



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



MassHealth  
Transmittal Letter STR-18  
January 2015

**TO:** Sterilization Clinics Participating in MassHealth  
**FROM:** Kristin L. Thorn, Medicaid Director   
**RE:** *Sterilization Clinic Manual* (Updated Sterilization Clinic Regulations)

This letter transmits revisions to the sterilization clinic regulations. MassHealth has updated the regulations so that they are consistent in format with other MassHealth provider regulations, including with respect to provisions on member and provider eligibility and recordkeeping requirements. MassHealth has also updated terminology and made certain changes to conform relevant sterilization provisions to updates being made to other MassHealth provider regulations. These changes continue to conform to federal standards.

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

If you have any questions about the information in this transmittal letter, please contact the MassHealth Customer Service Center at 1-800-841-2900, e-mail your inquiry to [providersupport@mahealth.net](mailto:providersupport@mahealth.net), or fax your inquiry to 617-988-8974.

**NEW MATERIAL**

(The pages listed here contain new or revised language.)

**Sterilization Clinic Manual**

Pages iv and 4-1 through 4-6

**OBSOLETE MATERIAL**

(The pages listed here are no longer in effect.)

**Sterilization Clinic Manual**

Pages iv and 4-1 through 4-4 — transmitted by Transmittal Letter STR-12

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Sterilization Clinic Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 485.000)	<b>Page</b> iv
	<b>Transmittal Letter</b> STR-18	<b>Date</b> 01/02/15

#### 4. Program Regulations

485.401: Introduction .....	4-1
485.402: Definitions .....	4-1
485.403: Eligible Members.....	4-1
485.404: Provider Eligibility .....	4-1
485.405: Covered Services .....	4-2
485.406: Assurance of Member Rights.....	4-2
485.407: Retroactive Eligibility .....	4-2
485.408: Locations in Which Sterilizations May Be Performed.....	4-2
485.409: Informed Consent Requirements .....	4-2
485.410: When Informed Consent Must Be Obtained.....	4-3
485.411: Consent Form Requirements.....	4-4
485.412: Maximum Allowable Fees.....	4-4
485.413: Recordkeeping Requirements .....	4-4

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>  Sterilization Clinic Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 485.000)	<b>Page</b> 4-1
	<b>Transmittal Letter</b> STR-18	<b>Date</b> 01/02/15

485.401: Introduction

130 CMR 485.000 applies to sterilization procedures for which sterilization clinics may claim payment under MassHealth.

485.402: Definitions

The following terms used in 130 CMR 485.000 have the meanings given in 130 CMR 485.402 unless the context clearly requires a different meaning.

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 that include the ability to consent to sterilization.

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

485.403: Eligible Members

- (A) (1) MassHealth Members. The MassHealth agency pays for sterilization clinic 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 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 about verifying member eligibility and coverage types, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

485.404: Provider Eligibility

Payment for the services described in 130 CMR 485.000 is made only to sterilization clinics that are participating in MassHealth as of the date of service. The eligibility requirements for sterilization clinics are as follows.

- (A) In State. A sterilization clinic located in Massachusetts is eligible to participate in MassHealth only if it licensed as a clinic by the Massachusetts Department of Public Health.

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 485.000)	<b>Page</b> 4-2
	<b>Transmittal Letter</b> STR-18	<b>Date</b> 01/02/15
Sterilization Clinic Manual		

(B) Out of State. A sterilization clinic located outside of Massachusetts is eligible to participate in MassHealth only if it meets the licensing requirements in its state, participates in that state's Medicaid program (or equivalent), and meets the requirements specified in 130 CMR 485.405 through 485.413.

485.405: Covered Services

The MassHealth agency pays for sterilization services provided to a member only if all of the following conditions are met.

- (A) The member has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 485.409 and such consent is documented in the manner described in 130 CMR 485.410.
- (B) The member is at least 18 years of age at the time consent is obtained.
- (C) The member is not a mentally incompetent individual or an institutionalized individual.

485.406: 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 payable under MassHealth.

485.407: 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 485.405 are met.

485.408: Locations in Which Sterilizations May Be Performed

Sterilizations must be performed by a licensed physician at a sterilization clinic.

485.409: Informed Consent Requirements

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 485.409(A) and (B), and such consent is documented as specified in 130 CMR 485.410.

- (A) The person who obtains consent (physician, nurse, or counselor, for example) must orally provide all of the following information and advice to the member requesting sterilization:
  - (1) advice that the individual is free to withhold or withdraw consent to 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 individual might be otherwise entitled;

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Sterilization Clinic Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 485.000)	<b>Page</b> 4-3
	<b>Transmittal Letter</b> STR-18	<b>Date</b> 01/02/15

- (2) a description of available alternative methods of family planning and birth control;
- (3) advice that the sterilization procedure is considered irreversible;
- (4) a thorough explanation of the specific sterilization procedure to be performed;
- (5) 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;
- (6) a full description of the benefits or advantages the member may expect as a result of the sterilization; and
- (7) advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in 130 CMR 485.410(A).

(B) The person who obtains consent must also:

- (1) offer to answer any questions the member may have about the sterilization procedure;
- (2) give the member a copy of the consent form;
- (3) make suitable arrangements to ensure that the information and advice required by 130 CMR 485.409(A) are effectively communicated to any member who is blind, deaf, or otherwise handicapped;
- (4) 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
- (5) allow the member to have a witness of the member's choice present when consent is obtained.

485.410: When Informed Consent Must Be Obtained

(A) 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 485.409. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

(B) 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:

- (1) in labor or childbirth;
- (2) seeking to obtain or obtaining an abortion; or
- (3) under the influence of alcohol or other substances that affect the individual's state of awareness.

(C) Shortly before the performance of the sterilization procedure, the physician performing the sterilization must orally inform the member of all of the information and advice specified in 130 CMR 485.409(A).

<b>Commonwealth of Massachusetts MassHealth Provider Manual Series</b>	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 485.000)	<b>Page</b> 4-4
	<b>Transmittal Letter</b> STR-18	<b>Date</b> 01/02/15
Sterilization Clinic Manual		

485.411: 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 *Sterilization Clinic Manual*.)

(A) Required Consent Form.

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

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

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

- (1) the original must be given to the member at the time of consent; and
- (2) a copy must be included in the member's permanent medical record at the site where the sterilization is performed.

(D) Provider Billing and Required Consent Form Submissions. 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 the sterilization procedure, each provider must submit a copy of the completed sterilization consent form with the claim.

485.412: Maximum Allowable Fees

The MassHealth agency pays sterilization clinics according to the rates and regulations established by the Executive Office of Health and Human Services (EOHHS) at 101 CMR 313.00: *Abortion and Sterilization Services Provided by Freestanding Clinics*. Payments are subject to the conditions, exclusions, and limitations set forth in 130 CMR 485.000 and 450.000: *Administrative and Billing Regulations*.

485.413: Recordkeeping Requirements

(A) Payment for any service listed in 130 CMR 485.000 is conditioned upon its full and complete documentation in the member's medical record. The sterilization clinic must maintain a record of all medical services provided to a member for at least six years following the date of service. See also the requirement contained in 130 CMR 485.411(C)(2).

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Sterilization Clinic Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 485.000)	<b>Page</b> 4-5
	<b>Transmittal Letter</b> STR-18	<b>Date</b> 01/02/15

- (B) The medical record must contain, but is not limited to, the following information:
- (1) the member's name, address, telephone number, date of birth, and MassHealth identification number;
  - (2) the date of service;
  - (3) the name, title, and signature of the person performing the service;
  - (4) the type of visit;
  - (5) medical history and history update;
  - (6) pertinent findings on examination;
  - (7) laboratory tests and results;
  - (8) abnormal findings and follow-up treatment;
  - (9) drugs administered or prescribed, including strength, dosage, route, regimen, and number of refills;
  - (10) drugs dispensed, including strength, dosage, route, regimen, and number of units;
  - (11) the contraceptive method used and any special instructions;
  - (12) a summary of counseling; and
  - (13) plans for follow-up.

(C) Basic information collected during previous visits with the member (for example, identifying data or medical history) does not need to be repeated in the medical record for subsequent visits as long as the entire medical record reflects continuity of care.

#### REGULATORY AUTHORITY

130 CMR 485.000: M.G.L. c. 118E, §§7 and 12.

<b>Commonwealth of Massachusetts</b> <b>MassHealth</b> <b>Provider Manual Series</b>  Sterilization Clinic Manual	<b>Subchapter Number and Title</b> 4. Program Regulations (130 CMR 485.000)	<b>Page</b> 4-6
	<b>Transmittal Letter</b> STR-18	<b>Date</b> 01/02/15

This page is reserved.