 <p>LA ALIANZA • THE ALLIANCE CENTRAL CALIFORNIA <b>ALLIANCE</b> FOR HEALTH</p>	<b>POLICIES AND PROCEDURES</b>
<b>Policy #: HS 3.48</b>	<b>Lead Department: Health Services</b>
<b>Title: Sterilization Consent Protocol</b>	
<b>Original Date: January 1996</b>	<b>Last Revision Date: July 2006</b>
<b>Approved by: Barbara Flynn, RN</b>	
<b>Applies to: All Lines of Business</b>	

***Policy Objective:***


To delineate the process for authorization of sterilization procedures.

***I. POLICY AND OBJECTIVES***


- II. Members who have procedures performed for the purpose of sterilization shall receive adequate information to make an informed decision. A properly executed Consent Form PM 330 shall reflect this decision.
- III. Members undergoing a hysterectomy shall be informed both orally and in writing that the procedure shall render the member permanently sterile. In addition, the members shall be informed of their right to a second opinion. A properly executed Consent Form PM 330 shall reflect this decision.
- IV. Informed consent is not required if the member has been previously sterilized as the result of a prior surgery, menopause, prior tubal ligation, pituitary or ovarian dysfunction, pelvic inflammatory disease, endometriosis or congenital sterility. In these cases, the provider must state the cause of sterility in the Remarks section of the claim form or as an attachment. This statement must be handwritten and signed by a physician. All assistant surgeons, anesthesiologist and inpatient provider claims must include a copy of the primary physician's statement.
- V. Informed consent is not required for a hysterectomy if it is performed in a life threatening emergency situation in which a physician determines that prior acknowledgment was not possible. In these cases, a handwritten statement of the nature of the emergency signed by the physician shall be attached to the claim. All assistant surgeon, anesthesiology and inpatient provider claims must include a copy of the primary physician's statement.
- VI. The Alliance is responsible for monitoring the provider to assure compliance with their responsibilities as previously outlined.

***VII. COVERAGE***

- A. Sterilization shall be covered only if all of the following are true:
  - 1. The member to be sterilized is at least 21 years of age at the time the consent for sterilization is obtained.
  - 2. The member is mentally competent.

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3. The member is able to understand the content and nature of the informed consent process; a mentally ill or mentally retarded member may consent to the sterilization if a physician determines the member is capable of understanding the nature and the significance of the sterilization procedure.
4. The member is not institutionalized.
5. The member has voluntarily given informed consent.
6. At least 30-days, but not more than 180-days, have passed between the date of the informed consent and the date of the sterilization. The calendar day after the date the informed consent was signed is the first day of the 30-day waiting period.
7. Sterilization may be performed at the time of emergency abdominal surgery or premature delivery if the following requirements have been met: (1) at least 72 hours have passed since the written informed consent was given and the performance of the procedure; (2) the member consented to the sterilization at least 30-days before the intended date of sterilization.
8. Medi-Cal regulations prohibit the giving of consent to sterilization at the same time a member 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 member 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.
9. Sterilization is covered only if all applicable requirements are met at the time the operation is performed. If the member obtains retroactive coverage, previously provided sterilization services cannot be covered by the Alliance unless all applicable requirements including the timely signing of an approved sterilization consent form have been met.
10. Reversals of sterilization procedures are not a covered benefit of the Medi-Cal program.

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11. Hysterectomy is not covered when performed solely for the purpose of rendering the member permanently sterile. A hysterectomy shall also not be covered if there is more than one purpose for the procedure and the hysterectomy would not be performed except for the purpose of rendering the member permanently sterile.

**VIII. INFORMED CONSENT PROCESS PERFORMED BY THE PROVIDER**

- A. The informed consent process shall be conducted either by a physician or by the physician's designee.
- B. A member has given informed consent only if-
  1. The provider who obtained consent for the sterilization procedure has completed the following requirements:
    - a. Offered to answer any questions the member may have had concerning the sterilization procedure.
    - b. Provided the member with a copy of the consent form and the booklet on sterilization published by the Department of Health Services.
    - c. Provided orally all of the following information to the member to be sterilized:
      - (1) Advice that the member 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 member might be otherwise entitled.
      - (2) A full description of available alternative methods of family planning and birth control.
      - (3) Advice that the sterilization procedure is considered to be irreversible.
      - (4) A thorough explanation of the specific sterilization procedure to be performed.

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- (5) A full description of the discomforts and risks that may accompany or follow the performance of 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 that may be expected as a result of the sterilization.
- (7) Approximate length of hospital stay.
- (8) Approximate length of time for recovery.
- (9) Financial cost to the member is NIL when the member is eligible for the month the service is to be provided;
- (10) Information that the procedure is established or new.
- (11) Advice that the sterilization shall not be performed for at least 30-days, except under the circumstances of premature delivery or emergency abdominal surgery as follows:
  - (a) Sterilization may be performed at the time of emergency abdominal surgery if the following conditions are met:
    - i) The patient consented to the sterilization at least 30-days before the intended date of sterilization.
    - ii) At least 72 hours have passed after written informed consent was given and the performance of the emergency surgery.
  - (b) Sterilization may be performed at the time of premature delivery if the following conditions are met:
    - i) The written informed consent was given at least 30-days before the expected date of delivery.

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ii) At least 72 hours have passed after written informed consent to be sterilized was given.

(12) The name of the physician performing the procedure; if another physician is to be substituted, the member shall be notified prior to administering pre-anesthetic medication of the physician's name and the reason for the change in physicians.


2. Suitable arrangements were made to ensure that the information specified above was effectively communicated to any member who is blind, deaf, or otherwise handicapped.
3. An interpreter was provided if the member to be sterilized did not understand the language used on the consent form or the language used by the member obtaining consent.
4. The member to be sterilized was permitted to have a witness of the member'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 completed and signed according the Medi-Cal Provider Manual for Medical Services.

C. The member may withhold or withdraw consent for sterilization at any time prior to the procedure without adverse effect to his/her participation in the Alliance or right to future care.

D. Within 72 hours prior to the time the member receives any pre-operative medication, the physician must advise the member that federal benefits shall not be withheld or withdrawn if the member chooses not to be sterilized.

E. Informed consent shall not be obtained while the member to be sterilized 's subject to the following:

1. In labor or within 24 hours postpartum or post abortion.
2. Seeking to obtain or obtaining an abortion.

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3. Under the influence of alcohol or other substances that affect the member's state of awareness.

***IX. STERILIZATION CONSENT DOCUMENTATION***

- A. The consent form shall include three signature certifications as follows:
  1. The member to be sterilized;
  2. The physician performing the sterilization;
  3. The interpreter, if present.
  
- B. The certifications assure the following:
  1. The member is mentally competent and knowledgeable and voluntarily consented.
  2. The member has received oral delivery of the requirements for informed consent.
  3. The member understood, to the interpreter's best belief, the translation of the physician's oral statements and the written consent statement.

***X. SANTA CRUZ COUNTY HEALTH OPTIONS TREATMENT AUTHORIZATION REQUEST (TAR) MONITORING PROCEDURE***

- A. The Alliance shall take the following steps to ensure provider compliance:
  1. Include in the Provider Orientation Manual, and provide periodically via the provider newsletter, a reminder to providers of regulations for informed consent for sterilization and hysterectomy.
  2. Send a copy of this protocol to all contracting providers who perform sterilization and hysterectomy procedures.
  3. Review the required TAR and any accompanying documentation to determine the following:
    - a. Medical necessity of a hysterectomy;
    - b. The necessity for an informed consent requirement; and

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- c. Proper completion and signing of the Consent Form PM330 in accordance with the Medi-Cal Provider Manual for Medical Services.
- 4. Defer and return TARs submitted without the appropriate form (PM330) to the provider for additional information according to standard TAR process described in the Alliance Utilization Management Protocol.

**Revision History:**

<b>Review Date</b>	<b>Revised Date</b>	<b>Approved By</b>
<b>December 1998</b>		<b>Barbara Flynn, RN</b>
<b>July 1999</b>		<b>Barbara Flynn, RN</b>
<b>July 2002</b>		<b>Barbara Flynn, RN</b>
<b>July 2006</b>		<b>Barbara Flynn, RN</b>