
CHAPTER 37: PHARMACY BENEFITS MANAGEMENT SERVICES

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PUBLIC HEALTH SERVICES 340B DRUG PRICING PROGRAM

The Drug Rebate program was established in 1990. The Veterans Health Care Act of 1992 established the 340B Drug Pricing Program through the enactment of Public Law 102-585. The Veterans Health Care Act of 1992 is codified as Section 340B of the Public Health Services (PHS) Act.

Section 340B of the Public Health Services Act requires drug manufacturers that receive reimbursement from state Medicaid programs to supply drugs to the 340B Drug Pricing Program at a discounted rate. The Office of Pharmacy Affairs (OPA) of the Bureau of Primary Health Care at the Health Resources and Services Administration (HRSA) administers the program. This Federal program is run by Apexus' Prime Vendor Program, which negotiates discounted drug products for use by covered entities that are certified as 340B providers.

To participate in the 340B program eligible entities must register with HRSA. Recertification must be completed annually, and 340B drugs may only be dispensed by eligible organizations to eligible patients. Drug manufacturers and HRSA have the authority to audit covered entities for program compliance. Additional information may be found on the HRSA website. (See Appendix N for contact information.)

Reimbursement Methodology**Covered Entity**

Self-administered drugs (ambulatory and retail medications) 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. 340B drug stock cannot be used in an inpatient setting.

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Contract Pharmacies

Covered entities that are not equipped to provide pharmacy services may contract with pharmacy providers. A “ship to, bill to” procedure is used in which the covered entity purchases 340B stock that is shipped directly to the contract pharmacy.

Claims billed to Medicaid by contract pharmacies are only excluded from Medicaid’s drug rebate program if the contract pharmacy is listed in the HRSA Exclusion File. To be listed in the exclusion file, the pharmacy:

- Has attested to HRSA that all of its Medicaid claims are “carved-in” to the 340B program; and
- All of their Medicaid claims are dispensed from 340B stock, whether the claims were billed for the covered entity or as part of the pharmacy’s regular retail business.

It is the responsibility of the covered entity to ensure their 340B program and any contract pharmacies are in compliance with HRSA requirements. Information on HRSA’s guidelines for contract pharmacy agreements, responsibilities and requirements can be located on HRSA website. (See Appendix N for contact information.)

NOTE: Refer to Section 37.2 Pharmacy Provider Enrollment and Participation Guidelines of this manual chapter for additional enrollment and participation information.

HRSA maintains a national 340B exclusion file for use by all state Medicaid programs during drug rebate invoicing. The file is available to the public for download. (See Appendix N for information on accessing the file.)

All 340B covered entities are required to determine whether their Medicaid claims are “carved-in” or “carved-out” of their 340B program. “Carved-in” means that all drug claims billed to Medicaid are dispensed from regular stock purchased through the 340B program. Each covered entity attests to its status to HRSA and only those that carve all Medicaid patients into their 340B programs are excluded from each state’s drug rebate program.

Claims billed to Medicaid by contract pharmacies are only excluded from drug rebate invoicing if the contract pharmacy has attested to HRSA that all Medicaid claims are “carved-in” to the 340B program and all of their Medicaid claims are dispensed from 340B stock. The covered

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entity's carved-in status does not apply to its network pharmacies. If the contract pharmacy bills Medicaid claims in its regular business, none of that pharmacy's claims will be excluded from drug rebate invoicing.

The Medicaid Program reviews the HRSA exclusion file quarterly with each invoicing cycle and removes providers from drug rebate invoicing according to the term dates provided by HRSA.

The Medicaid Program invoices drug manufacturers for fee-for-service Medicaid and managed care Medicaid claims. Claims billed by covered entities that are listed on the HRSA exclusion file are removed from invoicing for both fee-for-service and managed care Medicaid patients.

Questions regarding the 340B program should be directed to HRSA, Office of Pharmacy Affairs. (See Appendix N for contact information.)

Providers may also contact the Pharmacy Program.