

SECTION 1.7 STERILIZATION PROGRAM

A. GUIDELINES

1. Clients applying for tubal ligations or Essure® will be able to have the procedure done only through those agencies that have agreed to receive funding through a family planning contract and have agreed to handle all provider agreements and billing.
2. Men who are themselves family planning clients may have a vasectomy done by a private physician who will sign a Memorandum of Understanding (MOU) with the agency and accept up to the maximum reimbursable amount. The delegate agency agrees to handle the MOUs and all billing and payment with the vasectomy providers. (See Agreements for Subcontracted Services in Section 2.5 - Financial Management of the Administrative Manual.)
3. Agencies agree to track all clients signing consents for sterilizations to confirm that the client has either followed through with the procedure, and the hysterosalpingogram (HSG), or sperm count if indicated, or decided to cancel the procedure.
4. Project personnel must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo a sterilization procedure.
5. If the agency needs to prioritize requests, priorities considered should include:
 - a. Medical complications with other methods
 - b. Ability/inability to use other methods
 - c. Child bearing risk
 - d. Emotional risks
 - e. Socio-economic factors
 - f. Number of children
 - g. Age

B. REGULATIONS AND CONSENTS

1. All sterilization requests must follow the guidelines of the Department of Health and Human Services. Sterilization of clients as part of the Title X Program and the Colorado Family Planning Initiative (CFPI), must be consistent with 42 CFR part 50 subpart B, ("Sterilization of Persons in Federally Assisted Family Planning Projects")
http://www.hhs.gov/opa/familyplanning/toolsdocs/ofp_reqs_42cfr50_10-1-2000.pdf

The most recent edition of the guidelines is included in this section.

Agency personnel must familiarize themselves with these requirements.

2. Physicians may request this information from the delegate agency or CDPHE Family Planning Program.
3. Agencies must use the federal consent for sterilization. There are English and Spanish versions of the consent.
4. In accordance with Colorado Revised Statute 25-6-206, a consent form in Spanish must be used for those clients who are more familiar with that language.
5. The federal regulations state that the person must be 21 years of age at the time a sterilization consent is obtained and mentally competent. Consents may not be obtained while the person is in labor, under the influence of alcohol or other drugs, or having an

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abortion.

6. Federal and CFPI funding may not be used for hysterectomies or for the sterilization of persons in correctional facilities, mental hospitals, or other rehabilitative facilities.
7. A 30-day waiting period between the time of consent and the time of the operation is required with no more than 180 days passing between the date of informed consent and date of sterilization.

C. POSTPARTUM STERILIZATION

1. Consent for sterilizations to be done during the immediate postpartum period (during hospitalization following delivery) must be signed 30 days before the expected date of delivery (EDD). Do not approve unless this 30-day time frame is met. In the case of a premature delivery, or emergency abdominal surgery, the 30 day consent may be waived if at least 72 hours have passed since the client signed the consent.
2. In order to approve a postpartum sterilization procedure for a pregnant client, the following conditions must exist:
 - a. The client prior to her pregnancy was a family planning client or is at the present time willing to fulfill all the requirements in order to be counted as a family planning client.
 - b. The client signs the request for approval at least thirty (30) days before her EDD (due date).

D. MENTAL COMPETENCE

Clients who are known to be mentally incompetent, defined as individuals who have been found to be mentally incompetent by a federal, state, or local court of competent jurisdiction, shall not receive sterilization services. Clients who are believed to be in counseling or under the care of a psychiatrist, psychologist, or mental health counselor shall receive in-depth counseling prior to making a decision regarding permanent sterilization.

E. PROCEDURE

Personnel in all agencies must first determine if the client has private insurance, Medicaid, or Medicare. Colorado Family Planning Initiative (CFPI) Funding should only be used for those who have no other source of payment. For the purposes of this program, a large deductible may be considered enough of a barrier to services that the client is considered to have no coverage. This should be documented in the client's chart.

1. The agency shall negotiate MOUs (Memorandum of Understanding) with providers that allow payment to come from its (agency's) office and that explain the procedure for requesting reimbursement. CDPHE fiscal staff is available for consultation in arranging referral relationships and MOUs.
2. The agency will notify the client of instructions for setting up her/his appointment.
3. Agencies receiving sterilization funds will receive these funds through a separate contract. The agency does not submit any client specific information, procedure dates, or provider reimbursement information to the CDPHE Family Planning Program. Each agency will submit reimbursement requests a maximum of once per month.
4. Any agency providing or referring clients for Essure®, tubal ligations or vasectomies must establish a follow-up protocol to determine if the client actually had the procedure

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done and the reason any procedures were not completed. Agencies must maintain a record of all clients sent for referral and document the follow-up to record whether or not the procedure was completed, including the HSG or sperm count, if indicated. Documentation that the provider was paid for the procedure and F/U testing is also needed. This information is necessary for any future audits that may take place. This follow-up information should also be documented in the client's file.

F. LAPAROSCOPY PROCEDURE (TUBAL LIGATION)

1. The laparoscopy procedure is basically the same method as described in the sterilization booklet. In most instances, however, the 2 incisions are made, one at the umbilicus and the other midline approximately 2 inches above the pubic bone.
2. Medical guidelines require that the client must have had a physical exam within the past six months, and should bring the written results with her to the physician appointment. The following are guidelines for selecting appropriate clients:
 - a. The client must weigh no more than 250 pounds.
 - b. The client's medical problems must be under current treatment and under control (includes hypertension and diabetes).
 - c. The client should be informed that the surgeon makes the final decision as to whether the tubal will be done after the initial medical evaluation.

G. ESSURE

1. Essure is an in-office sterilization procedure approved by the FDA in 2002.
2. The procedure requires only a paracervical block and non-steroidal anti-inflammatory drugs (no general anesthesia).
3. A small coil device is inserted in each fallopian tube via hysteroscopy.
4. The coil sets up an inflammatory response that causes extensive fibrosis and occlusion of the fallopian tube.
5. Tubal occlusion is evaluated at 12 weeks post-procedure via hysterosalpingogram (dye study), also called a low pressure HSG.
6. As with vasectomy, this procedure is not immediately effective and an interim method of birth control for a minimum of three months must be provided to those women at risk of pregnancy.
7. Because this procedure is technically easier when the endometrium is thinner, consideration should be given to:
 - a. Administering a shot of Depo Provera® approximately 2 weeks before the scheduled procedure, which would serve the dual purpose of providing post-procedure contraception until tubal occlusion is assured.
 - b. Recommending the procedure is scheduled immediately after menses.

H. TUBAL LIGATION, ESSURE, OR VASECTOMY PROCEDURE COMPLICATIONS

1. Complications arising from a sterilization procedure or an associated procedure (e.g., HSG) are not the financial responsibility of the delegate agency. The delegate agency

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shall provide clients with information on what is and is not paid for by the program or delegate agency prior to the client signing the consent.

2. Examples of such complications include but are not limited to the following:
 - a. Bleeding problems at incision sites or internally.
 - b. Infection on or near sutures or incision sites, or peritonitis (infection inside abdomen).
 - c. Problems relating to the use of anesthesia, e.g. allergic reactions to drugs; aspiration pneumonia, etc.
 - d. Perforation of the uterus or fallopian tube
3. If the procedure is deemed unsuccessful, e.g., Essure coil perforates or expels and the fallopian tube is not occluded on HSG or the sperm count indicates patent vas deferens, client may be considered for a repeat sterilization procedure or alternate sterilization procedure (e.g., incisional procedure vs. Essure procedure) through Colorado Family Planning Initiative funding. Approval must be obtained from the Colorado Family Planning Initiative staff.
4. If the initial HSG at 3 months post procedure reveals tubal patency in the presence of a properly placed coil, a repeat HSG should be scheduled at 6 months. Colorado Family Planning Initiative funds may be used to pay for the additional HSG.

I. VASECTOMY

1. Some physicians send a tissue sample to a laboratory following a vasectomy. Consideration of the lab cost of for this histology should be included in the negotiated charge from the provider.
2. Colorado Department of Public Health and Environment (CDPHE) considers a pre-op exam and **a post**-procedure sperm count as part of the physician's coverage under payment for the basic procedure. Agencies or clients are not expected to pay an extra fee for this.
3. A hospital fee will not be paid for a vasectomy procedure.
4. Complications arising from a sterilization procedure or an associated procedure are not the financial responsibility of the delegate agency. The delegate agency shall provide clients with information on what is and is not paid for by the program or delegate agency prior to the client signing the consent.
5. Examples of such complications include but are not limited to:
 - a. Bleeding problems at incision site or internally.
 - b. Infection on or near sutures or incision site.
 - c. Problems relating to the use of anesthesia, e.g. allergic reactions to drugs, etc.

J. ASSISTANT PHYSICIAN

An assistant physician fee is not reimbursable for any sterilization procedures.

K. RE-APPLICATION FOR PROCEDURES

1. If a client applies for a sterilization procedure but does not have the procedure done

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within the allotted time frame, the agency can decide whether or not he/she may reapply within that fiscal year.

2. If a client fails to have a sterilization procedure done after applying two times, he/she should not be accepted again for funding, unless there are extenuating circumstances.

L. POST TUBAL LIGATION, ESSURE, AND VASECTOMY FOLLOW-UP APPOINTMENTS

1. The delegate agency is encouraged to include a follow up appointment with the physician as part of the negotiated price in the MOU.
2. This follow up appointment shall be considered part of the package and shall not be billed as a separate visit.
3. The delegate agency may provide follow-up care if the client is not experiencing any complications.

M. CONSENT AND COUNSELING

Each project should provide, either directly or by referral, voluntary female and male sterilization counseling and procedures for those clients requesting such, in accord with the following:

1. All clients making inquiry about a sterilization procedure will be given initial counseling by a nurse, nurse practitioner, physician, or allied medical personnel, and will be provided with printed and/or video educational material relevant to the procedure desired.
2. A study reported in the April 1996 issue of AJOG (CREST Study) provided evidence that the failure rates for tubal ligations are greater for younger women (under 30) than previously thought and can occur several years after the procedure. There is not enough long term data to rate whether this is also true for younger women (under 30) undergoing the Essure procedure.
 - a. For some women, particularly under 28 years, tubal ligation may not be as effective as the IUD, Depo Provera, or Implanon® used over 10 years. Please keep this in mind when counseling women under 28 years of age.
 - b. If a woman in her 20's can use one of the more effective methods of birth control, such as a hormonal method or an IUD, she may want to consider doing so for a few more years.
3. The decision for performing sterilization as a family planning procedure is a matter between a mentally competent individual of legal age and the physician, and must be the voluntary decision of the individual with no coercion. The client should participate in the decision as to the method of sterilization.
4. Each agency must ensure that the individual is given the necessary information to arrive at an informed decision. This must include but need not be limited to:
 - a. Information concerning the permanence of the procedure.
 - b. Review of available temporary contraceptive methods.
 - c. Information concerning the surgical procedure and risks involved (complications and failures).

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- d. Information and instructions concerning the need for follow-up, particularly for males.
 - e. Information concerning relative merits of male vs. female sterilization in any specific situation (vasectomy as safer and easier procedure).
 - f. Information that sterilization should not interfere with sexual function or pleasure.
 - g. Information that sterilization will not necessarily resolve pre-existing psychological problems.
5. Consideration should be given to the following as indications for in-depth counseling prior to arriving at the decision to perform voluntary sterilization:
- a. The individual has physical, mental, or emotional conditions that he/she assumes would be improved by sterilization.
 - b. The individual is suffering from temporary economic difficulties, which may improve (if this is the basis of the request).
 - c. The individual is making this decision during a time of crisis or extreme stress.
 - d. The individual or couple is uncertain as to future reproductive goals.
 - e. The individual counts on reversing the operation in the case of circumstances such as remarriage or death of children.
 - f. The individual is seeking sterilization because of pressure exerted by the sexual partner.
 - g. The individual is young and has never reproduced.
6. Contraindications to sterilization are:
- a. Return of reproductive function may be desired.
 - b. The individual is not of legal age.
 - c. The individual is not mentally competent to give consent for sterilization.
 - d. Any evidence that the individual has been coerced.
 - e. The client has physical problems that place him/her at high risk for surgery (e.g., history of bleeding disorders or coagulopathies). The relative risk of sterilization as opposed to pregnancy should be evaluated.
 - f. The client is allergic to any anesthetics. (This is a relative risk that should be assessed by the physician.)
 - g. An examination of a male client reveals local scrotal pathology. (This is a relative risk that should be assessed by the physician.)
7. Projects receiving Federal or Colorado Family Planning Initiative funds to support sterilization must obtain the client's informed consent for "non-therapeutic sterilization"* at least 30 days prior to the planned procedure. Informed consent shall comprise but not be limited to the following:
- a. A fair explanation of the procedures to be followed.
 - b. A description of the attendant discomforts and risk.
 - c. A description of the benefits to be expected.
 - d. An explanation concerning appropriate alternative methods of family planning and the effect and impact of the proposed sterilization, including the fact that it must be

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- considered to be an irreversible procedure.
- e. An offer to answer any inquiries concerning the procedures.
 - f. An explanation that the individual is free to withhold or withdraw his or her consent to the procedure at any time prior to the sterilization without prejudicing his or her future care, and without loss of other project or program benefits to which the individual might otherwise be entitled.
 - g. An interpreter must be provided if the client does not understand the language used on the consent form or the language used by the person obtaining the consent.
 - h. Suitable arrangements must be made for effective communication for clients who are blind, deaf or otherwise handicapped.
 - i. The informed consent must be documented by a complete consent form which meets the requirements of 42 CFP 50.202(d)(7). For approved sterilization consent forms see <http://www.opaclearinghouse.org/title.html> Pamphlets containing information that a client must have in order to give an informed consent have been published for the instruction of clients considering non-therapeutic sterilization. Videotapes on sterilization may be used as well.
 - j. If the physician performing the sterilization is not the person obtaining the individual's consent, there should be an oral explanation of the above points by such physician in order to be sure that the individual has been fully informed, understands the sterilization procedure, and has freely given consent.
8. Local laws should be followed in regard to obtaining consent of the spouse. There is no Federal requirement for spousal consent.
 9. "Non-therapeutic sterilization" means any procedure or operation, the purpose of which is to render an individual permanently incapable of reproducing, and which is not either (1) a necessary part of the treatment of an existing illness or injury, or (2) medically indicated as an accompaniment of an operation on the female genito-urinary tract. For purposes of this paragraph, mental incapacity is not considered an illness or injury.
 10. All females undergoing tubal occlusion such as Essure should be informed of the need for a follow up HSG three months after the procedure to assure tubal blockage. They and their partners should be provided with other contraceptive measures until their use is no longer necessary.
 11. All males undergoing vasectomy should be given appropriate postoperative semen analysis until aspermia is documented. They and their partners should be provided with other contraceptive measures until their use is no longer necessary.
 12. Questions counselors can use with clients considering sterilization:
 - a. What are some of your reasons for considering sterilization?
 - b. How do you think being sterile might affect your sexuality? Your self-image as a man/woman?
 - c. How do you feel about children?
 - d. How would feel about being sterile if you (re)marry? If something happened to your present children? If your economic situation were to change?
 - e. How long have you been thinking about becoming sterilized?
 - f. Have you been through any important life changes recently (such as divorce, abortion)?

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- g. Does your partner (if there is one) know about and feel comfortable with your decision?
- h. Do you realize that this procedure is considered permanent and means that you will not be able to biologically parent any/anymore children?