



Commonwealth of Massachusetts
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MASSHEALTH
TRANSMITTAL LETTER OPD-54
December 2004

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

This letter transmits revisions to the outpatient hospital regulations about prescription drugs. These revisions allow refills of prescriptions for up to one year, prohibit pharmacies from automatically refilling prescriptions without a request from the member or caregiver, describe the MassHealth 340B drug-pricing program for drugs obtained in accordance with Section 340B of Public Health Law 102-585, and make other clarifying changes.

MassHealth is removing Appendix M from the *Outpatient Hospital Manual*. Appendix M listed the nonlegend drugs that are covered by MassHealth. An up-to-date list of nonlegend drugs can be found at www.mass.gov/druglist.

These regulations are effective January 1, 2005.

If you have any questions, please call MassHealth Provider Services at 617-628-4141 or 1-800-325-5231.

NEW MATERIAL

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

Outpatient Hospital Manual

Pages iv-a, vi, 4-1 through 4-6, and 4-37 through 4-42

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Outpatient Hospital Manual

Pages iv-a, 4-1, 4-2, and 4-37 through 4-42 — transmitted by Transmittal Letter OPD-50

Pages vi, 4-5, and 4-6 — transmitted by Transmittal Letter OPD-48

Pages 4-3 and 4-4 — transmitted by Transmittal Letter OPD-52

Pages M-1 and M-2 — transmitted by Transmittal Letter OPD-53

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410.401: Introduction

130 CMR 410.000 establishes the requirements for the provision of services by hospital outpatient departments and hospital-licensed health centers under MassHealth. For the purposes of 130 CMR 410.000, "hospital outpatient department" refers to both hospital outpatient departments and hospital-licensed health centers. MassHealth pays for outpatient visits and ancillary services (such as radiographic views, laboratory tests, medical supplies, and pharmacy items) that are medically necessary and appropriately provided, as defined at 130 CMR 450.204. The quality of such services must meet professionally recognized standards of care. See 130 CMR 450.140 et seq. for regulations concerning Early and Periodic Screening, Diagnosis and Treatment (EPSDT).

410.402: Definitions

The following terms used in 130 CMR 410.000 have the meanings given in 130 CMR 410.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 410.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 410.000, and in 130 CMR 415.000 and 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.

Acute Inpatient Hospital – a facility that is licensed as a hospital by the Massachusetts Department of Public Health and that provides diagnosis and treatment for patients who have any of a variety of medical conditions requiring daily physician intervention as well as full-time availability of physician services; however, this does not include any facility that is licensed as a chronic disease and rehabilitation hospital, any hospital that is licensed primarily to provide mental health services, or any unit of a facility that is licensed as a nursing facility, a chronic disease unit, or a rehabilitation unit.

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

Cosmetic Surgery – a surgical procedure that is performed for the exclusive purpose of altering appearance and is unrelated to physical disease or defect, or traumatic injury.

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.

Emergency – the unexpected onset of symptoms or a condition requiring immediate medical or surgical care, including, but not limited to, accidents and illnesses such as heart attack, stroke, poisoning, convulsions, loss of consciousness, and cessation of breathing.

Family Planning – any medically approved means, including diagnosis, treatment, and related counseling, that assists individuals of childbearing age, including sexually active minors, in determining the number and spacing of their children.

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Functional Level – the degree to which an individual can function in the community. Progressive levels of impaired functioning are evaluated using a MassHealth-approved scale that has specific criteria for emotional stability, vocational/educational productivity, social relations, and self-care.

Functional Maintenance Program – a planned combination of social, vocational, and recreational services designed for individuals disabled by a chronic mental illness who need continuing services to maintain skills that allow them to function within the community but who do not require the more intensive care of inpatient or day treatment programs.

Hospital – a facility that is licensed or operated as a hospital by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health and that provides diagnosis and treatment on an outpatient basis for patients who have any of a variety of medical conditions.

Hospital-Licensed Health Center – a facility not physically attached to a hospital that operates under the hospital's license, falls under the fiscal, administrative, and clinical management of the hospital, and provides services to patients on an outpatient basis.

Hospital Outpatient Department – a department or unit within the physical framework of the hospital that operates under the hospital's license and provides services to members on an outpatient basis. Hospital outpatient departments include day-surgery units, primary-care clinics, specialty clinics, and emergency departments.

Inpatient Services – medical services provided to a member admitted to an acute inpatient hospital.

Institutionalized Individual – an individual who is either:

- (1) involuntarily confined or detained under a civil or criminal statute in a correctional or rehabilitative facility, including a psychiatric hospital or other facility for the treatment of mental illness; or
- (2) confined under a voluntary commitment in a psychiatric hospital or other facility for the care and treatment of mental illness.

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 for Drug Evaluation and Research (FDA CDER), or by the Massachusetts Drug Formulary Commission.

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Legend Drug – any drug for which a prescription is required by applicable federal or state law or regulation.

Maintenance Program — repetitive activities intended to maintain function that can be performed safely and effectively without the skilled assistance of a qualified therapist.

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 410.463(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 410.000.

Mental Illness – mental and emotional disorders as defined in the current *International Classification of Diseases, Clinical Modification* or the American Psychiatric Association's *Diagnostic and Statistical Manual* and manifested by impaired functioning in one or more of the following: emotional stability, vocational/educational productivity, social relations, and self-care.

Mentally Incompetent Individual – an individual who has been declared mentally incompetent for any purpose by a federal, state, or local court of jurisdiction, unless the individual has been declared competent to consent to sterilization.

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.

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

Observation Services – outpatient hospital services provided anywhere in an acute inpatient hospital, to evaluate a member's condition and determine the need for admission to an acute inpatient hospital. Observation services are provided under order of a physician, consist of the use of a bed and intermittent monitoring by professional licensed clinical staff, and may be provided for more than 24 hours.

Occupational Therapy – evaluation and treatment that includes the administration and interpretation of tests necessary for effective treatment planning; the development of daily living skills, perceptual motor skills, sensory integrative functioning, play skills, and prevocational and vocational work capacities; the design, fabrication, or application of selected orthotic and prosthetic devices or selected adaptive equipment; the use of designated modalities, superficial heat and cold, and neuromuscular facilitation techniques to improve or enhance joint motion muscle function; the design and application of specific therapeutic activities and exercises to enhance or monitor functional or motor performance and to reduce stress; and the adaptation of environments for the handicapped.

Outpatient Hospital Services – medical services provided to a member in a hospital outpatient department. Such services include, but are not limited to, emergency services, primary-care services, observation services, ancillary services, day-surgery services, and recovery-room services.

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Outpatient Services – medical services provided to a member in an outpatient setting including but not limited to hospital outpatient departments, hospital-licensed health centers, physicians’ offices, nurse practitioners’ offices, freestanding ambulatory surgery centers, day treatment centers, or the member’s home.

Outpatient Visit – an in-person encounter between an eligible member and a licensed practitioner (such as a physician, optician, optometrist, dentist, or therapist) or other medical professional under the direction of a licensed practitioner for the provision of outpatient services as defined in 130 CMR 410.402.

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.

Physical Therapy – evaluation and treatment that includes the performance and interpretation of tests; the use of therapeutic exercise, physical activities, mobilization, functional and endurance training, traction, bronchopulmonary hygiene postural drainage, temporary splinting and bracing, massage, heat, cold, water, radiant energy, electricity, or sound; and instruction of both the patient and the family in physical-therapy procedures as part of a patient's ongoing program.

Reconstructive Surgery – a surgical procedure that is performed to correct, repair, or ameliorate the physical effects of physical disease or defect (for example, correction of a cleft palate), or traumatic injury.

Sheltered Workshop – a program of vocational counseling and training in which the participants receive paid work experience or other supervised employment.

Speech/Language Therapy – evaluation of speech, language, voice, and fluency disorders. Such treatment includes improvement of receptive and expressive language abilities, articulation, oral motor function, rate, rhythm, and vocal quality.

Sterilization – any medical procedure, treatment, or operation performed to make an individual permanently incapable of reproducing.

Trimester – one of three three-month terms in a normal pregnancy. If the pregnancy has existed for less than 12 weeks, the pregnancy is in its first trimester. If the pregnancy has existed for 12 or more weeks but less than 24 weeks, the pregnancy is in its second trimester. If the pregnancy has existed for 24 or more weeks, the pregnancy is in its third trimester. For the purposes of 130 CMR 410.000, the elapsed period of gestation is calculated in accordance with regulations of the Massachusetts Department of Public Health currently or hereafter in force.

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Unit-Dose Distribution System — a means of packaging or distributing drugs, or both, 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.

Vocational Rehabilitative Services — services such as vocational assessments, job training, career counseling, and job placement.

410.403: Eligible Members

- (A) (1) MassHealth Members. MassHealth covers outpatient hospital 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) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

410.404: Provider Eligibility

Payment for the services described in 130 CMR 410.000 is made only to hospital outpatient departments participating in MassHealth on the date of service.

- (A) In State
- (1) To participate in MassHealth, acute hospital outpatient departments and hospital-licensed health centers located in Massachusetts must:
- (a) operate under a hospital license issued by the Massachusetts Department of Public Health;
 - (b) have a signed provider agreement that specifies a payment methodology with MassHealth; and
 - (c) participate in the Medicare program.
- (2) To participate in MassHealth, nonacute hospital outpatient departments located in Massachusetts must:
- (a) operate under a hospital license issued by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health;
 - (b) have a rate or rates of payment established by the Massachusetts Division of Health Care Finance and Policy; and
 - (c) participate in the Medicare program.

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(B) Out of State

- (1) Out-of-state hospital outpatient and hospital-licensed health center services provided to an eligible MassHealth member are reimbursable in the following instances:
 - (a) emergency care hospital outpatient services are provided to a member;
 - (b) hospital outpatient services are provided to a member who lives in a community near the border of Connecticut, Maine, New Hampshire, New York, Rhode Island, or Vermont and for whom the out-of-state hospital is nearer than one in Massachusetts providing equivalent medical services;
 - (c) hospital outpatient services are provided to a member who is authorized to reside or who is placed out of state by the Massachusetts Department of Social Services or by a Chapter 766 core team evaluation;
 - (d) hospital outpatient services are provided to a member who has been authorized by MassHealth to reside in an out-of-state nursing facility; or
 - (e) prior authorization has been obtained from MassHealth for nonemergency services provided to a member by an out-of-state hospital outpatient department that is more than 50 miles from the Massachusetts border.
- (2) To participate in MassHealth, an out-of-state hospital outpatient department or hospital-licensed health center must obtain a MassHealth provider number and meet the following criteria:
 - (a) it operates under a hospital license from or is approved as a hospital by the governing or licensing agency in its state;
 - (b) it participates in the Medicare program; and
 - (c) it participates in that state's medical assistance program (or the equivalent).
- (3) Payment for out-of-state hospital outpatient and hospital-licensed health center services is made in accordance with the medical assistance program (or equivalent) fee schedule of that state.

410.405: Noncovered Services

- (A) MassHealth does not pay for any of the following services:
- (1) nonmedical services, such as social, educational, and vocational services;
 - (2) cosmetic surgery;
 - (3) maintenance therapy;
 - (4) canceled or missed appointments;
 - (5) telephone conversations and consultations;
 - (6) court testimony;
 - (7) research or the provision of experimental, unproven, or otherwise medically unnecessary procedures or treatments, specifically including, but not limited to, sex-reassignment surgery, thyroid cartilage reduction and any other related surgeries and treatments, including pre- and post-sex-reassignment surgery hormone therapy. Notwithstanding the preceding sentence, MassHealth will continue to pay for post-sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993;
 - (8) the provision of whole blood; however, administrative and processing costs associated with the provision of blood and its derivatives are covered; and
 - (9) the treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment).

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410.461: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. MassHealth pays for legend drugs, nonlegend drugs, and those medical supplies listed at 130 CMR 410.462(C) 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 pharmacy determines that an emergency exists, MassHealth will pay a 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) MassHealth does not pay for prescription refills that exceed the specific number authorized by the prescriber.
- (2) MassHealth pays for a maximum of 11 monthly refills, except in circumstances described in 130 CMR 410.461(C)(3).
- (3) MassHealth 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 410.461(D).
- (4) MassHealth 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) MassHealth 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. MassHealth requires that all drugs be prescribed and dispensed in at least a 30-day supply, but no more than a 90-day supply, unless the drug is available only in a larger minimum package size, except as specified in 130 CMR 410.461(D)(2).
- (2) Exceptions to Days' Supply Limitations. MassHealth allows exceptions to the limitations described in 130 CMR 410.461(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;

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- (d) drugs packed in such a way that the smallest quantity that may be dispensed is larger than a 90-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); and
- (f) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs).

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

410.462: Pharmacy Services: Covered Drugs and Medical Supplies for MassHealth Members

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

(B) Medical Supplies. MassHealth pays only for the medical supplies listed in 130 CMR 410.462(B)(1) through (6):

- (1) blood and urine testing reagent strips used for the management of diabetes;
- (2) disposable insulin syringe and needle units;
- (3) insulin cartridge delivery devices and needles or other devices for injection of medication (for example, Epipens);
- (4) lancets;
- (5) drug delivery systems for use with metered dose inhalers (for example, aerochambers); and
- (6) alcohol swabs.

410.463: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. MassHealth 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 MassHealth for a nongeneric multiple-source drug (see 130 CMR 410.408); 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.

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(B) Drug Exclusions. MassHealth does not pay for the following types of drugs or drug therapy:

- (1) Cosmetic. MassHealth does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.
- (2) Cough and Cold. MassHealth does not pay for legend or nonlegend drugs used solely for the symptomatic relief of cough or 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. MassHealth does not pay for any drug used to promote male or female fertility.
- (4) Obesity Management. MassHealth does not pay for any drug used for the treatment of obesity.
- (5) Smoking Cessation. MassHealth does not pay for any drug used for smoking cessation.
- (6) Less-Than-Effective Drugs. MassHealth 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. MassHealth does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(C) Service Limitations.

- (1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 420.418(B). 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 420.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. MassHealth 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) MassHealth 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;
 - (c) drugs used for the treatment of male or female sexual dysfunction;
 - (d) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. MassHealth, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993; and
 - (e) topical acne products for members aged 21 or older. MassHealth pays for topical acne products for members under age 21, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.
- (3) MassHealth does not pay any additional fees for dispensing drugs in a unit-dose distribution system.
- (4) MassHealth does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as MassHealth determines to be consistent with current medical evidence.
- (5) MassHealth 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.

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(D) Insurance Coverage.

(1) Managed Care Organizations. MassHealth 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.

(2) 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 MassHealth for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether MassHealth generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 410.463(C)(2)(a), (c), (d), and (e). In such cases, the prescriber must obtain prior authorization from MassHealth in order for the pharmacy to bill MassHealth for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101 et seq. and the MassHealth Acute Hospital Request for Applications and Contract.

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410.464: Pharmacy Services: Drugs and Medical Supplies Provided by Hospital-Based Pharmacies

Drugs and medical supplies provided by hospital-based pharmacies must be provided and billed in accordance with MassHealth regulations governing pharmacy services in 130 CMR 406.000.

410.465: Pharmacy Services: Drugs and Medical Supplies for Members in Institutions

(A) MassHealth does not pay for nonlegend drugs or medical supplies provided to an institutionalized member, except in circumstances described in 130 CMR 410.465(C).

(B) MassHealth pays for legend drugs provided to an institutionalized member.

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

410.466: Pharmacy Services: Prior Authorization

(A) Prescribers must obtain prior authorization from MassHealth for drugs identified by MassHealth in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 410.462(A) and 410.463(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 MassHealth for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with the instructions in Subchapter 5 of the *Outpatient Hospital Manual*. If MassHealth approves the request, it will notify both the pharmacy and the member.

(C) MassHealth 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).) MassHealth acts on requests for prior authorization for a prescribed 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 from 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 410.461 through 410.466. MassHealth will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

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410.467: Pharmacy Services: Member Copayments

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

410.468: Participation in the 340B Drug-Pricing Program for Outpatient Pharmacies

(A) Notification of Participation. A hospital outpatient department or a hospital-licensed health center that is a 340B-covered entity may provide drugs to MassHealth members through the 340B drug-pricing program provided that it notifies MassHealth by submitting to MassHealth 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 hospital may provide and bill for 340B drugs to MassHealth members, provided directly or through a subcontract, after MassHealth confirms, in writing, its receipt of the hospital's notification and a copy of the OPA registration form, in accordance with 130 CMR 410.468(A).

(B) Subcontracting for 340B Outpatient Pharmacy Services.

(1) A hospital outpatient department or hospital-licensed health center that is 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 hospital 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 410.468(A) by submitting to MassHealth 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.

(2) The hospital is legally responsible to MassHealth for the performance of any subcontractor. The hospital 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.

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

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