



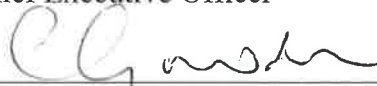
KERN HEALTH SYSTEMS

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POLICY AND PROCEDURES					
SUBJECT: Sterilization Consent			POLICY #: 2.19-P		
DEPARTMENT: Health Services – Quality Improvement					
Effective Date:	Review/Revised Date:	DMHC		PAC	
1997-08	12/12/2016	DHCS		QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	



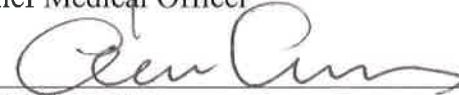
 Douglas A. Hayward
 Chief Executive Officer

Date 12/12/16



 Chief Medical Officer

Date 12/12/16



 Chief Operating Officer

Date 12-12-16



 Director of Claims

Date 12/8/16



 Administrative Director of Health Services

Date 12/7/16

POLICY:

To comply with federal and state regulations, Kern Health Systems (KHS) contracted providers will be required to obtain a sterilization consent form or Hysterectomy informed consent form for designated procedures prior to performing such procedures. The patient must meet the criteria in the guidelines that are established for sterilization and hysterectomy. KHS contracted providers should confirm that all of the applicable requirements are met at the time the procedure is performed, to receive reimbursement for performing such procedure.

DEFINITIONS:

Human Reproductive Sterilization	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
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	threatening to the mother (so called “therapeutic” sterilizations) are included in this 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 this definition. ¹
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PROCEDURES:

1.0 CRITERIA FOR ELIGIBILITY OF STERILIZATION PROCEDURE

All of the following criteria must be met in order for a sterilization procedure to be performed:

- A. The individual is at least 21 years old at the time written consent for sterilization is obtained. This is a federal requirement for sterilizations only, and is not affected by state law regarding the ability to give consent to medical treatment in general. The age limit is an absolute requirement. There are no exceptions for marital status, number of children, or for a therapeutic sterilization.
- B. 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 unless the individual has been declared competent for purposes which include the ability to consent to sterilization.²
- C. 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 a physician determines that the individual is capable of understanding the nature and significance of the sterilizing procedure.
- D. The individual is not institutionalized. For the purposes of reimbursement for sterilization, an institutionalized individual is a person who is:
 - (i) 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
 - (ii) Confined under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.
- E. The individual has voluntarily given informed consent in accordance with all of the federal requirements.
- F. 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:
 - (i) 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.
 - (ii) Sterilization may be performed at the time of premature delivery if the written informed consent was given at least 30 days before the expected date of delivery, and at least 72 hours have passed after written informed consent to be sterilized was given.

The sterilization operation must be requested without fraud, duress, or undue influence.³ Consent may not be obtained while the member is in labor, within 24 hours postpartum or postabortion, seeking to obtain or obtaining an abortion, or under the influence of substances that affect the member’s state of awareness.⁴

2.0 STERILIZATION CONSENT FORM

A completed consent form must accompany all claims for sterilization services.⁵ This requirement extends to all providers, attending physicians or surgeons, assistant surgeons, anesthesiologists, and facilities.

The only sterilization consent form accepted is the most current Department of Health Care Services' Consent Form (PM 330). (See Attachment A). Claims submitted with a computer generated form or any other preprinted forms are not reimbursed. However, the doctor or clinic name, and the name and address of the facility where the consent form is signed, may be stamped or typed in the appropriate fields of the PM 330. The form may then be photocopied prior to being completed and signed. Photocopies will only be acceptable if the entire form is legible.

Sterilization Consent forms and a patient's information booklet can be downloaded for printing, in English or Spanish.

Brochures: www.dhcs.ca.gov

Consent Form PM 330: https://files.medi-cal.ca.gov/pubsdoco/forms/PM-330_Eng-SP.pdf

Questions about Medi-Cal sterilization service can be directed to:

Department of Health Care Services
Medi-Cal Benefits, Waiver Analysis and Rates Division
MS 4601
1501 Capitol Avenue, Suite 71.4001
P.O. Box 997417
Sacramento, CA 95889-7417
(916) 552-9797

3.0 CERTIFICATION OF CONSENT

The sterilization consent form must be signed and dated by:

- 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

The member must be permitted to have a witness of his/her choice present when consent is obtained.⁶

3.1 Individual who Obtains Consent

Before obtaining consent, the person who obtains consent must provide the individual to be sterilized with a copy of the booklet on sterilization provided by DHCS in English and Spanish, offer 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:⁷

- A. 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

- 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 performance of the procedure, including an explanation of the type and possible 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. Financial cost to the patient (no cost for Medi-Cal members)
- J. Information as to whether the procedure is established or new
- K. Advice that the sterilization will not be performed for at least 30 days from the time the consent form is signed, except under the circumstances of premature delivery or emergency abdominal surgery
- L. The name of the physician performing the procedure. If another physician is substituted, it must be documented on the consent form and the patient shall be notified of the physician's name and the reason for the change in physicians prior to administering preanesthetic medication.

Suitable arrangements must be made to ensure that the information specified above was effectively communicated to any member who is blind, deaf, or otherwise handicapped.⁸

The person securing the 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.⁹
- 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.

3.2 Physician who Performs Sterilization

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 should not be withheld or withdrawn because of a decision not to be sterilized. For purposes of KHS regulations, the phrase "shortly before" means a period within 72 hours prior to the time the patient receives any preoperative medication.¹⁰
- 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.¹¹

- 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:

(i) 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; and 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.¹²

(ii) 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 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.

3.3 Interpreter

An interpreter must be provided if the member does not understand the language used on the consent form or the language used by the person obtaining consent.¹³ 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.

3.4 Distribution of Completed Consent Forms

A copy of the signed consent form must be¹⁴:

- A. Provided to the patient
- B. Retained by the physician and the hospital in the patient's medical records
- C. Attached to all claims for sterilization services

Requirement "C" extends to all providers including attending physicians or surgeons, assistant surgeons, anesthesiologists, and facilities.

4.0 HYSTERECTOMY INFORMED CONSENT

A hysterectomy is not covered under the Medi-Cal program if performed, or arranged, 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.¹⁵

Informed consent is not required if an individual has previously been sterilized as the result of prior surgery, menopause, prior tubal ligation, pituitary or ovarian dysfunction, pelvic inflammatory disease, endometriosis, or congenital sterility. When submitting a claim for a patient previously sterilized, the provider must state the cause of sterility. This statement

must be handwritten and signed by a physician.

There is no waiting period for a hysterectomy. There is no informed consent requirement if a hysterectomy is performed in a life-threatening emergency in which the physician determines prior acknowledgment was not possible. In this case, a statement handwritten and signed by the physician, certifying the nature of the emergency must accompany the claim. A diagnosis alone will not justify this service as an emergency.

A physician may perform or arrange for a 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. The person who secures authorization may transmit the written information to the patient on a hospital form, a physician-designed form, or a written statement.
- B. The individual or the individual's representative, if any, has signed a written acknowledgment of the receipt of the preceding information. The consent must be dated prior to the date of surgery. Although the consent form for sterilization (PM330) is not ideal for hysterectomy patients because the age and the waiting period are inapplicable, these forms are adequate so long as the name of the operation is clearly denoted as "hysterectomy". A consent form signed previously for tubal ligation, however, is not acceptable.
- C. The individual has been informed of the rights to consultation by a second physician.¹⁶

A copy of the written acknowledgment signed by the patient must be:

- A. Provided to the patient.
- B. Retained by the physician and the hospital in the patient's medical records.
- C. Attached to claims submitted by physician, assistant surgeons, anesthesiologists, and hospitals.¹⁷

5.0 STERILIZATION CONSENT FORM (PM 330) CORRECTIONS

Providers whose claims are denied with a result of incorrectly completed sterilization Consent Form will receive a package with the materials required for correcting the sterilization Consent Form. The package will include a Sterilization Consent Form Corrections letter explaining the process of correcting the sterilization Consent Form (see Attachment B), a sample sterilization Consent Form (see Attachment C) indicating the fields (numbers) on the form that were either completed incorrectly or contained insufficient information and a copy of the original claim. The provider then may resubmit the corrected form according to the instructions in the letter (attachment B).

ATTACHMENTS:

- ❖ Attachment A – *Sterilization Consent Form (PM330)*
- ❖ Attachment B - *Sterilization Consent Form Corrections letter*
- ❖ Attachment C – *Sample Sterilization Consent Correction form*

REFERENCE:

Revision 2016-12: Reviewed by QI Supervisor. Updated link to PM 330.

Revision 2015-07: Routine review performed by Quality Improvement Supervisor. **Revision 2012-01:** Revisions provided by Claims Manager. Address and web-sites updated. New Section 5.0 adds information to correct a sterilization consent form. **Revision 2010-05:** No revision required per Director of Quality Improvement, Health Education & Disease Management. Titles updated. **Revision 2009-07:** Reviewed by Director of Quality Improvement, Health Education & Disease Management. No revision needed, signature lines updated. Not reviewed by the AIS Compliance Department. **Revision 2006-09:** Revised per DIIS Workplan comments (04/26/06). **Revision 2005-08:** Policy reviewed by QI/UM Manager April 2004 and July 2005. **Revision 2002-08:** Revised per DHS Comment 05/13/02.

¹ COB Letter 87-1 §2.1

² 22 California Code of Regulations §51305.1(b)(1)

³ 22 California Code of Regulations §51305.3(a)(5)

⁴ 22 California Code of Regulations §51305.3(b)

⁵ 22 California Code of Regulations §51305.3(c)(3)

⁶ 22 California Code of Regulations §51305.3(a)(4)

⁷ 22 California Code of Regulations §51305.3(a)(1); COB Letter 87-1 §3.0

⁸ 22 California Code of Regulations §51305.3(a)(2)

⁹ 22 California Code of Regulations §51305.4(b)(1)

¹⁰ 22 California Code of Regulations §51305.4(c)(1)

¹¹ 22 California Code of Regulations §51305.4

¹² 22 California Code of Regulations §51305.4

¹³ 22 California Code of Regulations §51305.3(a)(3)

¹⁴ 22 California Code of Regulations §51305.3(c)

¹⁵ COB Letter 87-1 §2.2

¹⁶ 22 California Code of Regulations §51305.6

¹⁷ 22 California Code of Regulations §51305.6 (c)

CONSENT FORM
PM 330

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from [doctor or clinic]. When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a [Name of procedure]

The discomforts, risks and benefits associated with the operation have been explained to me. All of my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on [Mo] / [Day] / [Yr]

Grid for entering date of birth (Last, M, I)

I hereby consent of my own free will to be sterilized by [Doctor's name] by a

method called [Name of procedure]

My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

- Representatives of the Department of Health and Human Services.
Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature of individual to be sterilized Date: [Mo] / [Day] / [Yr]

INTERPRETER'S STATEMENT

If an Interpreter is provided to assist the individual to be sterilized: I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent

form in [language] language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Signature of Interpreter Date: [Mo] / [Day] / [Yr]

STATEMENT OF PERSON OBTAINING CONSENT

Before [Name of individual to be sterilized] signed the consent form, I explained to him/her the nature of the sterilization operation [Name of procedure], the fact that it is intended to be a final and irreversible procedure and the discomforts, risks, and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at anytime and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure.

Signature of person obtaining consent Date: [Mo] / [Day] / [Yr]

Name of Facility where patient was counseled

Address of Facility where patient was counseled City State Zip Code

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon

[Name of individual to be sterilized] on

[Date of Sterilization], I explained to him/her the nature of the sterilization operation [Name of procedure]

the fact that it is intended to be final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(Instructions for use of Alternative Final Paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery when the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph below which is not used.

(1) At least thirty days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box below and fill in information requested.)

A Premature delivery date: [Mo] / [Day] / [Yr] Individual's expected date of delivery: [Mo] / [Day] / [Yr] (Must be 30 days from date of patient's signature).

B Emergency abdominal surgery; describe circumstances: []

Signature of Physician performing surgery Date: [Mo] / [Day] / [Yr]

Dear Kern Health Systems Provider,

In reviewing the sterilization **Consent Form PM 330** accompanying your claim, we identified an area(s) of insufficient or incorrect information. As this information is required by State and Federal rules and regulations for sterilizations performed under the Medi-Cal program, we are unable to process your claim as it was submitted.

To facilitate the resolution of your denied claim, we have enclosed the materials necessary for properly completing the sterilization **Consent Form PM 330** in accordance with Medi-Cal specifications. These materials include the following:

- A copy of your original claim.
- A sample sterilization **Consent Form PM 330**, indicating the specific information required by KHS for proper claim adjudication.

The sample sterilization **Consent Form PM 330** on the reverse side of this letter shows the fields of information labeled numerically. To the right of the sample form is a corresponding explanation for each of these fields (numbers). We have marked on this sample form the fields (numbers) for which you must provide either corrected or additional information so that we can process your claim. These fields are marked with an "X".

Please provide the correct and or additional information, designated with an "X" on the sample sterilization **Consent Form PM 330**, in the corresponding field on the copy of your original sterilization **Consent Form PM 330**. For example, if number 4, "Patient's Name", is designated with an "X" on the sample sterilization **Consent Form PM 330**, provide the appropriate information in the corresponding field on the copy of your original sterilization **Consent Form PM 330**. All changed information should be initialed. Do not use correction fluid or tape to blot out errors. Errors should be lined out and initialed.

Please return the following to KHS, P.O. Box 25003 Bakersfield, Ca. 93311

- The copy of your original claim.
- The corrected copy of your original sterilization **Consent Form PM 330**.
- A copy of the Explanation of Benefits showing the denied claim.

If you need further assistance in submitting a corrected **Consent Form PM 330**, please contact your provider relations representative at (661) 664-5000.



