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

MassHealth
Transmittal Letter COH-9
January 2015

**TO:** Chronic Disease and Rehabilitation Outpatient Hospitals Participating in MassHealth

**FROM:** Kristin L. Thorn, Medicaid Director

**RE:** *Chronic Disease and Rehabilitation Outpatient Hospital Manual* (Updated Gender Dysphoria and Sterilization Policies; Out-of-State Chronic Disease and Rehabilitation Hospitals)

This letter transmits revisions to the Chronic Disease and Rehabilitation Outpatient Hospital (COH) regulations as they pertain to treatment for gender dysphoria, sterilization services, and out-of-state chronic disease and rehabilitation hospitals. A subsequent transmittal letter will be issued to address regulatory changes regarding abortion services.

**Gender Dysphoria Policy and Sterilization Provisions**

This letter transmits revisions to the outpatient hospital regulations to allow coverage of treatment of gender dysphoria, and to revise and clarify provisions regarding sterilization. Both categories of service occur in acute outpatient hospital settings.

**Out-of-State Chronic Disease and Rehabilitation Hospitals**

This letter also transmits revisions to these regulations to specify MassHealth outpatient hospital participation requirements and payment provisions for chronic disease, rehabilitation, or similar hospitals with both out-of-state inpatient facilities and in-state outpatient facilities.

**Effective Date**

These regulatory amendments are effective for dates of service on or after January 2, 2015.

**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.)

Chronic Disease and Rehabilitation Outpatient Hospital Manual

Pages iv, iv-a, vi, 4-1 through 4-18, 4-21 through 4-30, 4-39, and 4-40

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Chronic Disease and Rehabilitation Outpatient Hospital Manual

Page iv, 4-1 through 4-4, 4-15, 4-16, 4-39, and 4-40 — transmitted by Transmittal Letter COH-5

Page iv-a — transmitted by Transmittal Letter COH-6

Page vi — transmitted by Transmittal Letter COH-1

Pages 4-5 and 4-6 — transmitted by Transmittal Letter COH-7

Pages 4-7 through 4-12, 4-17, 4-18, and 4-21 through 4-30 — transmitted by Transmittal Letter COH-1

Pages 4-13 and 4-14 — transmitted by Transmittal Letter COH-4

4. Program Regulations

410.401: Introduction ..... 4-1
410.402: Definitions ..... 4-1
410.403: Eligible Members ..... 4-5
410.404: Provider Eligibility ..... 4-5
410.405: Noncovered Services ..... 4-7
410.406: Payment ..... 4-8
410.407: Certification ..... 4-9
410.408: Prior Authorization ..... 4-9
410.409: Recordkeeping (Medical Records) Requirements ..... 4-10
410.410: Assurance of Member Rights ..... 4-13
410.411: Emergency Services ..... 4-14
410.412: Utilization Management Program and Mental Health and Substance Abuse Admission Screening Requirements ..... 4-14
410.413: Medical Services Required on Site at a Hospital-Licensed Health Center ..... 4-15
410.414: Observation Services ..... 4-16
410.415: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services ..... 4-16
(130 CMR 410.416 through 410.419 Reserved)
410.420: Tobacco Cessation Services ..... 4-17
(130 CMR 410.421 through 410.430 Reserved)
410.431: Sterilization Services: Introduction ..... 4-21
410.432: Sterilization Services: Informed Consent ..... 4-22
410.433: Sterilization Services: Consent Form Requirements ..... 4-23
410.434: Abortion Services: Reimbursable Services ..... 4-25
410.435: Abortion Services: Certification for Payable Abortion Form ..... 4-25
410.436: Abortion Services: Out-of-State Abortions ..... 4-26
410.437: Family Planning Services ..... 4-27
410.438: Acupuncture ..... 4-28
(130 CMR 410.439 through 410.440 Reserved)
410.441: Early Intervention Program Services ..... 4-29
410.442: Home Health Agency Services ..... 4-29
410.443: Adult Day Health Program Services ..... 4-30
410.444: Adult Foster Care Services ..... 4-30
410.445: Psychiatric Day Treatment Program Services ..... 4-31
410.446: Dental Services ..... 4-31
(130 CMR 410.447 through 410.450 Reserved)
410.451: Therapist Services: Covered Services ..... 4-32
410.452: Therapist Services: Service Limitations ..... 4-33
410.453: Therapist Services: Recordkeeping Requirements ..... 4-33
(130 CMR 410.454 Reserved)

4. Program Regulations (cont.)


410.455: Laboratory Services: Introduction ..... 4-34
410.456: Laboratory Services: Payment ..... 4-34
410.457: Laboratory Services: Request for Services ..... 4-35
410.458: Laboratory Services: Recordkeeping Requirements ..... 4-35
410.459: Laboratory Services: Specimen Referral ..... 4-36
(130 CMR 410.460 Reserved)
410.461: Pharmacy Services: Prescription Requirements ..... 4-37
410.462: Pharmacy Services: Covered Drugs and Medical Supplies for MassHealth Members ..... 4-38
410.463: Pharmacy Services: Limitations on Coverage of Drugs ..... 4-39
410.464: Pharmacy Services: Drugs and Medical Supplies Provided by Hospital-Based Pharmacies ..... 4-41
410.465: Pharmacy Services: Drugs and Medical Supplies for Members in Institutions ..... 4-41
410.466: Pharmacy Services: Prior Authorization ..... 4-42
410.467: Pharmacy Services: Member Copayments ..... 4-42
410.468: Participation in the 340B Drug-Pricing Program for Outpatient Pharmacies ..... 4-43
(130 CMR 410.469 and 410.470 Reserved)
410.471: Mental Health Services: Introduction ..... 4-44
410.472: Mental Health Services: Noncovered Services ..... 4-44
(130 CMR 410.473 Reserved)
410.474: Mental Health Services: Definitions ..... 4-45
410.475: Mental Health Services: Staffing Requirements ..... 4-46
410.476: Mental Health Services: Treatment Procedures ..... 4-48
410.477: Mental Health Services: Utilization Review Plan ..... 4-48
410.478: Mental Health Services: Recordkeeping Requirements ..... 4-49
410.479: Mental Health Services: Service Limitations ..... 4-50
410.480: Mental Health Services: Child and Adolescent Needs and Strengths (CANS) Data Reporting ..... 4-53
410.481: Vision Care Services: General Requirements ..... 4-54
410.482: Vision Care Services: Prescription and Dispensing Requirements ..... 4-55
410.483: Vision Care Services: Recordkeeping Requirements ..... 4-56
410.484: Vision Care Service Limitations: Visual Analysis ..... 4-57
410.485: Vision Care Service Limitations: Dispensing Eyeglasses ..... 4-57
410.486: Vision Care Service Limitations: Lenses ..... 4-58
410.487: Vision Care Service Limitations: Other Restrictions ..... 4-59
410.488: Vision Care Service Exclusions ..... 4-60

Appendix A. Directory ..... A-1

Appendix C. Third-Party-Liability Codes ..... C-1

Appendix U. DPH-Designated Serious Reportable Events That Are Not Provider Preventable Conditions ..... U-1

Appendix V. MassHealth Billing Instructions for Provider Preventable Conditions ..... V-1

Appendix W. EPSDT Services: Medical Protocol and Periodicity Schedule..... W-1

Appendix X. Family Assistance Copayments and Deductibles..... X-1

Appendix Y. EVS/Codes Messages ..... Y-1

Appendix Z. EPSDT Services Laboratory Codes ..... Z-1

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.

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

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

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

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

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

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

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

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

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

Institutionalized Individual – an individual who is either:

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

(2) confined under a voluntary commitment in a psychiatric hospital or other facility for the care and treatment of mental illness.

Interchangeable Drug Product – a product containing a drug in the same amounts of the same active ingredients in the same dosage form as another product with the same generic or chemical name that has been determined to be therapeutically equivalent (that is, "A-rated") by the Food and Drug Administration for Drug Evaluation and Research (FDA CDER), or by the Massachusetts Drug Formulary Commission.

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

MassHealth Drug List – a list of commonly prescribed drugs and therapeutic class tables published by the MassHealth agency. The MassHealth Drug List specifies the drugs that are payable under MassHealth. The list also specifies which drugs require prior authorization. Except for drugs and drug therapies described in 130 CMR 410.463(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 410.000.

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

Mentally Incompetent Individual – an individual who has been declared mentally incompetent 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.

Multiple-Source Drug – a drug marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

Non-Drug Product List – a section of the MassHealth Drug List comprised of those products not classified as drugs (i.e., blood testing supplies) that are payable by the MassHealth agency through the Pharmacy Program. Payment for these items is in accordance with rates published in Executive Office of Health and Human Services (EOHHS) regulations at 114.3 CMR 22.00: *Durable Medical Equipment, Oxygen, and Respiratory Therapy Equipment* and 101 CMR 317.00: *Medicine. The MassHealth Non-Drug Product List* also specifies which of the included products require prior authorization.

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

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

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

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

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

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

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

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

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

Reconstructive Surgery – a surgical procedure that is performed to correct, repair, or ameliorate the physical effects of 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.

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

Unit-Dose Distribution System – a means of packaging or distributing drugs, or both, devised by the manufacturer, packager, wholesaler, or retail pharmacist. A unit dose contains an exact dosage of medication and may also indicate the total daily dosage or the times when the medication should be taken. Such unit doses may or may not be in unit-dose packaging.

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

410.403: Eligible Members

(A) (1) MassHealth Members. MassHealth covers outpatient hospital services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. 130 CMR 450.105: *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 MassHealth; and

(c) participate in the Medicare program.

(B) Out-of-State

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

(a) emergency care hospital outpatient services 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*.

(C) Chronic Disease, Rehabilitation, or Similar Hospitals with Both Out-of-State Inpatient Facilities and In-State Outpatient Facilities

(1) To participate in MassHealth, chronic disease, 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

(i) be appropriately licensed by the Massachusetts Department of Public Health;

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

(iii) participate in Medicare as a provider-based satellite of the out-of-state hospital.

(2) Payment for outpatient services at chronic disease, 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;
(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 410.462 through 410.465):
(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 vision care services such as, but not limited to, the following (see 130 CMR 410.481 through 410.489):
(1) absorptive lenses of greater than 25% absorption;
(2) photochromatic lenses, sunglasses, or fashion tints;
(3) treatment of congenital dyslexia;
(4) extended-wear contact lenses;
(5) invisible bifocals; and
(6) the Welsh 4-Drop Lens.

(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) 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 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) Nonacute 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 DHCFP and no more than those charges.
(b) For changes in charges, the appropriate regulations of the DHCFP apply.
(c) In those cases where a specific rate has been established by DHCFP 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 nonacute 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

(A) Hospital outpatient departments must receive certification from the MassHealth agency before providing the following services:

(1) adult day health services (for requirements, see 130 CMR 410.443);
(2) adult foster care services (for requirements, see 130 CMR 410.444); and
(3) psychiatric day treatment program services (for requirements, see 130 CMR 410.445).

(B) 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*.

(D) Time requirements for response from the MassHealth agency and rules that apply in determining the period within which the MassHealth agency acts on specific requests for prior authorization are set forth in the MassHealth administrative and billing regulations in 130 CMR 450.000. A service is authorized on the date the MassHealth agency transmits its decision about the request for prior authorization to the provider.

(E) Written notification of the prior-authorization decision is sent to the provider and indicates approval, deferral because additional information is necessary, modification, or denial. In the case of a modification or denial, the member is also notified. Notification of denial includes the reason for the decision. The member or the provider has the right to resubmit a request and provide additional information. The member may appeal the modification or denial of a prior-authorization request within 30 days after the date of receipt of the notice of denial. Procedures for such an appeal are set forth in 130 CMR 610.000.

(F) 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.

(G) 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.

(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. 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 hospital outpatient 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 following (see 130 CMR 410.453);
(1) a licensed physician's written referral for evaluation, referral for treatment, and renewal of referral (if applicable) every 60 days (see 130 CMR 410.451(B));
(2) the written comprehensive evaluation report (see 130 CMR 410.451(C));
(3) the name, address, and telephone number of the member's primary physician;
(4) a treatment notation for each date on which therapy was provided that includes at least the following:
(a) the specific therapeutic procedures and methods used;
(b) the amount of time spent in treatment; and
(c) the signature and title of the person who provided the service;
(5) at least weekly documentation of the following:
(a) the member’s response to treatment;
(b) any changes in the member’s condition;
(c) the problems encountered or changes in the treatment plan or goals, if any;
(d) the location where the service was provided if different from that in the evaluation report; and
(e) the signature and title of the therapist; and
(6) a discharge summary, when applicable.

(G) (1) 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 following (see 130 CMR 410.478):
(a) the member’s case number, address, telephone number, sex, age, marital status, next of kin, and school or employment status (or both);
(b) the date of initial contact and, if applicable, the referral source;

(c) a report of a physical examination performed within six months (if such an examination has not been performed in that period, one must be given within 30 days after the member's request for services or, if the member refuses to be examined, the record must document the reasons for the exam postponement);
(d) the name and address of the member's primary physician or medical clinic (a physician or medical clinic must be recommended if there is not one currently attending the member);
(e) a description of the nature of the member's condition;
(f) the relevant medical, social, educational, and vocational history;
(g) a comprehensive functional assessment of the member;
(h) the clinical impression of the member and a diagnostic formulation, including a specific diagnosis using ICD-9-CM or DSM III diagnosis codes;
(i) the member's treatment plan, updated as necessary, including long-range goals, short-term objectives, and the proposed schedule of therapeutic activities;
(j) a schedule of dates for utilization review to determine the member's progress in accomplishing goals and objectives;
(k) the name, qualifications, and discipline of the primary therapist;
(l) a written record of utilization reviews by the primary therapist;
(m) documentation of each visit, including the member's response to treatment, written and signed by the person providing the service, and including the therapist's discipline and degree;
(n) all information and correspondence about the member, including appropriately signed and dated consent forms;
(o) a medication-use profile; and
(p) when the member is discharged, a discharge summary.

(2) A brief history is acceptable for emergency or walk-in visits when the treatment plan does not call for extended care.

(H) Hospital pharmacies must maintain a record for each member of the drug and amount dispensed, the date, and the original prescription (see 130 CMR 410.467).

(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 (see 130 CMR 410.483).

(1) All health care findings resulting from a visual analysis, whether they are normal or abnormal, must be recorded. When extenuating circumstances prevent the use of one or more procedures normally done in a visual analysis, the record must contain the reasons that the tests were not performed.

(2) For comprehensive eye examinations and diagnoses, the record must contain the following information or test results:

(a) case history;
(b) visual acuity testing;
(c) ophthalmoscopy and external eye health examination;
(d) ocular mobility testing, heterophoria testing, and fusion testing;
(e) pupillary reflex testing;

(f) refraction (retinoscopy, subjective refraction, and keratometry);
(g) confrontation fields or other screening tests;
(h) tonometry, when medically indicated;
(i) case analysis and disposition; and
(j) biomicroscopy, when medically indicated.

(3) All consultation services must be fully documented in the record. A record for a consultation must contain the following information:
(a) the member's complaints and symptoms;
(b) the condition of the eye; and
(c) if applicable, the name of the person to whom a referral was made.

(4) All screening services must be fully documented in the record. A record for a screening service must note the chief complaint and must contain all findings of two or more of the following tests:
(a) visual acuity;
(b) distance vision and near vision;
(c) cover test;
(d) visual skills;
(e) tonometry; and
(f) biomicroscopy.

(J) For laboratory services, in addition to the applicable information required in 130 CMR 410.409(D) above, 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 prescriber (see 130 CMR 410.458):
(1) the name and any other means of identification of the person from whom the specimen was taken;
(2) the name of the prescriber or laboratory that submitted the specimen;
(3) the authorized requisition or order, or both;
(4) the location where the specimen was taken, if other than the hospital outpatient department;
(5) the date on which the specimen was collected by the prescriber or laboratory;
(6) the date on which the specimen was received in the laboratory;
(7) the condition of unsatisfactory specimens when received (for example, broken, leaked, hemolyzed, turbid, or insufficient sample size);
(8) the date on which the test was performed;
(9) the test name and the results of the test, or the cross-reference to results and the date of reporting; and
(10) the name and address of the laboratory to which the specimen was referred, if applicable.

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 these regulations 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 pays for emergency services provided in a hospital emergency room only when such services are medically necessary and the necessity is fully documented in the member's medical record.

(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 Abuse Admission Screening Requirements

(A) Utilization Management Program. The MassHealth agency will pay for procedures and hospital stays that are subject to the Utilization Management Program only if the applicable requirements of the program as described in 130 CMR 450.207 through 450.211 are satisfied. Appendix H 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 Abuse Admissions. The MassHealth agency pays for mental health and substance abuse services provided in an acute or nonacute inpatient setting only if the admitting provider has satisfied the screening requirements at 130 CMR 450.125.

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

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

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

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

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

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

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

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

410.414: Observation Services

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

(B) Nonreimbursable Services.

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

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

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

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

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

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

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

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

(130 CMR 410.416 through 410.419 Reserved)

410.420: 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:

(i) a review of the health consequences of tobacco use and the benefits of quitting;

(ii) a description of how tobacco dependence develops and an explanation of the biological, psychological, and social causes of tobacco dependence; and

(iii) 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:

(i) identification of personal risk factors for relapse and incorporation into the treatment plan;

(ii) strategies and coping skills to reduce relapse risk; and

(iii) 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:

(i) the correct use, efficacy, adverse events, contraindications, known side effects, and exclusions for all tobacco dependence medications; and

(ii) 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 old 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 aged 18 through 20; or

(b) CS-21 – for members aged 21 and 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 CPA-2 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), (B), and (C), when applicable. For all medically necessary abortions not included in 130 CMR 410.435(A), (B), or (C), the certification described in 130 CMR 410.435(D) is required on the CPA-2 form. The physician must indicate on the CPA-2 form which of the following circumstances is applicable, and must complete that portion of the form with the appropriate signatures.

(A) Life of the Woman Would Be Endangered. The attending physician must certify that, in his or her professional judgment, the life of the woman would be endangered if the pregnancy were carried to term.

(B) Severe and Long-Lasting Damage to the Woman's Physical Health. The attending physician and another physician must each certify that, in his or her professional judgment, severe and long-lasting damage to the woman's physical health would result if the pregnancy were carried to term. At least one of the physicians must also certify that he or she is not an "interested physician," defined herein as one whose income is directly or indirectly affected by the fee paid for the performance of the abortion; or who is the spouse of, or another relative who lives with, a physician whose income is directly or indirectly affected by the fee paid for the performance of the abortion.

(C) Victim of Rape or Incest. The physician is responsible for retaining signed documentation from a law enforcement agency or public health service certifying that the woman upon whom the procedure was performed was a victim of rape or incest that was reported to the agency or service within 60 days of the incident. (A public health service is defined as either an agency of the federal, state, or local government that provides health or medical services, or a rural health clinic, provided that the agency's principal function is not the performance of abortions.) The documentation must include the date of the incident, the date the report was made, the name and address of the victim and of the person who made the report (if different from the victim), and a statement that the report included the signature of the person who made the report.

(D) Other Medically Necessary Abortions. The attending physician must certify that, in his or her medical judgment, for reasons other than those described in 130 CMR 410.435(A), (B), and (C), the abortion performed was necessary in light of all factors affecting the woman's health.

410.436: Abortion Services: Out-of-State Abortions

The Division will pay for an abortion performed in an out-of-state facility only if the abortion meets the conditions specified in 130 CMR 410.434 and if prior authorization is requested and received from the Division.

(A) The recipient, the referring physician, the hospital outpatient department, or a referral agency may request prior authorization from the Division in writing. The request must be made in accordance with the instructions for requesting prior authorization for abortion services in Subchapter 5 of the *Outpatient Hospital Manual*.

(B) If the Division authorizes the abortion, it will issue a prior authorization slip directly to the out-of-state facility. The facility must attach the prior authorization slip to the claim form when requesting payment from the Division.

(C) Out-of-state abortion services will be authorized only when such services are not available in a Massachusetts facility.

(D) Prior authorization is not required for abortion services provided in the situations described in 130 CMR 410.404(B)(1).

410.437: Family Planning Services

(A) Reimbursable Services. The Division will pay for hospital outpatient services related to the timing and spacing of children. These services may include but are not limited to the following:

(1) nonpermanent contraceptive care;
(2) comprehensive medical examination;
(3) diagnosis and treatment of medical problems specific to reproduction as well as diagnosis of and appropriate referral for other medical problems;
(4) venereal disease testing and treatment;
(5) cervical cancer screening (Pap smear);
(6) breast examination;
(7) laboratory services related to family planning (for example, Pap smear, gonorrhea culture, vaginal culture and smear, blood test for venereal disease, hematocrit, complete blood count, urinalysis, and pregnancy testing); and
(8) family planning counseling, including discussions about family planning, human reproduction, and methods of contraception.

(B) The Norplant System of Contraception.

(1) Eligible Providers. The Division will pay outpatient departments for the insertion, reinsertion, and removal of the Norplant System of Contraception (Norplant) when the services are provided by a salaried physician, nurse practitioner, nurse midwife, or physician assistant. In order for the hospital to claim payment for Norplant services, the clinician performing the procedure must be trained by either the manufacturer of Norplant or another clinician who has been trained by the manufacturer.

(2) Patient Selection, Counseling Prior to Insertion, and Follow-Up.

(a) In order to prevent premature removal of Norplant, the Division requires careful patient selection and counseling prior to insertion. Counseling must be in accordance with the manufacturer's guidelines, and must include a detailed discussion of potential side effects, contraindications, benefits and risks, and other contraceptive options.
(b) A visit following insertion is also required as a condition of reimbursement. The visit must include an examination of the insertion site for complications, a review of potential side effects, and follow-up instructions. If more than one follow-up visit is necessary, the provider should bill each as a separate visit.
(c) The provider must make every effort possible to ensure that the recipient returns for the follow-up visit. This shall include, but not be limited to, scheduling the follow-up appointment on the day of insertion, recording the day of the follow-up appointment in the recipient's chart, mailing a reminder notice to the recipient, and reminding the recipient by telephone during the week of the scheduled appointment. The provider must document in the medical record the efforts made to ensure that the recipient returns for the follow-up visit. In order to ensure payment for the procedure, the provider must also document if the recipient fails to return for the follow-up visit.

(3) Service Limitations.

(a) The Division will pay for the insertion and reinsertion of Norplant for female recipients of childbearing age with menstrual histories. The Department will pay for the removal of Norplant for female recipients of all ages.

(b) The Division will pay for the insertion or reinsertion of Norplant only once per recipient per five-year period.

(c) If the recipient has a Norplant device implanted, no other form of contraception should be prescribed, with the exception of condoms. If the Norplant device is removed for any reason, however, the Division will pay for alternative types of contraception.

410.438: Acupuncture

(A) Introduction. MassHealth members are eligible to receive acupuncture for the treatment of pain as described in 130 CMR 410.438(C), for use as an anesthetic as described in 130 CMR 433.454(C): *Acupuncture as an Anesthetic*, and for use for detoxification as described in 130 CMR 418.406(C)(3): *Acupuncture Detoxification*.

(B) General. 130 CMR 410.438 applies specifically to acupuncture services rendered in a hospital by physicians and licensed practitioners of acupuncture.

(C) Acupuncture for the Treatment of Pain. MassHealth provides a total of 20 sessions of acupuncture for the treatment of pain per member per year without prior authorization. If the member's condition, treatment, or diagnosis changes, the member may receive more sessions of medically-necessary acupuncture treatment with prior authorization.

(D) Provider Qualifications for Acupuncture.

(1) Qualified Providers.

(a) Physicians

(b) Other practitioners who are licensed in acupuncture by the Massachusetts Board of Registration in Medicine under 243 CMR 5.00: *The Practice of Acupuncture*.

(2) Supervising Physicians. Supervising physicians must ensure that acupuncture practitioners for whom the physician will submit claims, possess the appropriate training, credentials, and licensure.

(E) Conditions of Payment. The MassHealth agency pays the hospital for services of an acupuncturist (in accordance with 130 CMR 410.438(F)) when the:

(1) services are limited to the scope of practice authorized by state law or regulation (including but not limited to 243 CMR 5.00: *The Practice of Acupuncture*);

(2) the acupuncturist has a current license or certificate of registration from the Massachusetts Board of Registration in Medicine; and

(3) services are provided pursuant to a supervisory arrangement with a physician.

(F) Acupuncture Claims Submissions.

(1) Hospitals may submit claims for on-site acupuncture services when physicians provide those services to MassHealth members or as an exception to 130 CMR 450.301(A) when a licensed practitioner under the supervision of a physician provides those services directly to MassHealth members. See Subchapter 6 of the *Acute Outpatient Manual* for service code descriptions and billing requirements.

(2) For MassHealth members receiving services under any of the acupuncture codes on the same date of service as a visit, the hospital may bill for both the visit and the acupuncture services performed or supervised by a hospital-based physician.

(130 CMR 410.439 through 410.440 Reserved)

410.441: Early Intervention Program Services

(A) An early intervention program provides services such as therapy and social, medical, educational, and developmental services for children aged three years or younger who are at biological, environmental, or established risk, and for their families.

(B) The MassHealth agency pays for services provided as part of an organized early intervention program by hospital outpatient departments. These services must be furnished in compliance with the MassHealth regulations governing early intervention program services in 130 CMR 440.000. (See Subchapter 5 of the *Outpatient Hospital Manual* for instructions about obtaining the *Early Intervention Program Manual*, which contains the necessary regulations.)

(C) Acute and nonacute hospital-based early intervention programs are paid according to the regulations governing early intervention services in 130 CMR 440.000: *Early Intervention Program Services*.

410.442: Home Health Agency Services

(A) A home health agency is a public or private agency or organization, or a subdivision of such an agency or organization that is primarily engaged in furnishing part-time skilled nursing and other therapeutic services to patients in their homes.

(B) The MassHealth agency pays for home health services provided by hospital-based home health agencies. These services must be furnished in compliance with the MassHealth regulations governing home health agency services in 130 CMR 403.000: *Home Health Agency*. (See Subchapter 5 of the *Outpatient Hospital Manual* for information about obtaining the *Home Health Agency Manual*, which contains the necessary regulations.)

(C) Acute hospital-based home health agencies will be paid according to the outpatient payment methodology established by the signed MassHealth provider agreement.

(D) Nonacute hospital-based home health agencies are paid according to the regulations governing home health services in 130 CMR 403.000: *Home Health Agency*.

410.443: Adult Day Health Program Services

(A) An adult day health program is an organized program of health care and supervision, restorative services, and social activities whose general goal is to provide an alternative to long-term institutional care.

(B) The MassHealth agency pays for services provided as part of an organized adult day health program by a hospital outpatient department. These services must be furnished in accordance with the MassHealth regulations governing adult day health programs in 130 CMR 404.000: Adult Day Health Services. (See Subchapter 5 of the Outpatient Hospital Manual for information about obtaining the Adult Day Health Manual, which contains the necessary regulations.)

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

(D) Nonacute hospital-based adult day health programs will be paid according to the regulations 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 room, board, and 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 the "Adult Foster Care Guidelines" issued by the MassHealth agency. (See Subchapter 5 of the Outpatient Hospital Manual for information about obtaining the "Guidelines" and 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 payment methodology established by the Office of Purchased Services in the Executive Office of Administration and Finance.

410.463: Pharmacy Services: Limitations on Coverage of Drugs

(A) Interchangeable Drug Products. The MassHealth agency pays no more for a brand-name interchangeable drug product than its generic equivalent, unless

(1) the prescriber has requested and received prior authorization from the MassHealth agency for a nongeneric multiple-source drug (see 130 CMR 410.408); and

(2) the prescriber has written on the face of the prescription in the prescriber's own handwriting the words "brand name medically necessary" under the words "no substitution" in a manner consistent with applicable state law. These words must be written out in full and may not be abbreviated.

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

(1) Cosmetic. The MassHealth agency does not pay for any drug used for cosmetic purposes or for hair growth.

(2) Cough and Cold. The MassHealth agency does not pay for any drugs used solely for the symptomatic relief of cough or colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless dispensed to a member who is a resident in a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR).

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

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

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

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

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

(C) Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 410.463(B). The limitations and exclusions in 130 CMR 410.463(B) do not apply to medically necessary drugs for MassHealth Standard enrollees under age 21. The MassHealth Drug List specifies the drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 410.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. *See* 130 CMR 450.303: *Prior Authorization*.

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

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

(b) nongeneric multiple-source drugs; and

(c) drugs related to gender-reassignment surgery, specifically including but not limited to, presurgery and postsurgery hormone therapy.

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

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

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

(D) Insurance Coverage.

(1) Managed Care Organizations. The MassHealth agency does not pay pharmacy claims for services to MassHealth members enrolled in a MassHealth managed care organization (MCO) that provides pharmacy coverage through a pharmacy network or otherwise, except for family planning pharmacy services provided by a non-network provider to a MassHealth Standard MCO enrollee (where such provider otherwise meets all prerequisites for payment for such services). A pharmacy that does not participate in the MassHealth member's MCO must instruct the MassHealth member to take his or her prescription to a pharmacy that does participate in such MCO. To determine whether the MassHealth member belongs to an MCO, pharmacies must verify member eligibility and scope of services through POPS before providing service in accordance with 130 CMR 450.107:*Eligible Members and the MassHealth Card* and 450.117: *Managed Care Participation.*

(2) Other Health Insurance. When the member's primary carrier has a preferred drug list, the prescriber must follow the rules of the primary carrier first. The provider may bill the MassHealth agency for the primary insurer's member copayment for the primary carrier's preferred drug without regard to whether the MassHealth agency generally requires prior authorization, except in cases where the drug is subject to a pharmacy service limitation pursuant to 130 CMR 410.463(C)(2)(a) and (c). In such cases, the prescriber must obtain prior authorization from the MassHealth agency in order for the pharmacy to bill the MassHealth agency for the primary insurer's member copayment. For additional information about third party liability, see 130 CMR 450.101: *Definitions* et seq. and the hospital's Request for Applications and Contract, if applicable.

(3) Medicare Part D.

(a) Overview. Except as otherwise required in 130 CMR 406.414(C)(2) and (3), for MassHealth members who have Medicare, the MassHealth agency does not pay for any Medicare Part D drugs, or for any cost-sharing obligations (including premiums, copayments, and deductibles) for Medicare Part D drugs, whether or not the member has actually enrolled in a Medicare Part D drug plan. Medications excluded from the Medicare Part D drug program continue to be covered for MassHealth members eligible for Medicare, if they are MassHealth-covered medications.

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