Final Adoption

June 30, 2017

101 CMR 331.00: PRESCRIBED DRUGS

Section

331.01: General Provisions

(1) Scope, Purpose and Effective Date. 101 CMR 331.00 governs the payment rates effective April 1, 2017 for drugs dispensed by providers to publicly-aided individuals and industrial accident 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. EOHHS may issue administrative bulletins to clarify its policy on and meaning of substantive provisions of 101 CMR 331.00, to publish procedure code updates and corrections, and as otherwise specified in 101 CMR 331.00.

(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 Actual Acquisition Cost (340B AAC). The amount a 340B covered entity pays for a drug purchased through the 340B Drug Pricing Program, net of discounts, rebates, charge backs, and other adjustments to the price of the drug.

340B Ceiling Price. The maximum amount that a manufacturer can charge a 340B covered entity for a drug purchased through the 340B Drug Pricing Program pursuant to Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992.

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.

Actual Acquisition Cost (AAC). The lowest price for the drug available from one or more surveys of pharmacy costs designated by EOHHS via administrative bulletin or other written issuance, or if EOHHS has not so designated one or more surveys, the drug's National Average Drug Acquisition Cost (NADAC). For a given drug, if no price is available from a survey of pharmacy costs designated by EOHHS via administrative bulletin or other written issuance, or, if EOHHS has not so designated one or more surveys and no NADAC is available for the drug, the drug's AAC is the drug's wholesale acquisition cost (WAC).

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.

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.

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 (MMAC). For multiple source drugs not designated as Brand Name Preferred and not certified as medically necessary (*i.e.*, drugs for which the prescriber has not designated "no substitution" and "brand name medically necessary" on the prescription form), an amount equal to 100% of the lowest price for a therapeutic equivalent of the drug available from one or more surveys of pharmacy costs designated by EOHHS via administrative bulletin or other written issuance, or if EOHHS has not so designated one or more surveys, the lowest National Average Drug Acquisition Cost (NADAC) for a therapeutic equivalent of the drug, for the most frequently purchased package size.

For multiple source drugs designated as Brand Name Preferred, the MMAC is an amount equal to the drug's AAC.

Most Frequently Purchased Package Size. The package size of a drug most frequently purchased by providers based on utilization data compiled by the MassHealth agency. Thus, that NDC number which is most often paid by the MassHealth agency, 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. The MassHealth agency

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.

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 Drug Pricing Program, as applicable, and out of state pharmacies described in 130 CMR 406.404(C): *Out-of-state Providers*.

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.

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 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. Required reports include, but are not limited to, reports required by the Center's regulation 957 CMR 6.00: *Cost Reporting Requirements*, and any additional reports requested by EOHHS to facilitate compliance with the requirements of 42 CFR Part 447.

(2) Penalty for Noncompliance. A purchasing governmental unit may reduce the payment rates of any provider that fails to timely file required information with the Center or EOHHS, as applicable, by 5% during the first month of noncompliance, and by an additional 5% during each month of noncompliance thereafter (*i.e.*, 5% reduction during the first month of noncompliance, 10% reduction during the second month of noncompliance, and so on). The purchasing governmental unit must notify the provider in advance of its intention to impose a penalty for noncompliance.

331.04: Payment for Prescription Drugs

(1) Payment for Multiple Source Drugs. Payment for multiple source drugs not designated as Brand Name Preferred and not certified as medically necessary (i.e., drugs for which the prescriber has not designated "no substitution" and "brand name medically necessary" on the prescription form), other than blood clotting factor and drugs obtained through the 340B Drug Pricing Program, must 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 AAC of the drug, 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 not obtained through the 340B Drug Pricing Program must 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 AAC of the drug, plus the appropriate dispensing fee as listed in 101 CMR 331.06; or

(c) 106% of the Average Sales Price of the drug, plus the appropriate dispensing fee as listed in 101 CMR 331.06; or

(d) the usual and customary charge.

(3) Payment for All Other Drugs. Payment for all other drugs not priced in accordance with 101 CMR 331.04(1) or (2), and not obtained through the 340B Drug Pricing Program, including single source drugs, multiple source drugs designated as Brand Name Preferred, and brand name drugs which have been certified as medically necessary (*i.e.*, drugs for which the prescriber has designated "no substitution" and "brand name medically necessary" on the prescription form), must not exceed the lowest of:

(a) The Massachusetts Maximum Allowable Cost of the drug, if any, plus the appropriate dispensing fee as listed in 101 CMR 331.06; or

(b) The AAC of the drug, plus the appropriate dispensing fee as listed in 101 CMR 331.06; or
(c) The usual and customary charge.

(4) Rate Limitation.
(a) Payments for multiple source drugs for which CMS has established Federal Upper Limits, and that have not been certified as medically necessary (i.e., drugs for which the prescriber has not designated "no substitution" and "brand name medically necessary" on the prescription form), must not exceed, in the aggregate and prior to the application of an federal or state drug rebates, the aggregate upper limit based on those Federal Upper Limits, regardless of whether payment amounts for individual drugs are determined pursuant to 101 CMR 331.04(1) or 101 CMR 331.04(3).
(b) Payments for multiple source drugs that have been certified as medically necessary (*i.e.*, drugs for which the prescriber has designated "no substitution" and "brand name medically necessary" on the prescription form), must not exceed, in the aggregate and prior to the application of an federal or state drug rebates, the lower of AAC plus the appropriate dispensing fee as listed in 101 CMR 331.06 and the usual and customary charge.

331.05: Payment for Over-the-counter Drugs

Payment to providers for an over-the-counter drug dispensed is the lowest of

(1) the Massachusetts Maximum Allowable Cost of the drug, if any, plus the appropriate dispensing fee as listed in 101 CMR 331.06; or

(2) the AAC of the drug, plus the appropriate dispensing fee as listed in 101 CMR 331.06; or

(3) the usual and customary charge.

331.06: Dispensing Fees

(1) Drugs. Except for compounded drugs and blood clotting factor obtained through the 340B Drug Pricing Program, the dispensing fee is $10.02 per prescription.

(2) Compounded Drugs. For compounded drugs, the dispensing fee is $10.02 plus
(a) an additional $7.50 for compounded drugs whose dispensing involves the mixing two or more commercially prepared products, compounding requiring the mixing two or more commercially prepared products; or

(b) an additional $10.00 for compounded drugs whose dispensing involves compounding lotions, shampoos, suspensions, or the mixing of powders or liquids into cream, ointment, or gel base; or
(c) an additional $15.00 for compounded drugs whose dispensing involves compounding capsules, troches, suppositories, or pre-filled syringes; or
(d) an additional $30.00 for compounded drugs needing a sterile environment when mixing.

331.07: Special Provisions

(1) Payment for Drugs Obtained through the 340B Drug Pricing Program.
(a) The payment for drugs other than blood clotting factor obtained through the 340B Drug Pricing Program and dispensed by 340B covered entities is the 340B AAC of the drug plus the appropriate dispensing fee as listed in 101 CMR 331.06.
(b) The payment for blood clotting factor obtained through the 340B Drug Pricing Program and dispensed by 340B covered entities is the 340B ceiling price of the drug, plus 2.75¢ per unit (IU/RCo/Fu/mcg) or such other amount as EOHHS may specify *via* administrative bulletin upon guidance or approval by CMS.

(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 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. 118E.