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405.401: Introduction

All community health centers (CHCs) participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to 130 CMR 405.000 and 130 CMR 450.000: *Administrative and Billing Regulations*.

405.402: Definitions

The following terms used in 130 CMR 405.000 have the meanings given in 130 CMR 405.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 405.000 is not determined by these definitions, but by application of 130 CMR 405.000 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 Law 102-585, the Veterans Health Care Act of 1992.

340B Drug Pricing Program. A program established by Section 340B of Public Law 102-585, the Veterans Health Care 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.

Family Practitioner. A licensed physician who is board-eligible or board-certified in family practice. A family practitioner provides continuous, accessible medical care with emphasis on the family unit that combines appreciation of both the biomedical and psychosocial dimensions of illness. The family practitioner assumes responsibility for and provides most of the member's health care, and coordinates the member's total health needs.

Family Therapy. A session for simultaneous treatment of two or more members of a family.

Freestanding Clinic. Any institution licensed as a clinic by the Massachusetts Department of Public Health pursuant to M.G.L. c. 111, § 51 that is not part of a hospital and that possesses its own legal identity, maintains its own patient records, and administers its own budget and personnel. Such institutions include CHCs and mental health centers.

Group Clinic Visit. A session conducted by a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, or registered nurse to introduce preventive medicine approaches to personal health and safety and to present self-help and personal management information concerning family medicine, adult medicine, sex education, and chronic illness. Tobacco cessation group clinic visits may be provided by MassHealth-qualified tobacco cessation counseling providers as defined in 130 CMR 405.472.

Group Therapy. Application of psychotherapeutic or counseling techniques to a group of persons, most of whom are not related by blood, marriage, or legal guardianship.

Health Practitioner. An individual who can diagnose and treat medical problems whether by authority of their own license or by the delegated authority of a licensed medical professional.

HIV Post-test Counseling Visit. A face-to-face meeting at the CHC between the member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, registered nurse, or counselor (working under the supervision of one of the aforementioned) for the purpose of providing counseling after HIV testing. Such counseling will include information about the implications of positive and negative test results, risk-reduction techniques, partner notification, and referral to medical and support services, in accordance with established protocols of the Massachusetts Department of Public Health.

HIV Pre-test Counseling Visit. A face-to-face meeting at the CHC between the member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, registered nurse, or counselor (working under the supervision of one of the aforementioned) for the purpose of providing counseling before HIV testing. Providers will offer information on risk factors and implications of both positive and negative test results, in accordance with established protocols of the Massachusetts Department of Public Health.

Home Visit. A face-to-face meeting between a member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, or registered nurse in the member's residence for examination, diagnosis, or treatment.

Hospital Visit. A face-to-face meeting between a member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, or registered nurse when the member has been admitted to a hospital by a physician on the CHC's staff.

Individual Medical Visit. A face-to-face meeting at the CHC between a member and a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, or registered nurse for medical examination, diagnosis, or treatment.

Individual Mental Health Visit. A face-to-face meeting at the CHC between a patient and either a psychiatrist or an advanced practice registered nurse (APRN) with a graduate degree and advanced training in psychiatric care (a psychiatric clinical nurse specialist or a psychiatric mental health nurse practitioner) within the community health center setting, for purposes of examination, diagnosis, or treatment.

Individual Therapy. Psychotherapeutic services provided to an individual.

Institutionalized Individual. For purposes of 130 CMR 405.428 through 405.430, an individual who is

(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 care and 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.

Mentally Incompetent Individual. For purposes of 130 CMR 405.428 through 405.430, 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.

Nursing Facility Visit. A visit by a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, or registered nurse to a member who has been admitted to a nursing facility, extended care facility, or convalescent or rest home.

Primary or Elective Care. Medical care required by individuals or families that is appropriate for the maintenance of health and the prevention of illness. This care includes, but is not limited to, physical examination, diagnosis and management of illness, ongoing health maintenance, accident prevention, and referral when necessary. This care does not require the specialized resources of a hospital emergency department.

Psychological Testing. The use of standardized test instruments to evaluate aspects of an individual's functioning, including aptitudes, educational achievements, cognitive processes, emotional conflicts, and type and degree of psychopathology.

Sterilization. Any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

Urgent Care. Medical services required promptly to prevent impairment of health due to symptoms that a prudent layperson would believe require medical attention, but are not life-threatening and do not pose a high risk of permanent damage to an individual's health. Urgent care does not include elective or primary care.

405.403: Eligible Members

(A) (1) MassHealth Members. The MassHealth agency covers CHC 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*.

405.404: Provider Eligibility

Payment for the services described in 130 CMR 405.000 will be made only to providers of CHC services who are participating in MassHealth on the date of service.

(A) In State. To participate in MassHealth, a CHC located in Massachusetts must meet the qualifications for certification or provisional certification in 130 CMR 405.405.

(B) Out of State. To participate in MassHealth, an out-of-state CHC must obtain a MassHealth provider number and meet the following criteria:

(1) if the center is required by its own state's law to be licensed, the center must be licensed by the appropriate state agency under whose jurisdiction it operates;

(2) the center must participate in its state's Medicaid program (or the equivalent); and

(3) the center must have a rate of payment established by the appropriate rate setting regulatory body of its state.

405.405: Certification

(A) Application. An application for certification as a CHC must be made on the form provided by the MassHealth agency and must be submitted to the MassHealth agency's program specialist for CHCs. Upon receipt of the completed application, the program specialist or their designee may arrange for a site visit with the applicant to determine compliance with 130 CMR 405.406 through 405.416, and if the applicant offers one or more of the services described in 130 CMR 405.431 through 405.471, compliance with the applicable portions of those sections. Based on the information revealed by the application and the site visit, the MassHealth agency will determine whether the applicant is certifiable, provisionally certifiable, or not certifiable. The program specialist will promptly notify the applicant of the determination in writing. If the applicant is not certifiable, the notice will contain a statement of the reasons for that determination.

(B) Certification. A determination of certifiability indicates that the applicant has been found by the MassHealth agency to be in compliance with 130 CMR 405.406 through 405.416 and, to the extent applicable, with 130 CMR 405.431 through 405.471. Upon such determination of certifiability, the CHC may enter into a provider contract with the MassHealth agency in accordance with 130 CMR 450.000: *Administrative and Billing Regulations*.

(C) Provisional Certification. Provisional certification means that the MassHealth agency has determined the applicant to be in compliance with 130 CMR 405.405(B) except for one or more of the following: 130 CMR 405.408(F): *Nutrition Services*, 405.408(C): *Obstetrics/Gynecology*, 405.414: *Translation Services*, or 405.415: *Emergency Backup Services*. If an applicant has been provisionally certified, the letter of notification will specify the certification requirements with which the applicant has failed to comply and the schedule for achieving compliance. When requirements for full certification have been met, the MassHealth agency will certify the CHC. Upon notice of provisional certification, the CHC may enter into a provider contract with the MassHealth agency in accordance with 130 CMR 450.000: *Administrative and Billing Regulations*, on the condition that such provider contract, by its own terms, will expire upon the date fixed in the letter of notification for full compliance.

(D) Review of Certification.

(1) The MassHealth agency's program specialist for CHCs has the right to review a certified or provisionally certified provider's continued compliance with the conditions for certification referred to in 130 CMR 405.405(A) through (C) upon reasonable notice and at any reasonable time during the hours of operation of the provider. The program specialist has the right to revoke the certification or provisional certification of a provider, subject to any applicable provisions of 130 CMR 450.000: *Administrative and Billing Regulations*, if such review reveals that the provider has failed or ceased to meet such conditions.

(2) Any changes in the manager or professional services director or in the scope of services provided by a CHC must be reported in writing to the MassHealth agency's program specialist for CHCs. Any additions to the scope of services must be approved in writing by the program specialist before they are payable by the MassHealth agency. Elimination of services may result in review of the CHC by the MassHealth agency to determine whether the CHC still meets the requirements for certification set forth in 130 CMR 405.405.

405.406: Administrative Requirements

A CHC must meet the administrative requirements specified in 130 CMR 405.406 to receive certification as outlined in 130 CMR 405.405.

(A) Licensing. The CHC must be licensed as a clinic by the Massachusetts Department of Public Health. For the purposes of 130 CMR 405.000, the term "licensee" means the entity named in the license issued by the Department of Public Health. A CHC can be comprised of multiple sites that are identified on the license as "satellites." Services provided at satellites are considered to be provided on site.

(B) Nonprofit Status. The CHC must be a nonprofit organization.

(C) Staffing.

(1) The CHC must employ an on-site manager who is qualified by education, training, or experience to serve as the administrator of the CHC. The manager is responsible to the licensee for both the management and administration of CHC services, for carrying out policies established or approved by the licensee, and for ensuring that the CHC complies with 130 CMR 405.000.

(2) The CHC must employ a professional services director who is a health practitioner qualified by education, training, or experience to direct and evaluate the provision of health services in the CHC. The professional services director must supervise the staff members providing health services and must ensure that treatment and care are both adequate and appropriate to the needs of members and are in compliance with 130 CMR 405.000. The professional services director must be either on site or on call at all times that the CHC is in operation.

(3) The same individual may serve as both the manager and the professional services director, if this individual meets the requirements in 130 CMR 405.406(C)(1) and (2).

(D) Minimum Hours. The CHC must be open for the delivery of medical services to the public on a regular schedule for a minimum of 20 hours per week. The schedule must be arranged to afford maximum access to members, such as by regularly scheduled evening or weekend clinic hours.

(E) Governing Board. The CHC must have a governing or advisory board that includes at least one person who regularly uses the services of the CHC. This person may not be employed by the CHC or the licensee while a member of the board. Matters subject to review by the board must include, but are not necessarily limited to, scope of services, budget, personnel policies, and program evaluation.

(F) Member Grievances. The CHC must have established written procedures for accepting, processing, and responding to member grievances.

405.407: Physician Time Required on Site

Except as specified in 130 CMR 405.407(A) and (B), a CHC must have at least one licensed physician on site during its hours of operation to treat medical problems outside the expertise of other health practitioners on the CHC's staff. This physician may leave the CHC for limited periods to visit CHC patients in their homes, in hospitals, or in nursing facilities; but they must be on call to the CHC during such periods.

(A) CHCs that are located in isolated rural areas where no licensed physician is available on a regular basis within a 20-mile radius and that have a licensed physician on call during all hours of operation may apply to the MassHealth agency's Program Specialist for community health centers for a waiver of this requirement.

(B) CHCs that employ family practitioners on site may substitute family practitioners for other specialists who are unavailable due to the center's geographic isolation, but whose specialized services must be provided on site. These specialties include pediatrics, obstetrics/gynecology, and internal medicine.

405.408: Medical Services Required on Site

A CHC must provide on site the medical services specified in 130 CMR 405.408. It is not necessary that all of these services be available during all hours of the CHC's operation, but all must be available to members on a regularly scheduled basis with sufficient frequency to ensure access to care and continuity of care. If the CHC does not serve patients of a particular age group, upon the prior written approval of the MassHealth agency, the CHC will not be required to provide pediatric or obstetrical/gynecological services or both (*see* 130 CMR 405.408(A) and (C)).

(A) Pediatric Services. A CHC must provide pediatric services.

(B) Internal Medicine. A CHC must provide internal medicine services.

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

(D) Health Education. A CHC 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 professional services director as possessing the qualifications and training necessary to provide health education to members.

(E) Medical Social Services. A CHC 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. A CHC 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 CHC 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

Academy of Nutrition and Dietetics. This individual is responsible for planning, directing, and evaluating the nutrition services provided at the CHC; for educating the CHC's staff about nutrition; for supervising any nutrition aides; for consulting with practitioners and other staff members of the CHC; 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.

405.409: Medical Services Required on Site or by Referral

All of the services listed in 130 CMR 405.409 must be provided on site or, alternatively, through a referral network. For the purpose of 130 CMR 405.409, a service furnished by a practitioner other than an employee or contractor of the CHC for which the practitioner, rather than the CHC, claims payment is not considered to be "on site," even if the service is provided on CHC premises. With the exception of audiology, electrocardiogram, laboratory, and radiology services, the CHC must notify the MassHealth agency, in writing, of each service listed in 130 CMR 405.409(A) through (N) that the CHC will provide on site. All services provided on site must be furnished by practitioners qualified to provide the service that are employees or contractors of the CHC. With the exceptions of audiology, electrocardiogram, laboratory, and radiology services provided on site (for which such services must be furnished and payment claimed by the CHC in accordance with applicable provisions set forth in 130 CMR 405.000 and Subchapter 6 of the *Community Health Center Manual*), all services set forth below that are provided on site must be furnished, and associated payment claimed by the CHC, in compliance with the applicable MassHealth regulations and Subchapter 6 for each such service, including applicable fee schedules. All services listed in 130 CMR 405.409(A) through (N) that are provided by referral must be based on written agreements between the CHC and each referral provider to ensure continuity of care, exchange of relevant health information such as test results and records, and avoidance of service duplication. Each referral provider must be a participating provider in MassHealth, and payment for the services provided by the referral provider must be claimed by the referral provider in compliance with the applicable MassHealth regulations for such service. All referrals must include follow-up to ensure that the referral process is successfully completed. Services that must be provided on site or through the referral network are the following:

(A) audiology services;

(B) chiropractor services;

(C) dental services;

(D) electrocardiogram (EKG) services;

(E) laboratory services;

(F) medical specialty services such as, but not limited to, cardiology and neurology;

(G) mental health services, including psychological testing;

(H) occupational therapy services;

(I) pharmacy services;

(J) physical therapy services;

(K) podiatry services;

(L) radiology services;

(M) speech/language therapy services; and

(N) vision care services.

(130 CMR 405.410 Reserved)

405.411: Continuity of Care

A CHC must maintain continuity of care in providing health services to members. Continuity of care ensures that a member will always be seen by a health practitioner knowledgeable about the member's case. Mere access to medical records by all practitioners who deliver services to a member will not suffice as a means of complying with 130 CMR 405.411.

405.412: Recordkeeping Requirements

(A) A CHC must comply with the MassHealth agency's recordkeeping regulation contained in 130 CMR 450.000: *Administrative and Billing Regulations*. In addition, each member's medical record must include the reason for each visit and the data upon which the diagnostic impression or statement of the member's problem is based, and must be sufficient to justify any further diagnostic procedures, treatments, and recommendations for return visits or referrals. Specifically, a medical record must include, but not be limited to

(1) the date of each service;
(2) the member's name and date of birth;
(3) the signature and title of the person performing the services;
(4) the member's medical history;
(5) the diagnosis or chief complaint;
(6) clear indication of all findings, whether positive or negative, on examination;
(7) any medications administered or prescribed, including strength, dosage, and regimen;
(8) a description of any treatment given;
(9) recommendations for additional treatments or consultations, when applicable;
(10) any medical goods or supplies dispensed or prescribed;
(11) any tests administered and their results;
(12) a notation of hospitalization ordered by a CHC practitioner and discharge summaries from such hospitalization; and
(13) notations of all referrals and results of referrals, including the referral provider's diagnoses, treatment plans, test results, and medical outcomes.

(B) Basic data collected during previous visits (for example, identifying data, chief complaint, and history) need not be repeated in the member's medical record for subsequent visits. However, data that fully document the nature, extent, quality, and necessity of care furnished to a member must be included for each service for which payment is claimed, along with any data that update the member's medical course. It is not necessary to include a full medical history in the medical record for any member who is seen by the CHC on a one-time emergency basis.

(C) For hospital visit services, there must be an entry in the hospital medical record corresponding to and substantiating each hospital visit for which payment is claimed. An inpatient medical record documents services provided to members and billed to the MassHealth agency if it conforms to and satisfies the medical records requirements set forth in the current Rules and Regulations for Hospitals in Massachusetts issued by the Massachusetts Department of Public Health. The CHC claiming payment for a hospital inpatient visit is responsible for the adequacy of the medical record documenting such visit. The physician must sign the entry in the hospital medical record that documents the findings of the comprehensive history and physical examination.

(D) Additional medical records requirements for other services can be found in the applicable sections of the MassHealth agency's regulations.

405.413: Coordination of Services

A CHC that provides any of the services listed in 130 CMR 405.409 or 405.471 must coordinate these services with all other services at the CHC. Such coordination includes at a minimum

(A) one central medical record for each member in which all health care services are recorded;

(B) medical accountability to the CHC's professional services director;

(C) administrative accountability to the CHC's manager;

(D) participation in the CHC's quality assessment program (if the special group of services has its own plan for quality assessment, this plan must be approved by the professional services director who must also receive progress reports);

(E) regular participation in the CHC's staff meetings and other appropriate activities by those professionals responsible for directing special services; and

(F) familiarity with the CHC's policies, procedures, staff, and scope of services by all personnel employed through special programs.

405.414: Translation Services

A CHC must employ at least one practitioner or translator conversant in the primary language of each substantial population (10% or more of the total member population) of non-English-speaking members that regularly uses the CHC.

405.415: Emergency Backup Services

(A) A CHC must provide either
(1) 24-hour-a-day on-site medical or emergency services or both; or
(2) an after-hours telephone service, and have a written agreement with a provider of 24-hour-a-day medical or emergency service or both.

(B) A recorded telephone message instructing members to call an emergency backup provider or a hospital emergency room does not suffice as compliance with the requirement of 130 CMR 405.415(A).

405.416: Quality Assessment Program

(A) A CHC must have in effect a program for internal quality assessment that is based on written policies, standards, and procedures, and that includes the following:
(1) a review of the CHC's performance including, but not limited to, adequacy of recordkeeping, referral procedures and follow-up, medication review, quality of patient care, and identification of deficient areas of performance;
(2) recommendations for correcting any deficiencies identified in the review; and
(3) a review of any such corrective action.

(B) These reviews must be conducted at least twice a year by a committee composed of the professional services director, representatives of each professional discipline on the CHC's staff, consumers, and, if possible, health professionals not employed at the CHC. Activities of the committee must be documented in minutes or a report and made available to the MassHealth agency upon request.

405.417: Maximum Allowable Fees

The Executive Office of Health and Human Services (EOHHS) determines the payment rate for CHC services in accordance with 101 CMR 304.00: *Rates for Community Health Centers*. For services payable to CHCs for which the maximum allowable fee is not listed in 101 CMR 304.00, EOHHS determines the payment rates in accordance with the applicable EOHHS pricing regulations that govern payment of those services.

Payment is subject to the conditions, exclusions, and limitations set forth in 130 CMR 405.000.

405.418: Nonreimbursable Services

(A) The MassHealth agency does not pay a CHC for performing, administering, or dispensing experimental, unproven, cosmetic, or otherwise medically unnecessary procedures or treatments.

(B) The MassHealth agency does not pay a CHC for 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 a CHC for the diagnosis of male or female infertility.

(130 CMR 405.419 and 405.420 Reserved)

405.421: Visits: Service Limitations

The following restrictions and limitations apply to visits as defined in 130 CMR 405.402.

(A) Individual Medical Visit. An individual medical visit, including family planning, may not be for an individual mental health service or for HIV pre- or post-test counseling visits.

(B) Individual Mental Health Visit. An individual mental health visit conducted by a person other than a psychiatrist or an advanced practice registered nurse (APRN) with a graduate degree and advanced training in psychiatric care (a psychiatric clinical nurse specialist or a psychiatric mental health nurse practitioner) is not reimbursable. Other mental health services provided by qualified clinicians and properly billed are reimbursable, but not as Individual Mental Health Visits.

(C) Group Clinic Visit. All instructional group sessions for members must be carried out by a physician, physician assistant, certified nurse practitioner, clinical nurse specialist, or registered nurse. A group visit conducted by other kinds of professionals (for example, social workers, counselors, or nutritionists) is not reimbursable as a group clinic visit. These limitations do not apply to group clinic visits for tobacco cessation.

(D) HIV Pre- and Post-test Counseling Visits. The CHC may be reimbursed for a maximum of two HIV pre-test counseling and two HIV post-test counseling visits per member per test. A maximum of four pre-test counseling visits and four post-test counseling visits per calendar year per member are reimbursable.

(E) Home Visit. A home visit must be used to deliver episodic care in the member's home when a health practitioner has determined that it is not advisable for the member to visit the CHC. The medical record must document the reasons for a home visit. A housebound member with chronic medical and nursing care needs must be referred to a Medicare-certified home health agency.

(F) Treatments or Procedures. The CHC may bill for a visit, a treatment, or a procedure, but may not bill for more than one of these services provided to the same member on the same date when the services are performed in the same location. This limitation does not apply to tobacco cessation counseling services provided by a physician or other qualified staff member under the supervision of a physician on the same day as a visit. Examples of treatments or procedures are a vasectomy, colposcopy, or an amniocentesis. X-rays, laboratory tests, and certain diagnostic tests may be billed in addition to an office visit.

(G) Immunization or Injection.

(1) The CHC may bill for either an office visit or vaccine administration, but may not bill for both an office visit and vaccine administration for the same member on the same date when the office visit and the vaccine administration are performed in the same location. This limitation does not apply to a significant, separately identifiable office visit provided by the same physician on the same day as the vaccine was administered.

(2) The MassHealth agency pays for the cost of the injectable material unless the Massachusetts Department of Public Health distributes the injectable material free of charge.

(H) Urgent Care. The MassHealth agency pays an enhanced fee for urgent care when such care is provided at the CHC Monday through Friday from 5:00 P.M. to 6:59 A.M., and from Saturday at 7:00 A.M. through Monday at 6:59 A.M.

(I) Individual Psychotherapy. The MassHealth agency pays for psychotherapeutic services provided to an individual member.

(J) Family and Couple Therapy. The MassHealth agency pays for therapy provided simultaneously in the same session to more than one member of the same family or to a couple whose primary complaint is the disruption of their marriage, family, or relationship. Payment is limited to one fee per session, regardless of the number of family members present or the presence of a cotherapist.

(K) Group Therapy.
(1) Payment is limited to one fee per group member with a maximum of 12 members per group regardless of the number of staff members present.
(2) The MassHealth agency does not pay for group therapy when it is performed as an integral part of a psychiatric day treatment program.

(L) Multiple-family Group Therapy.
(1) Payment is limited to one fee per group member with a maximum of 10 members per group regardless of the number of staff members present.
(2) The MassHealth agency does not pay for multiple-family group psychotherapy when it is performed as an integral part of a psychiatric day treatment program.

(M) Diagnostic Services. The MassHealth agency pays for the examination and determination of a patient's physical, psychological, social, economic, educational, and vocational assets and disabilities for the purpose of designing a treatment plan. This service includes an initial medication evaluation.

(N) Psychological Testing. The MassHealth agency pays for psychological testing only when provided by a licensed psychologist who either personally administers the testing or personally supervises such testing during its administration by an unlicensed psychologist.

405.422: Obstetric Services: Introduction

(A) The MassHealth agency offers two methods of payment for obstetric services: the fee-for-service method and the global-fee method. Fee for service requires submission of claims for services as they are performed and is available for covered obstetric services. The global-fee method is available only when the conditions in 130 CMR 405.423 are met.

(B) The MassHealth agency will pay for a delivery performed in a hospital by a physician or, in the case of a pelvic delivery, by a certified nurse midwife who meets the requirements in 130 CMR 405.427 when the physician or certified nurse midwife is a contractor or employee of the CHC. Such a delivery is covered provided that such a contractor or employee is not receiving a salary from a hospital or other institution to perform the same service. For each such delivery, the CHC may claim payment for the services of only one practitioner (that is, a CHC may not submit two claims for one delivery—one for a physician and one for a certified nurse midwife).

405.423: Obstetric Services: Global-fee Method of Payment

(A) Definition of Global Fee. The global fee is a single inclusive fee for all prenatal visits, the delivery, and one postpartum visit. The global fee is available only when the conditions in 130 CMR 405.423 are met.

(B) Conditions for Global Fee.

(1) General Requirements. Only the CHC may claim payment of the global fee. To qualify to receive a global fee payment, the CHC must coordinate a minimum of six prenatal visits, the delivery, and postpartum care, provided by a physician, a nurse, a certified nurse practitioner, a certified nurse midwife, or a physician assistant who is qualified to perform such services and is a contractor or employee of the CHC. Such an employee or contractor must not be receiving a salary from a hospital or institution to perform the same service. For example, if a staff physician from a hospital performs a delivery while on hospital salary for that service, the CHC must not bill for the global fee for that delivery, but may bill fee for service for the medical visits. However, those visits are not covered if provided by someone receiving a hospital or institutional salary to perform the same service.

(2) Standards of Practice. All the components of a global fee must be provided at a level of quality consistent with the standards of practice of the American College of Obstetrics and Gynecologists.

(3) Coordinated Medical Management. The CHC must provide referral to and coordination of the medical and support services necessary for a healthy pregnancy and delivery. This includes

(a) tracking and follow-up of the patient's activity to ensure completion of the patient care plan, with the appropriate number of visits;

(b) coordination of medical management with necessary referral to other medical specialties and dental services; and

(c) referral to WIC (the Special Supplemental Food Program for Women, Infants, and Children), counseling, and social work as needed.

(4) Health Care Counseling. In conjunction with providing prenatal care, the CHC must provide health care counseling to the woman over the course of the pregnancy. Topics covered must include, but are not limited to, the following:

(a) EPSDT screening for teenage pregnant members;

(b) smoking and substance abuse;

(c) hygiene and nutrition during pregnancy;

(d) care of breasts and plans for infant feeding;

(e) obstetrical anesthesia and analgesia;

(f) the physiology of labor and the delivery process, including detection of signs of early labor;

(g) plans for transportation to the hospital;

(h) plans for assistance in the home during the postpartum period;

(i) plans for pediatric care for the infant; and

(j) family planning.

(5) Obstetrical-risk Assessment and Monitoring. The CHC must manage the member's obstetrical-risk assessment and monitoring. Medical management requires monitoring the woman's care and coordinating diagnostic evaluations and services as appropriate. The professional and technical components of these services will be reimbursed separately and should be billed for on a fee-for-service basis. Such services may include, but are not limited to, the following:

(a) counseling specific to high-risk patients (for example, antepartum genetic counseling);
(b) evaluation and testing (for example, amniocentesis); and
(c) specialized care (for example, treatment of premature labor).

(C) Multiple Providers. When more than one provider is involved in prenatal, delivery, and postpartum services for the same member, the following conditions apply.

(1) The global fee may be claimed only by the CHC and only if the required services (minimum of six prenatal visits, the delivery, and postpartum care) are provided directly by a physician, a nurse, a certified nurse practitioner, a certified nurse midwife, or a physician assistant who is qualified to perform such services and is a contractor or employee of the CHC.

(2) If the CHC bills for the global fee, any provider who is not a contractor or employee of the CHC, but who performed prenatal visits or postpartum visits for the member may claim payment for such services only on a fee-for-service basis. If the CHC bills for the global fee, no other provider may claim payment for the delivery.

(3) If the CHC bills on a fee-for-service basis, any other provider may claim payment on a fee-for-service basis for prenatal, delivery, and postpartum services provided to the same member.

(D) Recordkeeping for Global Fee. The CHC is responsible for documenting, in accordance with 130 CMR 405.412, all the service components of a global fee. This includes services performed by contractors and employees of the CHC. A member's risk assessment and all their medical visits must be recorded in a way that allows for easy review of their obstetrical history. Hospital and ambulatory services must be clearly documented in each member's record.

405.424: Hysterectomy Services

(A) Nonpayable Services. The MassHealth agency does not pay for a hysterectomy provided to a member under the following conditions.

(1) The hysterectomy was performed solely for the purpose of sterilizing the member.

(2) If there was more than one purpose for the procedure, the hysterectomy would not have been performed but for the purpose of sterilizing the member.

(B) Hysterectomy Information Form. The MassHealth agency pays for a hysterectomy only when performed by a licensed physician in a hospital, and the appropriate section of the Hysterectomy Information (HI-1) form is completed, signed, and dated as specified in 130 CMR 405.424(B)(1) through (4).

(1) Prior Acknowledgment. Except under the circumstances specified below, the member and their representative, if any, must be informed orally and in writing before the hysterectomy operation that the hysterectomy will make them permanently incapable of reproducing. (Delivery in hand of the HI-1 form will fulfill the written requirement, but not the oral requirement.) Section (B) of the HI-1 form must be signed and dated by the member or their representative before the operation is performed, as acknowledgment of receipt of this information. Whenever any surgery that includes the possibility of a hysterectomy is scheduled, the member must be informed of the consequences of a hysterectomy, and must sign and date section (B) of the HI-1 form before surgery.

(2) Prior Sterility. If the member is sterile prior to the hysterectomy operation, the physician who performs the operation must so certify, describe the cause of sterility, and sign and date section (C)(1) of the HI-1 form.

(3) Emergency Surgery. If the hysterectomy is performed in an emergency, under circumstances that immediately threaten the member's life, and if the physician determines that obtaining the member's prior acknowledgment is not possible, the physician who performs the hysterectomy must so certify, describe the nature of the emergency, and sign and date section (C)(2) of the HI-1 form.

(4) Retroactive Eligibility. If the hysterectomy was performed during the period of a member's retroactive eligibility, the physician who performed the hysterectomy must certify that one of the following circumstances existed at the time of the operation:

(a) the member was informed before the operation that the hysterectomy would make them sterile (the physician must sign and date section (D)(1) of the HI-1 form);

(b) the member was sterile before the hysterectomy was performed (the physician must sign, date, and describe the cause of sterility in section (D)(2) of the HI-1 form); or

(c) the hysterectomy was performed in an emergency that immediately threatened the member's life and the physician determined that it was not possible to obtain their prior acknowledgment (the physician must sign, date, and describe the nature of the emergency in section (D)(3) of the HI-1 form).

(C) Submission of the Hysterectomy Information Form. Each provider must attach a copy of the completed HI-1 form to each claim form submitted to the MassHealth agency for hysterectomy services. When more than one provider is billing the MassHealth agency for the same hysterectomy, each provider must submit a copy of the completed HI-1 form.

(130 CMR 405.425 Reserved)

405.426: Obstetric Services: Fee-for-service Method of Payment

The fee-for-service method of payment is always available to a provider for obstetric services covered by MassHealth. If the global fee requirements in 130 CMR 405.423 are not met, the provider or providers may claim payment from the MassHealth agency only on a fee-for-service basis, as specified in 130 CM 405.426(A) and (B).

(A) If the pregnancy is terminated by an event other than a delivery, each provider involved in performing obstetric services for the member may claim payment only on a fee-for-service basis.

(B) When additional services (for example, ultrasound or special tests) are performed, the provider may claim payment for these only on a fee-for-service basis.

405.427: Certified Nurse-midwife Services

(A) Payable Services. The CHC may bill for services provided by a certified nurse midwife that relate to pregnancy, labor, birth, and the immediate postpartum period when the nurse midwife is a contractor or employee of the CHC. The following conditions also apply.

(1) The services must be limited to the scope of practice authorized by state law or regulation.
(2) The certified nurse midwife must meet the educational and certification requirements mandated by state law or regulation.
(3) The certified nurse midwife must enter into a formal collaborative arrangement with a physician or group of physicians as required by state law or regulation.
(4) The immediate postpartum period during which certified nurse-midwife services may be provided is defined as a period of time not to exceed six weeks after the date of delivery.
(5) Deliveries by a certified nurse midwife must occur in facilities licensed by the Department of Public Health for the operation of maternity and newborn services.

(B) Nonpayable Services.

(1) Childbirth education classes are not payable.
(2) Prenatal or postpartum care provided by a certified nurse midwife in the member's home is not payable.

(C) Educational and Certification Requirements. A certified nurse midwife on the staff of a CHC must have successfully completed a formal educational program for certified nurse midwives as required by the Massachusetts Board of Registration in Nursing.

(1) A nurse midwife who has completed such educational requirements may provide services to members before the first certification examination for which the nurse midwife is eligible.
(2) If the scheduled examination is missed, the nurse midwife must immediately cease providing services to members.
(3) Upon receiving notice of failure to pass the examination, the nurse midwife must immediately cease providing services to members.
(4) After passing the examination, the nurse midwife must be certified to practice by the Board of Registration in Nursing.
(5) When such certification expires or is suspended, the certified nurse midwife must immediately cease providing services to members.

405.428: Sterilization Services: Introduction

(A) Payable Services. The MassHealth agency pays for a sterilization service provided to an eligible 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 405.429, and such consent is documented in the manner and form described in 130 CMR 405.430.

(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. No provider may use any form of coercion in the provision of sterilization services. No provider, or agent or employee of a provider, may 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 405.428(A) are met.

(D) Locations in Which Sterilizations May Be Performed.

(1) Male sterilization must be performed by a licensed physician at the CHC.

(2) Female sterilization must be performed by a licensed physician in a hospital.

(3) A hospital in which a sterilization is performed must be licensed in compliance with 105 CMR 130.000: *Hospital Licensure*.

405.429: 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 405.429(A) and (B), and such consent is documented as specified in 130 CMR 405.430.

(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 might otherwise 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 from the date consent is given, except under the circumstances specified in 130 CMR 405.429(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 405.429(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 405.429. In the case of a 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 405.429(A)(1).

405.430: 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 *Community Health Center 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 old; or

(b) CS-21 for members 21 years of age 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 CHCs must bill with the appropriate sterilization diagnosis and service 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 CHC and a hospital), each provider must submit a copy of the completed sterilization consent form with the claim.

(2) A CHC 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.

(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 405.430(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 405.430(D)(2) (for example, the CHC and a hospital), each provider must submit a copy of the signed attachment along with the claim.

405.431: Laboratory Services: Introduction

The MassHealth agency only pays CHCs for those laboratory services listed in Subchapter 6 of the *Community Health Center Manual*. The MassHealth agency pays a CHC for laboratory services that are medically necessary for the diagnosis, treatment, and prevention of disease, and for the maintenance of the health of MassHealth members, subject to all the restrictions and limitations described in 130 CMR 405.000, and 450.000: *Administrative and Billing Regulations*. In order for a CHC to be paid for any laboratory service, a written request for that service from an authorized prescriber must be present in the member's medical record.

405.432: Laboratory Services: Eligibility to Provide Services

A CHC may claim payment for the laboratory services listed in Subchapter 6 of the *Community Health Center Manual* only when all of the following conditions are met.

(A) The laboratory services are performed in the CHC.

(B) The laboratory tests are performed on properly and regularly calibrated equipment, and daily controls are carried out.

(C) The CHC has been certified by the Centers for Medicare & Medicaid Services (CMS) for performing in-house clinical laboratory services, based on the criteria set forth in the Clinical Laboratory Improvement Amendments (CLIA) of 1988, as it may be amended. In addition, the CHC's laboratory must maintain its own quality-control program and successfully participate in one or more proficiency testing programs that cover all Medicare-certified specialties and subspecialties of the laboratory. The CHC must make the results of the proficiency testing programs available to the MassHealth agency and the Attorney General's Medicaid Fraud Division upon request or during an on-site visit.

(D) If the CHC is located in-state, the CHC has been approved by the Massachusetts Department of Public Health to perform in-house clinical laboratory services. If the CHC is located out-of-state, in addition to meeting the requirements of 130 CMR 405.404(B), 405.432(A) through (C), and 450.109: *Out-of-state Services*, the CHC must also meet its own state's requirements for performing in-house clinical laboratory services.

405.433: Laboratory Services: Service Limitations

(A) The MassHealth agency will not pay a CHC for services listed as noncovered services or for which payment limits apply in accordance with the MassHealth *Independent Clinical Laboratory Manual* at 130 CMR 401.000: *Independent Clinical Laboratory Services*.

(B) The MassHealth agency will not pay a CHC for routine specimen collection and preparation for the purpose of clinical laboratory analysis (for example, venipunctures; urine, fecal, and sputum samples; Pap smears; cultures; and swabbing and scraping for removal of tissue).

(C) The MassHealth agency does not pay a CHC for the professional component of a clinical laboratory service. The MassHealth agency will pay a CHC for the professional component of an anatomical service, as provided in Subchapter 6 of the *Community Health Center Manual* (for example, bone marrow analysis or analysis of a surgical specimen).

(D) In no event may a CHC bill or be paid separately for each of the tests included in a profile or panel test (as defined herein) when a profile or panel test has either been performed by that CHC or requested by an authorized person. A profile or panel test is defined as 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.

(1) The group of tests is designated as a profile or panel by the CHC performing the tests.

(2) The group of tests is performed by the CHC at a usual and customary fee that is lower than the sum of that CHC's usual and customary fees for the individual tests in that group.

(E) The MassHealth agency does not pay for tests performed for forensic purposes or any purpose other than those described in 130 CMR 433.438: *Clinical Laboratory Services: Introduction*, including but not limited to

(1) tests performed to establish paternity;

(2) tests performed pursuant to, or in compliance with, a court order (for example, monitoring for drugs of abuse); and

(3) post-mortem examinations.

(F) Some services listed in Subchapter 6 of the *Community Health Center Manual* are designated "IC", an abbreviation for individual consideration. This means that a specific fee could not be established. The payment for an IC service will be determined by the MassHealth agency based on the designation of the test as entered on the claim form.

(G) A CHC may not bill for a visit when a member is being seen for laboratory services only.

405.434: Laboratory Services: Services Performed by Outside Laboratories

(A) A CHC may not bill the MassHealth agency for laboratory services provided outside the CHC. In this case, the testing laboratory should bill the MassHealth agency directly for those services.

(B) When sending a specimen to an outside laboratory, the CHC must include the member's MassHealth identification number and the CHC's MassHealth provider number.

(130 CMR 405.435 through 405.440 Reserved)

405.441: Radiology Services: Introduction

The MassHealth agency will pay for the radiology services in Subchapter 6 of the *Community Health Center Manual* only when the services are provided at the written request of a licensed physician or dentist. All radiology equipment used in providing these services must be inspected and approved by the Massachusetts Department of Public Health.

For radiology services furnished as part of a chiropractor service provided on site at the CHC, such radiology services must be furnished and payment claimed by the CHC in compliance with the MassHealth chiropractor regulations at 130 CMR 441.000: *Chiropractor Services*, including applicable radiology fee schedules and Subchapter 6 of the *Chiropractor Manual*.

405.442: Radiology Services: Service Limitations

(A) Definitions.

Global Fee. The rate of payment for the two components of a radiology service: the professional component and the technical component.

Professional Component. The component of a radiology service for interpreting a diagnostic test or image.

Technical Component. The component of a radiology service for the cost of rent, equipment, utilities, supplies, administrative and technical salaries and benefits, and other overhead expenses.

(B) Payment of the Global Fee. The MassHealth agency will pay a CHC the global fee for performing a radiology service at the CHC when one of the following conditions is met.

(1) The CHC owns or leases the equipment for providing the technical component of the service, employs a technician to provide the technical component of the service, and employs a board-certified or board-eligible radiologist to provide the professional component of the service.

(2) The CHC employs a board-certified or board-eligible radiologist to provide the professional component of the service and the CHC subcontracts with a licensed Medicare-certified entity to provide the technical component of the service.

(3) The CHC subcontracts with a licensed Medicare-certified entity to provide the professional and technical component of the service.

(C) Subcontracting for Radiology Services.

(1) All subcontracts between the CHC and the licensed Medicare-certified entity must be in writing, ensure continuity of care, and be consistent with all applicable provisions of 130 CMR 405.000.

(2) The CHC is legally responsible to the MassHealth agency for the performance of any subcontractor. The CHC must ensure that every subcontractor is licensed and Medicare-certified, and that services are furnished in accordance with the MassHealth agency's regulations, including, but not limited to, those set forth in 130 CMR 450.000. The CHC must submit claims for payment for radiology services provided hereunder in accordance with the MassHealth agency's regulations and applicable fee schedules.

(D) Radiology Recordkeeping (Medical Records) Requirements. In addition to complying with the general recordkeeping requirements (*see* 130 CMR 405.412), the CHC must keep records of radiology services performed. All X-rays must be labeled with the following:

(1) the member's name;
(2) the date of the examination;
(3) the nature of the examination; and
(4) left and right designations and patient position, if not standard.

405.443: Radiology Services: Payment Limitations

(A) The maximum allowable fees include payment for both the technical and professional components of the radiology service. A CHC must not bill for either the professional or technical component separately.

(B) Radiology services that are not listed in Subchapter 6 of the *Community Health Center Manual* are not reimbursable when furnished in a CHC. The CHC should refer a member to a hospital for such services.

(C) Some services listed in Subchapter 6 of the *Community Health Center Manual* are designated "SP", an abbreviation for separate procedure. Radiology services that are performed at separate sittings on the same or different days are considered separate procedures. The CHC must not bill separately for a service listed as an SP service when this service is furnished as a portion of another radiology service at the same sitting.

(D) A CHC must not bill for a visit when a member is being seen for a radiology service only.

(130 CMR 405.444 through 405.450 Reserved)

405.451: Electrocardiogram (EKG) Services: Introduction

The MassHealth agency will pay for an electrocardiogram (EKG) service only when the service is provided at the written request of a CHC staff physician who will interpret or review the interpretation of the EKG. Documentation of the physician's request must be kept in the member's medical record.

405.452: Electrocardiogram (EKG) Services: Eligibility to Provide Services

A CHC may claim payment for electrocardiogram (EKG) services only when both of the following conditions are met.

(A) The CHC owns or rents its own EKG equipment.

(B) The EKG is taken at the CHC or at the member's home.

405.453: Electrocardiogram (EKG) Services: Payment Limitations

(A) The maximum allowable fees include payment for both the technical and professional components of the service. The test must be performed at the CHC and interpreted by a physician employed by the CHC.

(B) A CHC must not bill for a visit when a member is being seen for an EKG only.

(130 CMR 405.454 through 405.460 Reserved)

405.461: Audiology Services: Introduction

In order for a CHC to be paid for an audiology service other than a hearing test performed as part of an EPSDT services assessment (*see* 130 CMR 450.140 through 450.149), a written request must be made by a physician, physician assistant, or certified nurse practitioner who has found some indication of a hearing problem. Documentation of the request and of the hearing problem must be kept in the member's medical record.

405.462: Audiology Services: Eligibility to Provide Services

(A) A CHC may claim payment for a basic pure-tone (air and bone) evaluation by audiometer furnished to a member only when the following conditions are met.

(1) The CHC possesses on its premises a pure-tone audiometer, which must be calibrated at least once every six months. Records of calibrations must be kept and made available to the MassHealth agency upon request. The machine must be placed and testing conducted in a quiet room.

(2) The person conducting hearing evaluations is trained to perform hearing tests with an audiometer.

(3) The quality of the tester's work is assessed at least twice a year by an audiologist licensed or certified in accordance with 130 CMR 426.404: *Provider Eligibility*. The audiologist may be a consultant to the CHC.

(B) A CHC may claim payment for conducting acoustic impedance testing only when the following conditions are met.

(1) The test is conducted by an ASHA-certified audiologist on the premises of the CHC.

(2) The test is conducted by means of a functioning impedance bridge that is placed in a quiet room.

(C) If a problem or abnormality is detected or believed to be present after completion of either the basic pure-tone evaluation or the acoustic impedance test or both, the member must be referred to an otologist or an otolaryngologist for a more complete audiological evaluation and treatment as necessary.

405.463: Audiology Services: Payment Limitations

(A) Audiology services that are not listed in Subchapter 6 of the *Community Health Center Manual* are not reimbursable when furnished in a CHC.

(B) A CHC must not bill for a visit when a member is seen for audiology services only.

(130 CMR 405.464 and 405.465 Reserved)

405.466: Drugs: Participation in the 340B Drug Pricing Program

(A) Notification of Participation for Non-Pharmacy 340B Drugs. Except for drugs that are excluded from coverage for MassHealth members through the 340B Drug Pricing Program, a CHC that is a 340B-covered entity may provide drugs that are billed through the medical setting (that is, not billed through pharmacy point-of-sale adjudication) to MassHealth members through the 340B Drug Pricing Program. Before filling the prescription, the CHC must notify the MassHealth agency in writing that the 340B-covered entity is registered and approved by the federal Office of Pharmacy Affairs (OPA). Any drug excluded 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 designated consistent with all requirements of M.G.L. c. 118E, §13L. Nothing will otherwise limit the rights of the MassHealth agency to exclude any or all drugs from coverage for MassHealth members through the 340B Drug Pricing Program.

(130 CMR 410.466(B) Reserved)

(C) Termination or Changes in 340B Drug Pricing Program Participation. A CHC must provide the MassHealth agency 30 days written notice of its intent to discontinue, or change in any way material to MassHealth, the manner in which it provides 340B outpatient drugs for its MassHealth patients.

(130 CMR 410.466(D) Reserved)

(E) MassHealth Coverage of 340B Drugs at Pharmacies. The MassHealth agency does not cover drugs billed through pharmacy point-of-sale adjudication and acquired through the 340B Drug Pricing Program.

405.467: Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary community health care for EPSDT-eligible members in accordance with 130 CMR 450.140: *Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services: Introduction*, without regard to service limitations described in 130 CMR 405.000, and with prior authorization.

405.468: Drugs Administered in the CHC (Provider-administered Drugs)

(A) Drugs and biologicals dispensed in the CHC are payable, subject to the exclusions and service limitations at 130 CMR 405.417, 405.418, and 130 CMR 406.413(B): *Drug Exclusions* and (C): *Service Limitations*.

(B) The MassHealth agency does not pay separately for drugs that are considered routine and integral to the delivery of a service in the course of diagnosis or treatment. Such drugs are commonly provided without charge or are included in the CHC's fee for the service.

(C) The MassHealth agency does not pay separately for any oral drugs dispensed in the office for which the CHC has not requested and received prior authorization from the MassHealth agency, with the exception of oral vaccines and oral radiopharmaceuticals, which do not require prior authorization.

(D) Claims for drugs and biologicals that are listed in Subchapter 6 of the *Community Health Center Manual* must include the name of the drug or biological, strength, dosage, and number of Healthcare Common Procedure Coding System (HCPCS) units dispensed, National Drug Code (NDC), NDC units, and NDC unit of measurement. In addition, for drugs and/or biologicals that are listed as requiring individual consideration in Subchapter 6 of the *Community Health Center Manual,* a copy of the invoice showing the actual acquisition cost must be attached to the claim. Claims without this information are denied.

(E) The MassHealth agency pays only for prescription drugs that are approved by the U.S. Food and Drug Administration and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8. Payment is calculated in accordance with 101 CMR 331.00: *Prescribed Drugs.*

(F) The MassHealth agency does not pay for a biological if the Massachusetts Department of Public Health distributes the biological free of charge.

(G) Payment for drugs may be claimed in addition to an office visit.

(130 CMR 405.469 through 405.470 Reserved)

405.471: Optional Reimbursable Services

A CHC may elect to provide the following services on site or by referral, but it is not required to do so under 130 CMR 405.000. The CHC must notify the MassHealth agency in writing of each service listed in 130 CMR 405.471(A) through (E) that the CHC will provide on site and must enroll with MassHealth as that provider type. All services provided on site must be furnished by practitioners qualified to provide the service that are employees or contactors of the CHC, and associated payment claimed by the CHC, in compliance with the applicable MassHealth regulations and Subchapter 6 for each service, including applicable fee schedules. All services listed below that are provided by referral must be based on written agreements between the CHC and each referral provider to ensure continuity of care, exchange of relevant health information such as test results and records, and avoidance of service duplication. Each referral provider must be a participating provider in MassHealth, and payment for the services provided by the referral provider must be claimed by the referral provider in compliance with the applicable MassHealth regulations for such service. All referrals must include follow up to ensure that the referral process is successfully completed. Services the CHC may elect to provide include

(A) adult day health services;

(B) adult foster care;

(C) day habilitation;

(D) psychiatric day treatment; and

(E) home health services.

405.472: Tobacco-cessation Services

(A) Introduction. MassHealth members are eligible to receive tobacco cessation counseling services described in 130 CMR 405.472(B) and pharmacotherapy treatment, including nicotine replacement therapy (NRT), in accordance with 130 CMR 406.000*: Pharmacy Services*.

(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 405.472(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 healthcare 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

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 Personnel.

(a) Physicians, registered nurses, certified nurse practitioners, certified nurse midwives, psychiatric clinical nurse specialists, clinical nurse specialists, 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 institution of higher education with a minimum of eight hours of instruction.

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

(D) Tobacco-cessation Services: Claims Submission. A CHC may submit claims for tobacco-cessation counseling services that are provided by physicians, registered nurses, certified nurse practitioners, certified nurse midwives, psychiatric clinical nurse specialists and physician assistants, and MassHealth-qualified tobacco-cessation counselors according to 130 CMR 405.472(B) and (C). *See* Subchapter 6 of the *Community Health Center Manual* for service codes.

405.473: Fluoride Varnish Services

(A) Eligible Members. Members must be younger than 21 years old to be eligible for the application of fluoride varnish.

(B) Qualified Personnel. Physicians, physician assistants, certified nurse practitioners, registered nurses, licensed practical nurses, and medical assistants may apply fluoride varnish subject to the limitation of state law. To qualify to apply fluoride varnish, the individual must complete a MassHealth-approved training on the application of fluoride varnish, maintain proof of completion of the training, and provide such proof to the MassHealth agency upon request.

(C) Billing for a Medical Visit and Fluoride Varnish Treatment or Procedure. A CHC may bill for fluoride varnish services provided by a physician or a qualified staff member as listed in 130 CMR 405.473(B) under the supervision of a physician. The CHC may bill for a medical visit in addition to the fluoride varnish application only if fluoride varnish was not the sole service, treatment, or procedure provided during the visit. The dental enhancement fee may not be billed for a fluoride varnish application separately or in addition to a medical visit.

(D) Claims Submission. A CHC may submit claims for fluoride varnish services that are provided by physicians, physician assistants, certified nurse practitioners, registered nurses, licensed practical nurses, and medical assistants according to 130 CMR 405.473(C). *See* Subchapter 6 of the *Community Health Center Manual* for service codes.

405.474: Acupuncture Services

(A) Introduction. MassHealth members are eligible to receive acupuncture services in CHCs for the treatment of pain as described in 130 CMR 405.474(C). *See* 130 CMR 433.454(E): *Acupuncture as an Anesthetic* for use of acupuncture as an anesthetic, and 130 CMR 418.409(A)(10): *Acupuncture Withdrawal Management* for use of acupuncture for detoxification.

(B) General. 130 CMR 405.474 applies specifically to physicians and other licensed practitioners of acupuncture in a CHC. The requirements elsewhere in 130 CMR 405.000 that apply to a CHC, also apply to licensed practitioners of acupuncture, such as service limitations, recordkeeping, report requirements, and prior authorization requirements.

(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 be able to receive more sessions of medically necessary acupuncture treatment with prior authorization.

(D) Provider Qualifications for Acupuncture.

(1) Qualified Providers. MassHealth pays a CHC for acupuncture services only when the provider rendering the service is

(a) a physician; or

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

(2) Acupuncture Providers in CHCs. CHCs must ensure that acupuncture providers for whom the CHC will submit claims possess the appropriate training, credentials, and licensure.

(E) Conditions of Payment. The MassHealth agency pays the CHC for services of an acupuncturist qualified to render such services in accordance with 130 CMR 405.474(D) only when

(1) the services are limited to the scope of practice authorized by state law or regulation (such as 243 CMR 5.00: *The Practice of Acupuncture*); and

(2) the provider has a current license or certificate of registration from the Massachusetts Board of Registration in Medicine.

(F) Acupuncture Claims Submissions.

(1) CHCs may submit claims for acupuncture services when a provider qualified to render such services in accordance with 130 CMR 405.474(D) provides those services directly to MassHealth members. *See* Subchapter 6 of the *Community Health Center 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 an office visit, the CHC may bill for either an office visit or the acupuncture code, but may not bill for both an office visit and the acupuncture code for the same member on the same date when the office visit and the acupuncture services are performed in the same location. This limitation does not apply to a significant, separately identifiable office visit provided by the same CHC on the same day of the acupuncture service.

405.475: Medical Nutrition Therapy

(A) Introduction. MassHealth members are eligible to receive medical nutrition therapy services described in 130 CMR 405.475(B). *See* Subchapter 6 of the *Community Health Center Manual* for service code descriptions and billing requirements.

(B) The MassHealth agency pays for nutritional diagnostic therapy and counseling services for the purpose of management of a medical condition. Medical nutrition therapy services are payable when provided to eligible MassHealth members by the following providers:

(1) physicians;

(2) dietitians/nutritionists licensed by the Massachusetts Division of Professional Licensure, and the Board of Registration of Dietitians and Nutritionists;

(3) mid-level practitioners credentialed by the Commission on Dietetic Registration (CDR) (*e.g.*, certified nurse midwives, certified nurse practitioners, registered nurses, and physician assistants); or

(4) other health care providers licensed by the Massachusetts Division of Professional Licensure, and the Board of Registration of Dietitians and Nutritionists, with specific training in the provision of nutritional counseling as provided in 42 U.S.C. 1395x(vv)(2).

405.476: Diabetes Self-management Training

(A) Introduction. MassHealth members are eligible to receive diabetes self-management training (DSMT) services described in 130 CMR 405.476(B). *See* Subchapter 6 of the *Community Health Center Manual* for service code descriptions and billing requirements.

(B) The MassHealth agency pays for DSMT and education, which may include medical nutrition therapy, and are furnished to an individual with pre-diabetes or diabetes. DSMT services are payable when provided to eligible MassHealth members by the following providers:

(1) physicians;

(2) dietitians/nutritionists licensed by the Massachusetts Division of Professional Licensure, and the Board of Registration of Dietitians and Nutritionists;

(3) mid-level practitioners credentialed by the Certification Board for Diabetes Care and Education (CBCDE) (*e.g.*, nurse midwives, nurse practitioners, registered nurses, and physician assistants); or

(4) other health care practitioners with specific training in the provision of DSMT as provided in 42 U.S.C. 1395x(qq)(2).

405.477: CARES Program Services

(A) Introduction. The MassHealth Coordinating Aligned, Relationship-centered, Enhanced Support for Kids program (CARES program) is a Targeted Case Management (TCM) service rendered by CARES program providers certified in accordance with 130 CMR 405.477(D) to members younger than age 21 who satisfy the eligibility criteria in 130 CMR 405.477(C). The MassHealth agency pays for CARES program services provided by CARES program providers subject to restrictions and limitations in 130 CMR 405.477(A) through 405.477(H) and Appendix M of the *Physician Manual*.

(B) Definitions. The following terms used in 130 CMR 405.477(A) through 405.477(H) have the meanings given in 130 CMR 405.477(B) unless the context clearly requires a different meaning.

Comprehensive Assessment. A systematic, timely, and clearly documented screening process that provides the foundation for care coordination and the individual care plan. The assessment includes information and data from multiple sources and reflects key information about the member and their parent/guardian's needs and priorities.

Individual Care Plan (ICP). A plan that specifies the goals and actions to address the medical, educational, social, behavioral, or other services needed by the member and their parent/guardian.

Local Education Agency. A public authority legally constituted by the state as an administrative agency to provide control of and direction for kindergarten through grade 12 public educational institutions.

Medical Complexity. A combination of multiorgan system involvement from chronic health condition(s) that often result in functional limitations, ongoing use of medical technology, and high resource need and use.

Natural Supports. These supports include family, friends, neighbors, and self-help groups intentionally identified to support the member. This support system is an active component of the ICP to support the member and their parent/guardian.

Subspecialist. A provider who specializes in a narrow field of professional knowledge/skills within a medical specialty, such as pediatric congenital heart disease within the broad specialty of cardiology.

(C) Clinical Eligibility Criteria. To receive CARES program services, a member must

(1) be younger than 21 years old;

(2) not reside in a nursing facility or other inpatient facility for longer than six consecutive months at the time of seeking CARES program services; and

(3) satisfy

(a) all of the eligibility criteria in 130 CMR 405.477(C)(3)(b)1; and

(b) all of the eligibility criteria in either 130 CMR 405.477(C)(3)(b)2 or 130 CMR 405.477(C)(3)(b)3, as follows:

1. The member is a child with special health needs who requires ongoing medical management by at least two pediatric subspecialists. At least one of the specialists must treat a medical condition that results in all of the following:

a. functional impairment (*e.g.*, need for assistance with activities of daily living) that substantially interferes with or limits the member's role/functioning in family, school, and community activities. Functional impairment is defined as difficulties that substantially interfere with or limit the member in achieving or maintaining developmentally appropriate, social, behavioral, cognitive, communicative, or adaptive skills. Functional impairments of episodic, recurrent, and continuous duration are included unless they are temporary and expected responses to stressful events in the environment.

b. at least one condition must be

i. progressive, associated with persistent deteriorating health; or

ii. a chronic medical condition, expected to last at least a year and expected to: 1.) be episodically or continuously debilitating and 2.) require ongoing treatment for control of the condition that will use health care resources above the level of a healthy child; or

iii. a progressive or metastatic malignancy.

2. At the time the member begins receiving CARES program services, the member is at high risk for adverse health outcomes due to both of the following:

a. Demonstrated inability to coordinate multiple medical, social, and other services impacting medical condition, as evidenced by:

i. two or more unplanned emergency department visits within the past 180 days; or

ii. a documented pattern of multiple missed primary care physician (PCP) or subspecialty appointments; or

iii. chronic absenteeism from school directly related to the member's medical conditions.

b. Demonstrated health-related social needs impacting the management of the member's medical condition. Social complexity/health-related social needs are defined by at least one of the following:

i. experiencing homelessness or housing insecurity;

ii. experiencing food insecurity;

iii. parent/caregiver experiencing employment instability;

iv. lacking access to basic resources such as heat, electricity, internet, transportation, education, and social connections; or

v. living in unsafe or violent conditions.

3. The member requires more than two continuous hours of skilled nursing services to remain safely at home.

(D) Provider Requirements.

(1) Payment for services described in 130 CMR 405.477(A) through 405.477(H) will be made only to CHCs participating in MassHealth on the date of service that are also certified by the MassHealth agency for the provision of CARES program services at or associated with that service location on the date of service.

(2) A CHC seeking to provide CARES program services must meet the requirements in 130 CMR 405.477(A) through 405.477(H). A separate application for certification as a CARES program provider must be submitted for each CHC that seeks to render such services. The application must be made on the form provided by the MassHealth agency and must be submitted to the MassHealth agency's physician program. The MassHealth agency may request additional information from the applicant to evaluate the applicant's compliance with 130 CMR 405.477(A) through 405.477(H). Through this certification, the applicant must, among other requirements

(a) agree to enter into a written agreement with the MassHealth agency in which the applicant agrees to satisfy all of the requirements in 130 CMR 405.477(A) through 405.477(H);

(b) agree to establish, maintain, and comply with written policies and procedures to satisfy all the requirements in 130 CMR 405.477(A) through 405.477(H);

(c) agree to assess and annually reassess each member in its care in accordance with 130 CMR 405.477(E)(3)(a) and 130 CMR 405.477(F)(1)(a) to ensure that each such member satisfies, and continues to satisfy, the clinical eligibility criteria for receipt of CARES program services;

(d) agree to periodic inspections, by the MassHealth agency or its designee, that assess the quality of member care and ensure compliance with 130 CMR 405.477(A) through 405.477(H);

(e) submit a written description of

1. CARES program services offered by the applicant and its care objectives, and
2. how the applicant will fulfill the staffing requirements in 130 CMR 405.477(E);

(f) agree to participate in any CARES program provider orientation required by EOHHS;

(g) attest that it

1. actively provides covered services to MassHealth members younger than 21 years old with medical complexities; and
2. has the capacity to provide on-call care coordination to members assigned to the applicant 24 hours a day, 365 days per year;

(h) agree to provide any documentation, data, and reports as required by EOHHS;

(i) agree to subscribe to and participate in the statewide ENS (Event Notification Service) Framework described in 101 CMR 20.11: *Statewide Event Notification Service Framework*, including having the capacity to receive and send admission, discharge, and transfer messages, as that term is defined in 101 CMR 20.04: *Definitions*;

(j) agree to establish and implement policies and procedures to increase the technological capabilities to share information among providers involved in members' care, including increasing Health Information Exchange (HIE) connections and enhancing digital systems interoperability;

(k) agree to use CMS-required CEHRT (Certified Electronic Health Record Technology) criteria (2015 edition or subsequent editions) and updates to said criteria, to document and communicate clinical care information;

(l) agree to comply with the Office of the National Coordinator for Health Information Technology (ONC) guidance on USCDI (United States Core Data for Interoperability) for standardized health data exchange, or such other guidance and standards for health data exchange as specified by EOHHS;

(m) agree to submit to the MassHealth agency or its designee a statement of fiscal soundness attesting to the financial viability of the CARES program provider supported by documentation to demonstrate that the provider has adequate resources to finance the provision of services in accordance with 130 CMR 405.477(A) through 405.477(H); and
(n) agree to participate in any quality management and program integrity processes as required by the MassHealth agency.

(3) The MassHealth agency requires documentation from providers seeking to become CARES program providers. All required application documentation will be specified by the MassHealth agency and must be submitted and approved prior to participating as a CARES program provider in MassHealth.

(4) Based on the information provided in the certification application, the MassHealth agency will determine whether the applicant is certifiable as a CARES program provider. If the MassHealth agency determines that the applicant is not certifiable, the notice will contain a statement of the reasons for that determination and recommendations for corrective action so that the applicant may reapply for certification once corrective action has been taken.

(5) The certification is valid only for the CHC described in the application and is not transferable to any other provider. Any additional location established by the applicant at a satellite facility must obtain separate certification from the MassHealth agency in order to receive payment.

(E) CARES Team.

(1) The CARES program provider must establish a CARES team to meet the care coordination needs of members, including on call after-hours availability to assist as needed and to triage medical crises and emergencies. The CARES team must include a program director, senior care manager, care coordinator, and family support staff which may include a community health worker or peer, each of whom must satisfy the staff composition requirements specified in Appendix M of the *Physician Manual*. The CARES team must satisfy any other staff composition requirements specified in Appendix M of the *Physician Manual*. CARES team members may serve multiple roles for which they are qualified as long as the staffing responsibilities and programmatic requirements are met. In addition, care managers and supervisors serving on the CARES team must complete trainings as outlined in Appendix M of the *Physician Manual*. CARES program providers must establish policies and procedures relating to such trainings to ensure the completion of such trainings. CARES program providers must document compliance with training requirements for care managers and supervisors within three months of starting in that role.

(2) The CARES team is responsible for ensuring that needed medical, social, educational, and other CARES program services are accessed, coordinated, and delivered in a strength-based, individualized, member-driven, culturally informed, linguistically appropriate, and accessible manner. The CARES team must establish referral relationships with members' pediatric specialty providers, primary care providers, behavioral health providers, MassHealth managed care entities, and any other entity, agency, system, or provider as needed for the treatment of a member in the provider's care, as determined by the member's CARES team.

(3) The CARES team must

(a) conduct a comprehensive assessment of each member seeking CARES program services from the provider in order to determine that the member is clinically eligible to receive such services. The CARES team shall conduct this comprehensive assessment in accordance with 130 CMR 405.477(F) and Appendix M of the *Physician Manual*.
(b) make referrals for and coordinate services on- and off-site. These services include, but are not limited to, making referrals for and coordinating the following services:

1. medical and behavioral health care.
2. home and community long-term services and supports, such as durable medical equipment (DME) and continuous skilled nursing (CSN) services. For members enrolled in the Community Case Management (CCM) program, the CARES team will serve as the lead care coordination entity and will work directly with the CCM case manager to coordinate DME, CSN, and other home health services.
3. health-related social needs, goods, and services, including, but not limited to, housing stabilization and support services, utility assistance, and nutritional assistance.
4. educational services and entitlements.
5. any state agency services for which the member may be eligible.

(c) have standardized processes for referrals to ensure continuity of care, exchange of relevant health information, such as test results and records, and avoidance of service duplication. This process must also contain follow-up provisions to ensure that the referral is completed successfully.

(d) establish and maintain relationships with the member's health plan and any state or local agencies with which the member is involved, including, but not limited to, the Department of Children and Families (DCF), the Department of Developmental Services (DDS), the Department of Mental Health (DMH), the Department of Public Health (DPH), the Department of Transitional Assistance (DTA), the Department of Youth Services (DYS), and any Local Education Agency (LEA).

(e) support care coordination and facilitate collaboration through the establishment of regular case review meetings as specified in Appendix M of the *Physician Manual*.

(f) provide all CARES program services.

(F) Scope of Services. The CARES program provider must ensure that CARES program services are provided only by individuals serving on the CARES team who are qualified to render such services. Detailed service components are outlined in Appendix M of the *Physician Manual.*

(1) CARES program services must include at a minimum:

(a) a comprehensive assessment of the member at least once a year. These assessment activities include, but are not limited to:

1. taking the member's history, which must capture the full spectrum of medical, social, educational, and emotional needs;
2. identifying the member's needs and completing related documentation; and
3. gathering information from other sources such as the parent/guardian, medical providers, state agencies, social services providers, and educators, to complete the assessment or reassessment of the member.

(b) development of an ICP, which must be driven by the member and their parent/guardian, authorized health care decision maker, and other relevant providers, and it must be shared and included in transition of care communication with relevant providers, state agencies, and members of the care management team. The ICP must be in a form and format specified by the MassHealth agency and include:

1. goals and actions to address the medical, social, educational, and other services needed by the member;
2. a course of action to respond to the assessed needs of the member; and
3. an emergency plan;

(c) care coordination and family support activities such as, but not limited to:

1. having a designated CARES team member (either a care coordinator or a senior care manager) serve as the primary and "first line" contact for the member and their parent/guardian. The care manager must provide regular contact with the member and

their parent/guardian (either face-to-face or by telehealth, in accordance with the preferences of the member and their parent/guardian);

2. providing a phone number and on-call capacity 24 hours a day, 365 days per year to respond to and triage any medical and care coordination related questions;

3. helping the parent/guardian/caregiver advocate for and access resources and services to meet the family's needs;

4. maintaining effective, coordinated, and communicative relationships with designees from the member's care team, such as primary care physicians, health systems, specialty providers, dental providers, behavioral health providers, CCM, and CSN supports, and other state agencies, in order to facilitate coordination;

5. coordinating with early intervention providers and school and early childhood education providers;

6. coordinating access to DME, home care needs, scheduling appointments, referrals to providers for needed medical services, and assistance with prior authorization;

7. coordinating goods and services related to health-related social needs;

8. providing ongoing support in maintaining MassHealth eligibility, accessing any eligible benefits through state agencies, and coordinating with primary insurance for members who have third-party coverage;

9. providing intensive support for transitions of care between different health and community settings and the member's home; and

10. performing any other activities as detailed in Appendix M of the *Physician Manual*.

(d) appropriate services to address identified needs and achieve goals specified in the ICP;

(e) intensive support for member transitions into adult care, beginning once the member reaches 16 years old; and

(f) all monitoring and follow-up activities necessary to ensure that the ICP is implemented and adequately addresses the member's needs.

(2) A CARES program provider is responsible for providing any and all of the CARES program services described above to each member receiving CARES program services from that provider when medically necessary.

(G) Assignment and Removal of Assignment Procedures.

(1) To promote effective provision of TCM services and prevent duplication, a member seeking CARES program services may receive such services from only one CARES program provider at a time. To facilitate this requirement, a CARES program provider must, prior to rendering CARES program services to a member, check the Eligibility Verification System to determine whether the member has been assigned to another CARES program provider, in accordance with the process outlined in Appendix M of the *Physician Manual*.

(a) If the member is assigned to another CARES program provider, the provider from whom the member seeks CARES program services must decline to provide such services to the member and refer the member to the CARES program to which they are assigned.

(b) If the member is not assigned to another CARES program provider, and if the member agrees to receive CARES program from the CARES program provider, the CARES program provider must assign the member to the CARES program provider in accordance with the process outlined in Appendix M of the *Physician Manual*, including determining clinical eligibility and other education and information-sharing activities with the eligible member and parent/guardian.

(2) Removal of assignment. If a member no longer needs or is no longer eligible for CARES program services provided by the CARES program provider, the CARES program must

follow the removal of assignment procedures as specified in Appendix M of the *Physician Manual*, including convening a meeting with the member and their family to develop an aftercare/transition plan.

(H) Payment.

(1) The MassHealth agency pays a CARES program provider for CARES program services only if the member receiving CARES program services is eligible to receive such services under 130 CMR 405.477(C).

(2) The MassHealth agency pays a CARES program provider for services in accordance with the applicable payment methodology and rate schedule established by EOHHS. Rates of payment for CARES program services include only those services described in 130 CMR 405.477(F), and do not cover or include any direct medical care.

(3) The MassHealth agency makes a single monthly payment for all CARES program services rendered by a CARES program provider to a member during that calendar month. In order to qualify for payment of the monthly fee, the CARES program provider must provide at least two of the CARES program services described in the regulation to that member during that calendar month, with at least one of those services including live interaction between the provider and the member and their parent/guardian, whether in person or via telehealth. A CARES program provider may not bill MassHealth the monthly fee for any calendar month in which the provider renders only one of the services described in the regulation to the member.

(4) Payment for the CARES program is subject to the conditions, exclusions, and limitations in 130 CMR 405.000 and 450.000: *Administrative and Billing Regulations*.

(5) The MassHealth agency does not pay for CARES program services rendered to a member by a CARES program provider during any period of time in which the member is assigned to another CARES program provider.

(6) If the member assigned to a CARES program provider is admitted to a nursing facility or other inpatient facility during the period of assignment, the MassHealth agency pays for CARES program services rendered by that CARES program provider to that member for up to six consecutive months from the date of admission, subject to compliance with all applicable requirements in 130 CMR 405.477(A) through 405.477(H) and Appendix M of the *Physician Manual*. MassHealth will not pay for CARES program services rendered to any member who has resided in a nursing facility or other inpatient facility for more than six consecutive months.

(130 CMR 405.478 through 405.495 Reserved)

405.496: Utilization Management Program

The MassHealth agency pays 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 450.209 are satisfied. Appendix E of the *Community Health Center Manual* describes the information that must be provided as part of the review process.

REGULATORY AUTHORITY

130 CMR 405.000: M.G.L. c. 118E, §§ 7 and 12.