




Commonwealth of Massachusetts
Executive Office of Health and Human Services
Division of Medical Assistance

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MASSHEALTH
TRANSMITTAL LETTER OPD-50
March 2003

TO: Outpatient Hospitals Participating in MassHealth
FROM: Douglas S. Brown, Acting Commissioner 
RE: *Outpatient Hospital Manual* (Revised Regulations about Pharmacy Services)

This letter transmits revised outpatient hospital regulations. The pharmacy-related provisions have been revised to:

- remove the definitions of financial terms that apply only to pharmacies;
- modify the definition of interchangeable drug product;
- define the MassHealth Drug List;
- reduce the number of allowable refills from 11 to five;
- clarify specific drug limitations and prior-authorization requirements; and
- clarify the impact of managed-care enrollment and insurance coverage on MassHealth pharmacy claims.

These regulations are effective April 1, 2003.

NEW MATERIAL

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

Outpatient Hospital Manual

Pages iv-a, 4-1 through 4-4, 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(The pages listed here are no longer in effect.)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 through 4-4, and 4-37 through 4-42 — transmitted by Transmittal Letter OPD-48

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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. The Division 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.

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 Division-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 Therapy – repetitive therapy that is performed when a person can progress no further toward functional independence but that is or may be necessary to prevent regression.

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by the Division. 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, or dentist) 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 On-Line Processing System (POPS) – the on-line, 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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410.461: Pharmacy Services: Prescription Requirements

(A) Legal Prescription Requirements. The Division 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, the Division will authorize a pharmacy to dispense at least a 72-hour, nonrefillable supply of the drug in compliance with state and federal regulations.

(C) Refills.

- (1) The Division does not pay for prescription refills that exceed the specific number authorized by the prescriber.
- (2) The Division pays for a maximum of five monthly refills.
- (3) The Division pays for more than five refills within a six-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) The Division does not pay for any refill dispensed after six months from the date of the original prescription.
- (5) The absence of an indication to refill by the prescriber renders the prescription nonrefillable.

(D) Quantities.

- (1) Days' Supply Limitations. The Division 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. The Division 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;
 - (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).

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(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. The Division 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.
- (1) Legend Drugs. The Division 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.
 - (2) Nonlegend Drugs. The Division pays only for the nonlegend drugs listed in Appendix M of the *Outpatient Hospital Manual* (Nonlegend Drug List).
- (B) Medical Supplies. The Division pays only for the medical supplies listed below:
- (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 (for example, pens);
 - (4) lancets; and
 - (5) drug delivery systems for use with metered dose inhalers (for example, aerochambers).

410.463: Pharmacy Services: Limitations on Coverage of Drugs

- (A) Interchangeable Drug Products. The Division 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 Division 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. The Division does not pay for the following types of drugs or drug therapy:
- (1) Cosmetic. The Division does not pay for legend or nonlegend preparations for cosmetic purposes or for hair growth.
 - (2) Cough and Cold. The Division does not pay for legend or nonlegend preparations that contain an antitussive or expectorant as a major ingredient, or any drug used solely for the symptomatic relief of coughs and colds, when they are dispensed to a noninstitutionalized member.
 - (3) Fertility. The Division does not pay for any drug used to promote male or female fertility.
 - (4) Obesity Management. The Division does not pay for any drug used for the treatment of obesity.
 - (5) Smoking Cessation. The Division does not pay for any drug used for smoking cessation.
 - (6) Less-Than-Effective Drugs. The Division 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 Division does not pay for any drug that is experimental, medically unproven, or investigational in nature.
- (C) Service Limitations.
- (1) The Division 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 on the Division's Web site, and copies may be obtained upon request. The Division 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 Division 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. The Division, 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) retinoids for members aged 26 or older. The Division pays for retinoids for members under age 26, and all other topical acne products for members of all ages who have cases of acne Grade II or higher, without prior authorization.
 - (3) The Division does not pay any additional fees for dispensing drugs in a unit-dose distribution system.
 - (4) The Division does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the Division determines to be consistent with current medical evidence.

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(D) Insurance Coverage.

(1) Managed Care Organizations. The Division 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 the Division for the primary insurer's copayment for the primary carrier's preferred drug without regard to whether the Division generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR410.463(C)(2)(a), (c), (d), and (e). In such cases, the prescriber must obtain prior authorization from the Division in order for the pharmacy to bill the Division for the primary insurer's copayment.

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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 the Division's regulations governing pharmacy services in 130 CMR 406.000.

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

- (A) The Division does not pay for nonlegend drugs or medical supplies provided to an institutionalized member.
- (B) The Division pays for legend drugs and ostomy supplies provided to an institutionalized member.

410.466: Pharmacy Services: Prior Authorization

- (A) Prescribers must obtain prior authorization from the Division for drugs identified by the Division in accordance with 130 CMR 450.303. If the limitations on covered drugs specified in 130 CMR 410.462(A)(1) 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 the Division 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 the Division approves the request, it will notify both the pharmacy and the member.
- (C) The Division 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 Division 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.

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(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. The Division will evaluate the prior-authorization status of drugs on an ongoing basis, and update the MassHealth Drug List.

410.467: Pharmacy Services: Member Copayments

Under certain conditions, the Division 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 the Division's administrative and billing regulations at 130 CMR 450.130.

(130 CMR 410.468 through 410.470 Reserved)