

114.3 CMR: DIVISION OF HEALTH CARE FINANCE AND POLICY

114.3 CMR 31.00: PRESCRIBED DRUGS

Section

- 31.01: General Provisions
- 31.02: General Definitions
- 31.03: Reporting Requirements
- 31.04: Payment for Prescription Drugs
- 31.05: Payment for Over-the-counter Drugs
- 31.06: Dispensing Fees
- 31.07: Special Provisions
- 31.08: Severability

31.01: General Provisions

(1) Scope, Purpose and Effective Date. 114.3 CMR 31.00 governs the payment rates effective August 1, 2009 for Drugs dispensed by Providers to Publicly-aided Individuals and individuals covered by M.G.L. c. 152 (the Worker's Compensation Act).

(2) Coverage. The rates of payment under 114.3 CMR 31.00 are full compensation for professional services rendered, as well as for any related administrative or supervisory duties.

(3) Administrative Bulletins. The Division may issue administrative bulletins to clarify its policy on and meaning of substantive provisions of 114.3 CMR 31.00, or to publish procedure code updates and corrections.

(4) Disclaimer for Authorization of Services. 114.3 CMR 31.00 is not authorization for or approval of the services for which rates are established by 114.3 CMR 31.00. Purchasers are responsible for the definition, authorization, and approval of care and services extended to Publicly-aided individuals.

(5) Authority. 114.3 CMR 31.00 is adopted pursuant to M.G.L. c. 118G.

31.02: General Definitions

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.

8/20/2009

Actual Package Size. The package size of any drug for which a most frequently purchased package size has not been determined by the Division shall be the actual package size as indicated by the National Drug Code (NDC) listed on the container from which the pharmacist dispenses the drug.

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

Dispensing Fee. The fee paid, over and above the ingredient cost of the drug, to Providers by Governmental Units and purchasers under the Worker's Compensation Act for dispensing drugs to Publicly-aided individuals and/or industrial accident patients.

Division. The Division of Health Care Finance and Policy, established under M.G.L. c. 118G.

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.

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 percent.

Federal Upper Limit. The Federal Upper Limit as established by the Centers for Medicare and Medicaid Services (CMS) in 42 CFR 447.332.

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.

Massachusetts Upper Limit. For Multiple Source Drugs, an amount equal to one hundred thirty percent 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. The Massachusetts Upper Limit is also known as the Maximum Allowable Cost (MAC) as defined in MassHealth Regulation 130 CMR 406.000.

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

8/20/2009

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 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)).

Pharmacy. Any pharmacy registered by the Board of Registration in Pharmacy in accordance with the provisions of M.G.L. c. 112.

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.

Provider. Providers are defined as:

- (a) pharmacies, as defined in 114.3 CMR 31.02;
- (b) clinic pharmacies licensed by the Department of Public Health in accordance with the provisions of M.G.L. c. 111 and which also meet the current conditions of participation of the purchasing Governmental Unit or purchaser under M.G.L. c. 152; and
- (c) pharmacies, as defined in 114 CMR 31.02, operated by or under contract to 340B Covered Entities.

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.

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

Unit-dose Packaging. An individual drug product container usually consisting of foil, molded plastic, or laminate with indentations for a single solid oral dosage form, with any accompanying materials or components, including labeling. Each individual

8/20/2009

container fully identifies the drug and protects the integrity of the dosage. For purposes of 114.3 CMR 31.00, an assemblage of multiple, unlabeled single doses (traditional “bingo cards” or “bubble packs”) is not unit-dose packaging.

Unit-dose-return Fee. The fee paid by Governmental Units to Providers for accepting returned drugs in Unit-dose Packaging, as defined in 114.3 CMR 31.02, and in accordance with 130 CMR 406.446.

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.

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 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.

### 31.03: Reporting Requirements

(1) Required Reports and Records. Each Provider shall:

- (a) file such data and information as the Division shall reasonably require.
- (b) certify the accuracy and truthfulness of all data, information, reports, books, and records submitted to the Division.
- (c) make available to the Division all reports, books, and records relating to its operation for audit.
- (d) 340B Covered Entities must file, on a quarterly basis, additional data as described in the Division’s 340B-1 Report.

(2) Filing Dates.

- (a) Providers shall file all required reports and records with the Division within the time period specified by the Division in its request.
- (b) The Division may, for cause, extend the filing date for submission of required reports and records.

(3) Penalties. The Division may impose penalties for failure to comply with the reporting requirements under 114.3 CMR 31.03(1) and (2) in accordance with M.G.L. c. 118G, § 8.

31.04: Payment for Prescription Drugs

(1A) Payment for Multiple Source Drugs. Payment for Multiple Source Drugs shall not exceed the lowest of:

- (a) The Federal Upper Limit of the drug, if any, plus the appropriate Dispensing Fee as listed in 114.3 CMR 31.06; or
- (b) The Massachusetts Upper Limit of the drug, if any, plus the appropriate Dispensing Fee as listed in 114.3 CMR 31.06; or
- (c) The Estimated Acquisition Cost, plus the appropriate Dispensing Fee as listed in 114.3 CMR 31.06; or
- (d) The Usual and Customary Charge.

(1B) 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 114.3 CMR 31.06; or
- (b) The Massachusetts Upper Limit of the drug, if any, plus the appropriate Dispensing Fee as listed in 114.3 CMR 31.06; or
- (c) The Estimated Acquisition Cost, plus the appropriate Dispensing Fee as listed in 114.3 CMR 31.06;
- (d) The Medicare Part B rate; or
- (e) The Usual and Customary Charge.

(2) Payment for All Other Drugs. These include single source drugs 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) The Estimated Acquisition Cost, plus the appropriate Dispensing Fee as listed in 114.3 CMR 31.06; or
- (b) The Usual and Customary Charge.

(3) Rate Limitation. The rates determined under 114.3 CMR 31.04 shall not, in the aggregate, exceed the upper limits established pursuant to 42 CFR 447.331.

31.05: 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 114.3 CMR 31.06;
- (b) the Estimated Acquisition Cost plus the appropriate Dispensing Fee as listed in 114.3 CMR 31.06; or
- (c) the Usual and Customary Charge.

31.06: 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.

31.07: 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

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 9 cents per unit (IU/RCo/Fu/mcg). This rate includes supplies for standard infusion (e.g. Butterfly/ PIV access.)

(2) Unit-dose-return Fee. The Unit-dose-return Fee paid to Providers that dispense drugs in nursing facilities for accepting returned drugs in unit-dose packaging, in accordance with 130 CMR 406.446, is \$5.00 per unit-dose package.

8/20/2009

(3) Payment for Innovative Programs. Governmental Units may elect to purchase Drugs pursuant to a written agreement between an 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 the Division authorizing special Payment Rates for Drugs dispensed pursuant to such agreement.

31.08: Severability

The provisions of 114.3 CMR 31.00 are severable, and if any provision of 114.3 CMR 31.00 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 114.3 CMR 31.00 or application of such provisions to any Providers or circumstances other than those held invalid.

REGULATORY AUTHORITY

114.3 CMR 31.00: M.G.L. c. 118G.