

101 CMR 331.00: PRESCRIBED DRUGS

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331.01: General Provisions

- (1) Scope, Purpose and Effective Date. 101 CMR 331.00 governs the payment rates effective July 1, 2016 for Drugs dispensed by Providers to Publicly-aided Individuals and Industrial Accident Patients, and 340B entity patients.
- (2) Coverage. The rates of payment under 101 CMR 331.00 are full compensation for professional services rendered, as well as for any related administrative or supervisory duties.
- (3) Administrative Bulletins. The EOHHS may issue administrative bulletins to clarify its policy on and meaning of substantive provisions of 101 CMR 331.00, or to publish procedure code updates and corrections.
- (4) Disclaimer for Authorization of Services. 101 CMR 331.00 is not authorization for or approval of the services for which rates are established by 101 CMR 331.00. Purchasers are responsible for the definition, authorization, and approval of care and services provided to Publicly-aided individuals and Industrial Accident Patients.

331.02: General Definitions

340B Covered Entities. Facilities and programs eligible to purchase discounted drugs through a program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992.

340B Drug Pricing Program. A program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992, permitting certain grantees of federal agencies access to reduced cost drugs for their patients.

Actual Acquisition Cost (AAC). The amount a pharmacy pays for a drug, net of discounts, rebates, charge backs, and other adjustments to the price of the drug.

Brand Name Preferred. A Multiple Source Drug that is designated pursuant to 130 CMR 406.413(A)(3).

Center. The Center for Health Information and Analysis established under M.G.L. c. 12C.

Compounded Drug. Any drug, excluding cough preparations, in which two or more ingredients are extemporaneously mixed by a registered pharmacist.

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Dispensing Fee. The fee paid, over and above the ingredient cost of the drug, to Providers by Governmental Units and Purchasers under M.G.L. c. 152 for dispensing drugs to Publicly aided individuals and/or industrial accident patients.

Drug. A substance containing one or more active ingredients in a specified dosage form and strength and authorized by the purchasing Governmental Unit or Purchaser under M.G.L. c. 152. Each dosage form and strength is a separate Drug.

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Estimated Acquisition Cost. An estimate of the price generally and currently paid by non-340B covered entity Providers for the most frequently purchased package size of a drug. The Estimated Acquisition Cost is the drug wholesaler's acquisition cost (WAC) plus 5%.

EOHHS. The Executive Office of Health and Human Services established under M.G.L. c. 6A.

Federal Upper Limit. The Federal Upper Limit as established by the Centers for Medicare and Medicaid Services (CMS) by regulation or otherwise.

Fiscal Year. The annual accounting period adopted by a Provider.

Governmental Unit. The Commonwealth, any department, agency, board or commission of the Commonwealth, and any political subdivision of the Commonwealth.

Industrial Accident Patient. A person who receives medical services for which persons, corporations or other entities are in whole or part liable under M.G.L. c. 152.

Massachusetts Maximum Allowable Cost. For Multiple Source Drugs not designated as Brand Name Preferred, an amount equal to 130% of the price of the least costly therapeutic equivalent as listed in any United States published or other United States public source for the most frequently purchased package size, excluding the Average Manufacturer Price, as published by CMS. For Multiple Source Drugs designated as Brand Name Preferred, an amount equal to the lower of the Estimated Acquisition Cost or the Usual and Customary Charge for the preferred brand name drug

Most Frequently Purchased Package Size. The package size of a drug most frequently purchased by Providers based on utilization data compiled by MassHealth. Thus, that NDC number which is most often paid by the MassHealth, and verified by audit, if necessary, will be considered the most frequently purchased package size.

Multiple Source Drug. A drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

National Average Drug Acquisition Cost (NADAC). The National Average Drug Acquisition Cost as published by CMS.

National Drug Code (NDC) Number. A unique number issued by the United States Food and Drug Administration to identify drug products. The NDC number has three components: the first component identifies the drug manufacturer (Labeler No.); the second component identifies the product (Product No.); and the third component identifies the package size (Pkg.).

Over-the-counter Drug. Any drug for which no prescription is required by federal or state law. These drugs are sometimes referred to as non-legend drugs. MassHealth requires a prescription for both Prescription Drugs and Over-the-counter Drugs (*see* 130 CMR 406.411(A): *Legal Prescription Requirements*).

Prescription Drug. Any drug for which a prescription is required by applicable federal and/or state laws or regulations other than MassHealth regulations. These drugs are sometimes referred to as legend drugs.

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Provider. A pharmacy that is licensed by the Board of Registration in Pharmacy in accordance with the provisions of M.G.L. c. 112 or by the Department of Public Health in accordance with the provisions 105 CMR 700.004: *Registration Requirements*, and which also meets the current conditions of participation of the purchasing Governmental Unit, Purchaser under M.G.L. c. 152, or the 340B Program, as applicable.

Publicly-aided Individual. A person for whose medical or other services a Governmental Unit is in whole or in part liable under a statutory public program.

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Purchaser under M.G.L. c. 152. An insurance company, self insurer, or worker's compensation agent of a department of the Commonwealth, county, city or district which purchases medical services subject to M.G.L. c. 152, § 1.

Single Source Drug. A drug marketed or sold by only one manufacturer or labeler under one proprietary name.

Usual and Customary Charge. The lowest price that a Provider charges or accepts from any payer for the same quantity of a drug on the same date of service, in Massachusetts, including but not limited to the shelf price, sale price, or advertised price for any drug including an over-the-counter drug. If an insurer and the Eligible Provider have a contract that specifies that the insurer will pay an average or similarly computed fixed amount for multiple therapeutic categories of drugs with different acquisition costs, the fixed amount will not be the Provider's usual and customary charge.

Wholesale Acquisition Cost (WAC). A manufacturer's price published in a national price compendium or other publicly available source or an adjusted list price.

331.03: Reporting Requirements

(1) Required Reports. Reporting requirements are governed by 957 CMR 6.00: *Cost Reporting Requirements*.

(2) Penalty for Noncompliance. The purchasing governmental unit may reduce the payment rates by 15% for any provider that fails to submit required information to the Center. The purchasing governmental unit will notify the provider in advance of its intention to impose a rate reduction

331.04: Payment for Prescription Drugs

(1) Payment for Multiple Source Drugs. Payment for Multiple Source Drugs not designated as Brand Name Preferred shall not exceed the lowest of:

- (a) The Federal Upper Limit of the drug, if any, plus the appropriate Dispensing Fee as listed in 101 CMR 331.06; or
- (b) The Massachusetts Maximum Allowable Cost of the drug, if any, plus the appropriate Dispensing Fee as listed in 101 CMR 331.06; or
- (c) The Estimated Acquisition Cost, plus the appropriate Dispensing Fee as listed in 101 CMR 331.06; or
- (d) The Usual and Customary Charge.

(2) Payment for Blood Clotting Factor. Payment for Blood Clotting Factor shall not exceed the lowest of:

- (a) The Federal Upper Limit of the drug, if any, plus the appropriate Dispensing Fee as listed in 101 CMR 331.06; or
- (b) The Massachusetts Upper Limit of the drug, if any, plus the appropriate Dispensing Fee as listed in 101 CMR 331.06; or
- (c) The Estimated Acquisition Cost, plus the appropriate Dispensing Fee as listed in 101 CMR 331.06;
- (d) The Medicare Part B rate; or

(e) The Usual and Customary Charge.

(3) Payment for All Other Drugs. These include Single Source Drugs, Multiple Source Drugs designated as Brand Name Preferred, and brand name drugs which have been certified as medically necessary (*i.e.*, for which the prescriber has designated "no substitution" and "brand name medically necessary" on the prescription form). Payment shall not exceed the lower of:

(a) Maximum Allowable Cost

(b) The Estimated Acquisition Cost, plus the appropriate Dispensing Fee as listed in 101 CMR 331.06; or

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(c) The Usual and Customary Charge.

(4) Rate Limitation. The rates determined under 101 CMR 331.04 shall not, in the aggregate, exceed the upper limits established by the Centers for Medicare and Medicaid Services (CMS) by regulation or otherwise.

331.05: Payment for Over-the-counter Drugs

(1) Payment for Over-the-counter Drugs. Payment to Providers for an Over-the-counter Drug dispensed is the lowest of:

- (a) The Massachusetts Upper Limit of the drug plus the appropriate Dispensing Fee as listed in 101 CMR 331.06;
- (b) the Estimated Acquisition Cost plus the appropriate Dispensing Fee as listed in 101 CMR 331.06; or
- (c) the Usual and Customary Charge.

331.06: Dispensing Fees

(1) Drugs. Except for Compounded Drugs, the Dispensing Fee is \$3.00 per prescription.

(2) Compounded Drugs. For Compounded Drugs, the Dispensing Fee is \$3.00 plus:

- (a) An additional \$1.00 for:
  1. compounding ointments or solutions; or
  2. preparing solutions (excluding cough preparations) which involve the weighing of ingredients; or
- (b) An additional \$2.00 for:
  1. compounding suppositories; or
  2. compounding capsules, tablets, triturates or powders.

331.07: Special Provisions

(1) Payment for 340B Covered Entities.

(a) The payment for Drugs other than blood clotting factor, obtained through the 340B Program and dispensed by 340B Covered Entities is the Actual Acquisition Cost plus a \$10.00 Dispensing Fee.

(b) 340B Payment for Blood Clotting Factor for Hemophilia Treatment Centers

The payment for blood clotting factor obtained through the 340B program and dispensed by 340B covered entities is the actual acquisition cost plus a dispensing fee of .09¢ per unit (IU/RCo/Fu/mcg). This rate includes supplies for standard infusion (*e.g.* Butterfly/ PIV access.)

(2) Payment for Innovative Programs. Governmental Units may elect to purchase Drugs pursuant to a written agreement between a Provider and the purchasing agency. Such agreement must relate to an innovative program sponsored by the purchasing agency, and is subject to the approval of EOHHS authorizing special Payment Rates for Drugs dispensed pursuant to such agreement.

331.08: Severability

The provisions of 101 CMR 331.00 are severable, and if any provision of 101 CMR 331.00

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or application of such provisions to any Provider or any circumstances shall be held to be invalid or unconstitutional, such invalidity shall not be construed to affect the validity or constitutionality of any remaining provisions of 101 CMR 331.00 or application of such provisions to any Providers or circumstances other than those held invalid.

REGULATORY AUTHORITY

101 CMR 331.00: M.G.L. c. 118G.