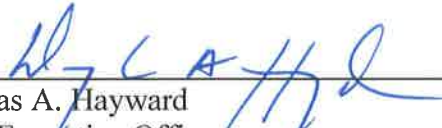





# KERN HEALTH SYSTEMS


KERN HEALTH SYSTEMS					
POLICY AND PROCEDURES					
SUBJECT: Sterilization Consent			POLICY #: 2.19-P		
DEPARTMENT: Health Services – Quality Improvement					
Effective Date:	Review/Revised Date:	DMHC		PAC	
1997-08	2/21/2020	DHCS		QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	

  
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 Douglas A. Hayward  
 Chief Executive Officer


Date 2/21/20

  
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 Chief Medical Officer

Date 2/20/2020

  
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 Chief Operating Officer

Date 2/13/2020

  
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 Chief Health Services Officer

Date 2/13/2020

  
 \_\_\_\_\_  
 Director of Claims

Date 1/29/2020

  
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 Director of Quality Improvement

Date 1/28/2020

**POLICY:**

To comply with federal and state regulations, Kern Health Systems (KHS) contracted providers will be required to obtain a sterilization consent form sterilization procedures (tubal sterilization, vasectomy and hysterectomy) 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:**

<b>Human Reproductive Sterilization</b>	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. 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. <sup>1</sup>
<b>Form PM330</b>	California Department of Health Care Services (DHCS) form entitled “Consent Form”

**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. 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.
- B. 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.
- C. 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.<sup>2</sup>
- D. 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.
- E. 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.
- F. The individual has voluntarily given informed consent in accordance with all of the federal requirements.
- G. 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.<sup>3</sup> 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.<sup>4</sup>

## **2.0 STERILIZATION CONSENT FORM**

A completed consent form must accompany all claims for sterilization services.<sup>5</sup> 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: <https://www.dhcs.ca.gov/Pages/permanentbirthcontrol.aspx>  
Consent Form PM 330: [https://files.medi-cal.ca.gov/pubsdoco/forms/PM-330\\_Eng-SP.pdf](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  
Benefits Division  
(916) 552-9400

## **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.<sup>6</sup>

### **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:<sup>7</sup>

- 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 treatment and without loss or withdrawal of any federally funded program benefits to which the patient might be otherwise entitled
- 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 pre-anesthetic 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.<sup>8</sup>

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.<sup>9</sup>
- 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.<sup>10</sup>

- 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.<sup>11</sup>
- 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.<sup>12</sup>
  - (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.<sup>13</sup> 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 be<sup>14</sup>:

- 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.<sup>15</sup>

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.<sup>16</sup>

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.<sup>17</sup>

## **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:

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**Revision 2020-01:** Reviewed by Director of Quality Improvement. Added clarification of sterilization procedures and of completion of the PM330 Sterilization Consent Form. **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 DHS 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.

<sup>1</sup> COB Letter 87-1 §2.1

<sup>2</sup> 22 California Code of Regulations §51305.1(b)(1)

<sup>3</sup> 22 California Code of Regulations §51305.3(a)(5)

<sup>4</sup> 22 California Code of Regulations §51305.3(b)

<sup>5</sup> 22 California Code of Regulations §51305.3(c)(3)

<sup>6</sup> 22 California Code of Regulations §51305.3(a)(4)

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

<sup>8</sup> 22 California Code of Regulations §51305.3(a)(2)

<sup>9</sup> 22 California Code of Regulations §51305.4(b)(1)

<sup>10</sup> 22 California Code of Regulations §51305.4(c)(1)

<sup>11</sup> 22 California Code of Regulations §51305.4

<sup>12</sup> 22 California Code of Regulations §51305.4

<sup>13</sup> 22 California Code of Regulations §51305.3(a)(3)

<sup>14</sup> 22 California Code of Regulations §51305.3(c)

<sup>15</sup> COB Letter 87-1 §2.2

<sup>16</sup> 22 California Code of Regulations §51305.6

<sup>17</sup> 22 California Code of Regulations §51305.6 (c)