

Informed Consent and Sterilization

Federal Medicaid law requires that a State plan must provide that its Medicaid agency will make a payment under the plan for sterilization procedures and hysterectomies only if all federal requirements are met.¹ In California, the conditions for sterilization procedures conform to federal regulations and are as follows:

Criteria for the Performance of Sterilization²

- The individual must be at least 21 years old at the time consent is obtained;
- The individual must not be mentally incompetent;
- The individual must be able to understand the content and nature of informed consent;
- The individual must not be institutionalized;
- The individual must have voluntarily given informed consent in accordance with the statutorily prescribed requirements;
- At least 30 days, but not more than 180 days must have passed between the date of written consent and the date of sterilization.³

Informed Consent Process for Sterilization⁴

- In order for informed consent to be given, the individual obtaining the consent must first offer to answer any question the patient may have concerning the procedure and provide the patient with a copy of the consent form and the booklet on sterilization provided by the Department of Health Services.
- The person who obtained the consent must have also orally provided 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 and without loss or withdrawal of any federally funded program benefits to which the individual might have otherwise been 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 the procedure, including an explanation of the type and possible effects of any anesthetic to be used;
 - A full description of the benefits and advantages that may be expected as a result of the sterilization;
 - The approximate length of the hospital stay;
 - The approximate length of the time for recovery;

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- The financial cost to the patient;
 - Information that the procedure is established or new;
 - Advice that the sterilization will not be performed for at least 30 days, except in specific circumstances surrounding emergency abdominal surgery and premature delivery.⁵
 - The name of the physician performing the procedure, or if another physician is to be substituted, the patient must be notified of the physician's name and the reason for the change prior to administering pre-anesthetic medication.
- Suitable arrangements must be made to ensure that all requisite information was effectively communicated to any individual who is blind, deaf, or otherwise disabled. Further, the person obtaining the consent must have provided an interpreter if the individual being sterilized did not understand the language used on the consent form, or by the person.
 - The individual being sterilized must be permitted to have a witness of the individual's choice present when consent is obtained.
 - The sterilization operation must be requested without fraud, duress, or undue influence.
 - Informed consent for sterilization may not be obtained while the individual is in labor or within 24 hours postpartum or post abortion; (ii) seeking to obtain an abortion; or (iii) under the influence of alcohol or other substances that affect the individual's state of awareness.
 - The informed consent procedure may be conducted either by the physician or the physician's designee.
 - A copy of the signed informed consent form shall be provided to the patient, retained by the physician and the hospital, and attached to the physician's billing form.

Certification of Informed Consent for Sterilization⁶

- The consent form provided by the Department of Health Services in English and Spanish is the only form approved for use and must be signed and dated by the individual to be sterilized, the interpreter if one is provided, the person who obtained the consent, and the physician who performed the sterilization procedure.⁷

Penalties for Failure to Comply with Sterilization Requirements

Penalties for Providers

No payment for care or services will be made under Medi-Cal to the attending physician for the costs of any voluntary non-emergency sterilization unless the authorization request is accompanied by the documents evidencing compliance with the requisite informed consent procedures.⁸

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Data acquired by the Department of Health Services regarding failure by health care providers to comply with the sterilization informed consent procedures promulgated in the Medi-Cal regulations will also be forwarded to the Medical Board of California.⁹ The Medical Board of California has authority under the Medical Practice Act to investigate complaints and discipline physicians who violate the law.¹⁰

The Medical Practice Act specifically provides that failure to comply with the requirements of informed consent for sterilization requirements under Medi-Cal constitutes unprofessional conduct.¹¹ The board has a variety of penalties it may impose at its discretion on providers that are found guilty of unprofessional conduct, including: revoking the physician's license, suspending the physician's right to practice for a period of not more than one year, placing the physician on probation, or subjecting the physician to any other discipline the administrative law judge deems proper.¹²

Currently, no cases have been brought that set a precedent for actions against physicians or surgeons for violating informed consent rules regarding sterilization. However, penalties imposed on physicians for other various acts of unprofessional conduct under the Medical Practice Act and upheld by California courts have included the following:

- A physician who sustained two misdemeanor convictions involving the consumption of alcoholic beverages was placed on three years probation and given several terms to meet, among them a psychiatric evaluation, testing, and treatment, medical evaluation and treatment, abstention from alcohol and use of controlled substances and community service.¹³
- A physician who employed an unlicensed person to engage in the practice of medicine had his approval to supervise physician's assistants revoked, along with his physician and surgeon's certificate.¹⁴ The revocation was then stayed for three years and the physician was placed on probation.
- Two physicians who had lawfully changed their names violated a provision requiring physicians to be licensed under their own names and obtain duplicate licenses for name changes were found guilty of unprofessional conduct and fined \$250 each.¹⁵
- A physician who pleaded guilty to soliciting the subornation of perjury, and who was also found to suffer from a mental illness that prohibited him from practicing medicine with reasonable skill was charged with unprofessional conduct and had his license revoked.¹⁶

Bringing a Complaint Under the Medical Practice Act

Under this Act, the Division of Medical Quality carries out all proceedings against a licensee for unprofessional conduct in accordance with the Administrative Procedure Act.¹⁷

Accusations may be raised against licensees by health care consumers and must be filed within three years of the board discovering the grounds for action, or within seven years after the act alleged for disciplinary action occurs, whichever event occurs first.¹⁸ As an alternative to filing

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or prosecuting a formal accusation, the Division of Medical Quality may also agree to issue a public letter of reprimand for minor violations after it has conducted its investigation.¹⁹

Penalties for Health Facilities

Failure by health facilities to comply with Medi-Cal regulation constitutes cause for suspension as a provider of services under Medi-Cal.²⁰

ENDNOTES

1 42 C.F.R. § 441.52.

2 Cal. Code Regs. tit. 22 § 51305.1 et seq. (CCH Incorporated through 2002 session); Cal. Welf. & Inst. Code § 14191 (West 2001). See California Medical Association v. Lackner, 124 Cal. App. 3d 28 (1981)(upholding the Department of Health Services' authority under Cal. Bus. & Prof. Code § 1250 to promulgate informed consent regulations). See also Medi-Cal Provider Manual, Part 2 – Obstetrics (OB), Sterilization (September 1999).

3 *But see* Cal. Code Regs. tit. 22 §§ 51305.1 subdvs. 6(A)(1), (2) & (B)(1), (2) (providing that sterilization may be performed at the time of emergency abdominal surgery if the written informed consent to be sterilized was given at least 30 days before the individual intended to be sterilized; and at least 72 hours have passed after written informed consent to be sterilized was given. Sterilization may also 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).

4 Cal. Code Regs. tit. 22 § 51305.3 et seq. (CCH Incorporated through 2002 session); Cal. Welf. & Inst. Code § 14191 (West 2001). See also Medi-Cal Provider Manual, Part 2 – Obstetrics (OB), Sterilization (September 1999).

5 For a description of specific services, see *supra* note 3.

6 Cal. Code Regs. tit. 22 § 51305.4 et seq. (CCH Incorporated through 2002 session); Cal. Welf. & Inst. Code § 14191 (West 2001). See also Medi-Cal Provider Manual, Part 2 – Obstetrics (OB), Sterilization (September 1999).

7 For a specific description of what each party must certify, see Cal. Code Regs. tit. 22 §§ 51305.4(b)-(e) (CCH Incorporated through 2002 session).

8 Cal. Welf. & Inst. Code § 14191 (West 2001).

9 Cal. Welf. & Inst. Code § 14193 (West 2001).

10 See <http://www.medbd.ca.gov/boardrole.htm>.

11 Cal. Bus. & Prof. Code § 2250 (West 1990). See also Cal. Bus. & Prof. Code § 2234(a) – (g)(stating that unprofessional conduct includes violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter; gross negligence, repeated negligent acts, incompetence, etc).

12 Cal. Bus. & Prof. Code § 2227 (a)(1) – (5) (West 2002).

13 Griffiths v. Medical Board of California, 96 Cal. App. 4th 757 (2002) (considering a doctor's violation of Cal. Bus. & Prof. Code § 2239).

14 Khan v. Medical Board of California, 12 Cal. App. 4th 1834 (1003)(stating that the court is required to give significance of every word of an act in pursuance of the legislative purpose, and that where the language is clear, there can be no room for interpretation.)(Internal citations omitted).

15 Lin v. Medical Board of California, 52 Cal. App. 4th 39 (1997) (upholding a provision of the Medical Practice Act, which by its terms stated that practicing medicine under a name different than the name licensed under constituted unprofessional conduct).

16 Krain v. Medical Board, 71 Cal. App. 4th 1416 (1999)(affirming the revocation of a physician's license under the Medical Practice Act).

17 Cal. Bus. & Prof. Code § 2230(a) (CCH Incorporated through 2002 session).

18 Cal. Bus. & Prof. Code § 2230.5 (West 2002).

19 Cal. Bus. & Prof. Code § 2233 (West 2002).

20 Cal. Welf. & Inst. Code § 14192 (West 2001).