient drug claims from the drug rebate process. The Agency's rebate vendor, Molina Medicaid Solutions, excludes all claims billed from covered entities from the rebate invoicing process. These entities are those whose National Provider Identifiers or Medicaid identification numbers are identified on the HRSA website as a 340B covered entity.

Reimbursement Policy

The Florida Medicaid reimbursement methodology for covered drugs is described in Rule 59G-4.251, Florida Administrative Code, and in the Florida Medicaid State Plan.

Covered entities and Federally Qualified Health Centers that fill Medicaid patient prescriptions with 340B drugs must bill Medicaid for reimbursement at Actual

Acquisition Cost plus the state allowable dispensing fee. Please see Appendix 1 for Agency rule and state plan language.

Appendix 1

Medicaid Rule Language:

59G-4.251 Florida Medicaid Prescribed Drugs Reimbursement Methodology.

(1) Reimbursement for prescribed drug claims is made in accordance with the provisions of Title 42, Code of Federal Regulations Sections 447.512-.516. Reimbursement for covered drugs dispensed by a licensed pharmacy, approved as a Medicaid provider, by an enrolled dispensing physician filling his own prescriptions, or by a medical professional administering injectable medications, shall not exceed the lower of:

(a) The estimated acquisition cost, defined as the lower of:

1. Average Wholesale Price (AWP) minus 16.4%, or Wholesaler Acquisition Cost (WAC) plus 1.5%, plus a dispensing fee of \$3.73;

2. The Federal Upper Limit (FUL) established by the Centers for Medicare and Medicaid Services, plus a dispensing fee of \$3.73; or

(b) The State Maximum Allowable Cost (SMAC), plus a dispensing fee of \$3.73; or

(c) The provider's Usual and Customary (U&C) charge, inclusive of dispensing fee.

(2) For drugs purchased by qualified entities under Section 340B of the Public Health Service Act:

Covered entities and Federally Qualified Health Centers or their contracted agents that fill Medicaid patient prescriptions with drugs purchased at prices authorized under Section 340B of the Public Health Service Act must bill Medicaid for reimbursement at the actual acquisition cost plus a dispensing fee of \$7.50 for these drugs.

Rulemaking Authority 409.919 FS. Law Implemented 409.906(20), 409.908, 409.912(39)(a) FS. History—New 1-28-09, Amended 8-23-09, 5-20-12.

Medicaid State Plan Language:

Attachment 4.19-B

7/1/2004 PRESCRIBED DRUGS

Reimbursement for prescribed drug claims is made in accordance with the provisions of 42 CFR 447.516, pertaining to upper limits.

1. Reimbursement for covered drugs dispensed by a licensed pharmacy that has been approved as a Medicaid provider, or a physician filling his own prescriptions if there is no licensed pharmacy within a ten mile radius of his office, shall not exceed the lowest of:

(a) For generic drugs:

i. The amount established by CMS as the Federal Upper Limit (FUL) in accordance with 42 CFR §447.516. Payment for multiple-source drugs for which CMS has established upper limit will not exceed, in the aggregate, the set upper limits plus a dispensing fee.

ii. The estimated acquisition cost (EAC) as established in Florida statute plus a dispensing fee~ the state maximum allowable cost (SMAC) plus a dispensing fee; or the provider's usual and customary charges to the general public (non-Medicaid).

iii. Products that are prohibited from generic substitution under state statutes may be declared "medically necessary" and reimbursed at the appropriate rate from the drug pricing file.

(b) For brand name drugs:

The estimated acquisition cost for the drug plus a dispensing fee; or the provider's usual and customary charges to the general public (non-Medicaid).

(c) 340B drugs:

Covered entities and Federally Qualified Health Centers that fill Medicaid patient prescriptions with 340B drugs must bill Medicaid for reimbursement at Actual Acquisition Cost plus the state allowable dispensing fee.