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

MassHealth
Transmittal Letter AOH-51
January 2022

TO: Acute Outpatient Hospitals Participating in MassHealth

FROM: Amanda Cassel Kraft, Assistant Secretary for MassHealth

RE: *Acute Outpatient Hospital Manual* Revised Regulations at 130 CMR 410.000

This letter transmits revisions to the acute outpatient hospital (AOH) regulations at 130 CMR 410.000 to conform to changes made in the pharmacy regulations at 130 CMR 406.000.

Participation in the 340B Drug Pricing Program for Pharmacy Services was amended (see 130 CMR 410.468) to give MassHealth the authority to exclude certain drugs from purchase through the 340B Drug-Pricing Program for MassHealth members. This authority applies to drugs that cost more than $100,000 per year gross cost per utilizer (as defined in 130 CMR 406.402) and is limited to no more than 25 drugs. It does not apply to claims paid utilizing the adjudicated payment amount per discharge (APAD) or adjudicated payment per episode of care (APEC) methodology, other than for drugs listed on the Acute Hospital Carve-Out Drugs List section of the MassHealth Drug List. MassHealth will provide notice of its intention to exclude drugs from purchase through the 340B drug pricing program consistent with requirements of M.G.L. c. 118E, §13L and allow for provider input.

These regulations are effective January 24, 2022.

MassHealth Website

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Questions

If you have any questions about the information in this transmittal letter, please contact the MassHealth Customer Service Center at (800) 841-2900, email 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.)

Acute Outpatient Hospital Manual

Pages iv, iv-a, 4-1 through 4-18, and 4-23 through 4-30

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Acute Outpatient Hospital Manual

Pages iv, iv-a, 4-1 through 4-18, and 4-23 through 4-30 — transmitted by Transmittal Letter AOH-40

4. Program Regulations

130 CMR 410.000: *Outpatient Hospital Services*

4. Program Regulations (cont.)

410.401: Introduction

130 CMR 410.000 establishes the requirements for the provision of services by hospital outpatient departments, hospital-licensed health centers, and other hospital satellite clinics under MassHealth. For the purposes of 130 CMR 410.000, "hospital outpatient department" may also refer to hospital-licensed health centers, and other hospital satellite clinics. MassHealth pays for outpatient hospital visits and ancillary services (such as radiographic views, laboratory tests, medical supplies, and drugs) 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.

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 Hospital – a facility that (i) is licensed as a hospital by the Massachusetts Department of Public Health (DPH) under M.G.L. c. 111, §51 (if in-state) or by the governing or licensing agency in its state (if out-of-state); (ii) is Medicare-certified and participates in the Medicare program; (iii) has more than 50% of its beds licensed as medical/surgical, intensive care, coronary care, burn, pediatric (Level I or Level II), pediatric intensive care (Level III), maternal (obstetrics), or neonatal intensive care beds (Level III) as determined by DPH (or if out-of-state, the governing or licensing agency in its state, and as determined by MassHealth) and; (iv) utilizes more than 50% of its beds exclusively as either medical / surgical, intensive care, coronary care, burn, pediatric (Level I or Level II), pediatric intensive care (Level III), maternal (obstetrics), or neonatal intensive care beds (Level III), as determined by MassHealth. An acute hospital is not a chronic disease and rehabilitation hospital or a hospital licensed primarily to provide mental health services, or any unit of a facility that is licensed as a nursing facility, chronic disease unit, or rehabilitation unit.

Acute Inpatient Hospital – an acute hospital that provides diagnosis and treatment on an inpatient basis 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 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, chronic disease unit, or a rehabilitation unit.

Chronic Disease and Rehabilitation Hospital (CDR) – a hospital licensed by the Massachusetts Department of Public Health (DPH) under M.G.L. c.111, §51 (or by the governing or licensing agency in its state (if out-of-state)), with a majority of its beds licensed to provide chronic care services, or comprehensive rehabilitation services, or both, to patients with appropriate medical needs, or that is operated by DPH's Bureau of Public Health Facilities. This definition includes such a hospital licensed with a pediatric specialty. Hospitals with 50% or more of their beds licensed as medical/surgical, intensive care, coronary care, burn, maternal (obstetrics) and neonatal intensive care beds (Level III) possess acute hospital licensure and do not meet the definition of a chronic disease and rehabilitation hospital.

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 as defined by the Food, Drug, and Cosmetic Act, containing one or more active ingredients in a specified dosage form and strength. Each dosage form and strength is a separate drug.

Emergency Medical Condition – a medical condition, whether physical or mental, manifesting itself by symptoms of sufficient severity, including severe pain, that the absence of prompt medical attention could reasonably be expected by a prudent layperson who possesses an average knowledge of health and medicine, to result in placing the health of the member or another person in serious jeopardy, serious impairment to body function, or serious dysfunction of any body organ or part, or, with respect to a pregnant woman, as further defined in §1867(e)(1)(B) of the Social Security Act, 42 U.S.C. §1395dd(e)(1)(B).

Emergency Services – medical services that are furnished by a provider that is qualified to furnish such services, and are needed to evaluate or stabilize an emergency medical condition.

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.

Gross Cost Per Utilizer Per Year – Annual cost per utilizer projected by EOHHS based on factors including actual or expected utilization, dosing information, duration of therapy, and the National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) (when NADAC is not available) of the covered drug prior to any federal or supplemental rebate.

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 (HLHC) – a hospital satellite clinic that also

(1) meets all MassHealth requirements for reimbursement as an HLHC as provided in 130 CMR 410.413; and

(2) is enrolled with the MassHealth agency as a hospital-licensed health center.

Hospital Outpatient Department –

(1) For an acute hospital, a department or unit within the physical framework of the hospital's inpatient facility that operates under the hospital's license and provides services to members on an outpatient basis. Acute hospital outpatient departments include day-surgery units, primary-care clinics, specialty clinics, and emergency departments.

(2) For a CDR hospital, a department or unit that operates under the hospital's license or is operated by the Department of Public Health's Bureau of Public Health Facilities, and provides services to members on an outpatient basis.

Hospital Satellite Clinic – a facility that

(1) operates under a hospital's license issued to an acute hospital (in the case of an acute hospital satellite clinic) or to a CDR hospital (in the case of a CDR hospital satellite clinic);

(2) is subject to the fiscal, administrative, and clinical management of the hospital;

(3) provides services to members solely on an outpatient basis;

(4) is not located at the same site as the hospital's inpatient facility; and

(5) demonstrates to the MassHealth agency's satisfaction that it has Centers for Medicare & Medicaid (CMS) provider-based status in accordance with 42 CFR 413.65.

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.

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, hospital-licensed health center, or other hospital satellite clinic, by or under the direction of a physician or dentist. 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 physician or dentist 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.

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.

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 and hospital-licensed health centers 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 to an acute hospital 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, chronic disease and rehabilitation hospital outpatient departments located in Massachusetts must

(a) operate under a hospital license issued to a CDR hospital by the Massachusetts Department of Public Health or be operated as a CDR hospital by the Department of Public Health's Bureau of Public Health Facilities;

(b) have a signed provider agreement for participation in MassHealth; and

(c) participate in the Medicare program.

(B) Out-of-State

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

(a) emergency services provided to a member;

(b) outpatient hospital services provided to a member whose health would be endangered if the member were required to travel to Massachusetts;

(c) outpatient hospital 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) outpatient hospital services provided to a member who is authorized to reside or

(f) who is placed out of state by the Massachusetts Department of Children and Families or by a Chapter 766 core team evaluation;
(g) outpatient hospital services provided to a member who has been authorized by the MassHealth agency to reside in an out-of-state nursing facility; or
(h) 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.

(2) To participate in MassHealth, an out-of-state hospital outpatient department 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, and the hospital licensure is appropriate to the services it seeks to provide under MassHealth (i.e., acute hospital or chronic disease and rehabilitation hospital);
(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 outpatient hospital services is made in accordance with 130 CMR 450.233: *Rates of Payment to Out-of-state Providers*.

(C) Chronic Disease and Rehabilitation, or Similar Hospitals with Both Out-of-state Inpatient Facilities and In-state Outpatient Facilities
(1) To participate in MassHealth, chronic disease and rehabilitation, or similar hospitals with both out-of-state inpatient facilities and in-state outpatient facilities must meet the following criteria:
(a) Out-of-state Outpatient Facilities. The hospital's out-of-state outpatient facilities must comply with 130 CMR 410.404(B).
(b) In-state Outpatient Facilities. The hospital's in-state outpatient facilities must
1. be appropriately licensed by the Massachusetts Department of Public Health;
2. have a signed provider agreement for participation in MassHealth; and
3. participate in Medicare as a provider-based satellite of the out-of-state hospital.
(2) Payment for outpatient services at chronic disease and rehabilitation, or similar hospitals with both out-of-state inpatient facilities and in-state outpatient facilities is made in accordance with 130 CMR 450.234(B): *Outpatient Services*.

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.

(B) The MassHealth agency does not pay for mental health services such as, but not limited to, the following (*see* 130 CMR 410.472):

(1) vocational rehabilitation services;
(2) sheltered workshops;
(3) 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);
(4) life-enrichment services; and
(5) alcohol or drug drop-in centers.

(C) The MassHealth agency does not pay for pharmacy services such as, but not limited to, the following (*see* 130 CMR 406.000: *Pharmacy Services*):

(1) any drug used for the treatment of obesity;
(2) cough and cold preparations;
(3) less-than-effective drugs; and
(4) drugs related to the treatment of male or female infertility.

(D) The MassHealth agency does not pay for certain vision care services and materials as specified in MassHealth regulations at 130 CMR 402.000: *Vision Care Services*.

(E) The MassHealth agency does not pay an independent practitioner for services provided to members in an outpatient department except when that practitioner has an active provider number issued by the MassHealth agency and meets one of the following criteria.

(1) The practitioner serves in an attending, visiting, or supervisory role at the hospital where the services are provided, is legally responsible for the management of the member's care, is physically present and actively involved in the treatment for which payment is claimed, and provides a service for which the MassHealth agency pays an independent practitioner when provided in an outpatient hospital setting. Supervisory surgeons must be scrubbed and physically present during the major portion of an operation.
(2) The independent practitioner, if serving as a salaried intern, resident, fellow, or house officer, provides services during off-duty hours at an institution that does not pay his or her salary.
(3) The independent practitioner receives a salary from an institution for administrative or teaching services, but not for delivery of care, and provides direct medical care to a member that meets the conditions set forth in 130 CMR 410.405(E)(1).

410.406: Payment

(A) Acute hospital outpatient departments and hospital-licensed health centers in Massachusetts are paid for services provided to eligible members according to the rate for services established in the signed MassHealth provider agreement, subject to the limitations set forth in 130 CMR 410.406.

(B) For purposes of making payments to acute hospital outpatient departments and hospital-licensed health centers in Massachusetts, the following limitations apply.

(1) The MassHealth agency does not pay for outpatient services provided to a member who is an inpatient at the same or a different hospital on the same day.
(2) The MassHealth agency pays only for emergency outpatient services provided to a member on the day that the member is discharged from the hospital, whether from the same or a different facility.
(3) If a member receives outpatient services at one facility and, later on the same day, is

admitted as an inpatient to another facility, the MassHealth agency pays both hospitals for services.

(4) When a member is admitted to inpatient status through the emergency department or outpatient department, the hospital must bill for only the inpatient stay. The MassHealth agency does not pay for services furnished in the emergency department or outpatient department on the admitting day.

(C) Chronic Disease and Rehabilitation hospital outpatient departments in Massachusetts are paid for services provided to eligible members according to the rate of payment established for each hospital in the signed MassHealth provider agreement, subject to the limitations set forth in 130 CMR 410.406(C)(1) and (2).

(1) Charges.

(a) The MassHealth agency pays only those charges contained in the charge book that the hospital has currently filed with the Center for Health Information and Analysis and no more than those charges.

(b) For changes in charges, the appropriate EOHHS regulations apply.

(c) In those cases where a specific rate has been established by EOHHS for a specific service or program (such as for adult day health services), the MassHealth agency pays no more than that rate.

(2) Payments. For purposes of making payments to chronic disease and rehabilitation outpatient hospitals, the following limitations apply.

(a) The MassHealth agency does not pay for outpatient services provided to a member who is an inpatient at the same or a different hospital on the same day.

(b) The MassHealth agency pays only for emergency outpatient services provided to a member on the day that he or she is discharged from the hospital, whether from the same or a different facility.

(c) If a member receives outpatient services at one facility and, later on the same day, is admitted as an inpatient to another facility, the MassHealth agency pays both hospitals for services.

(d) When a member is admitted to inpatient status through the emergency department or outpatient department, the hospital must bill for only the all-inclusive *per diem* rate for that day. The MassHealth agency does not pay for services furnished in the emergency department or outpatient department on the admitting day.

(D) The MassHealth agency pays for laboratory services in accordance with 130 CMR 410.456.

410.407: Certification

Hospital-based home health agencies must be certified by the Medicare program and must provide to the MassHealth agency, upon its request, documentation of that certification.

410.408: Prior Authorization

(A) For certain outpatient services described in 130 CMR 410.000, the MassHealth agency requires that the hospital outpatient department obtain prior authorization. No payment is made for outpatient services whenever a hospital is required, but fails, to obtain prior authorization from the MassHealth agency or its designee. It is the responsibility of the hospital to obtain the necessary prior authorization.

(B) Prior authorization determines only the medical necessity of the authorized service and does not

establish or waive any other prerequisites for payment, such as member eligibility or resort to health insurance payment.

(C) All requests for prior authorization must be submitted in accordance with the instructions in Subchapter 5 of the *Outpatient Hospital Manual*. For more information on requests for prior authorization, see 130 CMR 450.303: *Prior Authorization*.

(D) Members enrolled with a MassHealth managed care provider require service authorization before certain behavioral health services are provided. For more information, see 130 CMR 450.124: *Behavioral Health Services*.

(E) The hospital must obtain prior authorization for the following outpatient therapy services:
(1) more than 20 occupational-therapy visits or 20 physical-therapy visits, including group-therapy visits, for a member within a 12-month period; and
(2) more than 35 speech/language therapy visits, including group-therapy visits, for a member within a 12-month period.

410.409: Recordkeeping (Medical Records) Requirements

(A) Payment for any outpatient service covered by MassHealth is conditioned upon its full and complete documentation in the member's medical record. If the information in the member's record is not sufficient to document the service for which payment is claimed by the provider, the MassHealth agency will not pay for the service or, if payment has been made, will consider such payment to be an overpayment subject to recovery as defined in the MassHealth administrative and billing regulations in 130 CMR 450.000. Medical record requirements as set forth in 130 CMR 410.000 constitute the standard against which the adequacy of records is measured, as set forth in 130 CMR 450.000: *Administrative and Billing*.

(B) The MassHealth agency may request, and the hospital outpatient department must provide, any and all medical records (or clear photocopies of such records) corresponding to or documenting the services claimed, in accordance with M.G.L. c. 118E, § 38, and 130 CMR 450.000: *Administrative and Billing*. All components of a member's complete medical record (such as lab slips and X rays) do not need to be maintained in one file as long as all components are accessible to the MassHealth agency upon its request.

(C) The medical record must contain sufficient data to document fully the nature, extent, quality, and necessity of the care provided to a member for each date of service claimed for payment, as well as any data that will update the member's medical course. The data maintained in the member's medical record must also be sufficient to justify any further diagnostic procedures, treatments, recommendations for return visits, and referrals.

(D) Although basic data collected during previous visits (such as identifying data, chief complaint, or history) need not be repeated in the member's medical record for subsequent visits, the medical records for outpatient hospital services provided to members must include at least the following information:
(1) the member's name and date of birth;
(2) the date of each service;
(3) the reason for the visit;
(4) the name and title of the person who performed the service;
(5) the member's medical history;

(6) the diagnosis or chief complaint;
(7) a clear indication of all findings, whether positive or negative, on examination;
(8) any tests administered and their results;
(9) a description of any treatment given;
(10) any medications administered or prescribed, including strength, dosage, regimen, and duration of use;
(11) any anesthetic agent administered;
(12) any medical goods or supplies dispensed or supplied;
(13) recommendations and referrals for additional treatments or consultations, when applicable;
(14) the federally required consent form for sterilization or hysterectomy, when applicable; and
(15) such other information as is applicable for the specific service provided, or as is otherwise required in 130 CMR 410.000.

(E) When a member is referred from a private physician to a hospital outpatient department exclusively for the purpose of a diagnostic test, the following information, at a minimum, must be included in the member's medical record:
(1) the member's name and date of birth;
(2) the signed referral from the private physician authorizing the procedure;
(3) the date of service;
(4) the name and title of the person who performed the service; and
(5) a clear indication of all findings, whether positive or negative.

(F) For therapist services, in addition to the applicable information required in 130 CMR 410.409(D), the member's medical record must include at least the required records and information set forth in 130 CMR 410.453: *Therapist Services: Recordkeeping Requirements*.

(G) For mental health services, in addition to the applicable information required in 130 CMR 410.409(D), the member’s medical record must include at least the required records and information set forth in130 CMR 410.478.

(H) Hospital pharmacies must maintain a record for each member of the drug and amount dispensed, the date, and the original prescription (*see* also 130 CMR 406.000: *Pharmacy Services* and 130 CMR 450.205: *Recordkeeping and Disclosure*).

(I) For vision care services, in addition to the applicable information required in 130 CMR 410.409(D), the record must fully disclose all pertinent information about the services provided, including the date of service, the dates on which materials were ordered and dispensed, and a description of materials (including the frame style and the manufacturer's name) ordered and dispensed. Additional recordkeeping requirements for vision care services that must be followed are set forth in 130 CMR 402.000: *Vision Care Services*.

(J) For laboratory services, in addition to the applicable information required in 130 CMR 410.409(D), the member's medical record must contain a suitable record of each specimen and laboratory test result for at least six years from the date on which the results were reported to the authorized prescriber. Such a record must contain at least the information as specified in 130 CMR 401.417: *Recordkeeping Requirements* (see also 130 CMR 410.458).

410.410: Assurance of Member Rights

No provider shall use any form of coercion in the provision of any services (for example, abortion, sterilization, and family planning). Neither the MassHealth agency, nor any provider, nor any agent or employee of a provider, shall mislead any member into believing that a decision to receive any services reimbursable under 130 CMR 410.000 will adversely affect the member's entitlement to benefits or services for which the member would otherwise be eligible. The MassHealth agency has strict requirements for the confidentiality of patient records for all medical services reimbursable under MassHealth.

410.411: Emergency Services

(A) The MassHealth agency covers emergency services provided in a hospital emergency department without prior authorization.

(B) For services provided in the emergency department, handwritten or time-stamped documentation of the length of the member's stay in the emergency room must be kept in the member's record or on an easily accessible hospital log.

410.412: Utilization Management Program and Mental Health and Substance Use Disorder Admission Screening Requirements

(A) Utilization Management Program. The MassHealth agency pays for procedures and acute hospital stays that are subject to the acute hospital Utilization Management Program only if the applicable requirements of the program as described in 130 CMR 450.207: *Utilization Management Program for Acute Inpatient Hospitals* through 450.209: *Utilization Management: Prepayment Review for Acute Inpatient Hospitals* are satisfied. Appendices A and D of the *Acute Outpatient Hospital Manual* contains the name, address, and telephone number of the contact organization for the Utilization Management Program and describes the information that must be provided during the review process.

(B) Mental Health and Substance Use Disorder Admissions. The MassHealth agency will pay for mental health and substance use disorder services provided in an acute inpatient setting only if the admitting provider has satisfied the screening requirements established by MassHealth policy, bulletin or other issuance.

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 outpatient hospital services for EPSDT-eligible members in accordance with 130 CMR 450.140: *Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services: Introduction, 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)

410.420: Tobacco Cessation Services

(A) Introduction. MassHealth members are eligible to receive tobacco cessation counseling services described in 130 CMR 410.420(B) and pharmacotherapy treatment, including nicotine replacement therapy (NRT), in accordance with 130 CMR 406.000.

(B) Tobacco Cessation Counseling Services.

(1) MassHealth covers a total of 16 group and individual counseling sessions per member per 12-month cycle, without prior authorization. These sessions may be any combination of group and individual counseling. All individual counseling sessions must be at least 30 minutes, except for intake sessions, which must be at least 45 minutes. Intake sessions are limited to two per member per 12-month cycle, without prior authorization.

(a) Individual counseling consists of face-to-face tobacco cessation counseling services provided to an individual member by a MassHealth-qualified provider of tobacco cessation services as set forth in 130 CMR 410.420(B) and (C).

(b) Group tobacco treatment counseling consists of a scheduled professional counseling session with a minimum of three and a maximum of 12 members and has a duration of at least 60 to 90 minutes.

(c) Individual and group counseling also includes collaboration with and facilitating referrals to other health care providers to coordinate the appropriate use of medications, especially in the presence of medical or psychiatric comorbidities.

(2) The individual and group tobacco cessation counseling services must include the following:

(a) education on proven methods for stopping the use of tobacco, including a:

1. a review of the health consequences of tobacco use and the benefits of quitting;
2. a description of how tobacco dependence develops and an explanation of the biological, psychological, and social causes of tobacco dependence; and
3. a review of evidence-based treatment strategies and the advantages and disadvantages of each strategy;

(b) collaborative development of a treatment plan that uses evidence-based strategies to assist the member to attempt to quit, to continue to abstain from tobacco, and to prevent relapse, including:

1. identification of personal risk factors for relapse and incorporation into the treatment plan;
2. strategies and coping skills to reduce relapse risk; and
3. a plan for continued aftercare following initial treatment; and

(c) information and advice on the benefits of nicotine replacement therapy or other proven pharmaceutical or behavioral adjuncts to quitting smoking, including:

1. the correct use, efficacy, adverse events, contraindications, known side effects, and exclusions for all tobacco dependence medications; and
2. the possible adverse reactions and complications related to the use of pharmacotherapy for tobacco dependence.

(C) Provider Qualifications for Tobacco Cessation Counseling Services.

(1) Qualified Providers.

(a) Physicians, registered nurses, nurse practitioners, nurse midwives, and physician assistants may provide tobacco cessation counseling services without additional experience or training in tobacco cessation counseling services.

(b) All other providers of tobacco cessation counseling services must be under the supervision of a physician, and must complete a course of training in tobacco cessation counseling by a degree granting institute of higher education with a minimum of eight hours

of instruction.

(2) Supervision of Tobacco Cessation Counseling Services. A physician must supervise all non-physician providers of tobacco cessation counseling services.

(D) Tobacco Cessation Services: Claims Submission. An acute outpatient hospital may submit claims for tobacco cessation counseling services that are provided by physicians, or by mid-level providers under the supervision of a physician (i.e. nurse practitioner, registered nurse, nurse midwife, physician assistant, and MassHealth-qualified tobacco cessation counselor), according to 130 CMR 410.420(B) and (C). Acute outpatient hospital departments cannot bill separately for services provided by mid-level providers. See Subchapter 6 of the *Acute Outpatient Hospital Manual* for service codes and descriptions.

(130 CMR 410.421 through 410.430 Reserved)

410.431: Sterilization Services: Introduction

(A) Covered Services. The MassHealth agency pays for sterilization services performed by a licensed physician in an acute hospital outpatient department for a member only if all of the following conditions are met.

(1) The member has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 410.432, and such consent is documented in the manner described in 130 CMR 410.433.

(2) The member is at least 18 years of age at the time consent is obtained.

(3) The member is not a mentally incompetent individual or an institutionalized individual.

(B) Assurance of Member Rights. A provider must not use any form of coercion in the provision of sterilization services. The MassHealth agency, any provider, or any agent or employee of a provider, must not mislead any member into believing that a decision to have or not have a sterilization will adversely affect the member's entitlement to benefits or services for which the member would otherwise be eligible. The MassHealth agency has strict requirements for confidentiality of member records for sterilization services as well as for all other medical services covered by MassHealth.

(C) Retroactive Eligibility. The MassHealth agency does not pay for a sterilization performed during the period of a member's retroactive eligibility unless all conditions for payment listed in 130 CMR 410.431(A) are met.

410.432: Sterilization Services: Informed Consent

A member's consent for sterilization will be considered informed and voluntary only if such consent is obtained in accordance with the requirements specified in 130 CMR 410.432(A) and (B), and such consent is documented as specified in 130 CMR 410.433.

(A) Informed Consent Requirements.

(1) The person who obtains consent (a physician, nurse, or counselor, for example) must orally provide all of the following information and advice to the member requesting sterilization:

(a) advice that the member is free to withhold or withdraw consent for the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the member otherwise might be entitled;

(b) a description of available alternative methods of family planning and birth control;

(c) advice that the sterilization procedure is considered irreversible;

(d) a thorough explanation of the specific sterilization procedure to be performed;

(e) a full description of the discomforts and risks that may accompany or follow the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(f) a full description of the benefits or advantages that may be expected as a result of the sterilization; and

(g) advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in 130 CMR 410.432(B)(1).

(2) The person who obtains consent must also

(a) offer to answer any questions the member may have about the sterilization procedure;

(b) give the member a copy of the consent form;

(c) make suitable arrangements to ensure that the information and advice required by 130

CMR 410.432(A)(1) are effectively communicated to any member who is blind, deaf, or otherwise handicapped;

(d) provide an interpreter if the member does not understand the language used on the consent form or the language used by the person obtaining consent; and

(e) allow the member to have a witness of the member's choice present when consent is obtained.

(B) When Informed Consent Must Be Obtained.

(1) A member's consent for sterilization will be considered informed and voluntary only if such consent is obtained at least 30 days, but not more than 180 days, before the date of the sterilization procedure, except in the case of premature delivery or emergency abdominal surgery. A member may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery if at least 72 hours have passed since the member gave informed consent for the sterilization in the manner specified in 130 CMR 410.432. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

(2) A member's consent for sterilization will not be considered informed or voluntary if such consent is obtained or given while the member requesting sterilization is

(a) in labor or childbirth;

(b) seeking to obtain or obtaining an abortion; or

(c) under the influence of alcohol or other substances that affect the individual's state of awareness.

(3) Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the member of all of the information and advice specified in 130 CMR 410.432(A)(1).

410.433: Sterilization Services: Consent Form Requirements

Informed consent for sterilization must be documented by the completion of the MassHealth agency's Consent for Sterilization form in accordance with the following requirements. (Instructions for obtaining the Consent for Sterilization forms are located in Subchapter 5 of the *Outpatient Hospital Manual*.)

(A) Required Consent Form.

(1) One of the following Consent for Sterilization forms must be used:

(a) CS-18 – for members 18 through 20 years of age; or

(b) CS-21 – for members 21 years of age or older.

(2) Under no circumstances will the MassHealth agency accept any other consent for sterilization form.

(B) Required Signatures. The member, the interpreter (if one was required), and the person who obtained the consent for sterilization must all sign and date the Consent for Sterilization form (CS-18 or CS-21) at the time of consent. After performing the sterilization procedure, the physician must sign and date the form.

(C) Required Distribution of the Consent Form. The Consent for Sterilization form (CS-18 or CS-21) must be completed and distributed as follows:

(1) the original must be given to the member at the time of consent; and

(2) a copy must be included in the member's permanent medical record at the site where the sterilization is performed.

(D) Provider Billing and Required Submissions.

(1) All providers must bill with the appropriate sterilization diagnosis and services codes, and must attach a copy of the completed Consent for Sterilization form (CS-18 or CS-21) to each claim made to the MassHealth agency for sterilization services. This provision applies to any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing. When more than one provider is billing the MassHealth agency (for example, the physician and the hospital), each provider must submit a copy of the completed sterilization form with the claim.

(2) A provider does not need to submit a Consent for Sterilization form (CS-18 or CS-21) with a claim for a medical procedure, treatment, or operation that is not for the purpose of rendering an individual permanently incapable of reproducing. If the appropriate service code used to bill for such a medical procedure, treatment, or operation may also be used to bill for a sterilization, the claim will be denied unless at least one of the following justifications is present and documented on an attachment signed by the physician and attached to the claim:

(a) the medical procedure, treatment, or operation was a unilateral procedure and did not result in sterilization;

(b) the medical procedure, treatment, or operation was unilateral or bilateral, but the patient was previously sterile as indicated in the operative notes;

(c) the medical procedure, treatment, or operation was medically necessary for treatment of an existing illness or injury and was not performed for the purpose of sterilization; or

(d) the medical procedure, treatment, or operation was medically necessary for treatment of a life-threatening emergency situation and was not performed for the purpose of sterilization, and it was not possible to inform the member in advance that it would or could result in sterilization. Include the nature and date of the life-threatening emergency.

(3) In the circumstances set forth in 130 CMR 410.433(D)(2)(a) and (c), the medical records must also document that the member consented to the medical procedure, treatment, or operation after being informed that it would or could result in sterilization.

(4) When more than one provider is billing the MassHealth agency under the circumstances specified in 130 CMR 410. 433(D)(2) (for example, the physician and hospital), each provider must submit a copy of the signed attachment along with the claim.

410.434: Abortion Services: Reimbursable Services

The MassHealth agency pays for abortion services performed by a licensed physician in a hospital outpatient department only when all of the following conditions are met:

(A) the abortion is performed in accordance with law;

(B) the abortion is medically necessary—that is, according to the medical judgment of a licensed physician, necessary in light of all factors affecting the woman's health; and

(C) the abortion service is claimed according to the requirements in 130 CMR 410.435.

410.435: Abortion Services: Certification for Payable Abortion Form

All physicians and hospital outpatient departments must complete a Certification for Payable Abortion (CPA-2) form and retain the form in the member's record. (Instructions for obtaining the Certification for Payable Abortion form are in Subchapter 5 of the *Outpatient Hospital Manual*.) To identify those abortions that meet federal reimbursement standards, the MassHealth agency must secure on the CPA-2 form the certifications described in 130 CMR 410.435(A) through (C), when applicable. For all medically necessary abortions not included in 130 CMR 410.435(A) through (C),

governing adult day health services in 130 CMR 404.000: *Adult Day Health Services*.

410.444: Adult Foster Care Services

(A) An adult foster care program provides personal care services in a family-like setting to elderly or disabled individuals who are at imminent risk of institutional placement.

(B) The MassHealth agency pays for services provided by hospital-based adult foster care programs. These services must be furnished in compliance with 130 CMR 408.000: *Adult Foster Care Services*. (See Subchapter 5 of the *Outpatient Hospital Manual* for information about obtaining the *Adult Foster Care Manual*.)

(C) Acute hospital-based adult foster care programs will be paid according to the outpatient payment methodology established by the signed MassHealth provider agreement.

(D) Nonacute hospital-based adult foster care programs will be paid according to the regulations governing adult foster care services in 130 CMR 408.000: *Adult Foster Care Services.*

410.445: Psychiatric Day Treatment Program Services

(A) A psychiatric day treatment program is a planned combination of diagnostic, treatment, and rehabilitative services provided to mentally or emotionally disturbed persons who need more active or inclusive treatment than is typically available through a weekly visit for outpatient mental health services, but who do not need full-time hospitalization or institutionalization. Such a program uses multiple, intensive, and focused activities in a supportive environment to enable these individuals to acquire more realistic and appropriate behavior patterns, attitudes, and skills for eventual independent functioning in the community.

(B) The MassHealth agency pays for services provided as part of an organized psychiatric day treatment program by hospital outpatient departments that are enrolled with MassHealth as psychiatric day treatment programs. These services must be provided in compliance with the MassHealth regulations governing psychiatric day treatment program services in 130 CMR 417.000: *Psychiatric Day Treatment Program Services*. (See Subchapter 5 of the *Outpatient Hospital Manual* for instructions about obtaining the *Psychiatric Day Treatment Program Manual*, which contains the necessary regulations.)

(C) Acute hospital-based psychiatric day treatment programs are paid according to the outpatient payment methodology established by the signed MassHealth provider agreement.

(D) Nonacute hospital-based psychiatric day treatment programs are paid according to the regulations governing psychiatric day treatment services in 130 CMR 417.000: *Psychiatric Day Treatment Program Services.*

410.446: Dental Services

(A) The MassHealth agency pays for dental services provided by hospital outpatient departments. These services must be provided in compliance with the MassHealth regulations governing dental services in 130 CMR 420.000: *Dental Services*. (See Subchapter 5 of the *Outpatient Hospital Manual* for information about obtaining the *Dental Manual*, which contains the necessary regulations.)

(B) Acute hospital-based providers of dental services are paid according to the outpatient payment methodology established by the signed MassHealth provider agreement.

(C) Nonacute hospital-based providers of dental services are paid according to the regulations governing dental services in 130 CMR 420.000: *Dental Services*.

(130 CMR 410.447 through 410.450 Reserved)

410.451: Therapist Services: Covered Services

(A) The MassHealth agency pays for occupational, physical, and speech/language therapy provided in hospital outpatient departments by or under the supervision of licensed therapists. Therapist services include the following:

(1) individual treatment;
(2) comprehensive evaluation;
(3) group therapy; and
(4) design and fitting of an adaptive device.

(B) All therapy must be provided subsequent to a written referral from a licensed physician or licensed nurse practitioner. The MassHealth agency pays for continuing physical, occupational, or speech/language therapy only when the referral is renewed in writing every 60 days, subject to the prior-authorization requirements described in 130 CMR 410.408(E).

(C) Before therapy is initiated, a comprehensive evaluation of the member's medical condition, disability, and level of functioning must be performed to determine the need for treatment and, when treatment is indicated, to develop a treatment plan. A comprehensive evaluation must include preparation of a written report for the member's medical record that contains at least the following information:

(1) the member's name and address;
(2) the name of the referring physician or nurse practitioner;
(3) objective evaluation findings;
(4) a detailed treatment plan prescribing the type, amount, estimated frequency, and duration of therapy and indicating the diagnosis and anticipated goals, or the reason treatment is not indicated;
(5) a description of any conferences with the member, the member's family or clinician, or other interested persons;
(6) other health care evaluations, as indicated;
(7) a description of the member's psychosocial and health status that includes:
  (a) the present effects of the disability on both member and family;
  (b) a brief history, the date of onset, and any past treatment of the disability;
  (c) the member's level of functioning, both current and before onset of the disability, if applicable; and
  (d) any other significant physical or mental disability that may affect therapy;
(8) for speech/language therapy only:
  (a) assessments of articulation, stimulability, voice, fluency, and receptive and expressive language;
  (b) a description of the member's cognitive functioning; and
  (c) a description of the member's communication needs and motivation for treatment;
(9) for physical or occupational therapy only: a description of the member’s physical

limitations; and
(10) the therapist's signature and the date of the evaluation.

(D) The hospital must obtain prior authorization as a prerequisite to payment for certain outpatient therapy services pursuant to 130 CMR 410.408(E).

410.452: Therapist Services: Service Limitations

(A) The MassHealth agency pays for the establishment of a maintenance program and the training of the member, member's family, or other persons to carry it out, as part of a regular treatment visit, not as a separate service. The MassHealth agency does not pay for performance of a maintenance program, except as provided in 130 CMR 410.452(B).

(B) In certain instances, the specialized knowledge and judgment of a licensed therapist may be required to perform services that are part of a maintenance program, to ensure safety or effectiveness that may otherwise be compromised due to the member's medical condition. At the time the decision is made that the services must be performed by a licensed therapist, all information that supports the medical necessity for performance of such services by a licensed therapist, rather than a non-therapist, must be documented in the medical record.

(C) For each type of therapy, the MassHealth agency pays for no more than one individual visit and one group therapy session for a member per day.

410.453: Therapist Services: Recordkeeping Requirements

In addition to the information required in 130 CMR 410.409, the member's record must include the following:

(A) a licensed physician's or licensed nurse practitioner's written referral for evaluation, referral for treatment, and renewal of referral (if applicable) every 60 days (see 130 CMR 410.451(B));

(B) the written comprehensive evaluation report (*see* 130 CMR 410.451(C));

(C) the name, address, and telephone number of the member's primary physician;

(D) a treatment notation for each date on which therapy was provided that includes at least the following:
(1) the specific therapeutic procedures and methods used;
(2) the amount of time spent in treatment; and
(3) the signature and title of the person who provided the service;

(E) at least weekly documentation of the following:
(1) the member's response to treatment;
(2) any changes in the member's condition;
(3) the problems encountered or changes in the treatment plan or goals, if any;
(4) the location where the service was provided if different from that in the evaluation report; and
(5) the signature and title of the therapist; and

(F) a discharge summary, when applicable.

(130 CMR 410.454 Reserved)

410.455: Laboratory Services: Introduction

(A) 130 CMR 410.455 through 410.459 establish the requirements and procedures for clinical laboratory services provided by hospital outpatient departments. A clinical laboratory service includes the following types of services: microbiological, serological, chemistry, hematological, radioimmunoassay, cytological, immunological, pathological, or other examinations of materials derived from the human body to provide information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of any disease.

(B) The MassHealth agency does not pay separately for routine specimen collection and preparation for the purpose of clinical laboratory analysis (for example, venipuncture; urine, fecal, and sputum samples; Pap smears; cultures; and swabbing and scraping for removal of tissue.) Specimen collection and preparation is considered part of the laboratory service.

410.456: Laboratory Services: Payment

(A) Maximum Allowable Fees. The MassHealth agency pays an acute or a private chronic disease and rehabilitation hospital outpatient department for laboratory services in accordance with the rates set forth in regulations at 101 CMR 320.00: *Clinical Laboratory Services*, and 114.3 CMR 16.00: *Surgery and Anesthesia*, as applicable, subject to the conditions, exclusions, and limitations set forth in 130 CMR 410.000.

(B) Usual and Customary Fee. The term usual and customary in the hospital outpatient department laboratory context means the lowest fee charged by a hospital outpatient department laboratory for any laboratory service (including both individual and profile tests) specified in the hospital outpatient department's charge book or by such hospital, with the exception of a fee offered for a bulk purchase. (A bulk purchase is a single purchase of a laboratory service (one or more tests) to be uniformly and concurrently performed on a minimum of 40 specimens of the same type. A single purchase of various, non-uniform laboratory services, such as by a physician, is not considered a bulk purchase, regardless of the number of specimens presented by such a purchaser to the hospital outpatient department laboratory.)

(C) Profile or Panel Tests.

(1) A profile or panel test is any group of tests, whether performed manually, automatedly, or semiautomatedly, that is ordered for a specified member on a specified day and has at least one of the following characteristics.

(a) The group of tests is designated as a profile or panel by the hospital outpatient department laboratory performing the tests.

(b) The group of tests is performed by the hospital outpatient department laboratory at a usual and customary fee that is lower than the sum of that hospital outpatient department laboratory's usual and customary fees for the individual tests in that group.

(2) In no event shall a hospital outpatient department laboratory bill or be paid separately for each of the tests included in a profile test when a profile test has either been performed by that hospital outpatient department laboratory or requested by an authorized person.

410.457: Laboratory Services: Request for Services

In order to receive payment for a laboratory service, a hospital outpatient department must have received a written request by an authorized prescriber, as defined in 130 CMR 401.402: *Definitions*, to perform the service. Such written request must comply with the requirements specified in 130 CMR 401.416: *Reimbursable Services*.

410.458: Laboratory Services: Recordkeeping Requirements

In addition to meeting the recordkeeping requirements specified in 130 CMR 410.409, the hospital outpatient department must keep a suitable record of each specimen and laboratory test result for at least six years from the date on which the results were reported to the authorized prescriber. Such a record must contain the information specified in the MassHealth Independent Clinical Laboratory regulations at 130 CMR 401.417: *Recordkeeping Requirements*.

410.459: Laboratory Services: Specimen Referral

A hospital outpatient department may refer a specimen to an independent laboratory that is eligible to participate in MassHealth, or to another hospital laboratory that is eligible to participate in MassHealth. To be eligible, a hospital laboratory must be in a hospital that is licensed by the Massachusetts Department of Public Health and that is an approved Medicare provider. The referring hospital outpatient department laboratory must inform the prescriber of the name and address of the testing laboratory. The testing laboratory must inform the referring hospital outpatient department laboratory of the results of the test. Only the referring laboratory is authorized to bill the MassHealth agency.

(l30 CMR 410.460 Reserved)

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: *Pharmacy Services* 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)

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

(A) Notification of Participation. Except for drugs that cost $100,000 (gross cost per utilizer per year) that are designated as excluded from coverage for MassHealth members through the 340B Drug Pricing Program, 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). Any high-cost drug designated for exclusion from coverage for MassHealth members through the 340B Drug-Pricing Program will be communicated by provider bulletin or other written issuance from the MassHealth agency, and be consistent with all requirements of M.G.L. c. 118E, §13L, and shall include an opportunity for eligible providers to provide input regarding the designation. The MassHealth agency may designate up to 25 drugs for exclusion from coverage for MassHealth members through the 340B Drug Pricing Program. Any exclusion from coverage for MassHealth members through the 340B Drug Pricing Program does not apply to claims paid using the adjudicated payment amount per discharge (APAD) or adjudicated payment per episode of care (APEC) methodology, other than for drugs listed on the Acute Hospital Carve-Out Drugs List section of the MassHealth Drug List.

(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: *Pharmacy Services*, 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: *Pharmacy Services* 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)

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 noncovered services. Such programs include alcohol or drug drop-in centers.

(130 CMR 410.473 Reserved)