

**PARTNERSHIP HEALTHPLAN OF CALIFORNIA
POLICY/ PROCEDURE**

Policy/Procedure Number: MCUP3119 (previously under QI - MCQP1020, QP100120)		Lead Department: Health Services	
Policy/Procedure Title: Sterilization Consent Protocol		<input checked="" type="checkbox"/> External Policy <input type="checkbox"/> Internal Policy	
Original Date: QI Medi-Cal-4/25/1994 UM Medi-Cal-10/17/2012		Next Review Date: 06/08/2023 Last Review Date: 06/08/2022	
Applies to:	<input checked="" type="checkbox"/> Medi-Cal	<input type="checkbox"/> Employees	
Reviewing Entities:	<input checked="" type="checkbox"/> IQI	<input type="checkbox"/> P & T	<input checked="" type="checkbox"/> QUAC
	<input type="checkbox"/> OPERATIONS	<input type="checkbox"/> EXECUTIVE	<input type="checkbox"/> COMPLIANCE <input type="checkbox"/> DEPARTMENT
Approving Entities:	<input type="checkbox"/> BOARD	<input type="checkbox"/> COMPLIANCE	<input type="checkbox"/> FINANCE <input checked="" type="checkbox"/> PAC
	<input type="checkbox"/> CEO <input type="checkbox"/> COO	<input type="checkbox"/> CREDENTIALING	<input type="checkbox"/> DEPT. DIRECTOR/OFFICER
Approval Signature: Robert Moore, MD, MPH, MBA			Approval Date: 06/08/2022

I. RELATED POLICIES:

- A. MCUP3041 – Treatment Authorization Request (TAR) Review Process
- B. MPUP3078 – Second Medical Opinions
- C. MCUP3064 – Communication Services

II. IMPACTED DEPTS:

- A. Health Services
- B. Claims
- C. Member Services

III. DEFINITIONS:

- A. [Form PM330](#) – California Department of Health Care Services (DHCS) form entitled “Consent Form”
- B. 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.

IV. ATTACHMENTS:

- A. N/A

V. PURPOSE:

To describe the requisite consent procedures and delineate the conditions under which sterilization procedures (tubal sterilization, vasectomy and hysterectomy) are authorized under the Medi-Cal program in conformance with federal regulations.

VI. POLICY / PROCEDURE:

- A. Member Consent
 - 1. Members who have procedures performed for the purpose of tubal sterilization or vasectomy shall receive adequate information to make an informed decision. This decision shall be reflected by a properly executed [DHCS Consent Form PM 330](#).
 - 2. A physician may perform or arrange for a (non-emergency) hysterectomy only if:
 - a. The person who secures the authorization to perform the hysterectomy has informed the individual and the individual's representative, if any, orally and in writing that the hysterectomy will render the individual permanently sterile.

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- b. The individual (or representative) has signed a written acknowledgment of the receipt of the preceding information. The consent must be dated prior to the date of surgery.
 - c. The individual has been informed of the rights to consultation by a second physician. (see policy MPUP3078 – Second Medical Opinions).
 - d. A copy of the written acknowledgment signed by the patient must be:
 - 1) Provided to the patient
 - 2) Retained by the physician and the hospital in the patient's medical records, and
 - 3) Attached to claims submitted by physicians, assistant surgeons, anesthesiologists, and hospitals
 3. 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.
 4. Translation and interpretation services will be provided if the member to be sterilized does not understand the language used on the consent form or the verbal language used to obtain consent. Linguistic services are provided by Partnership HealthPlan (PHC) at no cost to monolingual, non-English speaking or Limited English Proficiency (LEP) Medi-Cal beneficiaries as well as eligible members with sensory impairment. These services include written translations, qualified oral interpreters, Video Remote Interpreters (VRI), sign language interpreters, use of California Relay Services for hearing impaired or bilingual providers and provider staff at key points of contact available in all languages spoken by Medi-Cal beneficiaries.
 5. Informed consent for sterilization is not required prior to a sterilizing or potentially sterilizing procedure 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 surgeon, anesthesiology and inpatient provider claims must include a copy of the primary physician's statement.
 6. The HealthPlan is responsible for monitoring providers to assure compliance with their responsibilities as previously outlined.
- B. Coverage Conditions
1. Some planned sterilization procedures require a Treatment Authorization Request (TAR). Providers should refer to the Medi-Cal Provider Manual/ Guidelines sections “Benefits: Family Planning” ([ben fam](#)) and “Sterilization” ([ster](#)) to determine if a TAR is required.
 2. Sterilization shall be covered only if all of the following are true:
 - a. The member to be sterilized is at least 21 years of age at the time the consent for sterilization is obtained.
 - b. The member is mentally competent (refer to definition of mentally incompetent at III.B).
 - c. The member is able to understand the content and nature of the informed consent process; a mentally ill or developmentally disabled 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.
 - d. The member is not institutionalized.
 - e. The member has voluntarily given informed consent.
 - f. At least 30 calendar days, but not more than 180 calendar days, have passed between the date of the written and signed 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-days waiting period.
 - 1) Tubal sterilization may be performed at the time of an emergency abdominal surgery if the member consented to the sterilization at least 30 calendar days before the intended date of

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sterilization AND at least 72 hours have passed after written informed consent was given and the performance of the emergency surgery.

- 2) Tubal sterilization may be performed at the time of premature delivery if the member gave written informed consent for sterilization at least 30 calendar days before the expected date of delivery AND at least 72 hours have passed after written informed consent to be sterilized was given.
 - g. Title 22 regulations prohibit giving consent to a tubal sterilization at the same time a member is seeking to obtain or is 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. This does not mean, however, that the two procedures may never be performed at the same time. If a 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.
 - h. 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 PHC unless all applicable requirements including the timely signing of an approved sterilization consent form were observed.
 - i. 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.
- C. Informed Consent Process Performed by the Provider:
The informed consent process shall be initiated by a physician or by the physician's designee (with an interpreter if needed), and then completed/confirmed by the physician performing the surgery. These activities are documented on the DHCS Consent [Form PM 300](#).
1. A member has given informed consent only if:
 - a. The provider who obtained consent for the sterilization procedure has completed the following requirements:
 - 1) Offered to answer any questions the member may have had concerning the sterilization procedure;
 - 2) Provided the member with a copy of the consent form and the [booklet on sterilization published by the Department of Health Care Services](#);
 - 3) Provided orally¹ all of the following information to the member to be sterilized:
 - a) 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;

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- b) A full description of available alternative methods of family planning and birth control;
 - c) Advice that the sterilization procedure is considered to be 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 performance of the procedure, including an explanation of the type and possible side 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;
 - g) Approximate length of hospital stay;
 - h) Approximate length of time for recovery;
 - i) Explanation that there is no financial cost to the member when they are eligible for Medi-Cal and have coverage with PHC for the month the service is to be provided;
 - j) Information that the procedure is established or new;
 - k) Advice that the sterilization shall not be performed for at least 30 calendar days, except under the circumstances of premature delivery or emergency abdominal surgery as detailed above in VI.B.1.f.
 - l) 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.
- b. Suitable arrangements were made to ensure that the information specified above was effectively communicated to any member who is visually or hearing impaired or otherwise disabled².
 - c. An interpreter will be provided if the member to be sterilized does not understand the language used on the consent form or the language used by the person obtaining consent.²
 - d. The member to be sterilized was permitted to have a witness of the member's choice present when consent was obtained.
 - e. The sterilization operation was requested without fraud, duress, or undue influence.
 - f. The appropriate consent form was properly completed and signed according to this policy.
2. 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 HealthPlan or right to future care.
 3. 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. The physician certifies this action by signing the Consent Form PM330.
 4. Informed consent shall not be obtained while the member to be sterilized is subject to the following:
 - a. In labor or within 24 hours postpartum or post abortion
 - b. Must not be within 30 calendar days of seeking to obtain or obtaining an abortion
 - c. Under the influence of alcohol or other substances that affect the member's state of awareness
- D. Sterilization Consent Documentation
1. The fully completed and signed consent form, as delineated above, shall be included in the member's medical record and include signature certifications as follows:

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- a. The member to be sterilized;
- b. The physician performing the sterilization;
- c. The interpreter, if required to obtain informed consent
2. The signature certifications assure the following:
 - a. The member is mentally competent and knowledgeably and voluntarily consented;
 - b. The member has received oral delivery of the requirements for informed consent;
 - c. The member understood, to the interpreter's best belief, the translation of the physician's oral statements and the written consent statement.
- E. Partnership HealthPlan of California Monitoring Procedure
 1. Claims submitted for procedures requiring informed consent are manually reviewed by the Claims Department for compliance.
 2. Review criteria included in the Facility Site Review:
 - a. Office staff have received training on informed consent requirements
 - b. Informed consent is present in the medical record for all operative and invasive procedures
 - c. A [DHCS Consent Form PM330](#) is present for human sterilization
 3. A Treatment Authorization Request (TAR) is required for hysterectomy and will be reviewed by the PHC Utilization Management (UM) staff for information about the medical necessity of a hysterectomy.

VII. REFERENCES:

- A. Title 22 California Code of Regulations [§ 51305.1](#)
- B. Medi-Cal Provider Manual/ Guidelines: Benefits: Family Planning (*ben fam*), Sterilization (*ster*)
- C. [DHCS Form PM 330 – Consent Form](#)
- D. [PM 330 Sterilization Consent Form Tips & Reminders for Successful Billing](#)
- E. [DHCS Sterilization Materials](#) (booklets on sterilization provided with consent forms)

VIII. DISTRIBUTION:

- A. PHC Department Directors
- B. PHC Provider Manual

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Senior Director, Health Services

X. REVISION DATES: 12/21/94; 10/10/97 (name change only), 06/20/01, 10/16/02; 02/16/05; 03/15/06; 03/21/07; 02/20/08; 03/18/09; 03/17/10; 05/18/11;(changed to UM) 10/17/12; 03/18/15; 03/16/16; 03/15/17; *06/13/18; 04/10/19; 05/13/20; 05/12/21; 06/08/22

*Through 2017, Approval Date reflective of the Quality/Utilization Advisory Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO:

In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:

- Consistent with sound clinical principles and processes
- Evaluated and updated at least annually

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- If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request

The materials provided are guidelines used by PHC to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under PHC. PHC's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.