4. Program Regulations

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423.401: Introduction

130 CMR 423.000 establishes the requirements for the provision and payment of freestanding ambulatory surgery center services under the MassHealth Program. The MassHealth agency pays for freestanding ambulatory surgery center services that are medically necessary and appropriately provided in the most cost-effective setting; that is, the total cost of the service (for example, the rate of payment for the corresponding payment group including directly related ancillaries, plus the cost of prosthetic devices or implants) does not exceed the cost to the MassHealth agency of providing that same service in any other medically appropriate setting, as determined by the MassHealth agency or its agent. The quality of the services delivered to MassHealth members must meet professionally recognized standards of care.

423.402: Definitions

The following terms used in 130 CMR 423.000 have the meanings given in 130 CMR 423.402, unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 423.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 423.000 and 450.000: Administrative and Billing Regulations.

Freestanding Ambulatory Surgery Center — a facility, geographically independent of any other health-care facility, that operates autonomously and functions exclusively for the purpose of providing outpatient same-day surgical, diagnostic, and medical services requiring a dedicated operating room and a postoperative recovery room. These surgical, diagnostic, and medical services provide diagnosis or treatment through operative procedures requiring general, local, or regional anesthesia to patients who do not require hospitalization or overnight services upon completion of the procedure, but who require constant medical supervision for a limited amount of time following the conclusion of the procedure. A freestanding ambulatory surgery center does not include individual or group-practice offices of private physicians, dentists, or podiatrists. These centers are referred to as surgical centers in 130 CMR 423.000.

Individual Consideration — a designation given to a claim that will receive individual consideration (I.C.) to determine payment where a fee could not be established.

Institutionalized Individual – 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 – 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 which include the ability to consent to sterilization.
Operative Report — a report that states the operation performed, the name of the member, the date of the operation, the preoperative diagnosis, the postoperative diagnosis, the names of the surgeon and his or her assistants, and the technical procedures performed.

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

423.403: Eligible Members

(A) MassHealth Members and Recipients of Emergency Aid to the Elderly, Disabled and Children Program.
   (1) MassHealth Members. The MassHealth agency pays for freestanding ambulatory surgical center services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in the 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 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) Member Eligibility and Coverage Type. For information on verifying member eligibility and coverage type, see 130 CMR 450.107: Eligible Members and the MassHealth Card.

423.404: Provider Eligibility

Payment for the services described in 130 CMR 423.000 will be made only to in-state and out-of-state surgical centers participating in MassHealth on the date of service. The MassHealth agency has established the provider eligibility requirements listed below for in-state and out-of-state providers. Providers must meet all of these requirements to participate in MassHealth as a surgical center.

(A) Procedures for Hospitalization. An in-state or out-of-state surgical center must have established procedures to ensure the transfer of a member to a hospital if an emergency occurs that requires treatment beyond the capabilities of the surgical center. Either the surgical center must have a written transfer agreement with a hospital, or all the dentists, physicians, and podiatrists with surgical privileges at the surgical center must have admitting privileges at the hospital. The hospital must be a MassHealth-participating provider, and must be licensed to operate as a hospital in accordance with 105 CMR 130.000: Hospital Licensure or with its own state's licensing agency.

(B) In-State Providers. To participate in MassHealth, an in-state surgical center must:
   (1) obtain a MassHealth provider number from the MassHealth agency;
   (2) operate under a clinic license issued by the Massachusetts Department of Public Health, in accordance with regulations at 105 CMR 140.000; Licensure of Clinics;
   (3) participate in the Medicare program as an ambulatory surgery center;
   (4) be accredited by a national accrediting body for ambulatory surgery centers; and
   (5) have a minimum of two dedicated operating rooms.
(C) Out-of-State Providers.

(1) To participate in MassHealth, an out-of-state surgical center must
   (a) obtain a MassHealth provider number from the MassHealth agency;
   (b) participate in its own state’s Medicaid program;
   (c) operate as a provider of surgical center services as authorized by the governing or
      licensing agency in its state;
   (d) participate in the Medicare program as an ambulatory surgery center;
   (e) be accredited by a national accrediting body for ambulatory surgery centers; and
   (f) have a minimum of two dedicated operating rooms.

(2) Out-of-state surgical center services provided to an eligible MassHealth member are
    payable only when
   (a) the surgical services are provided to a member who resides in a community located
      within a 50-mile radius of the Massachusetts border in Connecticut, Maine, New
      Hampshire, New York, Rhode Island, or Vermont and for whom the out-of-state
      freestanding ambulatory surgical center is nearer than a facility in Massachusetts
      providing equivalent surgical services; or
   (b) an out-of-state surgical center that is more than 50 miles from the Massachusetts
      border obtains prior authorization from the MassHealth agency to provide any surgical
      center services to a member. This prior authorization is required in addition to the prior-
      authorization requirements found at 130 CMR 423.406. All requests for prior
      authorization must be submitted in accordance with the instructions found in Subchapter
      5 of the Freestanding Ambulatory Surgery Center Manual. No payment will be made for
      such services unless prior authorization has been obtained from the MassHealth agency
      before the delivery of service. The MassHealth agency does not grant retroactive prior-
      authorization requests.
423.405: Payment

Payment for a surgical procedure performed at a surgical center consists of two components: the facility component and the professional component.

(A) Facility Component. The facility component is an all-inclusive fee that pays the surgical center for rent, equipment, utilities, supplies, salaries and benefits for administrative and technical staff, and other overhead expenses.

(1) This fee includes payment for
   (a) surgical center facilities and equipment;
   (b) nursing services, technician services, and other related services;
   (c) drugs, biologics, surgical dressings, supplies, splints, casts, appliances, and equipment directly related to the provision of the surgical procedures;
   (d) administrative, recordkeeping, and housekeeping items and services;
   (e) materials for anesthesia;
   (f) blood;
   (g) urinalysis and blood hemoglobin and hematocrit; and
   (h) diagnostic or therapeutic services related to the provision of the surgical procedure.

(2) Payment for both in-state and out-of-state surgical center services is made in accordance with the rate or rates of payment established for surgical centers by the Massachusetts Executive Office of Health and Human Services (EOHHS) at 114.3 CMR 47.00: Freestanding Ambulatory Surgical Facilities. Surgical procedures are classified into payment groups. All procedures within a payment group are assigned the same rate.

   (a) Multiple Procedures. If more than one payable surgical procedure requiring an unrelated operative incision is provided in a single operative session, the full maximum fee is 100 percent for the operative procedure in the highest payment group and a percentage of the payment-group rate, as determined by EOHHS, for each additional payable procedure.

   (b) Bilateral Procedures. If a payable surgical procedure provided in a single operative session is performed bilaterally, the full maximum fee is 150 percent of the payment-group rate for the operative procedure.

   (c) Cancelled Procedures. The MassHealth agency does not pay for a surgical procedure that has been cancelled or postponed, for any reason, before the procedure is initiated.

   (d) Terminated Procedures.
      (i) The MassHealth agency determines payment on an individual-consideration (I.C.) basis for procedures that have been terminated after the procedure has been initiated. Appropriate payment for an I.C. service is determined by the MassHealth agency based on the operative report of services furnished. Payment of prosthetic devices for a terminated procedure depends on the preparation of the device. The preparation of the prosthetic device must require distinct preliminary measures (for example, immersion in an antibiotic solution) and does not include the action of opening a sterile implant onto the surgical field or instrument table.
(ii) The facility must use the service code in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual designated for terminated procedures. An operative report, including the operative summary, nursing notes, and anesthesia record, must accompany the claim. If a report is not submitted, no payment will be made. If, after review of the operative summary, nursing notes, and anesthesia record, the MassHealth agency determines that there should be payment for the prosthetic device, then this payment is included in the payment for the terminated procedure.

(B) Professional Component. Payment for professional services furnished by a dentist, podiatrist, or physician in a surgical center will be made in accordance with the MassHealth agency’s regulations at 130 CMR 420.000: Dental, 424.000: Podiatrist, and 433.000: Physician, respectively. All professional services must be furnished by a provider participating in MassHealth.

423.406: Prior Authorization

(A) The MassHealth agency requires the surgeon to obtain prior authorization for services that are designated "P.A." in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual. No payment will be made for such services unless prior authorization has been obtained from the MassHealth agency before the delivery of service. The MassHealth agency will not grant retroactive prior-authorization requests.

(B) Prior authorization determines only the medical necessity of the authorized service and does not establish or waive any other prerequisites for payment such as, but not limited to, member eligibility or resort to health insurance payment.

(C) MassHealth regulations about prior-authorization requirements may be found in the individual program regulations for dentists, podiatrists, and physicians at 130 CMR 420.000: Dental, 424.000: Podiatrist, and 433.000: Physician, respectively.

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

The MassHealth agency pays for all medically necessary surgery center services for EPSDT-eligible members in accordance with 130 CMR 450.140: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services: Introduction through 450.149: EPSDT: Recordkeeping Requirements, without regard to service limitations described in 130 CMR 423.000, and with prior authorization.

(130 CMR 423.408 through 423.412 Reserved)
Surgical centers must maintain a medical-record system promoting quality and confidential patient care in accordance with Massachusetts Department of Public Health regulations at 105 CMR 140.000: Licensure of Clinics. This system must collect and retain data in a comprehensive and efficient manner and permit the prompt retrieval of information. Accurate and complete medical records must be maintained for each member receiving surgical services from the surgical center. The data maintained in the member’s medical record must also be sufficient to justify any further diagnostic procedures, treatments, recommendations for return visits, and referrals. The medical record must be clear and legible, and readily accessible to health care practitioners and the MassHealth agency. The medical record must be maintained by the surgical center for six years.

(A) Documentation. Payment for any service covered by MassHealth is conditioned upon its full and complete documentation in the member’s medical record. Payment for maintaining the member’s medical record is included in the fee for the facility component. Each medical record must contain sufficient information to fully document the nature, extent, quality, and necessity of the care furnished to the member for each date of service claimed for payment. If the information in the member’s record is not sufficient to document the service for which payment is claimed by the provider, the MassHealth agency will not pay for the service or, if payment has been made, may consider such payment to be an overpayment subject to recovery as defined in the MassHealth administrative and billing regulations in 130 CMR 450.000: Administrative and Billing Regulations. The medical record requirements in 130 CMR 423.000 constitute the standard against which the adequacy of records will be measured, as set forth in 130 CMR 450.000: Administrative and Billing Regulations.

(B) Components. The medical record must include the following:
   (1) patient identification, including name, date of birth, and the member’s MassHealth identification number;
   (2) medical history and dental history, as appropriate;
   (3) findings of physical examination and preoperative diagnosis;
   (4) results of any preoperative diagnostic studies (entered before surgery) if ordered, including laboratory and radiologic reports. These results include dated and mounted X rays, if applicable;
   (5) operative record documenting clinical findings, techniques of the operation, intraoperative medications administered, and type of surgical procedure;
   (6) pathologist’s reports on tissue removed in surgery, except those exempted by the governing body;
   (7) date of surgery;
   (8) surgeon’s name, address, and telephone number;
   (9) allergies and adverse drug reactions;
   (10) anesthesia record describing anesthetic agents used, dosages administered, and documentation of start and end times of general or intravenous anesthesia;
   (11) nursing notes (preoperative, intraoperative, and postoperative, including documentation of any medical goods or supplies dispensed);
   (12) patient’s surgical consent, with documentation of it as properly executed informed consent;
   (13) postoperative diagnosis;
(14) discharge summary, including recommendations and referrals for additional treatment or consultations, when applicable; and
(15) records pertaining to requests for laboratory, radiologic, and/or pathology information requested in relation to the surgical procedure.

(C) Clinical Laboratory and Radiology Services. For clinical laboratory services and radiologic services, additional information must be maintained in the member’s medical record in relation to the payable surgical procedure, as well as a record of each specimen and laboratory test result for at least six years from the date on which the results were reported to the prescriber. This record must include the following components:
   (1) name and any other means of identification of the patient from whom the specimen was taken, including date of birth and MassHealth member identification number;
   (2) site from which the specimen was obtained;
   (3) name of the person who obtained the specimen;
   (4) name of the person who ordered the laboratory test;
   (5) name of the person who ordered the radiologic service;
   (6) authorized requisition for the test;
   (7) name and address of the surgical center where the specimen was obtained;
   (8) date on which the specimen was collected by the prescriber or laboratory;
   (9) date on which the specimen was received in the laboratory;
   (10) condition of unsatisfactory specimens when received (for example, broken, leaked, hemolyzed, turbid, or insufficient sample size);
   (11) date on which the test was performed;
   (12) test name and the results of the test, or the cross-reference to results and the date of reporting;
   (13) name and address of the person performing the examination of the specimen; and
   (14) if applicable, the name and address of a second independent laboratory consulted to examine the specimen, as well as documentation stating the necessity for further examination.

(D) Pharmacy Services. Surgical center pharmacies must maintain, for six years, a record for each member of the drug and amount dispensed, the date, and the original prescription. Verbal orders for the administration of all drugs and biologicals must be followed by a written order signed by the prescriber at the completion of the surgical procedure.
423.414: Payable Surgical Procedures

The MassHealth agency pays surgical centers for those services listed in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual (see 130 CMR 423.401 for further requirements). All prosthetic devices, except intraocular lenses, whether implanted, inserted, or otherwise related to procedures on the current list of payable surgical procedures, are paid separately from the surgical center facility component. The above notwithstanding, providers must comply with the requirements specified in 130 CMR 423.401, which state that payment is provided only for services that are medically necessary and furnished in the least costly medically appropriate setting.

423.415: Service Limitations

(A) The MassHealth agency does not pay for experimental, unproven, cosmetic, or otherwise medically unnecessary procedures or treatments performed at the center.

(B) The MassHealth agency does not pay a surgical center for the treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment); however, the MassHealth agency will pay a surgical center for diagnosis of male or female infertility.

423.416: Sterilization Services: Introduction

(A) Covered Services. The MassHealth agency pays for sterilization services provided to a member only if all of the following conditions are met.
   (1) The member has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 423.417, and such consent is documented in the manner described in 130 CMR 423.418.
   (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.
   (4) The sterilization is performed by a licensed physician.

(B) Assurance of Member Rights. No provider may use any form of coercion in the provision of sterilization services. Neither the MassHealth agency nor any provider, nor any 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 under 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 423.416(A) are met.
423.417: 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 423.417(A) and (B), and such consent is documented as specified in 130 CMR 423.418.

(A) Informed Consent Requirements.

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

(a) advice that the member is free to withhold or withdraw consent for the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the member otherwise might be entitled;
(b) a description of available alternative methods of family planning and birth control;
(c) advice that the sterilization procedure is considered irreversible;
(d) a thorough explanation of the specific sterilization procedure to be performed;
(e) a full description of the discomforts and risks that may accompany or follow the procedure, including an explanation of the type and possible effects of any anesthetic to be used;
(f) a full description of the benefits or advantages that may be expected as a result of the sterilization; and
(g) advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in 130 CMR 423.417(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 423.417(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 423.417. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.
(2) A member’s consent for sterilization will not be considered informed or voluntary if such consent is obtained or given while the member requesting sterilization is:
   (a) in labor or childbirth;
   (b) seeking to obtain or obtaining an abortion; or
   (c) under the influence of alcohol or other substances that affect the individual's state of awareness.

(3) Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the member of all of the information and advice specified in 130 CMR 423.417(A)(1).

423.418: 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 Freestanding Ambulatory Surgery Center Manual.)

(A) Required Consent Form.
   (1) One of the following Consent for Sterilization forms must be used:
      (a) CS-18 – for members aged 18 through 20; or
      (b) CS-21 – for members aged 21 and older.
   (2) Under no circumstances will the MassHealth agency accept any other consent for sterilization form.

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

(C) Required Submission and Distribution of the Consent Form. The Consent for Sterilization form (CS-18 or CS-21) must be completed and distributed as follows:
   (1) the original must be given to the member at the time of consent; and
   (2) a copy must be included in the member’s permanent medical record at the site where the sterilization is performed.

(D) Provider Billing and Required Submissions.  
   (1) All providers must bill with the appropriate sterilization diagnosis and 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 physician and the freestanding ambulatory surgery center), each provider must submit a copy of the completed sterilization consent form with the claim.
(2) A provider does not need to submit a Consent for Sterilization Form (CS-18 or CS-21) with a claim for a medical procedure, treatment, or operation that is not for the purpose of rendering an individual permanently incapable of reproducing. If the appropriate service code used to bill for such a medical procedure, treatment, or operation may also be used to bill for a sterilization, the claim will be denied unless at least one 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 423.418(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 423.418(D)(2) (for example, the physician and the freestanding ambulatory surgery center), each provider must submit a copy of the signed attachment along with the claim.

423.419: Abortion Services

(A) Abortions may be performed in a surgical center in accordance with M.G.L. c. 112, s. 12I through 12N, inserted by Chapter 706 of the Acts of 1974, and with license rules and regulations of the Massachusetts Department of Public Health.

(B) A surgeon must certify that the abortion is medically necessary by completion of the Certification for Payable Abortion (CPA-2) form. The surgeon must comply with MassHealth regulations at 130 CMR 433.000: Physician.

(C) All surgical centers must attach a completed CPA-2 form to each claim form submitted to the MassHealth agency for a payable abortion. (Instructions for obtaining the CPA-2 form can be found in Subchapter 5 of the Freestanding Ambulatory Surgery Center Manual.) The surgical center must attach a copy of the completed CPA-2 form with each claim made to the MassHealth agency for a payable abortion. Service codes requiring a CPA-2 form are indicated in Subchapter 6 of the Freestanding Ambulatory Surgery Center Manual.

REGULATORY AUTHORITY

130 CMR 423.000: M.G.L. c. 118E, §§ 7 and 12.
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