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 COH-5
August 2008

TO: Chronic Disease and Rehabilitation Outpatient Hospitals Participating in MassHealth

FROM: Tom Dehner, Medicaid Director TD

RE: Chronic Disease and Rehabilitation Outpatient Hospital Manual (Revised Pharmacy Regulations)

This letter transmits revisions to the pharmacy regulations. These changes

- allow MassHealth to specify refill limitations in the MassHealth Drug List;
- include additional exceptions to the 30-day quantity limit to allow 90-day supplies
  - for all family planning drugs; and
  - when MassHealth is the secondary payer and the primary payer allows a 90-day supply;
- eliminate the requirement that 340B entities submit a copy of the form used to register with the federal 340B program when they enroll in the MassHealth 340B program. This is no longer necessary due to changes in the federal 340B program; and
- specify that all medical supplies and devices that are paid through POPS are now listed in the MassHealth Drug List in a section called the MassHealth Non-Drug Product List, instead of in the pharmacy regulations.

These regulations are effective September 15, 2008.

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

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

Chronic Disease and Rehabilitation Outpatient Hospital Manual

Pages iv, iv-a, 4-3 through 4-6, 4-15, 4-16, and 4-37 through 4-44

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(The pages listed here are no longer in effect.)

Chronic Disease and Rehabilitation Outpatient Hospital Manual

Page iv — transmitted by Transmittal Letter COH-1

Pages iv, 4-3 through 4-6, 4-15, 4-16, 4-37, and 4-38 — transmitted by Transmittal Letter COH-1

Pages iv-a and 4-39 through 4-44 — transmitted by Transmittal Letter COH-2

4. Program Regulations

4. Program Regulations (cont.)

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.

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.

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.

Maintenance Program – repetitive services, required to maintain or prevent the worsening of function, that do not require the judgment and skill of a licensed therapist for safety and effectiveness.

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by the MassHealth agency. 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.

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

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 – therapy services, including diagnostic evaluation and therapeutic intervention, designed to improve, develop, correct, rehabilitate, or prevent the worsening of functions that affect the activities of daily living that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Occupational therapy programs are designed to improve quality of life by recovering competence, preventing further injury or disability, and to improve the individual's ability to perform tasks required for independent functioning, so that the individual can engage in activities of daily living.

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, and day-surgery services.

Outpatient Services – medical services provided to a member in an outpatient setting including but not limited to hospital outpatient departments, hospital-licensed health centers or other hospital satellite clinics, 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.

Over-the-Counter Drug – any drug for which no prescription is required by federal or state law. These drugs are sometimes referred to as nonlegend drugs. The MassHealth agency requires a prescription for both prescription drugs and over-the-counter drugs (see 130 CMR 410:461(A))

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

Physical Therapy – therapy services, including diagnostic evaluation and therapeutic intervention, designed to improve, develop, correct, rehabilitate, or prevent the worsening of physical functions that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Physical therapy emphasizes a form of rehabilitation focused on treatment of dysfunctions involving neuromuscular, musculoskeletal, cardiovascular/pulmonary, or integumentary systems through the use of therapeutic interventions to optimize functioning levels.

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

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.

Satellite Clinic – a facility that operates under a hospital's license, is subject to the fiscal, administrative, and clinical management of the hospital, provides services to members solely on an outpatient basis, is not located at the same site as the hospital's inpatient facility, and demonstrates to the MassHealth agency's satisfaction that it has CMS provider-based status in accordance with 42 CFR 413.65.

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

Speech/Language Therapy – therapy services, including diagnostic evaluation and therapeutic intervention, that are designed to improve, develop, correct, rehabilitate, or prevent the worsening of speech/language communication and swallowing disorders that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Speech and language disorders are those that affect articulation of speech, sounds, fluency, voice, swallowing (regardless of the presence of a communication disability), and those that impair comprehension, or spoken, written, or other symbol systems used for communication.

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.

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. Such unit doses may or may not be in unit-dose packaging.

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 the MassHealth agency; 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 signed provider agreement for participation in the MassHealth program; and
(c) participate in the Medicare program.

(B) Out of State

(1) Out-of-state hospital outpatient and hospital-licensed health center services provided to an eligible MassHealth member are covered in the following instances:

(a) emergency care hospital outpatient services are provided to a member;

(b) hospital outpatient services 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 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 the MassHealth agency to reside in an out-of-state nursing facility; or

(e) prior authorization has been obtained from the MassHealth agency 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 Medicaid program (or the equivalent).

(3) Payment for out-of-state hospital outpatient and hospital-licensed health center services is made in accordance with the Medicaid (or equivalent) fee schedule of that state.

410.405: Noncovered Services

(A) The MassHealth agency does not pay for any of the following services:

(1) nonmedical services, such as social, educational, and vocational services;

(2) cosmetic surgery;

(3) canceled or missed appointments;

(4) telephone conversations and consultations;

(5) court testimony;

(6) 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, the MassHealth agency will continue to pay for post-sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993;

(7) the provision of whole blood; however, administrative and processing costs associated with the provision of blood and its derivatives are covered; and

(8) the treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment).

410.413: Medical Services Required on Site at a Hospital-Licensed Health Center

In order to be reimbursed at the rates established for hospital-licensed health centers (HLHCs), an HLHC must provide on site the medical services specified in 130 CMR 410.413(D), (E), and (F), and at least two of the medical services described in 130 CMR 410.413(A), (B), and (C). It is not necessary that all of these services be available during all hours of the HLHC's operation, but all services must be available to members on a regularly scheduled basis with sufficient frequency to ensure access to care and continuity of care.

(A) Pediatric Services. The HLHC must provide pediatric services.

(B) Internal Medicine. The HLHC must provide internal medicine services.

(C) Obstetrics/Gynecology. The HLHC must provide obstetrical and gynecological services. When a family practitioner is employed in place of a medical specialist in obstetrics/gynecology, the family practitioner must have admitting privileges to a hospital for delivery and obstetrical and gynecological backup.

(D) Health Education. The HLHC must provide health education designed to prepare members for their participation in and reaction to specific medical procedures, and to instruct members in self-management of medical problems and in disease prevention. Health education may be provided by any health practitioner or by any other individual approved by the HLHC's professional services director as possessing the qualifications and training necessary to provide health education to members.

(E) Medical Social Services. The HLHC must provide medical social services designed to assist members in their adjustment to and management of social problems resulting from medical treatment, specific disease episodes, or chronic illness. Medical social services must be provided by a clinical social worker who is licensed by the Massachusetts Board of Registration. This individual must be on site sufficient hours and with sufficient frequency to provide medical social services to members.

(F) Nutrition Services. The HLHC must provide counseling in the purchase, preparation, and consumption of proper nutrients to members who have been determined to require such counseling because of their health problems or because they have a high potential for developing health problems that might be avoided or made less severe through proper nutrition. Each HLHC must employ either a nutrition professional with a bachelor's or master's degree in public health nutrition, community nutrition, or human nutrition, or a dietitian who is currently registered by the American Dietetic Association. This individual is responsible for planning, directing, and evaluating the nutrition services provided at the HLHC; for educating the HLHC's staff about nutrition; for supervising any nutrition aides; for consulting with practitioners and other staff members of the HLHC; and for counseling members referred for nutrition information. The nutrition professional or registered dietitian must be on site at least one day per calendar month.

410.414: Observation Services

(A) Reimbursable Services. MassHealth covers medically necessary observation services provided by acute inpatient hospitals. Reimbursable observation services may exceed 24 hours, and do not need to be provided in a distinct observation unit. To qualify for reimbursement of observation services, the medical record must specifically document when those services began and ended, the purpose of observation, and the name of the physician who ordered it. Acute inpatient hospitals will be reimbursed for these observation services on an outpatient basis in accordance with the signed provider agreement with the MassHealth agency.

(B) Nonreimbursable Services.

(1) Nonreimbursable observation services include but are not limited to:

(a) services that are not reasonable or necessary for the diagnosis or treatment of the member; and

(b) routine preparation and recovery services associated with diagnostic testing or outpatient surgery.

(2) The following services are not reimbursable as a separate service:

(a) postoperative monitoring during a standard recovery period that should be characterized as recovery-room services; and

(b) observation services provided concurrently with therapeutic services such as chemotherapy.

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

The MassHealth agency pays for all medically necessary chronic disease and rehabilitation outpatient hospital services for EPSDT-eligible members in accordance with 130 CMR 450.140 et seq., without regard to service limitations described in 130 CMR 410.000, and with prior authorization.

(130 CMR 410.416 through 410.419 Reserved)

410.461: Pharmacy Services: Prescription Requirements

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

(B) Emergencies. When the pharmacist determines that an emergency exists, the MassHealth agency will pay 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) 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 410.461(C)(3), or where the MassHealth Drug List specifically limits the number of refills, duration of the prescription, or both.

(3) The MassHealth agency pays for more than 11 refills within a 12-month period if such refills are for less than a 30-day supply and have been prescribed and dispensed in accordance with 130 CMR 410.461(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 410.461(D)(2).

(2) Exceptions to Days' Supply Limitations.

(a) The MassHealth agency allows exceptions to the limitations described in 130 CMR 410.461(D)(1) for the following products:

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

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

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

(iv) drugs packed in such a way that the smallest quantity that may be dispensed is larger than a 30-day supply (for example, inhalers, ampules, vials, eye drops, and other sealed containers not intended by the manufacturer to be opened by any person other than the end user of the product);
(v) drugs in topical dosage forms that do not allow the pharmacist to accurately predict the rate of the product's usage (for example, lotions or ointments);
(vi) products generally dispensed in the original manufacturer's packaging (for example, fluoride preparations, prenatal vitamins, and over-the-counter drugs); and
(vii) methylphenidate and amphetamine prescribed in 60-day supplies;

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

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

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

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

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

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

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, the following rules apply.

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

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

(B) Non-drug Products paid Through POPS.

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

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

410.463: Pharmacy Services: 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 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.

(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 any drug used for cosmetic purposes or for hair growth.

(2) Cough and Cold. The MassHealth agency does not pay for any 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 a member who is a resident in a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR).

(3) Fertility. The MassHealth agency does not pay for any drug used to promote male or female fertility.

(4) Obesity Management. The MassHealth agency does not pay for any drug used for the treatment of obesity.

(5) Less-Than-Effective Drugs. The MassHealth agency does not pay for any drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.

(6) Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.

(7) Drugs for Sexual Dysfunction. The MassHealth agency does not pay for any drug when used for the treatment of male or female sexual dysfunction.

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 410.463(B). The limitations and exclusions in 130 CMR 410.463(B) do not apply to medically necessary drugs 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 410.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. See 130 CMR 450.303.

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

(a) immunizing biologicals and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH);

(b) nongeneric multiple-source drugs; and

(c) drugs related to sex-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy. The MassHealth agency, however, will continue to pay for post sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993.

(3) The MassHealth agency does not pay any additional fees for dispensing drugs in a unit-dose distribution system.

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

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

(D) Insurance Coverage.

(1) 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.

(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 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 410.463(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. and the hospital's Request for Applications and Contract, if applicable.

(3) Medicare Part D.

(a) 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.

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

(c) Cost-Sharing Assistance for MassHealth Members Enrolled in a Medicare Part D Prescription Drug Plan. For the purpose of 130 CMR 410.463(D)(3)(c)(i) and (ii), the "applicable MassHealth copayment" is the copayment the MassHealth member would pay for prescription drugs if the drugs were covered by MassHealth and not covered by Medicare Part D. MassHealth members who are enrolled in a Medicare Part D prescription drug plan and are charged a copayment or deductible in excess of the member's applicable MassHealth copayment for a drug that MassHealth would otherwise cover, must pay the applicable MassHealth copayment, and the MassHealth agency pays the difference between the applicable MassHealth copayment and the amount charged by the Medicare Part D prescription drug plan.

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 over-the-counter drugs or medical supplies provided to an institutionalized member, except in circumstances described in 130 CMR 410.465(C).

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

(C) The MassHealth agency 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 the MassHealth agency for drugs identified by the MassHealth agency 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 the MassHealth agency 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 *Acute Outpatient Hospital Manual* or the *Chronic Disease and Rehabilitation Outpatient Hospital Manual*, as applicable. If the MassHealth agency approves the request, it will notify both the pharmacy and the member.

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

(D) Prior authorization does not waive any other prerequisites to payment such as, but not limited to, member eligibility or requirements 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. The MassHealth agency evaluates the prior-authorization status of drugs on an ongoing basis, and updates the MassHealth Drug List accordingly.

410.467: Pharmacy Services: Member Copayments

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

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 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 hospital may bill for 340B drugs provided to MassHealth members, either provided directly or through a subcontract, after the MassHealth agency 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 agency approval.

(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 and is a MassHealth pharmacy provider, and that services are furnished in accordance with MassHealth pharmacy regulations at 130 CMR 406.000 and all other applicable MassHealth requirements, including but not limited to, those set forth in 130 CMR 450.000.

(C) Termination or Changes in 340B Drug-Pricing Program Participation. A hospital outpatient department or hospital-licensed health center 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.

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

(130 CMR 410.469 through 410.470 Reserved)

410.471: Mental Health Services: Introduction

A mental health program is a comprehensive group of diagnostic and treatment services, as outlined in 130 CMR 410.474, furnished to mentally or emotionally disabled persons and their families under the direction of a licensed psychiatrist. The MassHealth agency pays for mental health services provided in hospital outpatient departments subject to the restrictions and limitations in 130 CMR 410.472 through 410.479.

410.472: Mental Health Services: Noncovered Services

(A) Nonmedical Services. The MassHealth agency does not pay for nonmedical mental health services. These services include, but are not limited to, the following:

(1) vocational rehabilitation services;
(2) sheltered workshops;
(3) educational services;
(4) recreational services (play therapy, the use of play activities with a child in an identified treatment setting as an alternative to strictly verbal expression of conflicts and feelings, is not considered a recreational service and is covered);
(5) life-enrichment services (ego-enhancing services such as workshops or educational courses provided to functioning persons); and
(6) telephone conversations.

(B) Nonmedical Programs. The MassHealth agency does not pay for diagnostic and treatment services that are provided as an integral part of a planned and comprehensive program that is organized to provide primarily nonmedical or other nonreimbursable services. Such programs include alcohol or drug drop-in centers.

(130 CMR 410.473 Reserved)