

POLICY AND PROCEDURE

<b>Policy Manual: Medi-Cal Manual</b>	<b>Origination Date: 2006</b>	<b>Policy #: III STD 9.1</b>
<b>Policy Title: Sterilization</b>	<b>Revision Dates:</b>	
<b>Standards/ Services</b>	<b>Last Reviewed Date: 4/06</b>	<b>Page 1 of 8</b>

**Applies To:**

Any Medi-Cal Managed Care member wishing to utilize family planning services.

**Policy:**

- A. Members may access family planning services both within and outside of ProMed Health Network on a self-referral basis without prior authorization.
- B. ProMed will establish methodology to produce reports upon request on these services when ProMed has authorized.

**Human Reproductive Sterilization Definition**

Under the regulations, human reproductive sterilization is defined as any medical treatment, procedure or operation for the purpose of rendering an individual permanently incapable of reproducing. Sterilizations that are performed because pregnancy would be life threatening to the mother (so-called “therapeutic sterilizations”) are included in this definition.

**Coverage Conditions**

A sterilization will be covered by Medi-Cal only if the following conditions are met:

1. The individual is at least 21 years old at the time written consent for sterilization is obtained.

*Note: Under Medi-Cal regulations, a patient must be 21 years old to give consent to a sterilization. This is a federal requirement for sterilizations only and is not affected by state law regarding the ability to give consent to medical treatment generally. The age limit is an absolute requirement. There are no exceptions for marital status, number of children or for a therapeutic sterilization.*

2. The individual is not mentally incompetent. A mentally incompetent individual is a person who has been declared mentally incompetent by the federal, state or local court of competent jurisdiction for any purposes which include the ability to consent to sterilization.
3. The individual is able to understand the content and nature of the informed consent process as specified in this section. A patient considered mentally ill or mentally retarded may sign the consent form if it is determined by a physician that the individual is capable of understanding the nature and significance of the sterilizing procedure.
4. The individual is not institutionalized. For the purposes of Medi-Cal, an institutionalized individual 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.
5. The individual has voluntarily given informed consent in accordance with all the requirements prescribed in this section.
  6. At least 30 days, but not more than 180 days, have passed between the date of the written and signed informed consent and the date of the sterilization, except in the following instances:
    - Sterilization may be performed at the time of emergency abdominal surgery **if**:
      - The patient consented to the sterilization at least 30 days before the intended date of sterilization, **AND**
      - At least 72 hours have passed after written informed consent was given and the performance of the emergency surgery.
    - Sterilization may be performed at the time of premature delivery if the following requirements are met:
      - The written informed consent was given at least 30 days before the expected date of the delivery, **AND**
      - At least 72 hours have passed after written informed consent to be sterilized was given.
  7. **A completed consent form must accompany claims for sterilization services. This requirement extends to all providers, attending physicians or surgeons, who perform the actual procedure. Claims for presurgical visits and tests or services related to postsurgical complications do not require consent documentation.**

## **Informed Consent Process**

The informed consent process may be conducted either by a physician or by the physician's designee.

An individual has given informed consent only if:

1. The person who obtained consent for the sterilization procedure:
  - Offered to answer any questions the individual may have had concerning the sterilization procedure, **AND**
  - Provided the individual with a copy of the consent form and the booklet on sterilization published by the Department of Health Services, **AND**
  - Provided orally all of the following information to the individual to be sterilized:

- ✓ 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 or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.
  - ✓ A full description of available alternative methods of family planning and birth control.
  - ✓ Advice that the sterilization procedure is considered to be irreversible.
  - ✓ A thorough explanation of the specific sterilization procedure to be performed.
  - ✓ A full description of the discomforts and risks that may accompany or follow performing 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.
  - ✓ Approximate length of time for recovery.
  - ✓ Financial cost to the patient, if any
  - ✓ Information that the procedure is established or new.
  - ✓ Advice that the sterilization will not be performed for at least 30 days, except under the circumstances of premature delivery or emergency abdominal surgery.
  - ✓ The name of the physician performing the procedure; if another physician is to be substituted, the patient shall be notified of the physician's name and the reason for the change in physicians prior to administering preanesthetic medication.
2. Suitable arrangements were made to ensure that the information specified above was effectively communicated to any individual who is blind, deaf, or otherwise handicapped.
  3. 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.
  4. The individual to be sterilized was permitted to have a witness of the individual's choice present when consent was obtained.
  5. The sterilization operation was requested without fraud, duress, or undue influence.
  6. The appropriate consent form was properly filled out and signed.
  7. Informed consent may not be obtained while the individual to be sterilized is:
  8. Under the influence of alcohol or other substances that affect the individual's state of awareness.

9. In labor or within 24 hours postpartum or postabortion.

10. Seeking to obtain or obtaining an abortion.

- “Seeking to obtain” 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 an individual is undergoing the abortion procedure, including any period during which preoperative medication is administered.
- Medi-Cal regulations prohibit the giving of consent to a sterilization at the same time a patient is seeking to obtain or obtaining an abortion. This does not mean, however, that the two procedures may never be performed at the same time. If a patient gives consent to sterilization, then later wishes to obtain an abortion, the procedures may be done concurrently. An elective abortion does not qualify as emergency abdominal surgery, and this procedure does not affect the 30-day minimum wait.

### **Sterilization Consent Form (PM 330) General Information**

The only sterilization consent form accepted by Medi-Cal is the Department of Health Services Consent Form (PM 330). .

**The sterilization *Consent Form* requirements are imposed by the Federal government and can be found in *California Code of Regulations*, Title 22, Section 51305.4.**

### **Ordering Forms**

Sterilization *Consent Forms* (English on one side, Spanish on the other) may be ordered at the following address:

**Department of Health Services  
Warehouse  
1037 North Market Boulevard, Suite 9  
Sacramento, CA 95834-1917**

Provide the following information when ordering:

- ✓ Date
- ✓ Name of document, PM 330)
- ✓ Name of county
- ✓ Name of provider/facility
- ✓ Complete shipping address: street, city, state, ZIP code (P.O. Box not accepted)
- ✓ Quantity of forms requested
- ✓ Contact person and phone number

## **Sterilization Consent Form Instructions**

1. Name of physician or clinic. Name of the doctor, group, clinic or hospital. If the provider is a physician group, all names may appear (for example, Drs. Miller and Smith), the professional group name may be listed (for example, “Westside Medical Group”) or the phrase “and/or his/her associates” may be used. This line may be pre-stamped or typed.
2. Name of procedure. Enter the full name of the procedure. If completing the *Consent Form* in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the *Consent Form* (numbers 2, 6, 13 and 20) and must match name of procedure on the claim. This line may be pre-stamped or typed.
3. Patient’s birthdate. Month, day and year required and must match the patient’s date of birth on the claim. The patient must be at least 21 years of age at the time consent is obtained.
4. Patient’s name. Must be consistent throughout the *Consent Form* (numbers 4, 7, 12 and 18) and must match the patient’s name on the claim. Print the last name first; use one letter per square.
5. Physician’s name. If a group, all provider’s names may be listed, or the phrase “and/or his/her associates.” This line may be pre-stamped or typed.
6. Name of procedure. Enter the full name of the procedure. If completing the *Consent Form* in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the *Consent Form* (numbers 2, 6, 13 and 20). This line may be pre-stamped or typed.
7. Patient’s signature. If the patient signs the consent form with an “X”, a symbol/character or in a non-Arabic alphabet, the signature must be countersigned by a witness. Must be consistent throughout the *Consent Form* (numbers 4, 7, 12 and 18).
8. Date. Patient’s signature must be dated with month/day/year. The required 30-day waiting period is calculated from this date.

### **Interpreter’s Statement:**

9. Language. Indicate the language in which the patient was counseled, in other than English or Spanish.
10. Interpreter’s signature. A signature is required if an interpreter was used.
11. Date. Interpreter’s signature must be dated with month/day/year.

### **Statement Of Person obtaining Consent**

12. Patient’s name. Patient’s name must be consistent throughout the *Consent Form* (numbers 4, 7, 12 and 18) and must match the patient’s name on the claim.
13. Name of procedure. Enter the full name of the procedure. If completing the *Consent Form* in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the *Consent Form* (numbers 2, 6, 13 and 20). This line may be pre-stamped or typed.
14. Signature of person obtaining consent. Signature required from person providing sterilization counseling; it may be a physician or the physician’s designee.

15. Date. Signature of the person obtaining consent must be dated with month/day/year.
16. Name of facility. Name of place where patient was given sterilization counseling, for example, a physician's office, clinic, etc. (Not necessarily the facility where the procedure was performed.) May be pre-stamped or typed.
17. Address of facility. Complete mailing address of facility identified in number 16. Must include street address, city, state and ZIP code. Once this section is completed, the patient must be given a copy of the consent form. May be pre-stamped or typed.

### **Physician's Statement**

18. Patient's name. Patient's name must be consistent throughout the *Consent Form* (numbers 4, 7, 12 and 18) and must match the patient's name on the claim.
19. Date. Enter month/day/year. This date must match the date of the procedure on the claim.
20. Name of procedure. Enter the full name of the procedure. If completing the *Consent Form* in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the *Consent Form* (numbers 2, 6, 13 and 20). This line may be pre-stamped or typed.
21. Paragraph one. Do not cross off paragraph one if the minimum waiting period of 30 days has been met; cross off paragraph two if the minimum waiting period of 30 days has been met.
22. Paragraph two. Do not cross off paragraph two if the minimum waiting period of 30 days has not been met; cross off paragraph one if the minimum waiting period of 30 days has not been met. In addition, mark either box "A" for premature delivery or box "B" for emergency abdominal surgery.
23. Premature delivery. Mark box "A" if the minimum waiting period of 30 days has not been met due to a premature delivery. Complete date of premature delivery (number 24) and date delivery was expected (number 25).
24. Premature delivery date. Date of premature delivery with month/day/year. This date must be at least 72 hours from the date consent was given by the patient and the date of the sterilization procedure. Must be completed if box "A" is marked.
25. Individual's expected date of delivery. Date of patient's expected delivery with month/day/year as estimated by physician based on the patient's history and physical condition. Must be completed if box "A" is marked. This date must be at least 30 days from the date consent was given by the patient (as identified in number 8).
26. Emergency abdominal surgery. Mark box "B" if the minimum waiting period of 30 days was not met due to emergency abdominal surgery or if 72 hours has not passed between the date the patient gave consent and the date of the emergency abdominal surgery. Enter name of the operation performed and describe the circumstances.
27. Physician's signature. Signature of the physician who has verified consent and who actually performed the operation is required.

28. Date. Physician's signature must be dated with month/day/year. Date must be on or after the sterilization date (refer to number 19).





## Sterilization Consent Form Signature

1. The *Consent Form* must be signed and dated by the:
  - a. individual to be sterilized,
  - b. interpreter, if one is provided,
  - c. individual who obtains the consent, and
  - d. physician who performed the sterilization procedure.
  
2. The person securing consent shall certify by signing the *Consent Form* that he or she:
  - a. advised the individual to be sterilized, before the individual to be sterilized signed the *Consent Form*, that no federal benefits may be withdrawn because of the decision not to be sterilized.
  - b. explained orally the requirements for informed consent to the individual to be sterilized as set forth on the *Consent Form* and in regulations.
  - c. determined to the best of his/her knowledge and belief that the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.
  
3. The physician performing the sterilization shall certify by signing the *Consent Form* that:
  - a. The physician, shortly before the performance of the sterilization, advised the individual to be sterilized that federal benefits shall not be withheld or withdrawn because of a decision not to be sterilized. (For the purposes of Medi-Cal regulations, the phrase “shortly before” means a period within 72 hours prior to the time the patient receives any preoperative medication.)
  - b. The physician explained orally the requirements for informed consent as set forth on the *Consent Form*.
  - c. To the best of the physician’s knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.
  - d. At least 30 days have passed between the date of the individual’s signature on the *Consent Form* and the date the sterilization was performed, except in the following instances:
  - e. Sterilization may be performed 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; that at least 72 hours have passed after written informed consent to be sterilized was given; and the physician describes the emergency on the *Consent Form*.
  - f. Sterilization may be performed at the time of premature delivery if the physician certifies that the written informed consent was given at least 30 days before the expected date of the delivery. The physician shall state the expected date of the delivery on the *Consent Form*. At least 72 hours have passed after written informed consent to be sterilized was given.
  
4. The interpreter, if one is provided, shall certify that he or she:
  - a. Transmitted the information and advice presented orally to the individual to be sterilized,

- b. Read the *Consent Form* and explained its contents to the individual to be sterilized, and
  - c. Determined to the best of his/her knowledge and belief that the individual to be sterilized understood what the interpreter told the individual.
5. A copy of the signed *Consent Form* must be:
- a. Provided to the patient,
  - b. Retained by the physician and the hospital in the patient's medical records, and
  - c. Attached to all claims for sterilization services. This requirement extends to all providers: attending physicians or surgeons, assistant surgeons, anesthesiologists and facilities. Only claims directly related to the sterilization surgery, however, require consent documentation. Claims for presurgical visits and tests or services related to postsurgical complications do not require consent documentation.

### **Procedures Requiring a Sterilization Consent Form**

*A sterilization Consent Form (PM330) is required for claims submitted by the provider who actually performed the sterilization procedure for sterilization services for Medi-Cal members.* Claims submitted with any of the following CPT codes require PM330 forms.

<b>CPT code</b>	<b>Description</b>
55250	Vasectomy
55450	Ligation (percutaneous of vas deferens, unilateral or bilateral
58600	Ligation or transaction of fallopian tube(s), abd or vag approach, unilateral or bilateral
58605	Ligation or transaction of fallopian tube(s), abd or vag approach, postpartum, unilateral or bilateral, during same hospitalization
58611	Ligation or transaction of fallopian tube(s), when done at the time of cesarean delivery or intra abdominal surgery
58615	Occlusion of fallopian tube(s) by device (eg, band, clip, Falope ring) vaginal or suprapubic approach
58661	Laparoscopy, surgical; with removal of adnexal structures ( partial or total oophorectomy and/or salpingectomy
58670	Laparoscopy; surgical; with fulgeration of oviducts (with or without transection
58671	Laparoscopy; surgical; with occlusion of oviducts by device (eg, band, clip, Falope ring)
58700	Salpingectomy, complete or partial, unilateral or bilateral