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Pharmacy Facts

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Upcoming Regulation Changes — Prescribed Drugs Payment Methodology

The following describes changes to MassHealth payments for prescribed drugs pursuant to 101 CMR 331.00. These amendments are being adopted to comply with new federal rules governing Medicaid payments for covered outpatient drugs. Most significantly, the rules require state Medicaid programs 1) to pay pharmacies the "actual acquisition cost" (AAC) of drug ingredients; and 2) to pay pharmacies a "professional dispensing fee" for dispensing drugs. The rules also specify how states may develop these methodologies. **These changes will take effect on April 1, 2017**.

Pursuant to the authority of M.G.L. c. 118E and in accordance with M.G.L. c. 30A, a public hearing will be held on Friday April 21, 2017, at 1:30 p.m. in the First Floor Conference Room, 100 Hancock Street, Quincy, MA, relative to the emergency adoption of the amendments to 101 CMR 331.00.

A copy of the amended regulations can be found at http://www.mass.gov/eohhs/gov/laws-regs/hhs/community-health-care-providers-ambulatory-care.html#114_3_31.

Description of the Amendments

Implementing Actual Acquisition Cost (AAC): The amendments define AAC as the lowest price for the drug available from a survey of pharmacy costs, or, if no survey price is available, the drug's wholesale acquisition cost (WAC). For many drugs, the AAC will be the drug's National Average Drug Acquisition Cost (NADAC). In the amendments, AAC replaces estimated acquisition cost (EAC) in the methodologies for determining payments for drugs not obtained through the 340B drug pricing program.

Updating Massachusetts Maximum Allowable Cost: The amendments also update the definition of Massachusetts Maximum Allowable Cost, which is used in the methodologies for determining payments for certain drugs. The revised definition now incorporates an AAC-based methodology.

Updating Payment Methodology for Blood-Clotting Factor: The amendments update the methodology for determining payment for blood-clotting factor. Specifically, payment for blood-clotting factor not obtained through the 340B drug pricing program will be updated to include 106% of the average sales price in the methodology, replacing the Medicare Part B rate. Payment for blood-clotting factor obtained through the 340B drug pricing program will be updated to use the 340B ceiling price in the methodology, replacing the 340B AAC.

Updating Dispensing Fees: The amendments update dispensing fees to reflect the findings of a cost-of-dispensing survey conducted on behalf of the Commonwealth. The amendments increase to \$10.02 the dispensing fee for all noncompounded, non-340B drugs (increased from \$3.00 in the current regulation) and for all noncompounded 340B drugs other than blood-clotting factor (increased from \$10.00 in the current regulation). The amendments also update the dispensing fee for compounded drugs to \$10.02 plus one of four additional amounts ranging from \$7.50 to \$30.00, depending on the compounding process involved in dispensing the drug. The current regulation, by contrast, sets the compounded drug dispensing fee at \$3.00 plus either \$1.00 or \$2.00, depending on the compounding process involved. The amendments also update the dispensing fee for blood- clotting factor obtained through the 340B drug pricing program to 2.75 cents per unit from 9 cents per unit.

Others: The amendments also include a number of technical corrections and updates to reduce ambiguity, enhance consistency, and improve readability.



Selected Amendments to Prescribed Drugs Regulations (101 CMR 331.00)

331.04: Payment for Prescription Drugs

(1) <u>Payment for Multiple Source Drugs</u>. 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) <u>Payment for Blood Clotting Factor</u>. 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) <u>Payment for All Other Drugs</u>. 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) <u>Rate Limitation</u>.

(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 any 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.

Selected Amendments to Prescribed Drugs Regulations (101 CMR 331.00), cont'd

331.06: Dispensing Fees

- (1) <u>Drugs</u>. Except for compounded drugs and blood clotting factor obtained through the 340B Drug Pricing Program, the dispensing fee is \$10.02 per prescription.
- (2) <u>Compounded Drugs</u>. For compounded drugs, the dispensing fee is \$10.02 plus

(a) an additional \$7.50 for compounded drugs whose dispensing involves the mixing of 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 cents per unit (IU/RCo/Fu/mcg) or such other amount as EOHHS may specify via administrative bulletin upon guidance or approval by CMS.

POPS Billing Guide

A revised POPS Billing Guide will be posted to include changes due to the above regulation changes and other items. To view the Billing Guide, go to <u>www.mass.gov/masshealth/pharmacy</u> and click on the link for "MassHealth Pharmacy Publications and Notices for Pharmacy Providers," then "Draft POPS Billing Guide Standard D.0." **These changes will take effect on April 1, 2017**.

Highlights include this revised section for Compound Drug Claim Submission

Compound Claims

Pharmacy compound claims must be submitted through POPS for payment. All claims for compounds must be submitted online and must contain more than one ingredient. Each ingredient of the compound must be submitted.

- Each compound claim is limited to a maximum of 15 ingredient lines. Providers can submit only a single compound transaction within a single transmission. Noncovered ingredients will cause a claim to be denied. Each ingredient is subjected to the edits and audits within claim adjudication. If a claim is denied because of a noncovered ingredient, the provider may agree to accept payment for the approved ingredients making up the compound. To do this, enter a value of 08 (08=Process Compound for Approved Ingredients) in the Submission Clarification Code (Field 420-DK). This allows the pharmacy to communicate acceptance of payment for approved ingredients only and for the POPS system to process the compound for these approved ingredients. Compound reversals are processed like other D.0 transactions.
- Compounds may not be submitted as partial fills.

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- Compound claims must contain a DUR/PPS Segment with a distinct row, where DUR / PPS Level of Effort (474-8E) contains a MassHealth supported value and fields Reason for Service (439-E4), Professional Service Code (440-E5), Result of Service Code (441-E6), DUR Co-Agent ID Qualifier (475-J9), and DUR Co-Agent ID (476-H6) are not submitted. However in an effort to accommodate systems that are not able to suppress fields 439-E4, 440-E5, 441-E6, 475-J9, or 476-H6 on the row that communicates compound preparation effort, MassHealth will ignore if the submitted value is equal to spaces. Failure to submit this unique row will result in the claim being denied with NCPDP reject code 8E –M/I DUR/PPS Level Of Effort.
- MassHealth will retrospectively examine Level of Effort values entered on a compounded claim.

	O			Claim Billing/Claim	
	Segment Identification (111-AM) = 08			Rebill	
Field #	NCPDP Field Name	Value	Payer Usage	Payer Situation	Field Format
111-AM	Segment Identification		М		X(2)
473-7E	DUR/PPS Code Counter	Maximum of nine occurrences	R		9(1)
439-E4	Reason for Service Code	DD=Drug-drug interaction	Q***R***	Not used with 474- 8E/ Level of Effort when billing for preparing a compound prescription. Not required when Professional Service Code (440-E5)=MA	X(2)
		HD=High dose			
		ID=Ingredient duplication			
		TD=Therapeutic duplication			
		ER=Early refill			
440-E5	Professional Service Code	MA=Medication administration	Q***R***	Not used with 474- 8E/ Level of Effort when billing for preparing a compound prescription.	X(2)
		M0=Prescriber consulted			
		R0=Pharmacist consulted other source			
441-E6	Result of Service Code	1A=Filled as is, false positive	Q***R***	Not used with 474- 8E/ Level of Effort when billing for preparing a compound prescription.	X(2)
		1B=Filled prescription, as is			
		1C=Filled, with different dose			
		1D=Filled, with different directions		Not required when Professional Service Code (440-E5)=MA	
		1E=Filled, with different drug			
		1F=Filled, with different quantity			
		1G=Filled, with prescriber approval			

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	DUR/PPS Segment			Claim Billing/Claim	
	Segment Identification (111-AM) = 08			Rebill	
Field #	NCPDP Field Name	Value	Payer Usage	Payer Situation	Field Format
474-8E	DUR/PPS Level of Effort	00 =Not specified 11=Level 1—Less than five min. 12=Level 2—Less than 15 min. 13=Level 3—Less than 30 min. 14=Level 4—Less than one hour 15=Level 5—Greater than one hour	Q***R***	Must submit when billing for a compound prescription with a fill date of 04/01/2017 or later. MassHealth recognized values: 11—Compounded drugs whose dispensing involves mixing two or more commercially prepared products 12—Compounded drugs whose dispensing involves compounding lotions, shampoos, suspensions, or the mixing of powders or liquids into cream, ointment, or gel base 13—Compounded drugs whose dispensing involves compounding capsules, troches, suppositories, or prefilled syringes 14—Compounded drugs needing a sterile environment when mixing	9(2)
475-J9	DUR Coagent ID Qualifier		I***R***	Not used with 474- 8E/ Level of Effort when billing for preparing a compound prescription.	X(2)
476-H6	DUR Coagent ID		I***R**	Not used with 474- 8E/ Level of Effort when billing for preparing a compound prescription.	X(19)