Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
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Boston, MA 02111
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MASSHEALTH
TRANSMITTAL LETTER PHM-54
April 2006

TO: Pharmacies Participating in MassHealth

FROM: Beth Waldman, Medicaid Director BW

RE: *Pharmacy Manual* (Revision to Regulations About Medicare Part D)

This letter transmits revisions to the pharmacy regulations as a result of federal law enacting Medicare Part D and a new state law providing certain benefits to Medicare Part D-eligible members. The change applies to MassHealth members who have Medicare and who can enroll in a Medicare Part D drug plan.

Effective January 1, 2006, MassHealth provides assistance with Medicare Part D copayments, in accordance with Chapter 175 of the Acts of 2005.

Due to widespread and systemic problems across the Commonwealth with the implementation of Medicare Part D drug coverage, between January 7, 2006, and March 15, 2006, MassHealth provided temporary emergency coverage for outpatient prescription drugs for individuals with both Medicare and MassHealth. This coverage was available if a pharmacy was not able to bill a Medicare Part D plan or the Wellpoint/Anthem point-of-sale contingency plan.

Once the temporary emergency coverage ended, effective March 16, 2006, MassHealth began providing limited supplies of Medicare Part D-covered drugs, in accordance with Chapter 175 of the Acts of 2005.

These emergency regulations were effective January 1, 2006.

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 vi and 4-3 through 4-10

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(The pages listed here are no longer in effect.)

Pharmacy Manual

Pages vi and 4-3 through 4-6 — transmitted by Transmittal Letter PHM-51

Pages 4-7 through 4-10 — transmitted by Transmittal Letter PHM-53

Nonlegend Drug – any drug for which no prescription is required by federal or state law.

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.

Retail Establishment – a physical place of business at which the provider sells legend, nonlegend, and other pharmacy 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 and/or distributing drugs 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 health insurer or pharmacy benefit manager for the same quantity of a drug dispensed to a Massachusetts resident on the same date of service. When 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. NDC number will identify drugs.

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 agency's 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);
(3) participates in the Medicaid program or equivalent of the state in which the provider primarily conducts business; and
(4) agrees to use MassHealth's 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 provide and bill for 340B drugs to MassHealth members, 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 approval. The 340B-covered entity must comply with the requirements of 130 CMR 406.404(D)(1) 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 a copy of the OPA form used to certify the contracted pharmacy services for the 340B drug-pricing program.

(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, 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)

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;

(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.

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.

(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.

(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 Transitional Coverage. MassHealth pays for one-time supplies of prescribed medications, as described in 130 CMR 406.414(C)(2)(a) and (b). These payments will be authorized only if the MassHealth member's Medicare prescription drug plan will not cover the prescribed medication at the time the prescription is presented, if the medication is a MassHealth-covered medication, and for MassHealth members who would otherwise be entitled to MassHealth pharmacy benefits but for being eligible for Medicare prescription drug coverage. MassHealth limits on pharmacy coverage, including prior authorization, do not apply to such one-time supplies.

(a) Between January 1 and June 30, 2006, MassHealth pays for a one-time 30-day supply of prescribed medications. After this supply of the prescribed medication, MassHealth pays for a one-time 72-hour supply of the same prescribed medication.

(b) Effective July 1, 2006, MassHealth pays for a one-time 72-hour supply of prescribed medication.

(3) Cost-Sharing Assistance for Dually-Eligible MassHealth Members. Effective January 1, 2006, for dually-eligible MassHealth members who are enrolled in a Medicare Part D plan, MassHealth pays $1 toward a $2 copayment for generic drugs and $2 toward a $5 copayment for brand-name drugs.

(130 CMR 406.415 through 406.419 Reserved)