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MassHealth  
Transmittal Letter PHM-58  
August 2008

**TO:** Pharmacies Participating in MassHealth  
**FROM:** Tom Dehner, Medicaid Director   
**RE:** Pharmacy Manual (Revised Pharmacy Regulations)

This letter transmits revisions to the pharmacy regulations. These changes:

- alter the definition of “usual and customary charge,” by clarifying that pharmacy providers are required to include cash-paying customers along with insurers when determining the lowest payment that the provider will accept. The definition also clarifies that providers must include over-the-counter drug formulations when determining the lowest cost drug;
- allow MassHealth to specify refill limitations in the MassHealth Drug List;
- include additional exceptions to the 30-day quantity limit to allow 90-day supplies
  - for all family planning drugs; and
  - when MassHealth is the secondary payer and the primary payer allows a 90-day supply;
- add enrollment criteria for the Controlled Substance Management Program (CSMP) to continue the member’s participation in CSMP if the member was enrolled in the CSMP of a MassHealth-contracted managed care program at the time of enrollment in MassHealth;
- eliminate the requirement that 340B entities submit a copy of the form used to register with the federal 340B program when they enroll in the MassHealth 340B program. This is no longer necessary due to changes in the federal 340B program; and
- specify that all medical supplies and devices that are paid through POPS are now listed in the MassHealth Drug List in a section called the MassHealth Non-Drug Product List, instead of in the pharmacy regulations.

These regulations are effective September 15, 2008.

If you have any questions about the information in this transmittal letter please contact MassHealth Customer Service at 1-800-841-2900, e-mail your inquiry to [providersupport@mahealth.net](mailto:providersupport@mahealth.net), or fax your inquiry to 617-988-8974.

**NEW MATERIAL**

(The pages listed here contain new or revised language.)

**Pharmacy Manual**

Pages iv and 4-1 through 4-14

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Pharmacy Manual

Page iv — transmitted by Transmittal Letter PHM-53

Pages 4-1, 4-2, and 4-11 through 4-18 — transmitted by Transmittal Letter PHM-51

Pages 4-3 through 4-6 — transmitted by Transmittal Letter PHM-54

Pages 4-7 and 4-8 — transmitted by Transmittal Letter PHM-55

Pages 4-9 and 4-10 — transmitted by Transmittal Letter PHM-57

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b>  Table of Contents	<b>Page</b>  iv
	<b>Transmittal Letter</b>  PHM-58	<b>Date</b>  09/15/08

#### 4. Program Regulations

406.401: Introduction .....	4-1
406.402: Definitions .....	4-1
406.403: Eligible Members .....	4-4
406.404: Provider Eligibility .....	4-4
406.405: Drugs and Medical Supplies Provided Outside of Massachusetts .....	4-5
(130 CMR 406.406 through 406.410 Reserved)	
406.411: Prescription Requirements .....	4-6
406.412: Covered Drugs and Medical Supplies .....	4-7
406.413: Limitations on Coverage of Drugs .....	4-8
406.414: Insurance Coverage .....	4-9
(130 CMR 406.415 through 406.419 Reserved)	
406.420: Unit-Dose Packaging Requirement for Certain Drugs Dispensed in Nursing Facilities.....	4-10
406.421: Drugs and Medical Supplies for Institutionalized Members .....	4-10
406.422: Prior Authorization .....	4-11
406.423: Member Copayments .....	4-11
(130 CMR 406.424 through 406.430 Reserved)	
406.431: Payment Rates.....	4-11
(130 CMR 406.432 through 406.435 Reserved)	
406.436: Disclosure of Information .....	4-12
(130 CMR 406.437 through 406.441 Reserved)	
406.442: Controlled Substance Management Program .....	4-12
406.443: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services .....	4-13
(406.444 and 406.445 Reserved)	
406.446: Return of Unused Unit-Dose-Packaged Drugs Dispensed in Nursing Facilities .....	4-13

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-1
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

406.401: Introduction

All pharmacies participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to MassHealth regulations set forth in 130 CMR 406.000 and 450.000.

406.402: Definitions

The following terms used in 130 CMR 406.000 have the meanings given in 130 CMR 406.402, unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 406.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 406.000 and in 130 CMR 450.000.

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.

340B Entity Dispensing Fee – a fee paid to a 340B-covered entity, in addition to the actual acquisition cost of the drug, for dispensing a 340B drug to a MassHealth member. This dispensing fee is paid to the 340B-covered entity in accordance with Division of Health Care Finance and Policy (DHCFP) regulations at 114.3 CMR 31.00: Prescribed Drugs.

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

Actual Package Size – the package size of any drug for which the Massachusetts Division of Health Care Finance and Policy (DHCFP) has not determined the most frequently purchased package size is 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 active ingredients, at least one of which is a drug, are extemporaneously mixed by a registered pharmacist.

Controlled Substance – a drug listed in Schedule II, III, IV, V, or VI of the Massachusetts Controlled Substances Act (M.G.L. c. 94C).

Dispensing Fee – the fee paid, in addition to the ingredient cost of the drug, to a pharmacy for dispensing a drug to a member. This dispensing fee is paid in accordance with Division of Health Care Finance and Policy (DHCFP) regulations at 114.3 CMR 31.00.

Drug – a substance containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength is a separate drug.

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-2
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

Electronic Prescription – a prescription transmitted electronically in compliance with applicable state and federal law.

Estimated Acquisition Cost – an estimate of the price generally and currently paid by pharmacies for the most frequently purchased package size of a drug, as determined in accordance with DHCFP regulations at 114.3 CMR 31.00.

Federal Upper-Limit Price (FULP) – a price established by the federal Centers for Medicare & Medicaid Services (CMS) pursuant to 42 CFR 447.332 and U.S.C. §1396r-8(e).

Health Insurer – a private or public entity, including Medicare, that has a health plan or policy under which it pays for medical services provided to a member. An endorsed discount card issued in accordance with Section 1860D-31(a) of the Social Security Act is not considered a health-insurance plan or policy.

Interchangeable Drug Product – a product containing a drug in the same amounts of the same active ingredients in the same dosage form as another product with the same generic or chemical name that has been determined to be therapeutically equivalent (that is, “A”-rated) by the Food and Drug Administration Center for Drug Evaluation and Research (FDA CDER), or by the Massachusetts Drug Formulary Commission.

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by MassHealth. The MassHealth Drug List specifies the drugs that are payable under MassHealth. The list also specifies which drugs require prior authorization. Except for drugs and drug therapies described in 130 CMR 406.413(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 406.000.

Maximum Allowable Cost (MAC), also known as Massachusetts Upper-Limit Price (MULP) – an upper-limit price for multiple-source drugs as defined by DHCFP in 114.3 CMR 31.00.

Most Frequently Purchased Package Size – the package size of a drug most frequently purchased by pharmacy providers, based on utilization data compiled by MassHealth. The National Drug Code (NDC) that is most often paid by MassHealth and verified by audit, if determined necessary by MassHealth, is 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 US 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.”).

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-3
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

Non-Drug Product List – a section of the MassHealth Drug List comprised of those products not classified as drugs (i.e., blood testing supplies) that are payable by the MassHealth agency through the Pharmacy Program. Payment for these items is in accordance with rates published in Division of Health Care Finance and Policy regulations at 114.3 CMR 22.00: Durable Medical Equipment, Oxygen, and Respiratory Therapy Equipment and 114.3 CMR 17.00: Medicine. The MassHealth Non-Drug Product List also specifies which of the included products require prior authorization.

Over-the-Counter Drug – any drug for which no prescription is required by federal or state law. These drugs are sometimes referred to as nonlegend drugs. The MassHealth agency requires a prescription for both prescription drugs and over-the-counter drugs (see 130 CMR 406.411(A)).

Pharmacy Online Processing System (POPS) – the online, real-time computer network that adjudicates pharmacy claims, incorporating prospective drug utilization review, prior authorization, and member eligibility verification.

Prescription Drug – any drug for which a prescription is required by applicable federal or state law or regulation, other than MassHealth regulations. These drugs are sometimes referred to as legend drugs.

Retail Establishment – a physical place of business at which the provider dispenses prescription and over-the-counter drugs, and may provide products and services to the general public; a business conducted by mail, telephone, the Internet, or any other remote means does not constitute a “retail establishment.”

Single-Source Drug – a drug marketed or sold by 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 container fully identifies the drug and protects the integrity of the dosage. For purposes of 130 CMR 406.000, an assemblage of multiple, unlabeled single doses (traditional “bingo cards” or “bubble packs”) is not unit-dose packaging.

Unit-Dose-Return Fee – a fee paid to the pharmacy for accepting returned drugs in unit-dose packaging in accordance with 130 CMR 406.446.

Unit-Dose Distribution System – a means of packaging or distributing drugs, or both in unit doses, devised by the manufacturer, packager, wholesaler, or retail pharmacist. A unit dose contains an exact dosage of medication and may also indicate the total daily dosage or the times when the medication should be taken. Such unit doses may or may not be in unit-dose packaging.

Usual and Customary Charge – the lowest price that a pharmacy 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 of an over-the-counter drug. When an insurer and the pharmacy 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.

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-4
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08
Pharmacy Manual		

Wholesale Acquisition Cost (WAC) – a manufacturer’s price published in a national price compendium or other publicly available source. Where no published price is identified as the WAC, the WAC is equal to the wholesale net unit price as published by First Data Bank. If no wholesale net unit price is published, the WAC is equal to the lower of the direct price or an adjusted average wholesale price.

406.403: Eligible Members

- (A) (1) MassHealth Members. MassHealth covers pharmacy services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. 130 CMR 450.105 specifically states, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
- (2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.
- (B) Member Eligibility and Coverage Type. For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

406.404: Provider Eligibility

- (A) All Providers. A pharmacy must be a participant in MassHealth on the date of service in order to be eligible for payment.
- (B) In-State Providers. To be eligible for participation as a MassHealth provider, a pharmacy must
- (1) have a retail establishment located and doing business in the Commonwealth of Massachusetts;
  - (2) be licensed by the Massachusetts Board of Registration in Pharmacy in accordance with M.G.L. c. 112 or be licensed by the Massachusetts Department of Public Health as a pharmacy in a clinic setting in accordance with M.G.L. c. 111;
  - (3) be licensed by the federal Drug Enforcement Administration (DEA) and possess a DEA registration number; and
  - (4) agree to use the MassHealth Pharmacy Online Processing System (POPS) in real-time mode to submit claims.
- (C) Out-of-State Providers. A provider that does not meet the requirements of 130 CMR 406.404(B) may participate in MassHealth only if the provider meets the requirements of 130 CMR 450.109 and
- (1) is licensed by the Board of Registration in Pharmacy (or the equivalent) in the state in which the provider primarily conducts business;
  - (2) possesses a DEA registration number. If a pharmacy is licensed to dispense only Schedule VI drugs, a Massachusetts Controlled Substance Registration number may substitute for a DEA number;

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-5
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

(3) participates in the Medicaid program or equivalent of the state in which the provider primarily conducts business; and

(4) agrees to use the MassHealth agency Pharmacy Online Processing System (POPS) in real-time mode to submit claims.

(D) Participation in the 340B Drug-Pricing Program for Outpatient Pharmacy Services.

(1) Notification of Participation. A 340B-covered entity may provide drugs to MassHealth members through the 340B drug-pricing program provided that it notifies the MassHealth agency by submitting to the MassHealth agency a copy of the form used to register with the Health Resources and Services Administration, Office of Pharmacy Affairs (OPA), as a 340B-covered entity and, if applicable, a copy of the OPA form used to certify the contracted pharmacy services. The 340B-covered entity may bill for 340B drugs provided to MassHealth members, either provided directly or by subcontract, after the MassHealth agency confirms, in writing, its receipt of the 340B-covered entity's notification and a copy of its OPA registration form, in accordance with 130 CMR 406.404(D)(1).

(2) Subcontracting for 340B Outpatient Pharmacy Services.

(a) A 340B-covered entity may contract with a MassHealth pharmacy provider to dispense 340B drugs for the 340B-covered entity's MassHealth patients. All such subcontracts between the 340B-covered entity and a pharmacy provider must be in writing, ensure continuity of care, specify that the 340B-covered entity pays the pharmacy, specify that such payment constitutes payment in full for 340B drugs provided to MassHealth members, be consistent with all applicable provisions of 130 CMR 406.000, and are subject to MassHealth agency approval.

(b) The 340B-covered entity is legally responsible to the MassHealth agency for the performance of any subcontractor. The 340B-covered entity must ensure that every pharmacy subcontractor is licensed by the Massachusetts Board of Registration in Pharmacy and is a MassHealth pharmacy provider, and that services are furnished in accordance with MassHealth pharmacy regulations at 130 CMR 406.000 and all other applicable MassHealth requirements, including but not limited to, those set forth in 130 CMR 450.000.

(3) Termination or Changes in 340B Drug-Pricing Program Participation. A 340B-covered entity must provide the MassHealth agency 30 days' advance written notice of its intent to discontinue, or change in any way material to the MassHealth agency, the manner in which it provides 340B outpatient drugs for its MassHealth patients.

(4) Payment for 340B Outpatient Pharmacy Services. The MassHealth agency pays the 340B-covered entity for pharmacy services, whether provided and billed directly or through a subcontractor, at the rates established in DHCFP regulations at 114.3 CMR 31.00.

406.405: Drugs and Medical Supplies Provided Outside of Massachusetts

When provided out of state, drugs and medical supplies are reimbursable only if the member is temporarily out of state and requires drugs or medical supplies under the circumstances described in 130 CMR 450.109.

(130 CMR 406.406 through 406.410 Reserved)



<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-6
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

406.411: Prescription Requirements

(A) Legal Prescription Requirements. The MassHealth agency pays for prescription drugs, over-the-counter drugs, and items on the Non-Drug Product List only if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations. Each prescription for drugs in Schedules II through V must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber's Massachusetts Controlled Substance Registration number must appear on the prescription.

(B) Emergencies. When the pharmacist determines that an emergency exists, the MassHealth agency will pay the pharmacy for at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations. Emergency dispensing to a MassHealth member who is enrolled in the Controlled Substance Management Program (CSMP) must comply with 130 CMR 406.442(C)(2).

(C) Refills.

(1) The MassHealth agency does not pay for prescription refills that exceed the specific number authorized by the prescriber.

(2) The MassHealth agency pays for a maximum of 11 monthly refills, except in circumstances described in 130 CMR 406.411(C)(3), or where the MassHealth Drug List specifically limits the number of refills, duration of the prescription, or both.

(3) The MassHealth agency pays for more than 11 refills within a 12-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 406.411(D).

(4) The MassHealth agency does not pay for any refill dispensed after one year from the date of the original prescription.

(5) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.

(6) The MassHealth agency does not pay for any refill without an explicit request from a member or caregiver for each filling event. The possession by a provider of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription.

(D) Quantities.

(1) Days' Supply Limitations. The MassHealth agency requires that all drugs be prescribed in a 30-day supply, unless the drug is available only in a larger minimum package size, except as specified in 130 CMR 406.411(D)(2).

(2) Exceptions to Days' Supply Limitations.

(a) The MassHealth agency allows exceptions to the limitations described in 130 CMR 406.411(D)(1) for the following products:

(i) drugs in therapeutic classes that are commonly prescribed for less than a 30-day supply, including but not limited to antibiotics and analgesics;

(ii) drugs that, in the prescriber's professional judgment, are not clinically appropriate for the member in a 30-day supply;

(iii) drugs that are new to the member, and are being prescribed for a limited trial amount, sufficient to determine if there is an allergic or adverse reaction or lack of effectiveness. The initial trial amount and the member's reaction or lack of effectiveness must be documented in the member's medical record;

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-7
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

(iv) drugs packaged in such a way that the smallest quantity that may be dispensed is larger than a 30-day supply (for example, inhalers, ampules, vials, eye drops, and other sealed containers not intended by the manufacturer to be opened by any person other than the end user of the product);

(v) drugs in topical dosage forms that do not allow the pharmacist to accurately predict the rate of the product's usage (for example, lotions or ointments);

(vi) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs); and

(vii) methylphenidate and amphetamine prescribed in 60-day supplies;

(b) Drugs paid for by a member's primary insurance carrier that are dispensed in up to a 90-day supply when the MassHealth agency pays any portion of the claim, including the copayment portion or deductible, may be dispensed in up to a 90-day supply.

(c) Drugs used for family planning may be dispensed in up to a 90-day supply.

(E) Prescription-Splitting. Providers must not split prescriptions by filling them for a period or quantity less than that specified by the prescriber. For example, a prescription written for a single 30-day supply may not be split into three 10-day supplies. The MassHealth agency considers prescription-splitting to be fraudulent. (See 130 CMR 450.238(B)(6).)

(F) Excluded, Suspended, or Terminated Clinicians. The MassHealth agency does not pay for prescriptions written by clinicians

(1) who have been excluded from participation based on a notice by the U.S. Department of Health and Human Services Office of Inspector General; or

(2) whom the MassHealth agency has suspended, terminated, or denied admission into its program for any other reason.

#### 406.412: Covered Drugs and Medical Supplies

(A) Drugs. The MassHealth Drug List specifies the drugs that are payable under MassHealth. In addition, the following rules apply.

(1) Prescription Drugs. The MassHealth agency pays only for prescription drugs that are approved by the U.S. Food and Drug Administration and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8. Payment is calculated in accordance with DHCFP regulations at 114.3 CMR 31.00: Prescribed Drugs.

(2) Over-the-Counter Drugs. Payment by the MassHealth agency for over-the-counter drugs is calculated in accordance with DHCFP regulations at 114.3 CMR 31.00: Prescribed Drugs.

(B) Non-Drug Products Paid through POPS.

(1) The MassHealth agency pays through POPS, only for those products not classified as drugs that are listed on the non-drug product section of the MassHealth Drug List.

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-8
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08
Pharmacy Manual		

(2) Non-Drug Product List. – Payment for these items is in accordance with rates published in the Division of Health Care Finance and Policy regulations at 114.3 CMR 22.00: Durable Medical Equipment, Oxygen, and Respiratory Therapy Equipment and 114.3 CMR 17.00: Medicine. The MassHealth Non-Drug Product List also specifies which of the included products require prior authorization.

406.413: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. The MassHealth agency pays no more for a brand-name interchangeable drug product than its generic equivalent unless

- (1) the prescriber has requested and received prior authorization from the MassHealth agency for a nongeneric multiple-source drug (see 130 CMR 406.422); and
- (2) the prescriber has written on the face of the prescription in the prescriber's own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

(B) Drug Exclusions. The MassHealth agency does not pay for the following types of prescription or over-the-counter drugs or drug therapy.

- (1) Cosmetic. The MassHealth agency does not pay for any drug when used for cosmetic purposes or for hair growth.
- (2) Cough and Cold. The MassHealth agency does not pay for any drug used solely for the symptomatic relief of coughs and colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless dispensed to a member who is a resident in a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR).
- (3) Fertility. The MassHealth agency does not pay for any drug used to promote male or female fertility.
- (4) Obesity Management. The MassHealth agency does not pay for any drug used for the treatment of obesity.
- (5) Less-Than-Effective Drugs. The MassHealth agency does not pay for any drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
- (6) Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.
- (7) Drugs for Sexual Dysfunction. The MassHealth agency does not pay for any drug when used for the treatment of male or female sexual dysfunction.

(C) Service Limitations.

- (1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 406.413(B). The limitations and exclusions in 130 CMR 406.413(B)(1) through (5) do not apply to medically necessary drug therapy for MassHealth Standard enrollees under age 21. The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-9
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 406.000. The MassHealth Drug List can be viewed online at [www.mass.gov/druglist](http://www.mass.gov/druglist), and copies may be obtained upon request. See 130 CMR 450.303.

(2) The MassHealth agency does not pay for the following types of drugs or drug therapy without prior authorization:

- (a) immunizing biologicals and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH);
- (b) nongeneric multiple-source drugs; and
- (c) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. The MassHealth agency, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993.

(3) The MassHealth agency does not pay any additional fees for dispensing drugs in a unit-dose distribution system. The MassHealth agency does, however, pay a unit-dose return fee in accordance with 130 CMR 406.446.

(4) The MassHealth agency does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence.

(5) The MassHealth agency does not pay for any drugs that are provided as a component of a more comprehensive service for which a single rate of pay is established in accordance with 130 CMR 450.307.

#### 406.414: Insurance Coverage

(A) Managed Care Organizations. The MassHealth agency does not pay pharmacy claims for services to MassHealth members enrolled in a MassHealth managed care organization (MCO) that provides pharmacy coverage through a pharmacy network or otherwise, except for family planning pharmacy services provided by a non-network provider to a MassHealth Standard MCO enrollee (where such provider otherwise meets all prerequisites for payment for such services). A pharmacy that does not participate in the MassHealth member's MCO must instruct the MassHealth member to take his or her prescription to a pharmacy that does participate in such MCO. To determine whether the MassHealth member belongs to an MCO, pharmacies must verify member eligibility and scope of services through POPS before providing service in accordance with 130 CMR 450.107 and 450.117.

(B) Other Health Insurance. When the member's primary carrier has a preferred drug list, the prescriber must follow the rules of the primary carrier first. The provider may bill the MassHealth agency for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether the MassHealth agency generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 406.413(C)(2)(a) and (c). In such cases, the prescriber must obtain prior authorization from the MassHealth agency in order for the pharmacy to bill the MassHealth agency for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101 et seq.

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-10
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

(C) Medicare Part D.

(1) Overview. Except as otherwise required in 130 CMR 406.414(C)(2) and (3), for MassHealth members who have Medicare, the MassHealth agency does not pay for any Medicare Part D drugs, or for any cost-sharing obligations (including premiums, copayments, and deductibles) for Medicare Part D drugs, whether or not the member has actually enrolled in a Medicare Part D drug plan. Medications excluded from the Medicare Part D drug program continue to be covered for MassHealth members eligible for Medicare, if they are MassHealth-covered medications.

(2) Medicare Part D One-Time Supplies. The MassHealth agency pays for one-time supplies of prescribed medications, as described in 130 CMR 406.414(C)(2)(a) and (b), if the medication is a MassHealth-covered medication and the MassHealth member would otherwise be entitled to MassHealth pharmacy benefits but for being eligible for Medicare prescription drug coverage. MassHealth prior authorization does not apply to such one-time supplies. The MassHealth agency pays for the one-time supplies in all instances in which the pharmacist cannot bill a Medicare Part D prescription drug plan at the time the prescription is presented. The MassHealth agency pays for a one-time 72-hour supply of prescribed medications.

(3) Cost-Sharing Assistance for MassHealth Members Enrolled in a Medicare Part D Prescription Drug Plan. For the purpose of 130 CMR 406.414(C)(3)(a) and (b), the “applicable MassHealth copayment” is the copayment the MassHealth member would pay for prescription drugs if the drugs were covered by MassHealth and not covered by Medicare Part D. MassHealth members who are enrolled in a Medicare Part D prescription drug plan and are charged a copayment or deductible in excess of the member’s applicable MassHealth copayment for a drug that MassHealth would otherwise cover, must pay the applicable MassHealth copayment, and the MassHealth agency pays the difference between the applicable MassHealth copayment and the amount charged by the Medicare Part D prescription drug plan.

(130 CMR 406.415 through 406.419 Reserved)

406.420: Unit-Dose Packaging Requirement for Certain Drugs Dispensed in Nursing Facilities

For drugs listed in Appendix D of the *Pharmacy Manual*, the pharmacy must fill the prescription in unit-dose packaging when dispensed to MassHealth members residing in a nursing facility. See 130 CMR 406.446 for the pharmacy’s requirements to accept unused unit-dose-packaged drugs returned by a nursing facility.

406.421: Drugs and Medical Supplies for Institutionalized Members

(A) MassHealth pays for prescription drugs provided to institutionalized members.

(B) MassHealth does not pay for over-the-counter drugs or medical supplies provided to institutionalized members, except in circumstances described in 130 CMR 406.421(C).

(C) MassHealth pays for insulin prescribed for members who are residents of a nursing facility or rest home.

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-11
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

406.422: Prior Authorization

(A) Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by MassHealth in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 406.412(A) and 406.413(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to the MassHealth agency for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with 130 CMR 450.303, including but not limited to, the instructions for requesting prior authorization in the Pharmacy Online Processing System (POPS) billing guide and the MassHealth Drug List.

(C) The MassHealth agency will authorize at least a 72-hour emergency supply of a prescription drug to the extent required by federal law. (See 42 U.S.C. 1396r-8(d)(5).) The MassHealth agency acts on requests for prior authorization for a drug within a time period consistent with federal regulations.

(D) Prior authorization does not waive any other prerequisites to payment such as, but not limited to, member eligibility or requirements of other health insurers.

(E) The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 406.000. MassHealth evaluates the prior-authorization status of drugs on an ongoing basis, and updates the MassHealth Drug List accordingly.

406.423: Member Copayments

Under certain conditions, the MassHealth agency requires that members make a copayment to the dispensing pharmacy for each original prescription and for each refill for all drugs (whether prescription or over-the-counter) covered by MassHealth. The copayment requirements are detailed in 130 CMR 450.130.

(130 CMR 406.424 through 406.430 Reserved)

406.431: Payment Rates

The methods for determining payment of drugs are contained in regulations adopted by the Division of Health Care Finance and Policy (DHCFP) at 114.3 CMR 31.00: Prescribed Drugs. The methods for determining payment for medical supplies described in 130 CMR 406.412 are contained in DHCFP regulations at 114.3 CMR 22.00: Durable Medical Equipment, Oxygen, and Respiratory Therapy Equipment. For drugs obtained through the 340B Drug-Pricing Program, MassHealth pays the 340B-covered entity the actual acquisition cost of the drug plus the 340B-covered entity dispensing fee, as described in DHCFP regulations at 114.3 CMR 31.00: Prescribed Drugs. In the event of conflict between these MassHealth regulations and DHCFP regulations, DHCFP regulations govern.

(130 CMR 406.432 through 406.435 Reserved)

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-12
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

406.436: Disclosure of Information

In order for the MassHealth agency to verify a pharmacy's compliance with DHCFP regulations at 114.3 CMR 31.00: Prescribed Drugs, a pharmacy must, upon request, make available to the MassHealth agency for inspection and copying the following documentation:

- (A) all prescriptions (for both members and nonmembers) filled during the time period specified by the MassHealth agency with the names of the patients and all other identifying information blocked out;
- (B) all documentation of returned unused drugs from nursing facilities pursuant to 130 CMR 406.446, including the manifest for each shipment of returned drugs from the nursing facility; and
- (C) all documentation of a drug's cost to the pharmacy provider, all documentation regarding the amount the pharmacy provider has charged any entity, and the amount any purchaser or reimbursor has paid the pharmacy provider for any drug covered by MassHealth. This must include, but is not limited to, all documentation used to calculate charges billed to the MassHealth agency for any given date. In addition, all reports, books, and records related to its operation must be available for audit.

(130 CMR 406.437 through 406.441 Reserved)

406.442: Controlled Substance Management Program

(A) Introduction. The MassHealth agency has established a Controlled Substance Management Program for MassHealth members who use excessive quantities of prescribed drugs. Members in the Controlled Substance Management Program are restricted to obtaining prescribed drugs only from the provider that the MassHealth agency designates as the member's primary pharmacy.

(B) Criteria for Member Enrollment. The MassHealth agency may enroll in the Controlled Substance Management Program those MassHealth members who meet one of the following criteria:

- (1) members whom MassHealth determines use excessive quantities of prescribed drugs. For purposes of 130 CMR 406.442, "excessive quantities of prescribed drugs" is defined as 11 or more prescriptions, including original fill and refills, of one or more controlled substances from Schedule II, III, or IV over a three-month period, obtained from four or more prescribers or filled by four or more pharmacies; or
- (2) members who were enrolled in the Controlled Substance Management Program of a MassHealth-contracted managed care organization (MCO) at the time the member disenrolled from the MCO. When the MassHealth agency enrolls a member in the Controlled Substance Management Program it notifies the member accordingly.

(C) Service Restriction.

- (1) Except as outlined in 130 CMR 406.442(B), members enrolled in the Controlled Substance Management Program may obtain prescribed drugs only from the member's primary pharmacy as designated by the MassHealth agency, and only the member's primary pharmacy may receive payment from the MassHealth agency. Members who are enrolled in this program will be identified by the Recipient Eligibility Verification System (REVS) as participants in the Controlled Substance Management Program.

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-13
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08
Pharmacy Manual		

(2) The MassHealth agency authorizes a pharmacy other than the primary pharmacy to dispense a nonrefillable supply of a drug to a restricted member when the pharmacist has determined that the member's health or safety would be jeopardized without immediate access to that drug or if the prescription is for family planning.

(D) Responsibilities of Primary Pharmacy. The primary pharmacy must monitor the prescription utilization pattern of each member, and must exercise sound professional judgment when dispensing all prescription drugs. When the pharmacist reasonably believes that the member is presenting a prescription that is inappropriate for his or her medical condition, the pharmacist must contact the prescriber to verify the authenticity and accuracy of the prescription presented. Primary pharmacies that are found on review to be dispensing drugs in a manner that is inconsistent with professional standards may be subject to administrative action by the MassHealth agency, including the recovery of payments and the imposition of sanctions in accordance with 130 CMR 450.000.

(E) Change in Primary Pharmacy and Member Status.

(1) The member may ask the MassHealth agency to change the member's primary pharmacy designation only once per calendar year, unless the member can demonstrate that the designated primary pharmacy is unable to address the member's pharmacy needs due to a change in

- (a) the member's residence;
- (b) the member's medical condition; or
- (c) the primary pharmacy's business practices.

(2) The MassHealth agency may disenroll or transfer a member from a primary pharmacy if the pharmacy requests the change.

(3) MassHealth will periodically review the member's drug utilization on its own initiative, or upon the member's request, but no earlier than 12 months after the date on which the MassHealth agency enrolled the member in the Controlled Substance Management Program. If, after such review, the MassHealth agency determines that the member has not used excessive quantities of prescribed drugs for at least that 12-month period, the MassHealth agency will disenroll the member from the Controlled Substance Management Program and the member will no longer be subject to the restrictions of that program. However, the MassHealth agency may reenroll a member in that program at any time in accordance with the provisions of 130 CMR 406.442(B).

406.443: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary acute outpatient hospital services for EPSDT-eligible members in accordance with 130 CMR 450.140 et seq., without regard to service limitations described in 130 CMR 406.000, and with prior authorization.

(130 CMR 406.444 through 406.445 Reserved)

406.446: Return of Unused Unit-Dose-Packaged Drugs Dispensed in Nursing Facilities

(A) Creditable Drugs.

(1) The pharmacy must accept those unused drugs in unit-dose packaging that are listed in Appendix D of the *Pharmacy Manual* and that were dispensed to a MassHealth member



<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Pharmacy Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 406.000)	<b>Page</b> 4-14
	<b>Transmittal Letter</b> PHM-58	<b>Date</b> 09/15/08

in a nursing facility. The pharmacy must credit to the MassHealth agency the amount paid for the quantity of such drugs pursuant to 130 CMR 406.446(D). Such credit enables the pharmacy to retain the original dispensing fee and receive a unit-dose-return fee. The pharmacy must credit to the MassHealth agency within 15 days of receipt, unit-dose-packaged drugs that meet the requirements of 130 CMR 406.446(A)(2), unless they are excluded under 130

CMR 406.446(B). The pharmacy may return the unused supply to inventory for redispensing as permitted by federal and state law.

(2) The pharmacy must credit to the MassHealth agency unit-dose-packaged drugs returned by a nursing facility if they comply with all applicable state and federal requirements, including but not limited to those related to the safety, labeling, handling, and storage of drugs.

(B) Excluded Drugs. Of the drugs described in 130 CMR 406.446(A), the pharmacy must not credit the MassHealth agency for the following unit-dose-packaged drugs returned by a nursing facility:

- (1) drugs that were dispensed to a member whose other insurance paid for part or all of the prescription;
- (2) unused quantities of a prescription that are less than the minimum quantity identified in Appendix D of the *Pharmacy Manual*; and
- (3) drugs with an expiration date of less than 90 days from the date of the return.

(C) Dosage Changes. When the prescriber changes the dosage of any drug described in 130 CMR 456.621(A), and the previously prescribed dosage of the drug can be used to accommodate the new dosage, the nursing facility must use up existing supplies of the drug dispensed to the member and will apply a change-of-directions sticker over the directions on the pharmacy prescription label. The pharmacy must provide a new label for the prescription when requested by the nursing facility.

(D) Crediting MassHealth for Returned Drugs. The pharmacy must use POPS to reverse the initial claim for the drug by the quantity of the returned drug. The pharmacy must submit the reversal through POPS within 15 days of receipt of the drug from the nursing facility. The amount of the payment will be recalculated based on the adjusted quantity and the inclusion of the unit-dose-return fee.

(E) Recordkeeping Requirements. The pharmacy must establish tracking and recordkeeping systems for all unit-dose-packaged drugs returned pursuant to 130 CMR 406.446(A). The records must comply with requirements in 130 CMR 450.205, must standard business accounting practices, must be available for review by the MassHealth agency upon request, and must be kept for at least seven years from the date of the return. The records must include

- (1) the name of the member to whom the drugs were originally dispensed;
- (2) the date that the unused drugs were returned to the pharmacy;
- (3) the prescription number under which the unused drugs were originally dispensed;
- (4) the name and strength of the unused drugs;
- (5) the quantity of the doses returned;
- (6) the manifest from the nursing facility for each shipment of returned drugs; and
- (7) the name and quantity of drugs that were returned by the nursing facility, but that are unacceptable for redispensing.

#### REGULATORY AUTHORITY

130 CMR 406.000: M.G.L. c. 118E, §§7 and 12.