



Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
www.mass.gov/masshealth



MassHealth
Transmittal Letter AOH-39
September 2016

TO: Acute Outpatient Hospitals Participating in MassHealth
FROM: Daniel Tsai, Assistant Secretary for MassHealth
RE: *Acute Outpatient Hospital Services Manual* Revised Regulations (130 CMR 410.000)

This letter transmits revisions to the Acute Outpatient Hospital regulations at 130 CMR 410. The regulation is updated to remove pharmacy requirements covered in 130 CMR 406, replacing those requirements with a cross-reference to 130 CMR 406; to clarify the scope of remaining prescribed drug requirements in 130 CMR 410; and to update a 340B. These regulations are effective August 12, 2016.

- 130 CMR 410.461 is updated to replace requirements covered in 130 CMR 406 with a cross-reference to that regulation and to clarify the scope of remaining prescribed drug requirements in 130 CMR 410.
- 130 CMR 410.462 through 130 CMR 410.467, sections containing pharmacy requirements covered in 130 CMR 406, are deleted.
- 130 CMR 410.468 is amended to eliminate a requirement, which is also eliminated in 130 CMR 406, that 340B entities submit a copy of a now obsolete federal form to MassHealth.
- Conforming changes are made elsewhere in the regulation.

MassHealth Website

This transmittal letter and attached pages are available on the MassHealth website at www.mass.gov/masshealth.

Questions

If you have any questions about the information in this transmittal letter, please contact the MassHealth Customer Service Center 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.)

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Pages iv, iv-a, 4-1 through 4-6, and 4-37 through 4-44

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

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Pages 4-1 and 4-2 — transmitted by Transmittal Letter AOH-34

Pages iv, iv-a, 4-3 through 4-6, 4-39 and 4-40 — transmitted by Transmittal Letter AOH-33

Pages 4-37, 4-38, and 4-41 through 4-44 — transmitted by Transmittal Letter AOH-18

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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: *Medical Necessity*. 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: *Acute Inpatient Hospital Services* and 450.000: *Administrative and Billing Regulations*.

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.

Acupuncture – the insertion of metal needles through the skin at certain points on the body, with or without the use of herbs, with or without the application of an electric current, and with or without the application of heat to the needles, skin, or both.

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.

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

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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.

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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.

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 by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes that include the ability to consent to sterilization.

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.

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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 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.

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.

Reconstructive Surgery – a surgical procedure that is performed to correct, repair, or ameliorate the physical effects of disease or physical 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 for the purpose of rendering an individual permanently incapable of reproducing.

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

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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: *Coverage Types* 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: *Emergency Aid to the Elderly, Disabled and Children Program*.
- (B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

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.

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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 covered in the following instances:
- (a) emergency care hospital outpatient services provided to a member;
 - (b) hospital outpatient services provided to a member whose health would be endangered if the member were required to travel to Massachusetts;
 - (c) hospital outpatient services provided to a member when MassHealth determines on the basis of medical advice that the medical service is more readily available in the other state;
 - (d) it is general practice for members in a particular locality to use medical resources in another state;
 - (e) 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;
 - (f) hospital outpatient services provided to a member who has been authorized by the MassHealth agency to reside in an out-of-state nursing facility; or
 - (g) when 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 130 CMR 450.233: *Rates of Payment to Out-of-State Providers*.

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, cosmetic, or otherwise medically unnecessary procedures or treatments;
 - (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); however, MassHealth does pay for the diagnosis of infertility.

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410.461: Pharmacy Services: Drugs Dispensed in Pharmacies Including but not Limited to Hospital-based Pharmacies

(A) Coverage of drugs and medical supplies dispensed to MassHealth members by MassHealth pharmacy providers, and related prescription requirements for prescribing clinicians, are governed by 130 CMR 406.000 and 130 CMR 410.468

(B) Section 130 CMR 410.468 refers to prescription drugs dispensed in pharmacies, not to drugs administered in the office (Physician-Administered Drugs) and is only applicable to 340B-Covered Entities.

(130 CMR 410.462 through 410.467 Reserved)

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410.468: Participation in the 340B Drug-Pricing Program for Pharmacy Services

(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 that the 340B-covered entity is registered and approved by the federal Office of Pharmacy Affairs (OPA).

(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: *Administrative and Billing Regulations*.

(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 101 CMR 331.00: *Prescribed Drugs*.

(130 CMR 410.469 through 410.470 Reserved)

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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)