



Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
600 Washington Street
Boston, MA 02111
www.mass.gov/masshealth



MASSHEALTH
TRANSMITTAL LETTER PHM-53
November 2005

TO: Pharmacies Participating in MassHealth
FROM: Beth Waldman, Medicaid Director *BW*
RE: *Pharmacy Manual* (Revised Regulations)

This letter transmits revisions to the pharmacy regulations. The changes clarify that MassHealth does not pay for prescriptions if the prescribing clinician has been suspended, terminated from participation, or denied admission by MassHealth.

The revisions also include the following:

- limiting the days' supply to 30 days;
- adding methylphenidate and amphetamine to the exceptions to the days' supply limitations; and
- excluding drugs for the treatment of sexual dysfunction.

These regulations are effective December 1, 2005.

If you have any questions about the information in this transmittal letter please contact Affiliated Computer Systems (ACS) at 1-866-246-8503.

NEW MATERIAL

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

Pharmacy Manual

Pages iv and 4-7 through 4-10

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Pharmacy Manual

Pages iv, 4-7, and 4-8 — transmitted by Transmittal Letter PHM-51

Pages 4-9 and 4-10 — transmitted by Transmittal Letter PHM-52

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series PHARMACY MANUAL	SUBCHAPTER NUMBER AND TITLE TABLE OF CONTENTS	PAGE iv
	TRANSMITTAL LETTER PHM-53	DATE 12/01/05

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	4-6
(130 CMR 406.406 through 406.410 Reserved)	
406.411: Prescription Requirements	4-7
406.412: Covered Drugs and Medical Supplies	4-8
406.413: Limitations on Coverage of Drugs.....	4-9
406.414: Insurance Coverage	4-10
(130 CMR 406.415 through 406.419 Reserved)	
406.420: Unit-Dose Packaging Requirement for Certain Drugs Dispensed in Nursing Facilities.....	4-11
406.421: Drugs and Medical Supplies for Institutionalized Members	4-11
406.422: Prior Authorization	4-11
406.423: Member Copayments	4-12
(130 CMR 406.424 through 406.430 Reserved)	
406.431: Payment Rates.....	4-13
(130 CMR 406.432 through 406.435 Reserved)	
406.436: Disclosure of Information	4-14
(130 CMR 406.437 through 406.441 Reserved)	
406.442: Controlled Substance Management Program	4-15
(406.443 through 406.445 Reserved)	
406.446: Return of Unused Unit-Dose-Packaged Drugs Dispensed in Nursing Facilities	4-17

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series PHARMACY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 406.000)	PAGE 4-7
	TRANSMITTAL LETTER PHM-53	DATE 12/01/05

406.411: Prescription Requirements

(A) Legal Prescription Requirements. The MassHealth agency pays for legend drugs, nonlegend drugs, and those medical supplies listed at 130 CMR 406.412(B) 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, regardless of drug schedule, must contain the prescriber's unique DEA number. For Schedule VI drugs, if the prescriber has no DEA registration number, the prescriber must provide the state registration number 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).

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

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

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

(c) 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;

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series PHARMACY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 406.000)	PAGE 4-8
	TRANSMITTAL LETTER PHM-53	DATE 12/01/05

- (d) 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);
- (e) 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);
- (f) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs); and
- (g) methylphenidate and amphetamine prescribed in 60-day supplies.

(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 who:

- (1) 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) 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) Legend Drugs. The MassHealth agency pays only for legend 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) Nonlegend Drugs. Payment by the MassHealth agency for nonlegend drugs is calculated in accordance with DHCFP regulations at 114.3 CMR 31.00: Prescribed Drugs.

(B) Medical Supplies.

- (1) The MassHealth agency pays only for the following medical supplies through POPS:
 - (a) blood and urine testing reagent strips used for the management of diabetes;
 - (b) disposable insulin syringe and needle units;
 - (c) insulin cartridge delivery devices and needles or other devices for injection of medication (for example, Epipens);
 - (d) lancets;
 - (e) drug delivery systems for use with metered dose inhalers (for example, aerochambers); and
 - (f) alcohol swabs.
- (2) Payment and coverage for all other medical supplies are described in MassHealth durable medical equipment regulations at 130 CMR 409.000.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series PHARMACY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 406.000)	PAGE 4-9
	TRANSMITTAL LETTER PHM-53	DATE 12/01/05

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 drugs or drug therapy.

- (1) Cosmetic. The MassHealth agency does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.
- (2) Cough and Cold. The MassHealth agency does not pay for legend or nonlegend drugs 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 an institutionalized member.
- (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) Smoking Cessation. The MassHealth agency does not pay for any drug used for smoking cessation.
- (6) Less-Than-Effective Drugs. The MassHealth agency does not pay for 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.
- (7) Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.
- (8) Drugs for Sexual Dysfunction. The MassHealth agency does not pay for drugs 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 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, and copies may be obtained upon request. The MassHealth agency will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List accordingly. See 130 CMR 450.303.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series PHARMACY MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 406.000)	PAGE 4-10
	TRANSMITTAL LETTER PHM-53	DATE 12/01/05

- (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 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.

(130 CMR 406.415 through 406.419 Reserved)