



Policy Title: Sterilization and Informed Consent		POLICY #: 70.2.39	
		Line of business: ALL	
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Department Head: Sr. Director, UM 			Date: 3/21
Medical Services/P&T Committee: (If Applicable) PHP CMO 			Date: 3/21

PURPOSE

To establish a process that ensures the UM Department meets the federal requirements in the provision of voluntary non-emergency and emergency sterilizations.

To comply with the sterilization consent form requirements, in accordance with 42 CFR 441.258.

DEFINITION:

The term “sterilization” as used in Medi-Cal regulations, means any medical treatment, procedure or operation performed for the purpose of rendering a person of either gender permanently incapable of reproducing.

Sterilizations performed because pregnancy would be life-threatening to the mother (therapeutic sterilizations) are included in the definition. However, where sterilization is the unavoidable secondary result of a medical procedure and the procedure is not being done in order to achieve that secondary result, the procedure is not included in the definition.

POLICY

Covered Procedures

A sterilization is covered under the Medi-Cal Managed Care program only if all of the following are true:

The patient to be sterilized is at least 21 years of age at the time the consent for sterilization is obtained, is not mentally incompetent, is able to understand the intent and nature of the informed consent process, is not institutionalized, and has voluntarily given informed consent in accordance with the regulations. For purposes of these requirements, the following shall apply:

- A patient considered mentally ill or mentally retarded may consent to sterilization if a physician determines that the patient is capable of understanding the nature and significance of the sterilizing procedure.
 - A patient considered mentally ill or mentally retarded may consent to sterilization if a physician determines that the patient is capable of understanding the nature and significance of the sterilizing procedure.
 - A mentally incompetent patient is defined as a person who has been declared mentally incompetent by the federal, state or local court of competent jurisdiction for any purpose, unless the person has been declared mentally competent for purposes which include the ability to consent to sterilization.

- An institutionalized patient is a person who is involuntarily confined or detained under civil or criminal statute in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or confined under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.
- Sterilization is covered only if at least 30 days and not more than 180 days have passed between the date the informed consent was signed and the date the sterilization was performed. The calendar day after the date the informed consent was signed and the date the sterilization was performed. The calendar day after the date the informed consent was signed is the first day of the 30-day waiting period.
- A hysterectomy is not covered under the Medi-Cal Managed Care Program if performed, or arranged, for a Medi-Cal Managed Care beneficiary solely for the purpose of rendering the patient permanently sterile; or, if there is more than one purpose for the operation, if the hysterectomy would not be performed except for the purpose of sterilization.

Sterilization may be performed at the time of emergency abdominal surgery if:

- The patient consented to sterilization at least 30 days prior to the intended date of sterilization, or the expected date of delivery, and
- At least 72 hours have passed between the time that written informed consent to be sterilized was given and the time of emergency surgery or premature delivery.
- The physician describes the emergency on the consent form.

Sterilization may be performed at the time of premature delivery if the physician certifies that:

- That written informed consent was given at least 30 days before the expected date of delivery. The physician shall state the expected date of delivery on the consent form
- At least 72 hours have passed after written informed consent to be sterilized was given.

Informed Consent Process for Sterilization Other than Hysterectomy

The informed consent process shall be conducted by a physician or by the physician's designee. Before obtaining the consent, the person who obtains consent shall give the patient to be sterilized a copy of the booklet on sterilization published by the Department of Health Care Services and a copy of the consent form to answer any questions the patient may have concerning the sterilization procedure, and provide all of the following information, orally to the patient to be sterilized:

- Advice that the patient 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 or withdrawal of any federally funded program benefits to which the patient might be otherwise entitled.
- A full description of available alternative methods of family planning and birth control
- Advise that the sterilization procedure is considered to be irreversible
- A full description of the discomforts and risks that may accompany or follow performance of the procedure, including an explanation of the type and possible effects of any anesthetic to be used.
- A full description of the benefits or advantages that may be expected as a result of the sterilization
- Approximate length of hospital stay
- Advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in Section 51305.1.

- The name of the physician performing the procedure. If another physician is to be substituted, the patient shall be notified, prior to administering pre-anesthetic medication, of the physician's name and the reason for the change in physician.
- Suitable arrangements were made to ensure that all information specified in this section was effectively communicated to any individual who is blind, deaf, or otherwise handicapped.
- An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent.
- The individual to be sterilized was permitted to have a witness of the individual's choice present when consent was obtained.
- The informed consent process may be conducted either by a physician or by the physician's designee. A copy of the signed consent form shall be:
 - Provided to the patient
 - Retained by the physician and the hospital in the patient's medical records
 - Attached to the physician's billing form
- The sterilization operation was requested without fraud, duress, or undue influence
- The consent form requirements of Section 51305.4 were met.

If the sterilization procedure to be used requires an inpatient stay, the patient shall be advised of the duration of the stay. However, inpatient stays for sterilizations are not required and the Department encourages the use of outpatient procedures whenever the health and welfare of the patient allow.

- Approximate length of time for recovery
- Financial cost to the patient

When Not to Obtain Sterilization Consent

Informed consent may not be obtained while the patient to be sterilized is:

- Under the influence of alcohol or other substances that affect the patient's state of awareness, or
- In labor, or within 24 hours postpartum or post abortion, or
- Seeking to obtain or obtaining an abortion: "seeking to obtain an abortion" means that period of time during which the abortion decision and the arrangements for the abortion are being made. "Obtaining an abortion" means that period of time during which a patient is undergoing the abortion procedure including any period during which preoperative medication is administered.

Sterilization Consent Documentation

- I. Consent to Sterilization
 - Name of the Doctor or Clinic
 - Specify the Type of Operation
 - Date of Birth
 - Name of the Doctor or Clinic
 - Type of Operation
 - Patient's Signature
 - Date of Signature

By signing the sterilization consent form the patient is informed:

- That the decision for sterilization is completely voluntary
- That the decision not to be sterilized will not affect her/his right to future care or treatment nor lose any help or benefits from federal funds
- That sterilization is permanent and not reversible

- That the operation will not be done until at least 30 days have passed after signing the consent form.
- That patient should be at least 21 years old at the time of signing of the consent form
- That the consent expires 180 days from the date of the patient's signature
- Patient consents to release of medical records to Department of Health Care Services or federal-funded agencies
- Patient rejects temporary methods of birth control that are available
- Patient attests that she does not want to become pregnant, bear children, or gather children
- The name of the operation, risks and benefits are explained

II. Interpreter's Statement

- Language that the interpreter read the consent in
- Interpreter's signature
- Date of the signature

If an interpreter is provided, he or she shall certify by signing the consent form that he or she:

- Transmitted the information and advice presented orally to the patient to be sterilized
- Read the consent form and explained its contents to the patient to be sterilized, and
- Determined to the best of his/her knowledge and belief that the patient to be sterilized understood what the interpreter told the patient.

III. Statement of the Person Securing Consent

- Name of the Patient
- Type of Operation
- Signature of Patient Obtaining the Consent
- Date of the Signature
- Facility
- Facility's Address

The person securing the consent shall certify by signing the consent form that he or she:

- Advised the patient to be sterilized, before the patient to be sterilized signed the consent form, that no federal benefits shall be withdrawn because of the decision not to be sterilized.
- Explained orally the requirements for informed consent to the patient to be sterilized as set forth on the consent form and in regulations
- Determined to the best of his/her knowledge and belief that the patient to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

IV. Physician's Statement

- Name of the Patient
- Date of Sterilization
- Type of Operation
 - Instruction for use if performed over 30 days or less than 30 days but more than 72 hours
 - Physician's Signature
 - Date of Signature

The physician performing the sterilization shall certify by signing the consent form that:

- The physician, shortly before the performance of the sterilization, advised the patient to be sterilized that deferral benefits shall not be withheld or withdrawn because of a decision not to be sterilized. (For the purposed of Medi-Cal Managed Care regulations,

the phrase “shortly before” means a period within 72 hours prior to the time the patient receives any preoperative medication).

- The physician explained orally the requirements for informed consent as set forth on the consent form.
- To the best of the physician’s knowledge and belief, the patient to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.
- At least 30 days had passed between the date of the patient’s signature on the consent form and the date the sterilization was performed, except in the following circumstances:
 - At the time of emergency abdominal surgery if the physician certifies that the patient consented to the sterilization at least 30 days before he/she intended to be sterilized and that at least 72 hours had passed after written informed consent to be sterilized was given. The physician shall describe the emergency on the consent form.
 - At the time of premature delivery if the physician certifies that the written informed consent was given by the patient at least 30 days before the expected date of the delivery and that at least 72 hours had passed after written informed consent to be sterilized was given. The physician shall state the expected date of the delivery on the consent form.

INFORMED CONSENT FOR HYSTERECTOMY:

Although there is no waiting period for a hysterectomy, a hysterectomy for a Medi-Cal managed Care beneficiary is only covered if all of the following are true:

- The person who secures the authorization to perform the hysterectomy has informed the Medi-Cal Managed Care patient and her representative, if any, that a hysterectomy will render her permanently sterile. The information must have been given both orally and in writing.
- The patient, and her representative, if any, have signed a written acknowledgement of the receipt of the required information and have received a copy of the written acknowledgement; and
- The patient has been informed of the right to consultation with a second physician

EXCEPTIONS TO HYSTERECTOMY INFORMED CONSENT REQUIREMENT

- Informed consent is not required if the patient is previously sterile. In these cases, a handwritten statement, signed by the physician, documenting the cause of sterility shall be maintained in the patient’s medical record.
- There is also no informed consent requirement for a hysterectomy if it is performed in a life-threatening emergency situation in which the physician determines that prior acknowledgement was not possible. In these cases, a handwritten statement of the nature of the emergency, signed by the physician, shall be maintained in the patient’s medical record.

CONSENT RECORD RETENTION AND DISTRIBUTION

A copy of the signed consent form shall be:

- Provided to the patient
- Maintained in the patient’s medical record by the physician and the hospital

REFERENCES

CCR Title 22, Section 51305.1, 51305.3, 51305.4

ATTACHMENT:

Consent Form