

**COLORADO**

**Department of Public  
Health & Environment**

# Colorado Title X Program



## Clinical Manual

Revised February 2016

# Signature Page

Colorado Department of Public Health and Environment  
Title X Family Planning Program

CLINICAL MANUAL REVIEW  
Signature Page

The Family Planning Clinical Manual must be reviewed and signed in December annually by Physicians, Nurse Practitioners, Certified Nurse Midwives, Physician Assistants, Registered Nurses, Medical Assistants and Clinic Assistants providing clinical services in the Title X Family Planning Programs. Signature pages must be available for review during clinical site visits. Agencies with multiple sites should keep a copy of the signature page at each site or in the agency's local online drive. Family planning coordinators are asked to confirm obtaining annual staff and consulting physician signatures with the quarterly update.

The **February 2016** version of the Title X Family Planning Program Clinical Manual has been reviewed, discussed, and found appropriate for provision of care by the Nurse Practitioners, Certified Nurse Midwives, Physician Assistants, Registered Nurses, and Physicians listed below, for clients in the Title X Family Planning Program funded through the Colorado Department of Public Health and Environment.

The local agency consulting Physician authorizes the use of the Title X Family Planning Clinical Manual for Nurse Practitioners, Certified Nurse Midwives, Physician Assistants, and Registered Nurses. Medical Assistants and Clinic Assistants providing clinical care will do so based on local agency policies and procedures that follow the appropriate Nursing and/or Physician delegation rules and regulations promulgated by the respective Colorado Department of Regulatory Agency Boards.

Add more lines or additional pages as needed.

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***Federal Title X Program  
Providing Quality Family Planning Services (QFP)  
Recommendations of the CDC and U.S. Office of Populations Affairs:  
<http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>***

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# Section 1: Family Planning Health Care Services

Sexual health is a state of physical, emotional, mental, and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. (World Health Organization, 2002)

Musts: comprehensive history all clients; wt., ht., BMI ; BP; staff must stress the importance of and provide for health maintenance screening, including breast exam if appropriate; cervical cancer screening if appropriate; CT/GC screening for women 24 and younger, one screening test annually; comprehensive education regarding the chosen contraceptive method

## A. Introduction

1. Health care service policies are based on Providing Quality Family Planning Services, Recommendations of the CDC and the US Office of Population Affairs (QFP), Male Training Center for Family Planning and Reproductive Health, Preventative Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice, and the Program Requirements for Title X Funded Family Planning Projects. National guidelines and recommendations do not replace clinical judgment based on individual circumstances of the client.

<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/qfp.htm>

<http://www.hhs.gov/opa/program-guidelines/program-requirements/>

<http://fpntc.org/resources/new-recommendations>

[http://www.maletrainingcenter.org/wp-content/uploads/2014/09/MTC\\_White\\_Paper\\_2014\\_V2.pdf](http://www.maletrainingcenter.org/wp-content/uploads/2014/09/MTC_White_Paper_2014_V2.pdf)

QFP Mobile App

<http://fpntc.org/training-and-resources/quality-family-planning-services-mobile-app>

Refer to the family planning and related preventative health services checklists for men and women regarding service recommendations.

[http://fpntc.org/topics/family-planning-guidelines/qfp-recommendations?ff0\]=im\\_field\\_fpntc\\_topics%3A72](http://fpntc.org/topics/family-planning-guidelines/qfp-recommendations?ff0]=im_field_fpntc_topics%3A72)

2. Family planning services include contraceptive services, pregnancy testing and counseling, achieving pregnancy, basic infertility services, preconception health, sexually transmitted infection services. Breast and cervical cancer screening are related preventative services and are a required service. These service delivery topics are covered in separate sections of the clinical manual.
3. Other preventative health services for men and women such as screening for lipid disorders, colorectal cancer or osteoporosis are not covered in the QFP or CDPHE clinical manual. These other preventative health services may be offered on site or by referral.
4. Service sites must develop and implement plans to address the related social service and medical needs of clients as well as ancillary services needed to facilitate clinic attendance.

# Section 1: Family Planning Health Care Services

5. Title X family planning services were established to assist individuals in determining the number and spacing of their children through the provision of affordable voluntary family planning services (Program Requirements pg. 5). Clients may not be coerced to use contraception or to use any particular method of contraception. Service sites may not coerce anyone to undergo an abortion or sterilization procedure and staff may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure. A client's acceptance of family planning services must not be a prerequisite to eligibility for or receipt of any other services, assistance from, or participation in any other program that is offered by the grantee or sub-recipient. Clinical protocols should include a written statement to this effect.
6. Services must be provided without imposing any durational residence requirements or a requirement that the client be referred by a physician for services.
7. Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies or marital status.
8. Current (i.e., updated within the past 12 months) clinic protocols state that the following services will be offered to female, male and adolescent clients: contraception, pregnancy testing and counseling, services to assist with achieving pregnancy, basic infertility services, STD services, and preconception health services. Further, that breast and cervical cancer screening will be offered to female clients, and services will be offered to male clients in accordance with QFP.
9. The QFP encourages using a client centered approach to providing services. A client centered approach includes respecting the client's primary purpose for their visit; providing confidential services; offering a broad range of contraceptive methods; and delivering services in a culturally competent manner to meet the need of all clients including adolescents, those with limited English proficiency, racial and ethnic minorities, those with disabilities and those who are lesbian, gay, bisexual, transgender, or questioning their sexual identity (LGBTQ).
10. Clinical pathway of family planning services: Assess client's need for services (QFP pg. 5)
  - a. Reason for visit
  - b. Does the client have another source of primary health care
  - c. What is the client's reproductive life plan
  - d. Does the client need preconception health services, STD services or other related preventative health services
11. A medical history must be taken to ensure that the methods of contraception being considered by a client are safe for the client to use. In addition to contraceptive safety, the following comprehensive history for men and women includes health conditions to assess for preconception care services, infertility services, sexual health, and related family planning services.
12. The delivery of preconception, STI, and related health services should not become a barrier to a client's ability to receive contraceptive services. Receiving contraceptive or achieving pregnancy services is a priority. If other family planning services cannot be delivered at the initial visit, then follow-up visits should be scheduled. (QFP pg. 7)
13. The medical director or physician responsible for the service site(s) must sign the CDPHE clinical manual.

# Section 1: Family Planning Health Care Services

## B. A comprehensive history must be obtained for all clients

1. Assess all clients for their reproductive life plan. Use the One Key Question®, “Would you like to become pregnant in the next year?” or “Are you planning a pregnancy in the next year?” to make an initial assessment of a client’s plans for pregnancy and contraceptive needs.
2. Relevant family history to include breast or uterine cancer, history of myocardial infarct, stroke, or thromboembolic disorder before age 50, diabetes or other chronic or serious disorder, such as hypertension.
3. Gynecologic history, including age of menarche, date of last normal menstrual period, history of dysmenorrhea, hypermenorrhea, oligomenorrhea, polymenorrhea, intermenstrual bleeding, post-coital bleeding, dyspareunia, previous history of pelvic infection, sexually transmitted infections, or vaginal discharge, date of last Pap test and any abnormal Pap tests and follow up, infertility or difficulty conceiving, or prolonged time from discontinuing birth control to conceiving a pregnancy. For men: urological conditions, infertility or difficulty conceiving.
4. Obstetric history covering gravidity, parity, pregnancy outcome, i.e., number of abortions (spontaneous or induced), ectopic pregnancies, premature deaths, living children, breastfeeding status, and intervals between pregnancies. Specific complications of pregnancies should be recorded. For partners: pregnancy and parenthood status.

Medical and surgical history - special emphasis on systemic review:

- a. Cardiovascular history, including peripartum cardiomyopathy
- b. Thromboembolic disease
- c. Hypertension (essential or malignant)
- d. Vascular or migraine headaches with pertinent neurological aura
- e. Rheumatic disease such as systemic lupus erythematosus (SLE)
- f. Neurologic/visual disturbances
- g. Metabolic history
  - 1) Diabetes, prediabetes, or gestational diabetes
  - 2) Hepatic disease
  - 3) Hyperlipidemia
  - 4) Thyroid disorders
  - 5) Gall bladder disease
  - 6) Bariatric surgery
  - 7) Inflammatory bowel disease
- h. Cancer (potential or confirmed) history
  - 1) Diagnosed or suspected breast cancer
  - 2) Diagnosed or suspected reproductive tract cancer

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- i. Neurologic history
  - 1) Psychiatric disorders such as depression, anxiety, bipolar disorder, etc.
  - 2) Epilepsy
- j. Hematologic history
  - 1) Hemoglobinopathies (e.g., Sickle cell trait or disease, thalassemia)
  - 2) Blood dyscrasias
- k. Genito-urinary history
  - 1) Renal disease
  - 2) UTI
- l. Previous contraceptive use and any problems with method.
- m. Client's plans for any future pregnancies and when.
- n. Sexual history
  - 1) Review of recent sexual activity
  - 2) Time since last sexual encounter
  - 3) Number of partners and any new partners in the last 60 days
  - 4) Vaginal, rectal or pharyngeal exposure
  - 5) Gender of sexual partners
  - 6) STI symptoms
  - 7) Illness or evidence of STIs in recent partners
- o. History of or risk for sexually transmitted infections, including Hepatitis B and HIV, including client or partner history of IV drug use, multiple partners, bisexuality
- p. History of intimate partner violence (IPV)
- q. History of substance misuse or abuse
- r. History of smoking/tobacco use
- s. Immunization for mumps, measles, rubella (MMR), tetanus, pertussis, varicella, hepatitis B, Human Papilloma Virus, and annual flu vaccine.
- t. Nutritional history.
- u. Allergies.
- v. Current medications.

# Section 1: Family Planning Health Care Services

## C. Periodic health assessment for women and female to male transgender individuals

Most individuals will need no or few examinations or laboratory tests before starting a method of contraception. Unnecessary medical procedures and tests might create a barrier to contraceptive access for some women, especially adolescents. Exams and tests not routinely needed to safely start a healthy client on a contraceptive method are: pelvic exams, unless inserting an IUC or fitting a diaphragm; breast and cervical cancer screening; HIV screening; lipid, glucose, liver enzymes, and hemoglobin tests (QFP pg. 11). These exams and tests may be needed to address other health concerns though.

The following are guidelines for the periodic health examination. Guidelines should never be a substitute for sound clinical judgment. References used in preparing these guidelines include:

American College of Obstetrics and Gynecology (ACOG) [Well-Woman Visit, Committee Opinion No. 534, August 2012, Reaffirmed 2014;](#)

ACOG Annual Woman's Health Care and Well-Woman Recommendations <http://www.acog.org/About-ACOG/ACOG-Departments/Annual-Womens-Health-Care/Well-Woman-Recommendations>

1. General overall appearance – All clients
2. Height, weight, and Body Mass Index (BMI) – All clients
3. Blood pressure – All clients
4. Thyroid – ACOG recommends starting at age 19
5. Clinical Breast Exam – ACOG recommends starting at age 20. Individuals 20 to 39 years old should have a clinical breast exam every 1 to 3 years and an annual breast exam starting at 40 years old.
6. Heart – There is no recommendation for or against auscultation of the heart
7. Lungs – There is no recommendation for or against auscultation of the lungs
8. Abdomen – ACOG recommends starting at age 19
9. Extremities for varicosities and signs of phlebitis – There is no recommendation for or against examining extremities
10. Pelvic examination (including visualization and inspection of external genitalia, vagina, and cervix, and bimanual exam) – ACOG recommends starting at age 21, unless indicated by medical history at age <21. ACOG acknowledges that there is no evidence to support or refute the need to perform an annual pelvic exam for low risk asymptomatic women. The decision to perform a complete pelvic examination at the time of the periodic health examination for asymptomatic women should be a shared decision between the woman and her healthcare provider.
11. In July 2014 the American College of Physicians (ACP) recommended against performing screening pelvic examination in asymptomatic, non-pregnant, adult women (strong recommendation, moderate-quality evidence). (Qaseem A, Humphrey LL, Harris R, Starkey M, Denberg TD, for the Clinical Guidelines Committee of the American College of Physicians. Screening Pelvic Examination in Adult Women: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med.* 2014;161:67-72). <http://annals.org/article.aspx?articleid=1884537>

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The American Academy of Family Physicians endorsed ACP's recommendation in August 2014.

<http://www.aafp.org/patient-care/clinical-recommendations/all/screeningpelvicexam.html>

12. Taking these three recommendations into consideration, clinicians may provide a pelvic exam at the time of cervical cancer screening for healthy, asymptomatic women.
13. Rectal examination, as indicated by medical history or findings on pelvic exam
14. The USPSTF recommends high blood pressure and obesity screening in adults.

## **D. Periodic health assessment for men and male to female transgender individuals**

A physical exam may be provided as indicated and does not need to be performed before providing condoms.

USPTF "A" and "B" recommendations for preventative services may be referenced for guidance at the following link:

<http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/>

Male Training Center for Family Planning and Reproductive Health

<http://www.maletrainingcenter.org/>

Preventive Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice, 2014

[http://www.maletrainingcenter.org/wp-content/uploads/2014/09/MTC\\_White\\_Paper\\_2014\\_V2.pdf](http://www.maletrainingcenter.org/wp-content/uploads/2014/09/MTC_White_Paper_2014_V2.pdf)

A resource from the American Academy of Family Physicians:

The Adult Well Male Examination. Am Fam Physician. 2012 May 15; 85(10):964-971.

<http://www.aafp.org/afp/2012/0515/p964.html>

The USPSTF recommends against screening for testicular cancer in adolescent or adult males (2011).

<http://www.uspreventiveservicestaskforce.org/uspstf/uspstest.htm>

The USPSTF recommends against PSA-based screening for prostate cancer (2012).

<http://www.uspreventiveservicestaskforce.org/BrowseRec/Index/browse-recommendations>

This topic is in the process of an update [by the USPSTF \(11/2015\)](#)

A physical exam may include BP, height, weight, BMI, thyroid, heart, lung, extremities, breasts, abdomen, genital, prostate and rectal as indicated. The USPSTF recommends high blood pressure and obesity screening in adults.

STI exam includes (adopted from the Denver Metro Health Clinic)

1. Inspection of oral mucosa, if indicated
2. Inspection of skin for rashes and lesions
3. Inspection of pubic hair for lice and nits
4. Inspection of penis, including urethral meatus, retraction of foreskin, and expression of any discharge from the urethra.
5. Palpation of scrotal contents
6. Inspection of scrotum including anterior and posterior scrotal walls
7. Palpation of inguinal and femoral lymph nodes for lymphadenopathy

# Section 1: Family Planning Health Care Services

8. Inspection of perianal area, if indicated
9. Inspection of the anus if genital warts are present, if client has receptive anal sex, or if anorectal symptoms are present
10. Further examination as indicated by history or laboratory findings.

## E. Laboratory testing

1. See the Cervical Cancer Screening and Follow-up and STI Screening and Treatment protocols for more in-depth information:
  - a. Cervical cancer screening according to American Cancer Society (ACS)/ American Society for Colposcopy and Cervical Pathology (ASCCP) / American Society for Clinical Pathology (ASCP) guidelines  
Repeat according to Cervical Cancer Screening and Follow up protocol which is based on ASCCP guidelines. <http://www.asccp.org/Guidelines>
  - b. Chlamydia/Gonorrhea screening
    - 1) Screen all women <25 years of age annually (fee must be charged on sliding fee scale)
    - 2) Screen older woman who are at increased risk for CT/GC infection e.g new partner, multiple partners
    - 3) CT/GC testing for IUC insertion should be provided according to the routine screening schedule for client or on the day of IUC insertion.
    - 4) The USPSTF concluded that the evidence is insufficient to recommend for or against routinely screening men. (I Statement)
    - 5) According to the USPSTF " ... risk factors for [CT/GC] infection include having a new sex partner, more than 1 sex partner, a sex partner with concurrent partners, or a sex partner who has an STI; inconsistent condom use among persons who are not in mutually monogamous relationships; previous or coexisting STI; and exchanging sex for money or drugs. Prevalence is also higher among incarcerated populations, military recruits, and patients receiving care at public STI clinics. There are also racial and ethnic differences in STI prevalence. In 2012, black and Hispanic persons had higher rates of infection than white persons. Clinicians should consider the communities they serve and may want to consult local public health authorities for guidance on identifying groups that are at increased risk. Gonococcal infection, in particular, is concentrated in specific geographic locations and communities."
    - 6) 2014 USPSTF CT/GC screening recommendations: <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/chlamydia-and-gonorrhea-screening>
    - 7) 2015 CDC STD Treatment Guidelines: <http://www.cdc.gov/std/tg2015/>

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- c. Other laboratory tests, as indicated:
  - 1) Pregnancy test
  - 2) Microscopic examination of wet mounts or spun urines
  - 3) HIV testing or referral for HIV testing
  - 4) Diabetes screening. Diabetes screening for women with history of gestational diabetes
  - 5) Serology test for syphilis:
    - a) Client who reports having been exposed to, or suspects he or she may be infected with syphilis.
    - b) The CDC recommends annual screening for syphilis for men who have sex with men (MSM) (2015 CDC STD Treatment Guidelines). Also, consider screening female partners of bisexual men.
    - c) Client with previous positive serologic test for syphilis with incomplete or unknown treatment.
    - d) Client with undiagnosed genital lesion, suspicious rashes, or other physical signs consistent with syphilis.
    - e) Client request.
    - f) Client with a positive HIV or gonorrhea test.
    - g) Depending on other risk factors, clients with condyloma, herpes, or Chlamydia should be offered a serology test for syphilis.
  - 6) Hepatitis B and C testing (QFP)

## F. Provision of contraceptive methods

- 1. Optimally, a client should see a provider and receive their desired contraceptive method, if no contraindications, on the day of their initial visit.
- 2. Education should be provided as outlined below, in the respective contraceptive section and the US SPR. Preference should be given to the “Quick Start” approach to initiating the chosen method, as outlined in US SPR.
- 3. Dispensing of hormonal contraceptives may be provided by an RN (express visit) under physician signed standing orders for healthy, low risk clients, as described in Section 12 -Pharmaceuticals in the Clinical Manual and as set out in the individual’s job description.
- 4. Express visit components
  - a. A targeted family and personal medical history and method risk assessment must be provided (see express visit form)
  - b. Appropriate method provided according to US MEC risk categories
  - c. Provide a minimum of 3 months supply of a contraceptive method
  - d. Method education as outlined below
  - e. Family planning program consent is required
  - f. Physical assessment: at minimum - BP, weight, height, BMI, Urine pregnancy test - if indicated. CT/GC testing may also be performed.

# Section 1: Family Planning Health Care Services

- g. Staff must recommend the client return to see a provider for a comprehensive history, physical assessment and lab work as indicated.

## G. Client education/counseling

Individuals receiving family planning services may be provided information on the following, either verbally or in writing, when appropriate. Presentation of client education should be appropriate for client's age, knowledge, language, and socio-cultural background and should be documented in the medical record. Key principles of providing quality, client centered counseling include: 1) establish and maintain rapport with the client, 2) assess the client's needs and personalized discussion accordingly, 3) work with the client interactively to establish a plan, 4) provide information that can be understood and retained by the client, and 5) confirm client understanding (QFP).

1. Staff should use a tiered approach to presenting contraceptive methods with the most effective methods presented first, long acting reversible contraceptives (LARCs) (Tier 1), followed by moderately effective (Tier 2) and then lesser effective methods (Tier 3). (QFP)
2. Staff must provide clients with verbal detailed description of the client's selected method, demonstrate how to use the method, and give client the appropriate, method-specific information sheet including instructions for use. Information should include the following:
  - a. Mechanism of Action
  - b. Effectiveness
  - c. Advantages and indications
  - d. Possible side effects, complications and danger signs and symptoms
  - e. Managing missed pills, patch, ring, DMPA as indicated
  - f. Managing side effects and problems with method
  - g. User instructions for method
  - h. Instructions on how to discontinue method
  - i. Procedural instructions in case of an emergency
  - j. Instruction to call or return to the clinic at any time to discuss side effects or other problems, if she wants to change the method being used and when it is time to remove or replace the contraceptive method
  - k. Non-barrier contraceptive methods do not protect against STIs and HIV
  - l. Availability of emergency contraception
3. Information needed to make informed decisions about family planning, including reproductive life plan
4. Information about HIV and STI risks, infection prevention, actions to reduce transmission of HIV and STIs
5. Health promotion/disease prevention information (i.e. nutrition, exercise, smoking cessation, alcohol/drug use, mental health issues, intimate partner violence and sexual abuse)

For resources on screening for and referring clients for substance use and abuse see SBIRT Colorado, (Screening, Brief Intervention and Referral to Treatment) <http://www.improvinghealthcolorado.org/index.php> and Health

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Team Works <http://www.healthteamworks.org/guidelines/sbirt.html> (includes CRAFFT screening toolkit for adolescents)

IPV and sexual assault/abuse resources for clients and staff are available on the CDPHE – Family Planning Program web site <https://www.colorado.gov/cdphe/family-planning>

Colorado Quit Line <https://www.coquitline.org/>

CDPHE marijuana resources <https://www.colorado.gov/cdphe/marijuana-clinical-guidelines>

6. Breast awareness and self-exam. - Breast self-examination (BSE) is an option for women starting in their 20s. Women should be told about the benefits and limitations of BSE. Women should be aware of how their breasts feel and look normally and report any breast changes to their health professional right away.
7. Testicular Self Exam (TSE). Because regular TSE have not been studied enough to show it reduces the death rate from testicular cancer, the ACS does not have a recommendation on regular TSE for all men. Men should be aware of testicular cancer and see a doctor right away if they find a lump on a testicle. Provide instruction in TSE if client wishes to do a monthly TSE. ([American Cancer Society, Testicular Cancer](#), last revised 2/13/2015)
8. Information about and a strong recommendation for the Human Papilloma Virus (HPV) vaccine for individuals up through 26 years old
9. Hepatitis A and B vaccines information and recommendations
10. Immunization resources: <http://www.cdc.gov/vaccines/default.htm> and <http://www.immunize.org/>
11. Referral resources and information
12. Consistent and correct condom use to prevent pregnancy and protect against STIs and HIV
13. Sexuality and relationships
14. Sexual dysfunction

## H. Annual and re-visits for family planning and preventative services

1. Annual visits are provided for assessment of client's satisfaction or concerns with contraceptive method, preventative services such as blood pressure and body mass index screening, STI screening as indicated, and breast and cervical cancer screening, as indicated.
2. Lab tests as indicated or for subsequent boosters of HPV vaccine.
3. U.S. Selected Practice Recommendations, 2013 (US SPR) do not generally recommend routine follow up visits related for the safe and effective use of a contraceptive method after the initiation of a contraceptive method for healthy women. Exceptions would be specific women who would benefit from a routine follow up visit, such as women with certain medical conditions or characteristics, those with multiple medical conditions and adolescents. <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>
4. The US SPR recommends and clients must be advised to return to the clinic any time to discuss side effects other problems or if she wants to change her method.

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5. At other routine visits, an assessment should be made:
  - a. of the client's satisfaction and concerns with her method,
  - b. of any health status changes, including medications, that would change the appropriateness of her method (such as category 3 and 4 conditions in the US Medical Eligibility Criteria for Contraceptive Use, 2010 and updates (US MEC)),
  - c. blood pressure (combined methods),
  - d. for clients with an IUD/IUS, consider performing an exam to check for the presence and length of IUD/IUS strings,
  - e. consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

## I. LGBTQ Individuals, Family Planning Services and iCare

1. Care for all individuals is provided using a client centered approach, delivered in a culturally competent manner to meet the need of all clients including LGBTQ individuals.

### 2. Qualifying Clients

Individuals who identify as gay, lesbian, bisexual, transgender, queer or questioning (LGBTQ) interested in and who receive family planning services related to determining the number and spacing of their children may be enrolled in Title X as any other client would be (i.e. consented, registered, provided with contraceptive counseling, etc.). However, if a client declines services related to family planning (contraceptive counseling, reproductive life plan discussion, preconception counseling and care, achieving pregnancy and basic infertility care) would not be enrolled in Title X because they are not receiving a qualifying procedure or counseling.

### 3. iCare and Data Entry

For iCare purposes, in order for a client to be considered a qualifying family planning client, a qualifying procedure or counseling that occurred during the client's visit must be entered in to the iCare data base.

### 4. Transgender Clients and iCare Data Entry

Transgender clients' preferred gender identity should always be honored, and the pronouns and terminology that the client prefers should always be used. Clients' gender entry into iCare should be based on the clients' self-identified gender. If you have challenges coordinating the sex of a client and a method of contraceptive or qualifying procedure, please call the FP Unit and we will make sure the transgender client is identified correctly in the system. The Family Planning Annual Report (FPAR) reporting will use clients' self-identified gender and be explained in the notes sections of applicable FPAR tables.

### 5. LGBTQ Clients and Unintended Pregnancy

LGBTQ individuals can be at risk for unplanned pregnancy. The key is that obtaining family planning services is client directed – the client determines without coercion whether or not they are interested in receiving family planning services, regardless of gender identity or sexual orientation. STI testing by itself, without discussion of contraception and pregnancy prevention (or pregnancy planning) is not a Title X service. However, an STI visit may be a good way to introduce clients to family planning services.

# Section 1: Family Planning Health Care Services

LGBTQ individuals experience challenges in accessing LGBTQ-friendly care in their communities. Transgender individuals, in particular, experience discrimination and barriers to adequate health care services. According to One Colorado's *Invisible: The State of LGBT Health in Colorado*, "Almost 90 percent of respondents felt that if their provider was comfortable with their LGBT identity, they would consider that provider to be LGBT-friendly." Title X family planning clinics provide access to confidential, culturally sensitive health care services (including services to LGBTQ individuals) which include access to a broad range of contraceptive methods; breast and cervical cancer screening; STD and HIV testing and referral; and other prevention services.

## 6. Resources

The Center of Excellence for Transgender Health, University of California, San Francisco (UCSF) Department of Family and Community Medicine published a [Primary Care Protocol for Transgender Patient Care](#), April 2011. Covered topics pertinent to family planning services include [general prevention and screening](#) including sexual health and [fertility issues](#). Fertility issues should be discussed with transgender individuals particularly if the individual is considering hormone therapy. "Cross-sex hormone use may reduce fertility, and this may be permanent even if hormones are discontinued. Estrogen may have the effect of reducing libido, erectile function, and ejaculation. Testosterone generally increases libido. *Note:* Even though testosterone reduces fertility in transmen, testosterone is not a contraceptive substance; transmen having unprotected sex with fertile non-trans men are at risk for pregnancy as well as STIs." (Primary Care Protocol for Transgender Patient Care, Center of Excellence for Transgender Health, University of California, San Francisco, Department of Family and Community Medicine, April 2011, accessed 11/2015)

Download English and Spanish trans health fact sheets for clients including "Fertility and You", "Sexual Health for Transwomen" and "Sexual Health for Transmen" from the UCSF Center for Excellence for Transgender Health web site <http://transhealth.ucsf.edu/trans?page=lib-00-00>

Transgender resources

<http://www.glbtcolorado.org/transgender/transgender-programs-and-support/>

The CDC's STI Treatment Guidelines outline testing in special populations that includes men who have sex with men and women who have sex with women.

The Substance Abuse and Mental Health Services Administration published Top Health Issues for LGBT Populations, Information & Resource Kit, 2012. <http://store.samhsa.gov/shin/content/SMA12-4684/SMA12-4684.pdf>

The Resource Kit also includes helpful terms for prevention specialists and health care providers and information about gender identity. <http://www.samhsa.gov/behavioral-health-equity/lgbt>

AHRQ Health Care Innovations Exchange  
Innovations and Tools to Improve Quality and Reduce Disparities  
<https://innovations.ahrq.gov/>

National LGBT Health Education Center  
<http://www.lgbthealtheducation.org/>

# Section 1: Family Planning Health Care Services

One Colorado

<http://www.one-colorado.org/>

CDC - LGBT Health

<http://www.cdc.gov/lgbthealth/about.htm>

Health Resource and Services Administration - LGBT Health

<http://www.hrsa.gov/lgbt/>

The Center - Advancing LGBT Colorado, Health

<http://www.gbtcolorado.org/health/>

Healthcare Guild of Denver for Gender and Sexual Minorities

<http://denverhealthcareguild.wordpress.com/lgbtqia-resources/>

Planned Parenthood of the Rocky Mountains Transgender Health Services

<https://www.plannedparenthood.org/planned-parenthood-rocky-mountains/patient-resources/transgender-services>

GLMA Health Professionals Advancing LGBT Equality

Resources for clients and providers (note that providers are not screened by GLMA)

<http://www.glma.org/index.cfm?fuseaction=Page.viewPage&pageId=534>

# Section 1: Family Planning Health Care Services

## **J. Protocol Policy**

1. Services provided operate under written clinical protocols that are in accordance with nationally recognized standards of care, are approved by CDPHE, and signed by the physician and mid-level providers responsible for the service site.
2. Protocols are reviewed after additions or revisions by supervising physician and the mid-level provider.
3. Date and signature of physician and mid-level provider(s) is noted on protocols at review time.
4. Protocols developed by individual practitioners and physicians must be in line with the Program Requirements for Title X Funded Family Planning Projects under Section 1001, Public Health Service Act.

## **K. Clients Involved in Research Projects**

1. Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). The grantee/sub-recipient should advise their Regional Office in writing of any research projects that involve Title X clients (HHS Grants Policy Statement 2007, II-9). (Program Requirements for Title X Funded Family Planning Projects, Section 13.4 Human Subjects Clearance (Research) pg. 19)
2. Programs must advise the CDPHE Family Planning Program in writing of research projects involving Title X clients or resources. The CDPHE Family Planning Program must then forward the request to the regional Health and Human Services office and the Office of Population Affairs.



## Section 2: Contraceptive Services

- Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.
- Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a woman develops the condition while she is using the method. (US MEC 2010)

The US MEC summary sheet (updated 2012) only contains a subset of the recommendations from the US MEC. For complete guidance, see: <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

### B. Method Use

1. Providers should refer to the US SPR for information including how to initiate the chosen contraceptive method and how to address problems and side effects the client may experience with their method and instructions for incorrect method use.  
<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/usspr.htm>
2. Optimally, clients should be started on their method the day of their visit to the family planning clinic. Providers should be reasonably certain that a woman is not pregnant before starting her on a contraceptive method. In most cases a detailed history will provide the most accurate assessment of pregnancy risk for a woman who is starting a contraceptive method (US SPR pgs 5 – 7).
3. According to the US SPR, a provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets one of the following criteria:
  - a. Is less than or equal to 7 days after the start of normal menses
  - b. Has not had sexual intercourse since the start of last normal menses
  - c. Has been correctly and consistently using a reliable method of contraception
  - d. Is less than or equal to 7 days after spontaneous or induced abortion
  - e. Is within 4 weeks postpartum
  - f. Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority ( $\geq 85\%$ ) of feeds are Breastfeeds), amenorrheic, and less than 6 months postpartum (US SPR pg 7).
4. If a woman meets one of these criteria (and therefore the health care provider can be reasonably certain that she is not pregnant), a urine pregnancy test might be considered in addition to these criteria (based on clinical judgment), bearing in mind the limitations of the accuracy of pregnancy testing. If a woman does not meet any of these criteria, then the provider cannot be reasonably certain that she is not pregnant, even with a negative pregnancy test. Routine pregnancy testing for every woman is not necessary (US SPR pg 6).

## Section 2: Contraceptive Services

5. Emergency contraception should be considered for women who have had unprotected intercourse in the last 5 days. See Emergency Contraception section for more information.

### C. Method Education

1. Written method consents are no longer a Title X requirement. Clinics must continue the use of consents for contraceptive methods involving a procedure, i.e. implants and IUD/IUS methods.
2. Clients must continue to receive education regarding (1) contraceptive alternatives; and (2) the safety, effectiveness, potential side effects and complications, and any problems/benefits concerning the use of a contraceptive method
  - a. The Family Planning booklet describes all birth control methods and should be included in the new client packet and be available to returning clients as needed.
  - b. When appropriate, or if indicated by client, staff will discuss all methods in detail.
  - c. While all methods may be covered at the initial visit, the majority of time should be spent on the method of choice.
  - d. Staff providing client education should be knowledgeable, objective, non-judgmental, and sensitive to the rights and differences of clients as individuals. .
  - e. Staff must provide client with verbal detailed description of the client's selected method, demonstrate how to use the method, and give client the appropriate, method-specific information sheet including instructions for use. If a check off is used in the medical record to document that the client received specific method education, marking the check off indicates the following will have been included in the education. Information should include the following:
    - 1) Mechanism of Action
    - 2) Effectiveness
    - 3) Advantages and indications
    - 4) Possible side effects, complications and danger signs and symptoms
    - 5) Managing missed pills, patch, ring, DMPA as indicated
    - 6) Managing side effects and problems with method
    - 7) User instructions for method
    - 8) Instructions on how to discontinue method
    - 9) Procedural instructions in case of an emergency
    - 10) Instruction to call or return to the clinic at any time to discuss side effects or other problems, if she wants to change the method being used and when it is time to remove or replace the contraceptive method
    - 11) The contraceptive method (other than barrier methods) does not protect against STI-HIV and a barrier method should also be used for protection.



# Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Condition	Sub-Condition	GHC				POP				Injection				Implant				LNG-IUD				Cu-IUD			
		I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Ischemic heart disease <sup>a</sup> Liver tumors	Current and history of	4	2	3	3	2	2	3	3	2	2	3	3	2	2	3	3	2	2	3	3	2	2	3	3
	a) Benign																								
	i) Focal nodular hyperplasia ii) Hepatocellular adenoma <sup>a</sup> b) Malignant <sup>a</sup>	2	2	2	2	4	3	3	3	4	3	3	3	4	3	3	3	4	3	3	3	4	3	3	3
Malaria	(such as older age, smoking, diabetes and hypertension)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	Multiple risk factors for arterial cardiovascular disease	3/4 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	3 <sup>a</sup>	2 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	3 <sup>a</sup>	2 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	3 <sup>a</sup>	2 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	3 <sup>a</sup>	2 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	3 <sup>a</sup>	2 <sup>a</sup>	2 <sup>a</sup>	3 <sup>a</sup>	3 <sup>a</sup>
Obesity	a) ≥30 kg/m <sup>2</sup> body mass index (BMI)	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1
	b) Menarche to <18 years and ≥30 kg/m <sup>2</sup> BMI	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1
Ovarian cancer <sup>a</sup> Parity	a) Nulliparous	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Parous	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Past ectopic pregnancy Pelvic inflammatory disease	a) Past, (assuming no current risk factors of sexually transmitted infections [STIs]) i) with subsequent pregnancy ii) without subsequent pregnancy	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Current	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Peripartum cardiomyopathy <sup>a</sup>	a) Normal or mildly impaired cardiac function	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	i) <6 months ii) ≥6 months b) Moderately or severely impaired cardiac function	4	1	1	1	4	1	1	1	4	1	1	1	4	1	1	1	4	1	1	1	4	1	1	1
Postabortion	a) First trimester	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	b) Second trimester c) Immediately post-septic abortion	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
Postpartum (see also breastfeeding)	a) <21 days i) with other risk factors for venous thromboembolism (VTE) ii) without other risk factors for VTE	4	1	1	1	4	1	1	1	4	1	1	1	4	1	1	1	4	1	1	1	4	1	1	1
	c) >42 days a) <10 minutes after delivery of the placenta b) 10 minutes after delivery of the placenta to <4 weeks c) ≥4 weeks d) Puerperal sepsis	3*	1	1	1	3*	1	1	1	3*	1	1	1	3*	1	1	1	3*	1	1	1	3*	1	1	1
Pregnancy	a) On immunosuppressive therapy	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*
	b) Not on immunosuppressive therapy	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1
Rheumatoid arthritis	a) Uncomplicated	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Schistosomiasis	b) Fibrosis of the liver <sup>d</sup>	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Severe dysmenorrhea		3*	1	1	1	3*	1	1	1	3*	1	1	1	3*	1	1	1	3*	1	1	1	3*	1	1	1

<sup>a</sup>Please see the complete guidance for a clarification to this classification. <sup>b</sup>Condition that exposes a woman to increased risk as a result of unintended pregnancy. Updated June 2012. This summary sheet only contains a subset of the recommendations from the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. For complete guidance, see: <http://www.cdc.gov/esp/conditiohealth/uniintendpregnancy/USMEC.htm>.

## Section 3: Tier 1 Method - Intrauterine Contraception

CDPHE Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs publication Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/QFP.htm>, the CDC U.S. Medical Criteria for Contraceptive Use, 2010 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2013 (US SPR). These recommendations can be accessed at the following link: [http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception\\_Guidance.htm](http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception_Guidance.htm)

Providers should sign up to receive email updates to these recommendations. Also available for download are an US MEC APP and US SPR eBook.

Resources:

The Contraceptive Choice Project for resources regarding counseling, training, troubleshooting and forms:

<http://www.choiceproject.wustl.edu/> and

<http://www.larcfirst.com/choiceresults.html>

ACOG LARC resources: <http://www.acog.org/more-info/increasinglarc>

### A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Providers should use a tiered approach to presenting contraceptive methods with the most effective Tier 1 methods presented first, long acting reversible contraceptives (LARCs), followed by Tier 2 moderately effective and Tier 3 lesser effective methods. (QFP)

IUCs are Tier 1 contraceptive methods.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

- Category 1: A condition for which there is no restriction for the use of the contraceptive method.
- Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.
- Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.
- Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

A US MEC summary table (updated 2012) only contains a subset of the recommendations from the US MEC. See complete guidance and summary table at

<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

Please see the US SPR for more information. Page numbers to the US SPR are provided throughout this section.

<http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf>

## Section 3: Tier 1 Method - Intrauterine Contraception

### B. Objective Data

1. History and Physical exam (See Section 1 - Health Care Services of the Clinical Manual).
2. Laboratory tests may include:
  - a. Cervical cancer screening within the normal screening interval for the client. Cervical intraepithelial neoplasia (CIN) is listed as a category 2 (a condition for which the advantages of using the method generally outweigh the theoretical or proven risk) for Mirena and a category 1 (a condition for which there is no restriction for the use of the contraceptive method) for ParaGard. An IUD/IUS should not be initiated for a client who has cervical cancer. Continuing an IUD/IUS for a client diagnosed with cervical cancer is a category 2. (USMEC 2010)
  - b. GC and Chlamydia tests according to national screening guidelines and within the normal screening interval for the client. Screening may be provided at time of IUC insertion if screening has not previously been done.

### C. Assessment and Plan

1. Client Education/ Informed Consent
  - a. Have client read the FDA approved client brochure for the particular IUC that she is to have inserted.
  - b. Provide anticipatory counseling and reinforce the effects of the IUC on the menstrual cycle.
  - c. Client must sign an IUC procedure consent and a copy of the consent must be provided to the client along with the IUC package insert.
2. Pre-insertion Management
  - a. Prophylactic antibiotics are generally not recommended for IUC insertion (US SPR 2013).
  - b. Sub-bacterial endocarditis (SBE) prophylaxis prior to IUC insertion is not recommended (American Heart Association, JAMA 264: 2919, 1990; AMA Drug Evaluation 4:1, 1994). Routine administration of prophylactic antibiotics solely to prevent endocarditis is not recommended for clients undergoing genitourinary tract procedures. (American Heart Association, Circulation 2007;116:1736-1754) Routine antibiotic prophylaxis to prevent pelvic infection is not recommended before IUD insertion. (American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin No. 121, July 2011, Reaffirmed 2013. <http://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Long-Acting-Reversible-Contraception-Implants-and-Intrauterine-Devices>)
  - c. For pre-insertion pain management, clients may be given a non-steroidal anti-inflammatory drug (NSAID) one hour prior to insertion.
  - d. Local anesthesia at the tenaculum site: options included 1) no anesthesia or 2) apply benzocaine 20% gel first at the tenaculaum site then leave a gel-soaked cotton tipped applicator in the cervical canal for 1 minute before proceeding with the IUD insertion, or 3) inject 1 ml of local anesthetic lip into which the tenaculaum will be placed (Zieman M., Hatcher RA. Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2015, p. 891)
3. Initiation of IUC – see US SPR pages 8 – 9 and follow manufacturer’s instructions for insertion of IUC device.

## Section 3: Tier 1 Method - Intrauterine Contraception

4. Insertion
  - a. Document baseline pulse and blood pressure prior to insertion.
  - b. Document pelvic exam done prior to insertion as to uterine position, size, cervix and discharge appearance and any abnormalities.
  - c. Document IUC type, depth to which uterus is sounded, string length after insertion and trimming, and lot # and expiration date of the IUC.
5. Post-insertion of the IUC - Vasovagal observation
  - a. Blood pressure and pulse should be taken and recorded.
  - b. If vital signs indicate a vasovagal response, record BP and pulse frequently (every 5-15 minutes).
  - c. Client should not be allowed to leave the clinic until stable.
  - d. Clients with persistent vasovagal symptoms should be evaluated for perforation, abdominal bleeding, etc.
6. Post-IUD/IUS Insertion Education
  - a. Client should be instructed on the expiration period for the IUC.
    - 1) ParaGard is approved for 10 years.
    - 2) Mirena is approved for 5 years.
    - 3) Skyla is approved for 3 years
    - 4) Liletta is currently approved for 3 years
  - b. Need for back up contraception, if indicated
  - c. Reinforce the signs and symptoms of possible IUC complications. Instruct the client to call the clinic for any of the following:
    - 1) Late or missed period if using ParaGard; abnormal spotting or bleeding; signs or symptoms of pregnancy.
    - 2) Pelvic or lower abdominal pain; pain with intercourse
    - 3) Exposure to STIs; abnormal vaginal discharge
    - 4) Not feeling well – fever or chills
    - 5) Inability to locate IUC string, changes in string length
    - 6) Known partial or full expulsion
  - d. Instruct the client to check for the string before intercourse, during her first menstrual cycle, and then after each menses
  - e. Inform the client if she wishes to discontinue the use of her IUC to make an appointment with her provider to have it removed. If she does not wish to become pregnant, she must start a new method on or before the day she has her IUC removed.

## Section 3: Tier 1 Method - Intrauterine Contraception

### 7. Follow-up Visits

Scheduling of follow up visits is at the provider's discretion. Routine follow up visits after IUC insertion are not required unless the provider feels that the client would benefit (e.g. adolescents, certain medical conditions) (US SPR pgs. 11 -12).

- a. An IUS evaluation form is available for documentation
- b. Advise women to return at any time to discuss side effects or other problems or if she wants to change her method
- c. At other routine visits, assess: client's satisfaction and any concerns with method, any changes in health status that would change the appropriateness of IUC use (category 3 or 4 US MEC), consider exam for IUC string check
- d. Hemoglobin/ Hematocrit if indicated
- e. Review of IUC danger signs.
- f. Reinforce the importance of an annual visit and cervical cancer screening according to screening guidelines.

### D. Management of Complications/Side Effects

#### 1. Client diagnosed with PID (see US SPR pg 13)

- a. Treat for PID as outlined in the CDC STD Treatment Guidelines. "if an IUD user receives a diagnosis of PID, the IUD does not need to be removed ." Centers for Disease Control and Prevention (CDC), Sexually Transmitted Diseases Treatment Guidelines, 2015, MMWR 2015; 64/No. RR-3, p. 82) however, close clinical follow up is required.
- b. Inform the client to seek care immediately if her symptoms do not improve or worsen. Reassess in 48 to 72 hours. If no improvement consider IUC removal. Continue antibiotics and refer for care.
- c. If the IUC is removed, contraceptive counseling is necessary.
  - 1) If the client is mid-cycle, and has recently had intercourse, inform her of the risk of removing the IUC and a possible subsequent pregnancy. Offer ECP. If the client decides she does not want removal, documentation must exist of discussion of need for close clinical follow up.
  - 2) If IUC is removed, be certain the client leaves the clinic with an alternative method of birth control.

#### 2. Actinomyces on Pap test - SYMPTOMATIC OF PID

- a. Client must receive/be referred for intensive antibiotic therapy, along with the removal of the IUD/IUS, as this bacterium prefers to grow on foreign bodies. Physician consultation is required.
- b. Client must be counseled on the use of a different method of contraception.

#### 3. Actinomyces on Pap test - ASYMPTOMATIC OF PID

Pelvic actinomycosis is a rare (<.001%) but serious condition. The relationship between actinomyces found on a Pap test in the asymptomatic IUC user and development of a pelvic actinomycosis infection is not clear. Therefore, management of the asymptomatic IUC user with a Pap with actinomyces is not

## Section 3: Tier 1 Method - Intrauterine Contraception

clearly established. There has only been one small, randomized controlled trial, and the results established no superior approach. “Although options for management have included oral antibiotics, removal of the IUD, or both, current recommendations for asymptomatic clients with an IUD and actinomyces found by cervical cytology screening focus on expectant management. Both the UK Faculty of Family Planning and the Standards and Guidelines of the Planned Parenthood Federation of America recommend continued IUD use and client education about the small risk of actinomycosis” (ACOG Practice Bulletin No. 121, July 2011, Reaffirmed 2013). With this in mind, each agency’s practitioners should discuss the management of actinomyces on Pap test in an asymptomatic IUC user with the medical consultant and determine the approach to be used.

- a. Review the result with the cytologist/pathologist to confirm the diagnosis.
  - b. The IUC does not have to be removed, but the client should be informed and questioned about any symptoms suggestive of PID. If she is asymptomatic, nothing more is required.
  - c. Treatment of asymptomatic actinomyces on Pap test is not required, as the actinomyces is a normal vaginal organism. Detecting its presence on Pap test represents colonization rather than infection in a client without pelvic tenderness. Review the signs and symptoms of PID with the client.
  - d. Since the importance of clearing the actinomyces colonization in the asymptomatic client is not established, there is no basis for recommending a repeat Pap to check for clearing of actinomyces.
4. Spotting, Bleeding (see US SPR pgs 12-13)
- a. Rule out pregnancy, infection or partial expulsion and manage appropriately.
  - b. If client complains of excess bleeding within the first three months after insertion,
    - 1) Reassure that it is likely to get better in subsequent cycles,
    - 2) Check HCT or HGB and give iron supplement, if indicated,
    - 3) For Copper IUC: US SPR recommends short term NSAIDs for 5-7 days.
    - 4) Rule out other pathology related to vaginal bleeding.
5. Cramping or Pain – varying degrees of discomfort may be felt at the time of insertion and may be followed by cramping pain over the next 10-15 minutes.
- a. Pain with sounding of the uterus during insertion
    - 1) Go slowly, consider smaller sound
    - 2) If severe, check alignment of uterine cavity on bimanual exam, and consider using a paracervical block before proceeding.
  - b. Pain at the time of insertion persists, with signs of abdominal tenderness
    - 1) If the string is present, treat as pelvic infection
    - 2) If the string is absent, consider possibility of perforation, migration, expulsion or pregnancy and refer to physician or emergency room.
    - 3) If severe: rule out perforation, pregnancy or infection. Check blood pressure and pulse. Consider removing the IUC if indicated.

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- 4) If mild: prescribe a mild analgesic such as Ibuprofen.
6. Severe post-insertion reaction, such as syncope
  - a. If placement is questionable, remove the IUC. An IUC can be re-inserted now or at a later date.
  - b. If the IUC is properly placed, and pulse <60 beats/min, consider the use of ammonium capsules (smelling salts). If symptoms persist, consider atropine 0.5 mg IV. IV fluids may be helpful.
  - c. Call 911 for emergency services
  - d. Remove the IUC if necessary
  - e. See 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science and bradycardia algorithm for guidance.  
[http://circ.ahajournals.org/content/122/18\\_suppl\\_3/S729.long#sec-77](http://circ.ahajournals.org/content/122/18_suppl_3/S729.long#sec-77)
7. Partial expulsion of IUC
  - a. Without signs of infection, remove IUC and another IUC may be inserted if reasonably certain woman is not pregnant and urine pregnancy test is negative.
  - b. With PID or question of PID, treat with antibiotics and remove the partially expelled IUC. Provide alternative contraception. Another IUC may be inserted after 3 cycles.
  - c. Consider ECP
8. Pregnancy with IUC in situ (See US SPR pg 14) - A woman pregnant with an IUC in place must be evaluated promptly to confirm an intrauterine pregnancy and to exclude an ectopic pregnancy.
  - a. Do highly sensitive pregnancy test and pelvic exam
  - b. If the client is pregnant and the IUC string is visible, the IUC should be removed, regardless of plans to continue or terminate the pregnancy.
    - 1) Counsel the client that an ectopic pregnancy, SAB, or sepsis is a possibility and review signs and symptoms of each.
    - 2) Refer the client for health care services.
    - 3) If the client chooses to keep the IUC, advise her to seek care promptly and especially with heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever (US SPR).
  - c. If the client is pregnant and the string not visible, explain the risks of ectopic pregnancy, SAB and sepsis with an IUC in situ during pregnancy.
    - 1) Review the warning signs of infection, SAB and ectopic pregnancy, including where to seek emergency care.
    - 2) Refer to physician immediately for follow-up.
  - d. Ectopic pregnancy

IUC significantly reduces a woman's risk of an ectopic pregnancy, because the IUC prevents all types of pregnancies. Should a pregnancy occur with an IUC in place, the ratio of ectopic to intrauterine pregnancies may be increased. (Contraceptive Technology, 20th Edition, p. 157)

## Section 3: Tier 1 Method - Intrauterine Contraception

9. Absent IUC Strings (See US SPR pg. 14)
  - a. If menses have not been missed and there is no abdominal pain:
    - 1) After ruling out pregnancy, attempt to determine if the IUC is in the uterus by gently exploring the cervix for the strings.
    - 2) If the strings are located, bring them to their appropriate place.
    - 3) If the strings are not found, the clinician may elect to discuss and provide an alternative method of contraception with the client and have her return with the next menses to check again for the string OR obtain a pelvic ultrasound to determine if the IUC is in the uterus.
      - a) If the IUC is seen on ultrasound, clarify the location to R/O perforation. If the IUC is in the uterus, nothing else needs to be done.
      - b) If the IUC is not located by pelvic ultrasound, order an abdominal X-ray to differentiate IUC expulsion from translocation into the abdominal cavity. Translocated intraperitoneal IUC should be removed as promptly as possible, as copper-bearing IUDs are known to cause dense adhesions.
  - b. If menses have been missed and/or there are signs and symptoms of infection:
    - 1) Rule out pregnancy
    - 2) See management of pregnancy with IUD/IUS in situ or PID with IUD/IUS.

### E. IUD/IUS Removal

1. Subjective Data
  - a. LMP and previous menstrual period
  - b. Medical history update
  - c. History of recent intercourse, if client not menstruating
  - d. Reason for IUC removal
2. Objective Data
  - a. Physical exam/pelvic exam as indicated.
  - b. Laboratory as indicated.
3. Assessment and Plan
  - a. Client requesting reinsertion of IUC:

Reinsertion may be done at the same visit
  - b. Client requesting change in contraceptive method
    - 1) Counsel regarding other methods of birth control. Hormonal methods may be initiated before the IUC is removed.
    - 2) Remove IUC. If client is not menstruating, counsel on risks of pregnancy. Consider ECP.
    - 3) Provide interim method of birth control, as indicated.

## Section 3: Tier 1 Method - Intrauterine Contraception

- 4) If pregnancy is desired, preconception counseling, including the benefits of folic acid, should be provided.
- c. Client symptomatic of PID – refer to Item D. above.

Intrauterine Device/System Consent Form, IUD/IUS Evaluation Form, and IUD/IUS Insertion Progress Note  
<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

## Section 4: Tier 1 Method - Contraceptive Implants

CDPHE Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs publication Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/QFP.htm>, the CDC U.S. Medical Criteria for Contraceptive Use, 2010 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2013 (US SPR). These recommendations can be accessed at the following link: [http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception\\_Guidance.htm](http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception_Guidance.htm)

Please refer to these recommendations when providing contraceptive care. Providers should sign up to receive email updates to these recommendations. Also available for download are an US MEC and QFP APP and US SPR eBook.

Resources:

The Contraceptive Choice Project for resources regarding counseling, training, troubleshooting and forms:

<http://www.choiceproject.wustl.edu/> and <http://www.larcfirst.com/choiceresults.html>

ACOG LARC resources: <http://www.acog.org/more-info/increasinglarc>

### A. Method selection

A broad range of contraceptive methods should be available to the client either in the clinic or by referral.

Providers should use a tiered approach to presenting contraceptive methods with the most effective Tier 1 methods presented first, long acting reversible contraceptives (LARCs), followed by Tier 2 moderately effective and Tier 3 lesser effective methods. (QFP)

Contraceptive implants are a Tier 1 and a very effective contraceptive method.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

- Category 1: A condition for which there is no restriction for the use of the contraceptive method.
- Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.
- Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.
- Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

The US MEC summary sheet (updated 2012) only contains a subset of the recommendations from the US MEC. For complete guidance, see: <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

### B. Initial Objective Data

1. Visit according to Section 1: Health Care Services of the Clinical Manual.
2. Laboratory tests according Section 1: Health Care Services of the Clinical Manual.

## Section 4: Tier 1 Method - Contraceptive Implants

### C. Assessment/Plan

1. Client Education/Informed Consent
  - a. Client must sign the contraceptive implant insertion consent and information sheet.
  - b. Inform client that implants offers no protection against sexually transmitted infections; advised client to use condoms if she has concerns about potential exposure. Document this discussion in the client record.
  - c. Certain medications may make implants less effective, specifically those that induce cytochrome P450 enzymes resulting in an increased clearance of sex hormones in the liver. Some examples are: phenytoin, carbamazepine, phenylbutazone, barbiturates, the herbal remedy St. John's Wort, rifampin/rifampicin, griseofulvin (see package insert for complete list). Women in long-term treatment with these drugs should consider another method of birth control.
  - d. Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive. (USMEC 2010)
  - e. Inform client that if she wishes to discontinue the implant, she should make an appointment at the clinic for removal. If she does not wish to become pregnant she must start using another method on the day of removal.
  - f. Insertion of implants - follow manufacturer insertion instructions, including verifying the presence of the implant in the woman's arm, immediately after insertion by palpation. The client should also be able to palpate the implant. Also see instructions regarding a non-palpable implant. <https://www.merckconnect.com/nexplanon/overview.html> (See US SPR for initiation of the method, pgs 14 -17).

### E. Follow-Up

1. The client may return for an insertion site check if she has concerns about the implant insertion site.
2. Clients should be advised to call the clinic for an appointment for any of the following:
  - a. arm pain; pus or bleeding at the insertion site; expulsion of the rod;
  - b. heavy vaginal bleeding that is unusual for this client;
  - c. concern that she might be pregnant, including delayed menstrual cycles after a long interval of regular cycles;
  - d. onset or worsening of migraine headaches, repeated very painful headaches or blurred vision;
  - e. severe lower abdominal pain (rule out ectopic pregnancy).
3. Management of Post-Insertion Side Effects/ Complications

## Section 4: Tier 1 Method - Contraceptive Implants

- a. Arm pain, pus, or bleeding at insertion site
  1. Management
    - a) Advise the client to apply ice packs to the area for bruising, swelling, bleeding; moist heat for signs of infection.
    - b) Advise to take Ibuprofen or other non-steroidal anti-inflammatory medication to relieve the discomfort.
    - c) In case of infection of the insertion site, consultation with medical back-up may be indicated to select a therapeutic treatment drug.
  2. Follow-up
    - a) Consider contacting the client within 48-72 hours to confirm improvement.
  3. Education
    - a) Instruct client to keep wound site clean and dry for 24 hours.
    - b) Inform client that there might be irritation of a superficial nerve from the implants; paresthesia or paresthesia-like events may occur.
    - c) Expulsion or migration of implant might be possible.
- b. The implants appears to be coming out

Assessment/management - If the implant is protruding from the incision site, the implant should be removed and a new implant inserted at a different site.
- c. Heavy or prolonged vaginal bleeding
  1. Assessment
    - a) Review client history, including sexual history, other symptoms, contact to STIs.
    - b) Physical examination and appropriate lab work should be done to rule out pregnancy, STIs or underlying gynecologic problem (US SPR pg 17).
  2. Management – if no underlying gynecologic problem
    - a) Any low-dose combination birth control pill for one or more cycles, if no contraindications to estrogen, or
    - b) NSAIDS for short term treatment (5-7) days (US SPR pg.17)
- d. Amenorrhea from the time of implant insertion, or after a pattern of regular periods
  1. Assessment
    - a) Evaluate for pregnancy
  2. Management
    - a) If pregnancy test is positive:

## Section 4: Tier 1 Method - Contraceptive Implants

- 1) Remove implant if client wishes to continue the pregnancy.
  - 2) Refer for immediate follow-up if ectopic pregnancy is suspected.
  - 3) Leave the implant in if the client plans an abortion.
- b) If the pregnancy test is negative:
- 1) Discuss amenorrhea with client and reassure her that amenorrhea is a normal side effect of implant use.
  - 2) Implant may be removed if client desires.

e. Headache

1. Assessment

- a) Review headache history.
- b) Take blood pressure.

2. Management

- a) Refer to physician for further evaluation, if indicated.
- b) If a client develops migraine headaches with aura or other neurological symptoms while using the implant, the theoretical or proven risk of continuing the implant usually outweigh the advantages of using the method. (USMEC 2010). The implant should be removed.

f. Development of ischemic heart disease or stroke while using implant

The theoretical or proven risk of continuing the implant usually outweigh the advantages of using the method (USMEC 2010). Implant should be removed.

4. Client should be encouraged to return for annual visit.

### F. For Clients Desiring Removal

1. Subjective

If the client desires removal before three years, investigate the user's reasons for desiring removal. If, after counseling, the client still desires removal, the procedure should be scheduled.

2. Client Education

- a. Inform client that removal may take more time and may be more difficult than the insertion.
- b. This information should be included in a removal consent
- c. The client should be counseled on alternative contraceptive methods, and if she does not desire a pregnancy at this time, a method should be provided, as appropriate.

3. Removal of implants – follow manufacturer's removal instructions. The exact location of the implant in the arm should be verified by palpation before the removal procedure.

<https://www.merckconnect.com/nexplanon/overview.html>

## Section 4: Tier 1 Method - Contraceptive Implants

4. Non-palpable/deep implants – follow manufacturer’s instructions. The implant should always be located before removal. Nexplanon is radiopaque and can be located using CT scan, 2-dimensional x-ray, ultrasound, and MRI. The manufacturer recommends the following routes of localization:
  - a. Confirm the presence of the implant using 2-dimensional x-ray
  - b. Use ultrasound to localize the implant and guide removal
5. Follow-Up
  - a. The client may return for a removal site check if she has concerns about the implant removal site
  - b. Client should be encouraged to return for annual visit.

Nexplanon insertion progress note and insertion and removal consents:

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

## Section 5: Tier 2 Method - DMPA

CDPHE Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs publication Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/QFP.htm> , the CDC U.S. Medical Criteria for Contraceptive Use, 2010 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2013 (US SPR). These recommendations can be accessed at the following link: [http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception\\_Guidance.htm](http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception_Guidance.htm)

Please refer to these recommendations when providing contraceptive care. Providers should sign up to receive email updates to these recommendations. Also available for download are an US MEC APP and US SPR eBook.

### A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Providers should use a tiered approach to presenting contraceptive methods with the most effective Tier 1 methods presented first, long acting reversible contraceptives (LARCs), followed by Tier 2 moderately effective and Tier 3 lesser effective methods. (QFP)

Depot medroxyprogesterone acetate (DMPA), marketed as Depo Provera® is a Tier 2 contraceptive method.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

- Category 1: A condition for which there is no restriction for the use of the contraceptive method.
- Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.
- Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.
- Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

The US MEC summary table (updated 2012) only contains a subset of the recommendations from the US MEC. See complete guidance and summary table at

<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

### B. Initial Objective Data

1. Visit according to Section 1 - Health Care Services of the Clinical Manual.
2. Laboratory tests according to Section 1 - Health Care Services of the Clinical Manual.

### C. DMPA Assessment and Plan

1. Client Education/Informed Consent
  - a. DMPA offers no protection against sexually transmitted infections, including HIV.
  - b. Likelihood of irregular spotting for up to the first nine months, and of the likelihood of amenorrhea after the first year.

## Section 5: Tier 2 Method - DMPA

- c. Fertility can return immediately after missing her next timed injection, or be delayed up to 12 months, and she should discuss her fertility plans with her provider.
  - d. If client wishes to discontinue the use of this method for any reason, she should not get her reinjection at 12 weeks. She will have to wait for any side effects to wear off. If she does not wish to become pregnant, she must start a new method before the next shot would be due.
  - e. Review information regarding loss of bone mineral density with the client, information from the studies showing reversal of the bone loss and information regarding measures for bone strength such as calcium and vitamin D intake and weight-bearing exercise. “Concerns regarding the effect of DMPA on BMD should neither prevent practitioners from prescribing DMPA nor limit its use to 2 consecutive years”. (ACOG Committee Opinion Number 415, September 2008 Depot Medroxyprogesterone Acetate and Bone Effects)
  - f. Aminoglutethimide can decrease the effectiveness of DMPA. The drug is usually used to suppress adrenal function in selected cases of Cushing’s disease (Contraceptive Technology 20<sup>th</sup> Edition, pg. 213).
  - g. The use of hormonal contraceptives, including combined hormonal contraceptives, progestin-only pills, DMPA, and implants, is safe for women at high risk for HIV infection or infected with HIV (US MEC category 1), and all women who use contraceptive methods other than condoms should be counseled regarding the use of condoms and the risk of sexually transmitted infections. (USMEC 2010) and (Update to CDC’s US Medical Eligibility Criteria for Contraceptive Use, 2010: Revised Recommendations for the Use of Hormonal Contraception Among Women at High Risk for HIV Infection or Infected with HIV. MMWR June 22, 2012/ 61(24);449-452)
  - h. Some studies suggest that women using progestin-only injectable contraception might be at increased risk for HIV acquisition; other studies do not show this association. CDC reviewed all available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk for HIV acquisition, women using progestin only injectable contraception should be strongly advised to also always use condoms and take other HIV preventive measures. (Update to CDC’s US Medical Eligibility Criteria for contraceptive Use, 2010: Revised Recommendations for the Use of Hormonal Contraception Among Women at High Risk for HIV Infection or Infected with HIV. MMWR June 22, 2012/ 61(24);449-452)
  - i. Some studies indicate that women using DMPA are at risk for weight gain. Women should be advised that their appetite may increase, and to be aware of changes in caloric intake to avoid this effect.
2. Administering the injection of DMPA
- a. See the US SPR for timing of initiation of DMPA, need for back up contraception, and reinjection, starting on page 17.
  - b. Rarely, an anaphylactic or anaphylactoid reaction may occur immediately following DMPA injection. Manage as per agency’s Medical Emergencies protocol. Some clinics encourage women to remain in the vicinity of the clinic for 20 minutes after an injection. (Contraceptive Technology, 20<sup>th</sup> Revised Edition, p. 225). To prevent severe allergic reactions, ask women if they have experienced significant itching or redness at the site of previous DMPA injections and do not repeat DMPA if allergic reaction is suspected.
  - c. DMPA 150 mg/ml in a deep IM injection. Do not massage site.
  - d. DMPA SQ 104 Provera in a subcutaneous injection. Do not massage site.

## Section 5: Tier 2 Method - DMPA

3. See the US SPR pg 21-22 for information on addressing bleeding irregularities during DMPA use.

Hormonal contraceptives evaluation form:

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

## Section 6: Tier 2 Method - Combined Hormonal Methods: Oral Contraceptives, Vaginal Ring, Hormonal Patch

CDPHE Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs publication Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/QFP.htm>, the CDC U.S. Medical Criteria for Contraceptive Use, 2010 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2013 (US SPR). These recommendations can be accessed at the following link: [http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception\\_Guidance.htm](http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception_Guidance.htm)

Providers should sign up to receive email updates to these recommendations.

### A. Method selection

A broad range of contraceptive methods should be available to the client either in the clinic or by referral.

Providers should use a tiered approach to presenting contraceptive methods with the most effective methods presented first, long acting reversible contraceptives (LARCs), followed by moderately effective and lesser effective methods. (QFP)

Oral contraceptives, the contraceptive ring, and contraceptive patch are Tier 2 contraceptive and are moderately effective.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

- Category 1: A condition for which there is no restriction for the use of the contraceptive method.
- Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.
- Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.
- Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

**A US MEC summary table (updated 2012) only contains a subset of the recommendations from the US MEC. See complete guidance and summary table at**

<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

### B. Management of Women with Special Considerations Requiring Further Evaluation

1. An adverse cardiovascular risk profile or multiple risk factors for arterial cardiovascular disease is classified as Category 3/4, a condition for which the theoretical or proven risks usually outweigh the advantages of using the method or represents an unacceptable health risk if the method is used. (US MEC).

If a woman has two or more risk factors, the case must be evaluated by, and use of oral contraceptives approved by a physician. Risk factors include the following:

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

- a. Age  $\geq$ 35;
- b. Smoking cigarettes;
- c. High cholesterol levels;
- d. Diabetes;
- e. Hypertension.

### 2. Diabetes mellitus

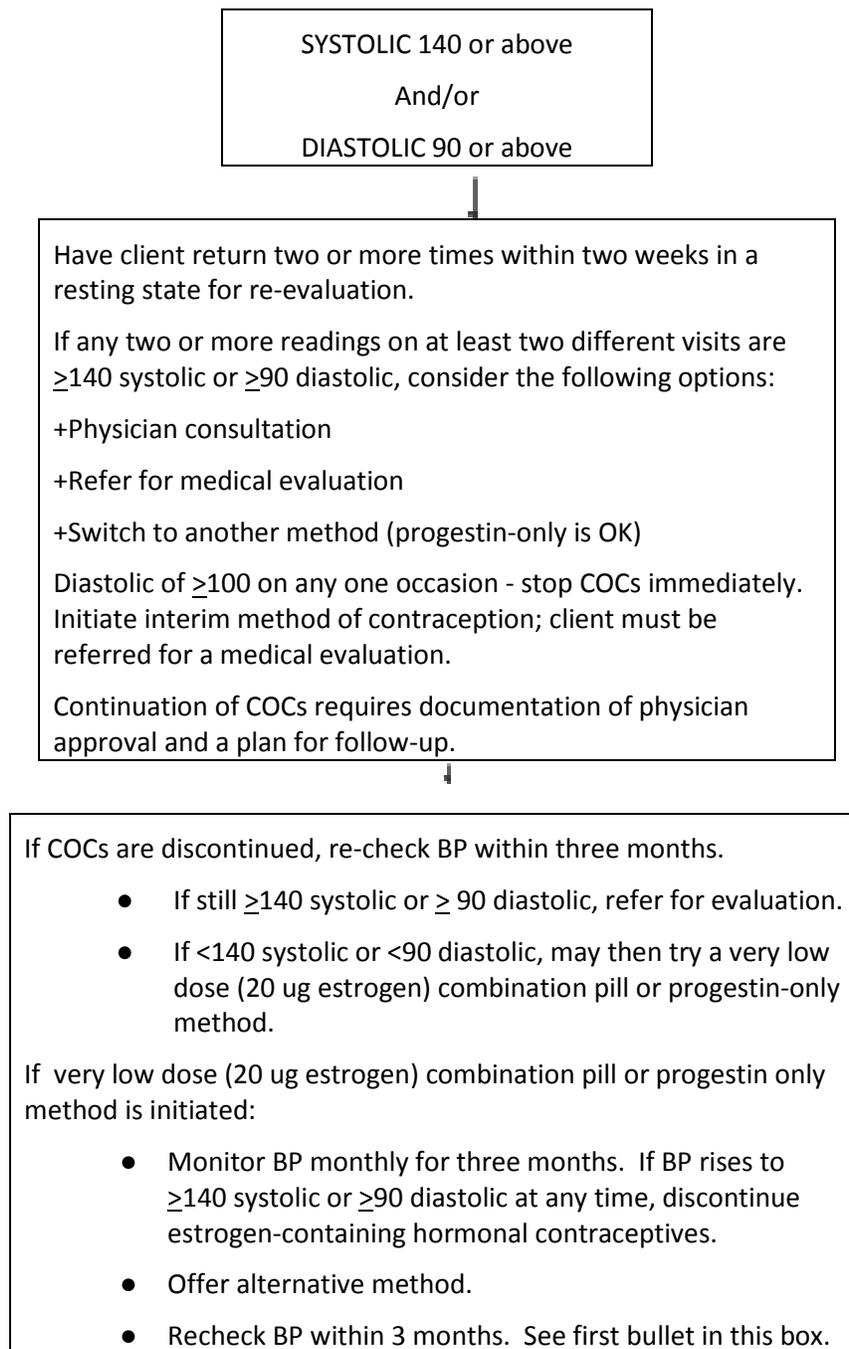
- a. Combined hormonal contraceptive use in women with diabetes must be individualized. As risk factors increase in number or severity, it may become less appropriate to prescribe combined hormonal contraceptives
- b. Consider involving the primary care provider managing the client's diabetes if she is initiated on combined contraceptives.

### 3. High Blood Pressure

- a. If hypertension is controlled with diet or medication, the complete cardiovascular risk profile must be considered.
- b. Hypertension is classified as Category 3 for combined hormonal methods, a condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- c. Combined hormonal contraceptives may induce hypertension in a very small percentage of previously normotensive women. If a combined hormonal contraceptive user is found to have a significant rise in blood pressure to 140 systolic or above/ 90 diastolic or above, the rise could be due to the use of the method.
- d. Management - Please refer to the flow chart on the next page for management of hypertension that occurs in women using combined hormonal methods.

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

### Flow Chart for the Management of Clients Using Combined Oral Contraceptives (COCs) Who Develop High Blood Pressure



## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

### 1. Headaches

- a. Management of non-migrainous headaches (classification category 2) that start or worsen after the initiation of combined hormonal methods is up to the discretion of the practitioner and client. “Classification depends on accurate diagnosis of those severe headaches that are migrainous and those headaches that are not. Any new headache or marked changes in headaches should be evaluated. Classification is for women without any other risk factors for stroke. Risk for stroke increases with age, hypertension and smoking.” (US MEC 2010) and may include any of the following:
  - 1) Referral for headache evaluation;
  - 2) Change in pill prescription including very low dose COCs (20 ug), or progestin only methods;
  - 3) Change in birth control method;
  - 4) For headaches during the hormone free interval, instruct the client to skip the week of placebo pills or hormone free interval and immediately start a new cycle (see extended use regimen, pg. 44).
- b. Common Migraine Headaches (without focal neurologic symptoms [aura, visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities]) (without aura, age < 35 yrs – classification category 2 for initiation and category 3 for continuation of combined hormonal methods)
  - 1) A trial of a combined hormonal method may be provided for women with a history of migraine headaches without focal neurological symptoms. The client must be advised to report any increase in the frequency and severity of such headaches. The initiation of an estrogen containing method to women  $\geq 35$  years old with a history of migraine headaches without focal neurological symptoms is a category 3, a condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
  - 2) If migraines worsen in frequency or severity, or if focal neurological symptoms or signs (aura, visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities) occur, combined hormonal methods must be discontinued. Women who develop focal neurological symptoms or signs should be referred promptly for neurologic evaluation. If a woman  $\geq 35$  years old develops migraine headaches without aura or other neurological symptoms, combined hormonal methods must be discontinued.
- c. Migraine headache with aura at any age is classified as a Category 4 for combined methods and represents an unacceptable health risk if the method is used.

2. Age: For individuals 40 and older the use of combined hormonal contraceptives (CHC) is a category 2, a condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The risk for cardiovascular disease increases with age and might increase with CHC use. In the absence of other adverse clinical conditions, CHCs can be used until menopause (US MEC 2010) Combined oral contraception (COC) or vaginal ring may be continued to the early 50s unless contraindicated. Combined hormonal methods may be used for non-obese, nonsmoker clients without cardiovascular risk factors.

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

### 3. Seizure Disorders

- a. A majority of women with seizure disorders will notice no change in the frequency or severity of seizure activity as a result of initiating oral contraceptives.
- b. Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in combined hormonal contraceptive users. It is the responsibility of the provider to review a client's anti-seizure medication(s) for potential drug interaction with oral contraceptives.
- c. Use of backup barrier methods, and the benefits and risks of using combined hormonal contraceptives in women with seizure disorders should be discussed with women who use anti-seizure drugs but who need a high degree of protection. Women who are on certain anti-seizure medications and choose to use combined hormonal contraceptives should be advised to use a back up method, such as condoms. Any breakthrough bleeding during this time may indicate a decrease in circulating levels of estrogen and progestin. Such a decrease could result in ovulation. Absence of breakthrough bleeding does not confirm adequate serum hormone levels.
- d. Continued use of a barrier method with combined hormonal contraceptives (dual method use) or switching to Depo Provera or an IUC may be advised.

### 4. Drug Interactions

- a. Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. These medications include phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine (USMEC 2010).
- b. Gabapentin (Neurontin®), vigabatrin, ethosuximide and lamotrigine (Lamictal®) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid (Depakote®) and felbamate (Felbatol®) do not increase breakdown of hormones and may even increase hormone levels. Pharmacokinetic studies show levels of lamotrigine decrease significantly during combined hormonal method use. This may result in an increase in seizure activity (USMEC 2010).
- c. Rifampin increases hepatic clearance of estrogens and progestins; it is recommended that clinicians not prescribe combined hormonal contraceptives for women on this drug (USMEC 2010).
- d. Broad-spectrum antibiotics: Hormone levels in women using combined hormonal methods are not lowered by the use of ampicillin, amoxicillin, clarithromycin, metronidazole, quinolones, doxycycline, tetracycline, or fluconazole. Virtually every COC user taking these antibiotics has hormone levels that remain well within the therapeutic range for contraceptive efficacy. As a result, back-up methods should not be necessary unless the client has problems taking her pills, e.g., if her underlying medical condition interferes with pill taking or absorption. (Contraceptive Technology, 20th Edition, pp. 305)

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

- e. Combined hormonal methods can decrease clearance of benzodiazepines such as diazepam (Valium), nitrazepine, chlordiazepine, alprazolam, which suggests the need for lower doses of these medications. Clearance of bronchodilators such as theophylline, aminophylline and caffeine as well as anti-inflammatory corticosteroids may also be reduced.
- f. More rapid clearance of acetaminophen and aspirin is also reported.
- g. The FDA has alerted providers that the use of St. John's Wort may decrease the therapeutic effect of combined hormonal methods.
- h. Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive. When a combined oral contraceptive is chosen, a preparation containing a minimum of 30 ug ethinyl estradiol (EE) should be used. (USMEC 2010)
- i. Most studies suggest no association between use of hormonal contraception and progression of HIV, as measured by CD4+ count  $<200$  cells/mm<sup>3</sup>, initiation of antiviral therapy, or mortality.

(See Updated to CDC's US MEC; Revised Recommendations for the Use of Hormonal Contraception Among Women at High Risk for HIV Infection or Infected with HIV MMWR/June 22,2012/Vol.61/No.24 for more information).

<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm>

### C. Client Education/Informed Consent – must include:

1. Fact sheet on all contraceptive options available if she is a new client or is undecided as to what method she wishes to use;
2. Fact sheet on the client's chosen method
3. A copy of the FDA approved detailed client labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the client;
4. Instructions on correct use of the method. See US SPR starting on page 22 and for COC instructions, see Contraceptive Technology, 20th Edition, pp. 320-322; for Ortho Evra pp. 353-355; for Nuva Ring pp. 360-365;
5. Information about the effectiveness of her method and that the effectiveness of combined hormonal contraception may be decreased by some medications (See Drug Interactions of this Section);
6. The importance of scheduled follow-up visits (See Follow Up of this Section);
7. Importance of informing other providers of their use of contraceptives;
8. Information regarding discontinuation of her method. If she does not wish to get pregnant, she should start using another method before the day she was due to start her next cycle;

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

9. Information regarding sexually transmitted infections (STIs), including counseling that combined hormonal contraceptives provide no protection. Use of either male or female condoms should be recommended for clients in need of protection from STIs.
10. Non contraceptive benefits of the method
11. Possible side effects and how to manage side effects
12. Warning signs and symptoms and to seek care immediately for rare but serious adverse events, such as heart attack, stroke, blood clot in extremity or lungs.

### D. Medical Screening and Evaluation

1. History – (See Section 1- Health Care Services of the Clinical Manual)
2. Examination – (See Section 1 - Health Care Services of the Clinical Manual)
3. Laboratory – (See Section 1 - Health Care Services of the Clinical Manual)
4. Provision of hormonal contraceptives through Express Visit (See Section 1. Health Care Services – of the Clinical Manual)

### E. Provision of Combined Hormonal Contraceptive

Combined hormonal contraceptives can be initiated at any time if it is reasonably certain that the client is not pregnant. If the health care provider is uncertain whether the client is pregnant, the benefits of starting combined hormonal contraceptives likely exceed any risk. Starting combined hormonal contraceptives should be considered at any time with a follow up pregnancy test in 2-4 weeks. (US SPR 2013)

1. A health-care provider can be reasonably certain that a client is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:
  - a. is  $\leq 7$  days after the start of normal menses
  - b. has not had sexual intercourse since the start of last normal menses
  - c. has been correctly and consistently using a reliable method of contraception
  - d. is  $\leq 7$  days after spontaneous or induced abortion
  - e. is within 4 weeks postpartum
  - f. is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [ $\geq 85\%$ ] of feeds are breastfeeds), amenorrheic, and  $< 6$  months postpartum (US SPR pg 7)
2. A blood pressure must be documented for all clients starting a combined hormonal and then checked and documented periodically as long as the woman is using a combined method.
3. Provide or prescribe up to a 1 year supply of the contraceptive method, e.g. 13, 28 day pill packs. The more cycles provide, the higher the continuation rates.

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

### Starting Combined Hormonal Contraceptives (US SPR)

CURRENT METHOD	START METHOD	BACK UP
No effective contraception in preceding cycle	Any time if provider is reasonably certain the woman is not pregnant.	If started with in first 5 days since menses started, no back up required. If > 5 days after menses started, use back up method for 7 days
Another hormonal method	Start immediately if it is reasonably certain woman is not pregnant.	If > 5 days since her menstrual bleeding started back up method for 7 days is recommended
IUD/IUS	On the same day that the IUD/IUS is removed if no unprotected intercourse (used a barrier method) for 7 days before IUD/IUS removal Start hormonal method at least 7 days before the IUD/IUS is removed. *Consider need for ECPs at time of IUD/IUS removal	Back up method for 7 days  No need for back up
After first or second trimester loss (up to 28 weeks gestation) or termination	Start immediately or up to 7 days after loss or termination	Back up method for 7 days unless method started at same time as termination
Postpartum Not breastfeeding	When medically eligible and reasonably certain the woman is not pregnant and at 21-42 days postpartum in women who have no risk factors for VTE (Category 2); If greater than 42 days post partum (Category 1) See Update US MEC: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period <a href="http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm">http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm</a>	Back up method recommended for 7 days
Postpartum Breastfeeding	When medically eligible and reasonably certain the woman is not pregnant and at 30 – 42 days postpartum if no risk factors for VTE (Category 2); If greater than 42 days postpartum (Category 2)	Back up method recommended for 7 days

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

### F. Guidelines for Combined Method Use

#### 1. Oral contraceptives

- a. Missed or late Oral Contraceptive Pills: See US SPR pg 27  
<http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf>
- b. Vomiting or diarrhea while using COCs: See US SPR pg 30  
<http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf>
- c. Extended Use or Continuous Cycling: Consider offering clients the opportunity of fewer or no withdrawal bleeds during the year by skipping the placebo pills, particularly if they experience estrogen withdrawal symptoms such as headache when taking the placebo pills during the fourth week of the pill pack. The prescription needs to be written for 16-17 cycles/year, (or more if client plans to skip spacer pills all together). As an alternative to the more expensive products with dedicated packaging for extended use, select a monophasic pill for extended use or continuous cycling. Please refer to, Contraceptive Technology, 20th Revised Edition, pp. 292-294. Inform clients of the possibility of unscheduled bleeding with extended or continuous use of combined hormonal contraceptives. This usually occurs during the first 3 to 6 months of use and is generally not harmful. If indicated, evaluate for incorrect use of method, interactions with other medications, infection, pregnancy, etc. (US SPR pp 28-29)

#### 2. Ortho Evra

- a. Delayed application or detachment of patch: See US SPR pg 28  
<http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf>
- b. Ortho Evra should be stored below 85 degrees F.
- c. May be applied to abdomen, buttock, upper outer arm or upper torso (excluding breast)
- d. Ortho Evra is applied weekly for 3 weeks on the same day of the week each week. There is a one-week patch free interval. This should never be more than 7 consecutive days.
- e. It is preferable for the client to place a new patch on a fresh area of skin to avoid skin reactions
- f. Recommendations for continuous cycling of Ortho Evra vary.

#### 3. Nuva Ring

- a. Delayed insertion or reinsertion with combined vaginal ring: See US SPR pg 29  
<http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf>
- b. Nuva Ring must be stored in refrigerator at 36-46 degrees F prior to dispensing. Nuva Ring may be stored by the client for up to 4 months at or below 77 degrees F (room temperature). The client label should have an expiration date that does not exceed 4 months from the date of dispensing or the product expiration date, whichever comes first.
- c. The exact position of Nuva Ring in the vagina is not important for efficacy.

## Section 6: Tier 2 Method - Combined Hormonal Methods, Oral Contraceptives, Vaginal Ring, Hormonal Patch

- d. If the client feels discomfort, Nuva Ring is probably not inserted far enough in the vagina.
- e. Nuva Ring should be inserted and removed on the same day of each week (three weeks apart) and at about the same time
- f. Dispose of the used ring in a waste receptacle.
- g. The menstrual period will usually begin two to three days after the ring is removed and may not have finished before the next ring is inserted.
- h. Clients may use vaginal yeast medication while Nuva Ring is in place.
- i. Extended Use or Continuous Cycling: Consider offering clients the opportunity of fewer withdrawal bleeds during the year by skipping the ring-free week, particularly if they experience estrogen withdrawal symptoms such as headache during the ring-free week. Each ring can be left in place for one calendar month, then removed and immediately replaced with a new ring on the first of each month. The prescription is still written for 12 or 13 rings/year. Inform clients of the possibility of unscheduled bleeding with extended or continuous use of combined hormonal contraceptives. This usually occurs during the first 3 to 6 months of use and is generally not harmful. If indicated, evaluate for incorrect use of method, interactions with other medications, infection, pregnancy, etc. (US SPR pp 28-29)

### G. Follow Up

1. Routine follow up is not recommended unless indicated. Provider recommendations for follow up visits are based on factors such as whether the woman has certain medical conditions or multiple medical conditions in need of monitoring.
2. Advise woman to return to the clinic at any time to discuss side effects, problems or if she wants to change her method.
3. At other routine visits the client should be assessed for her satisfaction with her method, changes in health status including medications that would impact the safe use of her method (e.g. category 3 and 4 conditions for the method), assess blood pressure, consider assessing weight changes.
4. Monitor blood pressure as indicated or when client returns for annual visit.

Hormonal Method Evaluation Form

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

## Section 7: Tier 2 Method - Progestin Only Pills (POP)

CDPHE Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs publication Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/QFP.htm>, the CDC U.S. Medical Criteria for Contraceptive Use, 2010 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2013 (US SPR). These recommendations can be accessed at the following link: [http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception\\_Guidance.htm](http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception_Guidance.htm) Providers should sign up to receive email updates to these recommendations.

### A. Method selection

A broad range of contraceptive methods should be available to the client either in the clinic or by referral. Providers should use a tiered approach to presenting contraceptive methods with the most effective methods presented first, long acting reversible contraceptives (LARCs), followed by moderately effective and lesser effective methods. (QFP)

Progestin only oral contraceptive are a Tier 2 contraceptive and are moderately effective. US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a woman develops the condition while she is using the method. (US MEC 2010)

- Category 1: A condition for which there is no restriction for the use of the contraceptive method.
- Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.
- Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.
- Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

A US MEC summary table (updated 2012) only contains a subset of the recommendations from the US MEC. See complete guidance and summary table at

<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

### B. Management of Women with Special Considerations Requiring Further Evaluation

#### 1. Drug Interactions

- a. Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. These medications include phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine (USMEC 2010).
- b. Gabapentin (Neurontin®), vigabatrin, ethosuximide and lamotrigine (Lamictal®) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid

## Section 7: Tier 2 Method - Progestin Only Pills (POP)

(Depakote®) and felbamate (Felbatol®) do not increase breakdown of hormones and may even increase hormone levels. No drug interactions have been reported among epileptic women taking lamotrigine and using POPs (USMEC 2010).

- c. Rifampin increases hepatic clearance of estrogens and progestins; it is recommended that clinicians not prescribe hormonal contraceptives for women on this drug (USMEC 2010).
- d. Use of broad-spectrum antibiotics, antifungals, and antiparasitics with POPs is a Category 1 (US MEC 2010).
- e. The FDA has alerted providers that the use of St. John's Wart may decrease the therapeutic effect of combined hormonal methods.
- f. Antiretroviral (ARV) drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between many ARV drugs (particularly some NNRTIs and ritonavir-boosted protease inhibitors) and hormonal contraceptives. These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. Thus, if a woman on ARV treatment decides to initiate or continue hormonal contraceptive use, the consistent use of condoms is recommended to both prevent HIV transmission and compensate for any possible reduction in the effectiveness of the hormonal contraceptive. (USMEC 2010)
- g. Most studies suggest no association between use of hormonal contraception and progression of HIV, as measured by CD4+ count <200 cells/mm<sup>3</sup>, initiation of antiviral therapy, or mortality. (For more information see Updated to CDC's US MEC; Revised Recommendations for the Use of Hormonal Contraception Among Women at High Risk for HIV Infection or Infected with HIV MMWR/June 22,2012/Vol.61/No.24 for more information).

### C. Client Education/Informed Consent – must include:

1. Fact sheet on all contraceptive options available if she is a new client or is undecided as to what method she wishes to use;
2. Fact sheet on the client's chosen method
3. A copy of the FDA approved detailed client labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the client;
4. Instructions on correct use of the method. See US SPR starting on page 29 and for progestin only pill instructions, see Contraceptive Technology, 20th Edition, pp. 237-247  
<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm>
5. Information about the effectiveness of her method and that the effectiveness of hormonal contraception may be decreased by some medications (See Drug Interactions of this Section);
6. The importance of scheduled follow-up visits (See Follow Up of this Section);
7. Importance of informing other providers of their use of oral contraceptives;
8. Information regarding discontinuation of her method. If she does not wish to get pregnant, she should start using another method before the day she was due to start her next cycle;
9. Information regarding sexually transmitted infections (STIs), including counseling that hormonal contraceptives provide no protection. Use of either male or female condoms should be recommended for clients in need of protection from STIs.
10. Non contraceptive benefits of the method
11. Possible side effects and how to manage side effects

## Section 7: Tier 2 Method - Progestin Only Pills (POP)

12. Warning signs and symptoms and to seek care immediately for rare but serious adverse events, such as heart attack, stroke, blood clot in extremity or lungs.

### D. Medical Screening and Evaluation

1. History – (See Section 1 - Health Care Services of the Clinical Manual)
2. Examination – (See Section 1 - Health Care Services of the Clinical Manual)
3. Laboratory – (See Section 1 - Health Care Services of the Clinical Manual)
4. Provision of hormonal contraceptives through Express Visit (See Section 1 - Health Care Services of the Clinical Manual)

### E. Provision of POPs

1. Follow US SPR recommendations for initiation of POPs (pgs. 29-33)  
<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm>
2. POPs can be started at any time if it is reasonably certain that the woman is not pregnant. If the health care provider is uncertain whether the woman is pregnant, the benefits of starting hormonal contraceptives likely exceed any risk.
3. Starting hormonal contraceptives should be considered at any time with a follow up pregnancy test in 2-4 weeks. (US SPR 2013 pgs. 30-31). POPs may be started in lactating and non-lactating women at any time postpartum. The U.S. Medical Eligibility Criteria for Contraceptive Use lists POPs as a Category 2 (the advantages of using the method generally outweigh the theoretical or proven risks) for breastfeeding women less than one month post partum. (Also see Contraceptive Technology, 20th Edition, Chapter 18: Postpartum Contraception and Lactation, pp. 483-511)
4. A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:
  - a. is  $\leq 7$  days after the start of normal menses
  - b. has not had sexual intercourse since the start of last normal menses
  - c. has been correctly and consistently using a reliable method of contraception
  - d. is  $\leq 7$  days after spontaneous or induced abortion
  - e. is within 4 weeks postpartum
  - f. is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [ $\geq 85\%$ ] of feeds are breastfeeds), amenorrheic, and  $< 6$  months postpartum (US SPR pg 7)
5. A pregnancy that does occur in a woman taking mini-pills is more likely to be ectopic. Some sources postulate that 10% of pregnancies that occur to mini-pill users are ectopic (Contraceptive Technology, 20th Edition, p.241).
6. POPs inhibit ovulation in about half of cycles, though rates vary widely by individual. Serum levels peak at two hours after taking a POP and return to baseline at 24 hours. Taking POPs at the same time each day is important. It takes 48 hours to achieve the contraceptive effect on cervical mucus. (US SPR pg 31).
7. A blood pressure must be documented for all women starting a hormonal method and then checked and documented periodically as long as the woman is using the method.
8. Provide or prescribe up to a 1 year supply of the contraceptive method, e.g. 13, 28 day pill packs. The more cycles provide, the higher the continuation rates.
9. See US SPR 2013 for instructions on missed POPs and vomiting or severe diarrhea that occurs within 3 hours after taking a pill.

## Section 7: Tier 2 Method - Progestin Only Pills (POP)

### F. Follow Up

1. Routine follow up is not recommended unless indicated. Provider recommendations for follow up visits are based on factors such as whether the woman has certain medical conditions or multiple medical conditions in need of monitoring.
2. Advise woman to return to the clinic at any time to discuss side effects, problems or if she wants to change her method.
3. At other routine visits the client should be assessed for her satisfaction with her method, changes in health status including medications that would impact the safe use of her method (e.g. category 3 and 4 conditions for the method), assess blood pressure, consider assessing weight changes.
4. Monitor blood pressure as indicated or when client returns for annual visit. (US SPR)

## Section 8: Tier 3 Methods - Barrier Methods

CDPHE Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs publication Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/QFP.htm> , the CDC U.S. Medical Criteria for Contraceptive Use, 2010 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2013 (US SPR). These recommendations can be accessed at the following link: [http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception\\_Guidance.htm](http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception_Guidance.htm) Providers should sign up to receive email updates to these recommendations. Also available for download are an US MEC APP and US SPR eBook.

### A. Method selection

A broad range of contraceptive methods must be available to the client either in the clinic or by referral.

Providers should use a tiered approach to presenting contraceptive methods with the most effective Tier 1 methods presented first, long acting reversible contraceptives (LARCs), followed by moderately effective Tier 2 methods and lesser Tier 3 effective methods. (QFP)

Barrier methods are tier 3 methods and not as effective in preventing pregnancy as hormonal methods and LARCs.

US MEC Categories of medical eligibility criteria for contraceptive use to use when assessing the safety of a contraceptive method for women with specific medical conditions or characteristics.

- Category 1: A condition for which there is no restriction for the use of the contraceptive method.
- Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method generally can be used but follow up may be required.
- Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. Use of the method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account, and careful follow up is required. The provision of a method to a woman with a condition classified as Category 3 requires careful clinical judgment and access to clinical services.
- Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a woman develops the condition while she is using the method. (US MEC 2010)

For complete US MEC guidance see (pgs.65-70): <http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf> Barrier methods are not addressed in the US SPR.

## Section 8: Tier 3 Methods - Barrier Methods

**B. Diaphragm** (See <http://www.caya.us.com/> for information about the Caya® single size contoured diaphragm and <http://www.coopersurgical.com/Products/Clinics-Offices#page=1&min=0&max=0&mn=&vn=&tp=d4ac51de-a163-4574-b458-4ba705cab112&prop=13|55> for information about Milex diaphragms)

1. Non-contraceptive benefits

- a. Protection from some sexually transmitted infections.
- b. Lower risk of cervical dysplasia and cancer.

2. Subjective data – History (See Section 1 Health Care Services)

Cautions - The following conditions may preclude satisfactory use or make use of the diaphragm inadvisable:

- a. History of Toxic Shock Syndrome.
- b. Allergy to rubber, latex, polyurethane, or spermicide. Current diaphragm on the market from Cooper Surgical, Milex Arching and Omniflex is made from silicone and is latex free according to Cooper Surgical web site. Package insert and directions for use in English and Spanish are available for download. <http://www.coopersurgical.com/Products/Clinics-Offices#page=1&min=0&max=0&mn=&vn=&tp=d4ac51de-a163-4574-b458-4ba705cab112&prop=13|55>  
Caya® diaphragm (latex free according to web site) <http://www.caya.us.com/index.html>
- c. Recurrent urinary tract infections.
- d. Abnormalities in vaginal anatomy that interfere with satisfactory fit or stable placement.
- e. Inability of client to correctly insert or remove.
- f. Full-term delivery less than 6 weeks ago.
- g. Need for HIV protection -There is a lack of protection against HIV and some STIs. Client must use a condom if at risk.
- h. A high risk for HIV infection is a condition that represents an unacceptable health risk if the contraceptive method (diaphragm with spermicide) is used. Repeated and high dose use of the spermicide nonoxynol-9 has been associated with increased risk for genital lesions, which might increase the risk for HIV infection. Category 4 ((Centers for Disease Control (CDC) U.S. Medical Eligibility Criteria for Contraceptive Use, (USMEC) 2010. MMWR Early Release 2010; 59 May 28, 2010).
- i. In client with HIV or AIDs, use of spermicides and/or diaphragms (with spermicide) can disrupt the cervical mucus, which may increase viral shedding and HIV transmission to uninfected partners Category 3 (USMEC 2010).

3. Objective data

- a. Physical examination as indicated (See – Health Care Services).
- b. Laboratory tests as indicated (Health Care Services).

4. Assessment and plan - Client education (See Contraceptive Technology 20<sup>th</sup> Edition (2011) pgs.391-415 for more information)

- a. Insertion technique.
- b. Instructions in use of method

## Section 8: Tier 3 Methods - Barrier Methods

- c. Inform client of effectiveness: pregnancy rate 12% with typical use and 6% with perfect use. (Contraceptive Technology 20th Edition pg. 50)
  - d. Use and care of the diaphragm.
  - e. Document that the client demonstrates the ability to properly insert and remove the diaphragm.
  - f. Document that literature and instructions, including the package insert, for diaphragm use were given.
  - g. The client should be able to leave the diaphragm in place for a minimum of 6-8 hours without discomfort at least once before she uses it for contraception.
  - h. Client should be informed that if she wishes to become pregnant, she simply needs to discontinue the use of the diaphragm.
  - i. The client should also leave the diaphragm in place for a minimum of 6-8 hours at least once before returning for a fit check.
  - j. Counsel regarding emergency contraception in the event the diaphragm is not used, or becomes dislodged during use.
5. Side effects and complications
- a. Toxic Shock Syndrome  
Sudden high fever, vomiting, diarrhea, dizziness, fainting, weakness, sore throat, aching muscles and joints, and rash (like a sunburn) occurring in association with use of diaphragm has been reported. Client must seek emergency care for symptoms of toxic shock syndrome.
  - b. Vaginal or urinary tract infections
  - c. Local irritation
  - d. Allergic reaction to rubber, latex, polyurethane, or spermicide and/or local skin irritation of client or partner.
  - e. Pelvic discomfort, cramps, or pressure on the bladder or rectum due to improper fit.
  - f. Foul odor or vaginal discharge if the diaphragm is left in the vagina for longer than recommended.
6. Follow up visits
- a. Offer revisit approximately one month after the initial fitting.
    - 1) During the first month of use, instruct client to practice insertion and removal, and to determine the comfort of the diaphragm.
    - 2) The day of the appointment, the client wears the diaphragm to the clinic. The clinician should check the position and fit of the diaphragm.
  - b. The client should return for annual visits and evaluation of the diaphragm fit.
  - c. The diaphragm should be refit annually after a weight gain or loss of 10 pounds or more, after an abortion, or after a full-term pregnancy.
  - d. The client should be encouraged to call the clinic if she experiences problems with the diaphragm.

## Section 8: Tier 3 Methods - Barrier Methods

### C. Foams, Jellies, Creams, Suppositories, Vaginal Contraceptive Film

1. Non-contraceptive benefits

Available without a prescription.

2. Subjective data

Cautions - spermicides are not a reasonable choice in the following circumstances:

- a. Anal sex.
- b. Vaginal intercourse multiple times each day.
- c. A high risk for HIV infection is a condition that represents an unacceptable health risk if the contraceptive method (spermicide) is used. Repeated and high dose use of the spermicide nonoxynol-9 has been associated with increased risk for genital lesions, which might increase the risk for HIV infection. Category 4 (USMEC 2010).
- d. In client with HIV or AIDs, use of spermicides can disrupt the cervical mucus, which may increase viral shedding and HIV transmission to uninfected partners Category 3 (USMEC 2010).
- e. Allergy or sensitivity to spermicide.
- f. Abnormalities in the vaginal anatomy preventing proper insertion or retention of spermicide.
- g. Inability to learn correct insertion technique.

3. Assessment and plan – Client Education (See Contraceptive Technology 20<sup>th</sup> Edition, 2011 pgs.391-408 for more information)

- a. Clients should be advised to incorporate the use of the condom to increase the effectiveness of spermicidal creams, jellies, foams, suppositories, and film.
- b. Inform client of spermicide effectiveness: pregnancy rate of 28 % with typical use and 18% with perfect use (Contraceptive Technology 20th Edition pg. 50)
- c. Provide clients with appropriate fact sheets specific to their product of choice and should be instructed to follow the package insert for directions on use.
- d. Counsel regarding emergency contraception in the event the spermicide is not used according to directions.

4. Side effects and complications

- a. Temporary skin irritation or allergy (male or female).
- b. Unpleasant taste during oral-genital sex.
- c. Failure of suppositories to melt or foam in the vagina, which may decrease effectiveness.

### D. FemCap®

1. Non-contraceptive benefit

Possible protection against sexually transmitted infections affecting the upper genital tract.

## Section 8: Tier 3 Methods - Barrier Methods

### 2. Subjective data - History ( – Health Care Services)

Cautions - The following conditions may preclude satisfactory use or make use of FemCap inadvisable:

- a. History of Toxic Shock Syndrome.
- b. CIN or cervical cancer
- c. Allergy to spermicide, rubber, latex or polyurethane.
- d. Abnormalities in vaginal anatomy that interfere with a satisfactory fit or stable placement.
- e. Vaginal bleeding from any cause, including menstrual flow.
- f. Full-term delivery within the past 6 weeks or recent spontaneous or induced abortion.
- g. Inability of client to correctly insert or remove.
- h. Need for HIV protection.
- i. High risk for HIV – Repeated and high-dose use of the spermicide nonoxynol-9 has been associated with creased risk for genital lesions, which might increase the risk of HIV infection. Catagory 4 (USMEC 2010)
- j. HIV infection - Use of spermicides can disrupt the cervical mucosa, which may increase viral shedding and HIV transmission to uninfected sex partners. Category 3 (USMEC 2010)

### 3. Objective data

- a. Physical examination as indicated (Section1 Health Care Services)
- b. Laboratory tests as indicated (Section 1 Health Care Services)

### 4. Assessment and plan – Client Education (See Contraceptive Technology 20<sup>th</sup> Edition , 2011 pgs. 391-408 for more information)

- a. Review the use and care of the FemCap.
- b. Inform client of effectiveness: pregnancy rate of 9.5% for nulliparous women and 20.5% fro parous women. (Contraceptive Technology 20th Edition pg. 397)
- c. Document that instructions for FemCap use were reviewed.
- d. Document that the client demonstrates the ability to properly insert and remove the FemCap.
- e. Instruct the client to stop using the FemCap and return to clinic for evaluation if symptoms of vaginal or cervical irritation develop.
- f. Client should be informed that if she wishes to become pregnant, she simply needs to discontinue the use of the FemCap.
- g. Advise the client of signs and symptoms of Toxic Shock Syndrome (TSS) and instruct her to seek emergency medical care if they occur.
- h. Counsel regarding emergency contraception in the event the FemCap becomes dislodged or is not used properly.

## Section 8: Tier 3 Methods - Barrier Methods

5. Side effects and complications
  - a. Toxic Shock Syndrome - sudden high fever, vomiting, diarrhea, dizziness, fainting, weakness, sore throat, aching muscles, and joints and rash (like a sunburn) has occurred in association with use of the cervical cap. Client to seek immediate emergency care with Toxic Shock Syndrome symptoms.
  - b. Allergic reaction to rubber, latex, polyurethane or spermicide, or local skin irritation to either client or partner.
  - c. Rare cases of vaginal/cervical trauma, including abrasion or laceration.
  - d. Foul odor or vaginal discharge if the FemCap is left in the vagina longer than recommended (48 hours maximum).
6. Follow up visits
  - a. The client should return for annual visits and recheck of the FemCap fit.
  - b. The client should return for an examination and to have the cervical cap fit checked six weeks after childbirth, miscarriage, abortion, or pelvic surgery, including LEEP or conization.

### E. Condom (male and female)

1. Non-contraceptive benefits
  - a. Protection against sexually transmitted infections, including HIV.
  - b. Available without a prescription at low cost.
  - d. Male participation in contraception.
  - e. Prevention of premature ejaculation.
  - f. Prevention of sperm allergy in women.
2. Subjective data

Cautions - Male condoms do have disadvantages that may lead to inconsistent or lack of use. Encourage couples to try different brands and lubricants until they find one that is acceptable.

  - a. Allergy to latex or spermicide in condoms. Plastic condoms are an excellent alternative.
  - b. An inability, in some men, to maintain an erection if condom is used.
  - c. Male partner will not accept responsibility for birth control.
  - d. Natural membrane condoms are contraindicated where there is a risk of infection since they allow passage of very small viruses such as the human immunodeficiency virus (HIV).
  - e. Condoms with spermicidal lubricant should not be used for anal intercourse; for multiple acts of vaginal intercourse each day (>2 times); or for those at high risk for HIV.
3. Assessment and plan – Client Education (See Contraceptive Technology 20<sup>th</sup> Edition, 2011 pgs.391-408 for more information)
  - a. Give client a condom fact sheet. Advise that female condoms may be squeaky during use.

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- b. Inform client of effectiveness: male condom - pregnancy rate 18% with typical use and 2% with perfect use. Female condom - pregnancy rate 21% with typical use and 5% with perfect use (Contraceptive Technology 20th Edition pg. 50)
  - c. Counsel regarding emergency contraception in the event of condom breakage.
4. Side effects and complications
- g. Breakage.
  - h. Allergy or skin irritations.

Condom Information Sheet

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

## Section 9: Tier 3 Methods - Natural Family Planning

### A. Definition

1. The Fertility Awareness Method is another name for periodic abstinence or Natural Family Planning, which is an accepted method of birth control. See Contraceptive Technology 20<sup>th</sup> Edition, pages 417-424 for more information.
2. There are four basic types of the Fertility Awareness Method

- a. Basal body temperature (BBT)

Method based on using BBT alone to limit unprotected intercourse to the postovulatory infertile time.

- b. Ovulation, mucous or Billings method

Method based on evaluating cervical mucus changes signifying ovulation. Unprotected intercourse would be limited to the postovulatory infertile times.

Examples and more information:

Two Day Method®

<http://irh.org/twoday-method/>

<http://www.twodaymethod.com/>

Billings Ovulation Method™

<http://billings.life/en/>

- c. Calendar methods

Method based on predicting ovulation using the client's menstrual history. Examples and more information: Standards Day Method®

<http://irh.org/standard-days-method/>

Cycle Beads®

Uses color coded beads (Cycle Beads) to monitor the days of a women's menstrual cycle

<http://www.cyclebeads.com/>

- d. The sympto-thermal method: Combines BBT with one or 2 of the other Fertility Awareness Methods allowing a woman to be more accurate in predicting her safe days than if she used any one method alone.

### B. Effectiveness

1. First year typical use failure rates for fertility awareness methods range from 12 % to 25% (Zieman M, Hatcher RA. Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2015, pg. 53).

### C. Patient education

Patients should be screened to determine likelihood of success for this method. Some factors to consider are whether the method will be used:

- a. By the couple.
- b. By an individual with one other partner.

## Section 9: Tier 3 Methods - Natural Family Planning

- c. By an individual with more than one partner.
  - d. Out of religious conviction or other reason.
2. Couples desiring to use the method out of religious conviction should be referred to local teachers able to provide the religious component. In no case should clinic staff attempt to provide religion-based education.
  3. While all temporary methods of birth control require integration into the client's lifestyle and social and sexual practices, the Fertility Awareness Method requires additional attention.
  4. This is particularly true for the woman who is using the Fertility Awareness Method with partner(s) who have little or no education in, understanding of, or commitment to this method.
  5. This woman then must take full responsibility for ensuring the sometimes lengthy periods of abstinence and must understand her need to control social situations (shift work, alcohol use, and attention to schedules and details) in the use of the Fertility Awareness Method.

### **D. Referrals**

1. Group or one-to-one instruction is strongly recommended to all clients interested in this method.
2. Each clinic should develop its own referrals for the Fertility Awareness Method since this varies from community to community.

### **E. Documentation**

Couple or single partner use of the Fertility Awareness Method should be documented in the client's chart together with the plan for use.

# Section 10: Emergency Contraception

CDPHE Title X Family Planning Program contraceptive protocols are based on the CDC and U.S. Office of Population Affairs publication Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/QFP.htm>, the CDC U.S. Medical Criteria for Contraceptive Use, 2010 (US MEC) and updates and the CDC U.S. Selected Practice Recommendations, 2013 (US SPR). These recommendations can be accessed at the following link: [http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception\\_Guidance.htm](http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/Contraception_Guidance.htm)

Providers should sign up to receive email updates to these recommendations. Also available for download are an US MEC and QFP APP and US SPR eBook.

## A. Emergency Contraception

1. May be provided to a woman with a history of unprotected intercourse within past 120 hours to prevent unintended pregnancy but should be used as soon as possible after unprotected intercourse.
2. Levonorgestrel 1.5 mg. EC: Plan B may be purchased over the counter without restrictions on age or gender of purchaser. In February 2014 the FDA announced that manufacturers of generic EC products could apply for OTC labeling. Generic EC products (e.g. Take Action and Next Choice One Dose) can be sold directly on store shelves without prescription.
3. Precautions – There are no medical contraindications to the use of combined or progestin only emergency contraceptive pills with the exception of pregnancy. If a woman is already pregnant, treatment is ineffective. (Contraceptive Technology 20<sup>th</sup> Edition, p.129). Breast feeding is a category 1 (A condition for which there is no restriction for the use of the contraceptive method) for levonorgestrel and combined oral contraceptive pills used as EC.
4. Ulipristal acetate (UPA) (ella®) is a progesterone agonist/antagonist which became available in the US by prescription in December 2010. Ella reduces the risk of pregnancy the entire course of 120 hours after unprotected intercourse. Ella is not recommended for breastfeeding women. Ella is contraindicated for use in the case of known or suspected pregnancy. The risks to a fetus when ella is administered to a pregnant woman are unknown. If this drug is inadvertently used during pregnancy, the woman should be apprised of the potential for hazard to the fetus, according to the ella package insert.
5. A copper-releasing IUD may be used for emergency contraception within 5 days after the first act of unprotected intercourse.
6. Clients should be counseled that the copper IUD is the most effective form of EC, followed by UPA, and then by levonorgestrel, and that these differences are greater with increasing time from unprotected intercourse and increasing weight.

## B. Examination/Laboratory Testing

Urine pregnancy test, if indicated.

If inserting IUD, bimanual exam, cervical inspection, STI screening (See IUD Protocol)

## C. Assessment/Plan (Also see US SPR pgs. 34 -35)

1. The following outlines the pill dosing for hormonal emergency contraception:

## Section 10: Emergency Contraception

BRAND NAME	NUMBER OF TABLETS FOR EACH DOSE (only one dose required)
Plan B (0.75 mg Levonorgestrel)	2 tablets at the same time
Next Choice One Dose (1.5 mg Levonorgestrel)	1 tablet
Plan B One Step (1.5 mg Levonorgestrel)	1 tablet
ella (30 mg ulipristal acetate)	1 tablet

BRAND NAME	NUMBER OF TABLETS FOR EACH DOSE (2 doses, 12 hours apart are required)
Lo/Ovral, Nordette, Levlen	4 tablets
Allesse	5 tablets
Triphasil, (yellow pills only)	4 tablets

- Over-the-counter anti-nausea medication such as Dramamine/Bonamine may be recommended with use of combined hormonal options in the second table.

### D. Follow-Up

- Initiation of on-going contraception
  - Any regular contraceptive method can be started immediately after the use of levonorgestrel or combined estrogen and progestin EC. The woman needs to abstain from sexual intercourse or use barrier contraception for 7 days. (US Selective Practice Recommendations for Contraceptive Use, 2013 (US SPR 2013))
  - Any regular contraception method can be started immediately after the use of UPA. The woman needs to abstain from sexual intercourse or use barrier contraception for 14 days. (US SPR 2013).
  - Depo Provera may be administered immediately. If Depo Provera is administered immediately, consider having the client return in 2-3 weeks for a repeat pregnancy test (Zieman M., Hatcher RA et al. Managing Contraception. Tiger, Georgia: Bridging the Gap Foundation, 2015, pg 82). Offer and do a pregnancy test, if indicated, before administering Depo Provera. Client must be counseled that since ECP is not 100% effective, pregnancy cannot be ruled out prior to injection. While there is no clear association with harmful fetal

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effects, the client should be informed that the manufacturer does not recommend administering Depo Provera if pregnancy cannot be ruled out. The client needs to abstain from sexual intercourse or use barrier contraception for 7 days.

- d. ParaGard IUD may be inserted as an alternative to EC pills. (See IUD Protocol).
2. If the patient has not had any bleeding within three weeks of taking emergency contraception or has reason to suspect she may be pregnant, a urine pregnancy test should be done.

### E. Education

1. Emergency contraception information and the emergency contraception progress note form must be reviewed with the client. Consideration should be given to using the progress note as a means of documenting the client's need for emergency contraception. A record must be established for any client receiving a visit for emergency contraceptive services.
2. Inform women that levonorgestrel (LNG) EC is not as effective for overweight and obese women, LNG EC "showed a rapid decrease of efficacy with increasing body mass index (BMI), reaching the point where it appeared no different from pregnancy rates expected among women not using EC at a BMI of 26 compared with a BMI of 35 for UPA." (Trussell, J., Raymond, E., Cleland, K. Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy, September 2015, pg 5 <http://ec.princeton.edu/questions/ec-review.pdf> ). UPA is recommended for overweight and obese women. UPA is also more effective than LNG EC at days 4 and 5 after unprotected intercourse. (The same resource notes that the European Medicines Agency, after reviewing additional data from three WHO trials that did not find reduced efficacy with increasing weight or BMI, removed a statement regarding weight and effectiveness from the European LNG EC package insert).
3. Due to ulipristal's high affinity for binding to progesterone receptors, ulipristal may reduce the effectiveness of a woman's regular contraceptive method. Condoms should be recommended for 2 weeks after ulipristal use.
4. Counseling and documentation should be done regarding birth control methods.
5. There appears to be no harm for repeat use of levonorgestrel emergency contraception. Ulipristal emergency contraception is not recommended for repeated use in the same menstrual cycle.
6. The patient should be given a copy of the FDA package insert provided by the manufacturer of the pills.
7. There should be documentation of patient instructions to return for a follow up visit in three weeks if she has no menstrual period for a pregnancy test or if she desires family planning services.
8. The client must be given emergency contact information.
9. Provide information on emergency contraception regardless of the method the client is using. Consider including a package of emergency contraception to take home.
10. In an effort to reduce barriers to accessing emergency contraception, males should be able to purchase emergency contraceptive pills for their partners. Please note that 340B purchased ECP may not be provided to male clients for their partners or to individuals who are not clients of the clinic and do not have a medical record at the clinic. A separate stock of non-340B product should be used for this purpose.

The Emergency Contraception Progress Note

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

## Section 10: Emergency Contraception

Client EC education posters from Bedsider.org:

<https://www.dropbox.com/s/1narvw1ti16pqns/help-during-an-oops-moment-english-poster.pdf?dl=0>

<https://www.dropbox.com/s/mjcyhfgme3i5xqi/help-during-an-oops-moment-spanish-poster.pdf?dl=0>

# Section 11: Sterilization

## 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 the CDPHE 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/pdfs/42-cfr-50-c.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. All sections of the consent must be completed.
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 abortion.

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6. Federal 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 procedure 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 Title X 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 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.

# Section 11: Sterilization

## F. Laparoscopy Procedure (Tubal Ligation)

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.

1. 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<sup>®</sup> 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 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.

## Section 11: Sterilization

- 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). Approval must be obtained from the CDPHE Title X 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. Title X 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 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.

# Section 11: Sterilization

## 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 Nexplanon® 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).
  - 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.

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- 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 include:
- 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 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 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.

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- i. The informed consent must be documented by a completed consent form (with all sections completed, including the provider performing the procedure signature) which meets the requirements of 42 CFP 50.202(d)(7). For approved sterilization consent forms see [http://www.hhs.gov/opa/order-publications/#pub\\_sterilization-pubs](http://www.hhs.gov/opa/order-publications/#pub_sterilization-pubs). A copy of the completed consent should be included in the medical record. 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)?
    - 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?

## Section 12: Pregnancy Testing and Counseling

Pregnancy testing and counseling services are part of the core family planning services as outlined in Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (QFP), April 25, 2014 (<http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf> pages 13-14). Pregnancy diagnosis and counseling must be provided to all clients in need of this service. Visits for pregnancy testing should include discussion around the client's reproductive life plan.

### A. Standard

1. All clients receiving a pregnancy test will be offered information and counseling regarding their test results.
2. This should include the limitations of the test itself, options for a positive test result, and contraceptive choices, preconception counseling or infertility counseling for a negative test result.

### B. Subjective Data

1. Clients complete "Request for Pregnancy Test" form or agency-specific form.
2. Data to be included in charting and referral:
  - a. Menstrual History
    - 1) First day of last menstrual period
    - 2) Was this a normal period, i.e., amount of flow, time of month?
    - 3) If not, when was last normal menstrual period?
    - 4) Are periods usually regular? How often do periods come? How long do they last? Is the flow heavy, medium, scant?
    - 5) Has client missed a period(s) before?
  - b. Symptoms of Pregnancy Other Than Amenorrhea
    - 1) Early
      - a) Breast tenderness
      - b) Nausea or vomiting
      - c) Urinary frequency
    - 2) Late
      - a) Enlargement of abdomen
      - b) Fetal movement
  - c. Obstetrical History
    - 1) Number of pregnancies (gravida)
    - 2) Number of children (para)
    - 3) Number of spontaneous abortions
    - 4) Number of therapeutic abortions
    - 5) History ectopic pregnancies

## Section 12: Pregnancy Testing and Counseling

- d. Birth Control History
  - 1) Is the client consistently using a method of birth control? If not, how long has she been having unprotected intercourse?
  - 2) If client is presently using birth control, what method, and is she using it correctly?
  - 3) If client had been using birth control in the past, what method, when, and why did she discontinue its use?
- e. Sexual History

When was the last time that the client had intercourse?
- f. Determine if this is a planned/wanted pregnancy.

How does she feel about being pregnant?

### C. Objective Data

- 1. Physical exam, as indicated
  - a. Client with a positive pregnancy test should be counseled to have a physical exam performed as early as possible if not performed at the time of the pregnancy test.
- 2. Laboratory
  - a. Urine HCG
  - b. Consider CT/GC testing
- 3. Assessment and Plan

Offer all clients information and counseling about the results of their tests, including accuracy and the chance for false-negative or false-positive results.

### D. Counseling Results

- 1. Positive test results
  - a. Staff must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:
    - 1) Prenatal care and delivery
    - 2) Infant care, foster care or adoption
    - 3) Pregnancy termination
  - b. If requested to provide such information and counseling, staff must provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the client indicates she does not wish to receive such information and counseling. (Wording from Title X Program Requirements for Title X Funded Family Planning Projects, pg16). Staff should provide the information the client requests.
  - c. Help the client to explore alternatives and feelings as realistically as possible. Assist the client in understanding the impact of this decision on her life.

## Section 12: Pregnancy Testing and Counseling

- d. Evaluate the client's support systems. Which significant others in the client's life know about the pregnancy? How does she/he feel about the pregnancy and about the client's decision? Staff should realize that the kind of support that the client receives in her decision-making is very important.
    - 1) Does the father of the child know? Is he involved in the decision-making? Does the client communicate well with the father of the child?
    - 2) Do the parents know? Are they involved in the decision? Does the client communicate well with her parents?
  - e. Address the psychosocial implications of a positive test.
    - 1) Does the client have personal goals, i.e., education, career, and are these congruent with parenthood?
    - 2) Does the client already have a child, or has she been involved in raising siblings, and can she utilize those experiences in her decision-making?
    - 3) Is she ready to be responsible for another person for at least eighteen years?
    - 4) Is the client prepared for the change in her lifestyle and identity?
    - 5) Is she ready for the financial responsibility?
    - 6) Is she aware of the emotional responsibility of being a parent?
  - f. If the client has arrived at a decision, ask "Will you share with me how you made your decision?"
  - g. If the client is unable to decide, decision counseling should be initiated. The extent of the counseling is at the discretion of the provider and should be determined by the client's needs and the time frame available. Particular efforts should be made when counseling adolescents. Additional support may be available through a social worker or local mental health clinic.
  - h. Written referrals should be given as requested by the client; referrals for further counseling should be encouraged if deemed necessary by clinic staff.
2. Continuing the pregnancy
- a. Provide information on the importance of early and continued prenatal care, basic guidelines regarding drugs, alcohol, smoking, and diet during pregnancy and referral to prenatal services.
  - b. Ensure that all clients understand the importance of prenatal care early in pregnancy and on a continuing basis, even if the client has not determined whether the pregnancy will be continued.
  - c. Emphasize the dangers to the fetus of smoking, alcohol and substance use (over-the-counter, prescription, and/or illicit drug use).
  - d. Provide brochures regarding healthy behaviors during pregnancy and referrals to programs that help clients reduce or stop unhealthy behaviors.
  - e. Review danger signs and symptoms of pregnancy.
  - f. Counsel about the impact of diet on fetal development and appropriate nutrition information, particularly regarding folic acid supplementation.
  - g. Counsel about the availability of prenatal care and give referral information. Give information about

## Section 12: Pregnancy Testing and Counseling

Medicaid eligibility if applicable. The client may also be referred to a Prenatal Plus or Nurse Home Visitor provider if she meets the eligibility criteria for either of these programs.

- h. Agencies are encouraged to follow-up with clients to determine if they are receiving prenatal care.
- i. Document counseling, referral and follow up attempts in the client's record.
- j. Client may wish to discuss immediate post delivery LARC insertion with her provider.

### 3. Adoption

- a. All staff responsible for options counseling should be able to impart accurate information regarding adoption. This should include services offered by agencies, birth mother rights, a basic overview of the process, and appropriate referrals.
- b. Clients are made aware of adoption options including designated adoption and open adoption.
- c. Clients should understand that relinquishment is final and permanent, but that at any time up to the signing of the final orders, a woman can change her mind.
- d. Clients are made aware of counseling, financial assistance, housing, and other services that may be available through adoption agencies. In addition, the client is given appropriate referrals to reputable agencies that can provide more extensive, non-coercive counseling, as needed. Each family planning agency should explore the adoption agencies in its particular area and determine services provided and qualifications of staff (adoption agency professionals' education and professional credentials) and assure coercion is not used.
- e. Basic prenatal education, discussion of pregnancy danger signs and referrals for prenatal care, Medicaid and/or Prenatal Plus or Nurse Home Visitor program should always be offered as indicated (see previous section).

### 4. Pregnancy Termination

- a. Discuss pregnancy termination as a legal option for a woman with a positive pregnancy test.
- b. Elicit how the client feels about pregnancy termination. Be sensitive to religious and cultural backgrounds. Assess for coercion. Assess whether the client has a support system of family and friends.
- c. Provide basic information about the procedure. As appropriate, explain, medical abortion, vacuum aspiration, and amnio abortion procedures, time limitations, and consent requirements.
- d. Explain that there is no evidence of abortion affecting future conception.
- e. Offer follow-up counseling services as indicated.
- f. Inform minors that Colorado requires parental notification or a judicial bypass prior to a minor obtaining an abortion. It is the responsibility of the facility to which she is referred to meet this requirement.
- g. Give the client up to three referral sources (if possible) for pregnancy termination.
- h. Emphasize that abortion is not a method of birth control and discuss methods of birth control that can be used afterwards.
- i. Client may wish to discuss immediate post abortion LARC insertion with her provider

## Section 12: Pregnancy Testing and Counseling

### 5. Negative Test Results

- a. Work with the client to determine other causes of delayed/missed menses including:
  - 1) Pregnancy, but with hormone levels too low for a positive test and/or testing done too soon after the last act of unprotected intercourse.
  - 2) Not pregnant, with delay or absence of ovulation
  - 3) Absence of menses due to medication, especially hormonal contraceptives, including Mirena IUD
- b. If the client is not using birth control and desires pregnancy, the following information should be given: (See Sections 13 and 14 of the Clinical Manual)
  - 1) Information about optimizing chances of conception (i.e., timing and frequency of intercourse).
  - 2) The availability of infertility services, if client has been unable to conceive for 1 year or more (six months if age  $\geq$  35).
  - 3) The impact of diet on fetal development, specifically, folic acid supplementation.
  - 4) Preconception counseling
- c. If the client is not using birth control and does not want to become pregnant, provide the following information and services:
  - 1) Contraceptive services. Reinforce the fact that client information is confidential, and that the family planning clinic is available as a resource for birth control information and pregnancy determination.
  - 2) Offer emergency contraception and information about emergency contraception.
  - 3) Optimally, offer same day contraceptive services. If this is not possible, the client should be encouraged to return for an express visit or comprehensive visit to obtain contraceptive services.
  - 4) If the client cannot be jump started on a hormonal method of birth control at the visit, an interim method of birth control should be made available (e.g., foam and condoms).
  - 5) If the client desires to start a LARC method and the method cannot be provided on the day of her visit, offer and provide a bridge method (e.g. OCs, DMPA, Ring, Patch if no risk factors) until the client can return for a LARC method.
- d. If the client is using birth control, provide the following information:
  - 1) Education, as appropriate, about her birth control method. Correct any misinformation leading to incorrect usage. If the client is not using her method correctly, consider providing emergency contraception as indicated.
  - 2) A referral to the family planning clinic as indicated. Reinforce the fact that all available information is confidential, and that the family planning clinic is available as a resource for emotional support, birth control information, and pregnancy determination.

## Section 12: Pregnancy Testing and Counseling

- 3) If appropriate, have the client return to clinic in two weeks for a repeat pregnancy test if menses has not occurred or have her return 10-14 days after the last act of unprotected intercourse.

6. Document all test results, counseling and follow-up in the client's record.

### E. ADOPTION information for staff

One of the options in a pregnancy is to make an adoption plan for a child. It is important that staff doing options counseling be well informed of current regulations so that they may offer an accurate picture to clients.

A counselor can affect the decision made by a young woman, particularly when the woman learns of an unintended pregnancy. Tone of voice, body language, and even the wording of the various options can make a difference in the way a woman looks at her choices.

It is imperative that staff doing options counseling have thoroughly explored their own views toward adoption. It is a value-laden issue that should be explored with staff during in-service training or at a staff meeting. Clarification of feelings toward adoption and accurate information about it can allow staff to put their feelings aside when counseling clients. Adoption agency staff are generally very willing to provide in-service training and reference materials.

Each family planning agency should explore the adoption agencies in its particular area and determine services provided and qualifications of staff (adoption agency professionals' education and professional credentials) and assure coercion is not used.

Adoptions have declined significantly since the 60's. Pregnancy counselors may assume their clients are not interested. The client may be hesitant to ask for more information because she may feel that considering adoption means she is a bad person. Counselors may not have accurate information about adoption. There is generally not much support for adoption among family and friends. This is especially hard for teenagers. If adoption is to be a viable option for them, they must be connected to counseling and support to help them be sure about their decision, and to deal with their own uncertainty and fears as well as the negative reactions they may get from school officials, friends, and family.

Adoption can be a positive life decision for a birth mother and it is important that each client receiving pregnancy counseling have the opportunity to explore the option. Do not assume because she does not ask, she is not interested.

If you are interested in training in adoption counseling, call your Family Planning Nurse Consultant.

### **Legal Process for Adoption (for staff informational purposes only, legal advice should not be provided to clients)**

Relinquishment of parental rights by Colorado law must be voluntary and requires a legal procedure to protect the rights of the birth parents and the child. Most agencies will prepare and process all legal documents and accompany the birth mother to the court hearing. Two separate legal processes complete an adoption in Colorado. The first is the relinquishment of a child by his/her birth mother and birth father; the second is the adoption of the same child by the adoptive parents. This transfer of custody to complete an adoption normally takes place in two separate hearings.

#### 1. Pre-Delivery

- a. Birth mother receives counseling
- b. Birth mother can make an adoption plan

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### 2. Post-Delivery

- a. Birth mother continues to receive counseling
- b. A petition to relinquish is prepared and signed by both birth parents\* and filed with the court.
- c. A court date is set. Birth parents can sign an Expedited Relinquishment set of forms. These forms are submitted to the court without the necessity of a court appearance.
- d. A private court hearing is held in the judge's chambers.
- e. Judge determines:
  - 1) Birth mother has received appropriate counseling.
  - 2) Birth mother understands permanence of decision and resources available to her should she choose to parent.
  - 3) Birth father has legally relinquished rights.
- f. Judge signs final order of relinquishment.
- g. The relinquishment is final. The child is free for adoption.
- h. Adoptive parents petition the court to finalize the adoption. The adoption is final within six months of the relinquishment hearing.

\* If the birth father is unknown, refuses to acknowledge paternity, or cannot be located, there are steps that can be taken to allow this process to continue.

### F. ABORTION ACTIVITIES information for staff

1. This program does not provide or encourage abortion as a method of family planning.
2. Permissible abortion-related activities
  - a. Information and counseling regarding options of pregnancy may be supplied to those clients who do not desire to continue their pregnancies and may be interested in obtaining abortions.
  - b. Clients may be referred to providers to obtain abortions. Giving the client names and addresses and/or telephone numbers of providers of abortion services is acceptable, without further affirmative action by program personnel to secure the services of that provider.
  - c. Collection of statistical data and information regarding abortion is acceptable.
3. Non-permissible activities related to abortion
  - a. "Pregnancy Counseling" in the sense of encouraging persons to obtain abortions is not allowed.
  - b. This does not preclude counseling offering various options regarding pregnancy, which may include abortion; this may not be the only option discussed.
  - c. Appointments for abortions may not be made by program personnel.
  - d. Provision of transportation to enable a woman to obtain an abortion is not allowed.
  - e. Production and showing of movies that tend to encourage or promote a favorable attitude toward abortion are prohibited.

## Section 12: Pregnancy Testing and Counseling

- f. Providing speakers to debate in opposition to “Right to Life” anti-abortion speakers is prohibited.

Request for pregnancy test form

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

# Section 13: Achieving Pregnancy and Basic Infertility Services

Basic infertility services and counseling around achieving pregnancy are included as core family planning services in the Providing Quality Family Planning Services Recommendations of the CDC and the US Office of Population Affairs (QFP). <http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf> Pages 14-16.

The American Society for Reproductive Medicine provides resources for both clients <http://www.reproductivefacts.org/> and health professionals <http://www.asrm.org/?vs=1>.

Resources are also available from the CDC Reproductive Health - Infertility web site <http://www.cdc.gov/reproductivehealth/Infertility/index.htm>

American Urological Association <http://www.auanet.org/> offers clinical guidelines and best practice statements. Practice statements regarding male infertility are located at the following link <http://www.auanet.org/education/best-practice-statements.cfm>

Preventative Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice, Male Training Center for Family Planning and Reproductive Health [http://www.maletrainingcenter.org/wp-content/uploads/2014/09/MTC\\_White\\_Paper\\_2014\\_V2.pdf](http://www.maletrainingcenter.org/wp-content/uploads/2014/09/MTC_White_Paper_2014_V2.pdf)

Colorado Family Planning Programs must provide basic infertility service including basic education and fertility assessment, as indicated. Basic services include history and physical exam, laboratory testing (e.g. hemoglobin or hematocrit, Pap test, gonorrhea and Chlamydia), counseling, and appropriate referral for those requiring more extensive assessment and treatment.

## A. Subjective

Comprehensive medical history, including:

1. Detailed reproductive history; sexual history including sexually transmitted infections and PID;
2. History for women should include menstrual history; medical conditions associated with reproductive failure (e.g. thyroid disorders, hirsutism or other endocrine disorders) current medications and allergies; prior surgeries; previous hospitalizations; serious illness or injuries; cervical cancer screening and any follow up treatment; (QFP page 15)
3. History for men should include systemic medical illnesses such as diabetes mellitus, prior surgeries, medications and allergies, lifestyle exposures, gonadal toxin exposure including heat (QFP page 15)
4. Duration of infertility; previous tests and treatment; contraceptive history; coital frequency and timing
5. Number of pregnancies, spontaneous abortions and current lactation status; if previous pregnancies were conceived with a different partner;
6. Length of time required to initiate each pregnancy;
7. Complications of any pregnancy.

## B. Objective

1. Physical examination with special attention for women to body habitus, BMI, fat and hair distribution, acne, secondary sex characteristics, abnormalities of the thyroid gland, galactorrhea, and pelvic exam.
2. Male physical exam includes examination of the penis; including the location of the urethral meatus; palpation of the testes and measurement of their size; presence and consistency of both the vasa and epididymides;

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presence of a varicocele; secondary sex characteristics including body habitus, hair distribution and breast development; and digital rectal exam (The Optimal Evaluation of the Infertile Male: AUA Best Practice Statement 2010 <https://www.auanet.org/education/best-practice-statements.cfm>)

3. Appropriate laboratory testing, including a pregnancy test and STI screening. The QFP recommends a semen analysis for men and referral for further evaluation if the test is abnormal. Additional testing for woman may include TSH and prolactin levels, FSH if suspect menopause.

## C. Plan

### 1. Client Education

Counseling should cover the following:

- a. Anatomy and physiology;
- b. Menstrual cycle and fertile periods;
- c. Timing of intercourse: Every 1-2 days beginning soon after the menstrual period ends. The cycle day of ovulation can be estimated by subtracting 14 from the number of days in a woman's usual menstrual cycle— e.g. day 14 in a 28-day cycle and day 16 in a 30-day cycle
- d. Methods or devices designed to determine or predict ovulation (e.g. over the counter ovulation kits, cycle beads); Fertility awareness techniques (BBT and cervical mucous changes during the cycle) and optimizing timing of intercourse;
- e. Counsel regarding health issues that can reduce fertility: e.g. being overweight (or underweight in women), smoking, excessive alcohol consumption, recreational drugs, most vaginal lubricants
- f. Validation of feelings/anxiety about fertility issues.

### 2. Referral

Referral is indicated with report of regular, unprotected intercourse with the same partner for one year or more without conceiving.

Typically, the client and partner should try to conceive for 12 months before being referred, however; a referral should be expedited in the following circumstances:

- a. Woman is over the age of 35;
- b. History of irregular menstrual cycles;
- c. Man has history of bilateral cryptorchidism or other infertility risk factors
- d. Known history of a disease or a condition in either partner which could cause fertility problems (i.e., previous pelvic surgery, PID, ectopic pregnancy or symptoms suggestive of endometriosis in the woman or mumps for the man);
- e. Couple questions the male partner's fertility or if the man questions his fertility
- f. Neither partner has ever produced a pregnancy despite having unprotected intercourse.

# Section 14: Preconception and Interconception Health Services

## Resources:

- National Preconception Curriculum and Resource Guide for Clinicians  
<http://beforeandbeyond.org/>
- Health Team Works Preconception Care Guidelines  
<http://www.healthteamworks.org/guidelines/preconception.html>
- CDC Preconception Health and Healthcare  
<http://www.cdc.gov/preconception/index.html>
- One Key Question®  
<http://www.onekeyquestion.org/>
- Providing Quality Family Planning Services, Recommendations of the CDC and the US Office of Population Affairs (QFP)  
<http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>
- BeforePlay  
<http://www.beforeplay.org/>

## A. Preconception and Interconception Counseling

Emphasize the importance to family planning clients on establishing a reproductive life plan. Discuss a reproductive life plan with clients receiving contraceptive, pregnancy testing, and counseling, and basic infertility, sexually transmitted infection and preconception health services. (QRP pg. 7).

Use the One Key Question®, “Would you like to become pregnant in the next year?” to make an initial assessment of a client’s plans for pregnancy and contraceptive needs.

Further questioning may include asking if the client has children now, does the client want to have children (or more children) in the future, and how many children the client would like to have and when.

Provide preconception counseling as a part of family planning services, as appropriate. Couples or individuals planning a pregnancy, seeking infertility services, or at high risk for an unplanned pregnancy should be offered preconception counseling. Clients contemplating pregnancy within the next year should be given the opportunity for special counseling prior to discontinuing their method, with the objective of improving the outcome of a planned pregnancy.

1. Female screening and history. Also see <http://www.cdc.gov/preconception/careforwomen/index.html>
  - a. Medical history, including heart disease, hypertension, anemias or blood disorders, liver disease, diabetes, epilepsy, asthma, renal disease, SLE and Rheumatoid arthritis, thyroid disease. ([Health Team Works Guideline for Preconception and Interconception Care](#) 2009 )
  - b. Reproductive history including previous pregnancy problems, preterm delivery, stillbirth, recurrent pregnancy loss.

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- c. STI history including genital herpes, HIV, Hepatitis B, Chlamydia, gonorrhea, syphilis.
- d. Medication history
- e. Occupational and environmental exposures history
- f. Tobacco, alcohol, or drug use.

Alcohol and substance abuse guidelines are available for download from Health Team Works (<http://www.healthteamworks.org/guidelines/sbirt.html>) and from SBIRT Colorado (<http://improvinghealthcolorado.org/>)

Guidelines include:

- 1) Alcohol and Substance Use Screening, Brief Intervention and Referral to Treatment (SBIRT) Guideline (September 2011)
- 2) Guidance on Marijuana Supplement (February 2014)
- 3) Prescription Drug Abuse Prevention Supplement (September 2011)
- 4) Fetal Alcohol Spectrum Disorder Supplement (August 2010)
- 5) CRAFT Toolkit for screening youth for substance use (June 2010)

The Substance Abuse and Mental Health Services Administration (SAMHSA) also provides resources for health care providers. <http://www.samhsa.gov/> and <http://www.integration.samhsa.gov/clinical-practice/sbirt>

CDPHE Marijuana resources for health care providers  
<https://colorado.gov/cdphe/marijuana-clinical-guidelines>

It is recommended that clients be screened for tobacco use at every visit and for alcohol and drugs at least yearly. Offer tobacco cessation counseling and referral to the Colorado QuitLine  
<https://www.coquitline.org/>

Prescription drug misuse and abuse is the fastest growing drug problem in the US.

There is no known time or amount of alcohol that is safe during pregnancy.

Clinics should have substance use and abuse community referral resources available for clients in need of services.

- g. Social history including intimate partner violence (IPV).

Clinicians should screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services.

IPV resources for staff and clients

<http://www.thehotline.org/help/> National Domestic Violence Hotline

<http://ccadv.org/> Colorado Coalition Against domestic Violence

<http://www.futureswithoutviolence.org/> Futures Without Violence

<http://www.ccasa.org/> Colorado Coalition Against Sexual Assault

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<http://www.loveisrespect.org/> Resource for youth regarding dating and relationships

<http://www.acf.hhs.gov/programs/fysb/programs/family-violence-prevention-services> HHS Family Violence Prevention & Services

- h. Nutritional history
- i. Family history, including anemias or blood disorders, diabetes, genetic conditions or birth defects.
- j. Screen for immunization status including Rubella immune status and for age appropriate vaccinations such as influenza, Tdap, MMR, varicella, pneumococcal and meningococcal, Hepatitis B
- k. USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women. Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up (B recommendation) (USPSTF Screening for Depression Adults 2016). “Screening should be implemented with adequate systems in place. “Adequate systems in place” refers to having systems and clinical staff to ensure that patients are screened and, if they screen positive, are appropriately diagnosed and treated with evident based care or referred to a setting that can provide the necessary care” (JAMA Volume 315, Number 4, January 26, 2016). See the following link for more information:  
<http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/depression-in-adults-screening1> . Consider using the Patient Health Questionnaire-2 (PHQ-2), not as a diagnosis tool, but as a first step to assess the need for more in-depth screening and referral for care.

In the last 2 weeks:

- 1) Have you had little interest or pleasure in doing things?
- 2) Have you felt down, depressed or hopeless?

A “yes” answer to either question is considered a positive screen. The Health Team Works web site provides more in-depth screening tools such as the Patient Health Questionnaire-9 (PHQ-9) or for women who are pregnant or have recently had a baby, the Edinburgh Postnatal Depression Scale.

See Health Team Works Adult Depression Guidelines and Guidelines for Adolescent Depression in Primary Care <http://www.healthteamworks.org/guidelines/depression.html>

USPSTF Depression in Children and Adolescents: Screening 2016

<http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/depression-in-children-and-adolescents-screening1>

Pregnancy Related Depressive Symptoms Guidance

<http://www.healthteamworks.org/guidelines/prd.html>

Clinics must have mental health community referral resources available for clients in need of services.

- 2. Male screening and history. Also see <http://www.cdc.gov/preconception/careformen/index.html>
  - a. Past medical and surgical history that may impair reproductive health such as genetic conditions, history of reproductive failures, conditions that impair sperm quality such as obesity, diabetes mellitus, and varicocele.

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- b. Environmental exposures, hazards and toxins.
  - c. Tobacco, alcohol and drug use.
  - d. Screen for immunization status and for age appropriate vaccinations such as influenza, Tdap, MMR, varicella, pneumococcal and meningococcal, Hepatitis B.
  - e. STI history including genital herpes, HIV, Hepatitis B, Chlamydia, gonorrhea, syphilis.
  - f. Screen for depression when staff assisted depression care supports are in place to ensure accurate diagnosis, effective treatment, and follow up. (QRP pg. 17)  
A resource for men: <http://mantherapy.org/>
3. Physical exam may include
- a. Height, weight, and body mass index
  - b. Blood pressure
4. Lab tests as indicated
5. General education
- a. The need for early and continuing care during pregnancy, with referral to prenatal care providers, if requested.
  - b. The importance of good nutrition, including the addition of 400-800 µg of folic acid supplemented per day to decrease the risks of neural tube defects. The importance of being a healthy weight before and during pregnancy.
  - c. Warnings regarding the use of tobacco, alcohol, and drugs during the preconception period as well as during pregnancy.
  - d. Counseling regarding HIV testing. The standard is for all pregnant women to be tested, regardless of risk status (Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant women in Health Care Settings, MMWR September 22, 2006/55 (RR14); 1-17). There are benefits to women and men of knowing their HIV status before a pregnancy.
  - e. The importance of being up to date on immunizations prior to pregnancy.
  - f. The importance of spacing pregnancies.
  - g. Explanation regarding referrals for care as indicated.
6. Recommendations for Stopping Birth Control Methods
- a. Oral contraceptive/contraceptive patch/contraceptive vaginal ring
    - 1) There is no evidence to recommend that a period of time elapse between the cessation of hormonal contraceptive use and initiation of a planned pregnancy.
    - 2) Client may be advised to return for evaluation if menstrual periods do not resume six to eight weeks after cessation of these hormonal contraceptives.

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- b. IUD  
No special recommendations
- c. Depo-Provera  
Since ovulation may take as long as 9-12 months to return, it is advisable to have the client plan to stop the injections up to a year before she wishes to become pregnant, and to use another method of birth control until conception is desired.
- d. Contraceptive implant  
No special recommendations

# Section 15: Sexually Transmitted Infections (STI) and HIV Screening Services

STI services, including HIV testing, are one of six core family planning services which also include contraceptive services, pregnancy testing and counseling, achieving pregnancy, basic infertility services, and preconception health. (Providing Quality Family Planning Services Recommendations of the CDC and the US Office of Population Affairs (QFP).

<http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf> Pages 17-20).

Providers should consult the Centers for Disease Control and Prevention (CDC). Sexually Transmitted Diseases Treatment Guidelines, 2015 (CDC STD Guidelines 2015). MMWR 2015; 64 (No. 3). <http://www.cdc.gov/std/tg2015/default.htm> and updates to the Guidelines for STI diagnosis and treatment information.

A treatment app provides easy access to updated treatment and alternative treatment regimens:

<http://www.cdc.gov/std/tg2015/default.htm>

Other resources:

- Denver PTC <https://www.denverptc.org/>
- CDPHE <https://www.colorado.gov/pacific/cdphe/dceed>
- HIV/AIDS Treatment, Prevention and Research <http://aidsinfo.nih.gov/>
- Information and resources <http://www.aids.gov/> , <http://www.cdc.gov/hiv/> , <http://aidsvu.org/> , <http://www.cdc.gov/hiv/basics/prep.html>
- National HIV/AIDS Strategy Updated to 2020 <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/overview/index.html>
- CDC STD web site includes client handouts <http://www.cdc.gov/std/>
- Mountain and Plains AIDS Education Center, HIV education and resources for healthcare professionals <http://www.mpaetc.org/>
- UCSF Clinician Consultation Center <http://nccc.ucsf.edu/>

## A. STI Prevention includes

1. Risk reduction counseling.
2. Abstinence and reduction of number of sex partners.
3. Pre-exposure vaccination: HPV, Hepatitis A and B.
4. Barrier methods: male and female condoms.
5. Note: Spermicides containing N-9 may disrupt genital or rectal epithelium and have been associated with an increased risk of HIV infection. Condoms with N-9 are no more effective than condoms without N-9. Therefore, N-9 alone or in a condom should not be recommended for STD or HIV prevention. (2015 CDC STD Treatment Guidelines, pg. 5)
6. Retest after STI treatment to check for re-infection (e.g. 3 months after treatment for Chlamydia or gonorrhea).

## B. For each STI, the CDC Treatment Guidelines generally include the following information:

1. Diagnostic considerations

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2. Treatment, recommended and alternative regimens
  3. Management of sex partners
  4. Follow up
  5. Special considerations such as pregnancy or HIV infection
- C. Please consult the CDC Treatment Guidelines directly regarding STI screening and treatment. The following is general information regarding providing STI services and topics specific to family planning. The CDC recommends the Five Ps for assessing clients: Partners, Prevention of Pregnancy, Protection from STDs, Practices, and Past History of STDs.**
1. History as indicated
    - a. Signs and symptoms such as unusual discharge, presence of lesions, lower abdominal, scrotal or pelvic pain, fever/chills, dysuria, dyspareunia, spotting between periods or with intercourse and duration of symptoms
    - b. Number of partners, any new partners in the last 60 days, partners are men, women or both
    - c. Known recent exposure to STI
    - d. Positive STI test in the past year
    - e. Vaginal, oral, or anal intercourse
    - f. LMP, any unprotected intercourse since LMP, contraceptive method using, pregnancy signs and symptoms
    - g. Breastfeeding
    - h. Medication allergies
  2. Examination
    - a. BP, heart rate and temperature, if indicated
    - b. Throat exam if history includes oral intercourse
    - c. Abdominal tenderness or masses
    - d. Regional or generalized lymphadenopathy
    - e. Visual inspection external genitalia for discharge or lesions
    - f. Visual inspection vagina and cervix for discharge or lesions, cervical friability
    - g. Uterus/ovaries or scrotal contents – palpation for uterine and adenexal tenderness, cervical motion tenderness
    - h. Anal exam if history includes anal intercourse
  3. Labs may include
    - a. Chlamydia –gonorrhea Nucleic Acid Amplification Test (NAAT). Specimen sources: urine, urethra, cervix, vagina. Contact your lab regarding obtaining pharyngeal and anal specimens. Labs must validate CT/GC tests for pharyngeal and rectal sites. Specimens of choice: urine for men, self collected vaginal for women.

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Provide CT/GC test for mucopurulent cervicitis or urethritis. Recommendation for women with hysterectomy - urine specimen.

- b. Wet prep, if indicated
- c. Pregnancy test, if indicated
- d. Syphilis test, if indicated. The CDC currently recommends screening with a non-treponemal test (RPR or VDRL) and confirm with a treponemal test (TPPA or FTA-ABS). Many laboratories are switching to screening tests based on detection of treponemal antibody : enzyme immunoassay (EIA) or chemiluminescent immunoassay (CIA). Check with your lab regarding the test used and interpretation. (CDC STD Treatment Guidelines 2010 pgs 26 -28).
- e. HIV
- f. Hepatitis B and C

CDC Recommendations for the Identification of Chronic Hepatitis C Virus Infection among Persons Born During 1945–1965:

- 1) In addition to testing adults of all ages at risk for HCV infection, CDC recommends:
- 2) Adults born during 1945–1965 should receive one-time testing for HCV without prior ascertainment of HCV risk (Strong Recommendation, Moderate Quality of Evidence)
- 3) Testing should be initiated with anti-HCV. A reactive result should be followed by nucleic acid test (NAT) for HCV RNA.
- 4) All persons identified with HCV infection should receive a brief alcohol screening and intervention as clinically indicated, followed by referral to appropriate care and treatment services for HCV infection and related conditions. (QFP pg. 19) See the following link for more HCV information <http://www.cdc.gov/hepatitis/hcv/>

#### 4. Treatment according to current CDC STD Treatment Guidelines

- a. If client is presumptively treated for CT with azithromycin and the GC test later comes back as positive, treat GC with ceftriaxone and azithromycin (again) - ceftriaxone and azithromycin is a dual treatment to treat GC.
- b. Providers should have a low threshold for treating PID

#### 5. Management of sex partners

- a. All sex partners of clients who have a positive STI test should be evaluated and treated if their last sexual contact with the client was within 60 days before onset of symptoms or diagnosis of infection in the index client. If a client's last sexual intercourse was > 60 days before onset of symptoms or diagnosis, the client's last partner should be treated.
- b. For heterosexual clients with a lab confirmed positive CT or GC whose partner's treatment cannot be ensured or is unlikely, consideration should be given to the use of expedited partner therapy (EPT) (CDC STD Treatment Guidelines 2010, pg 52), if medication is sent home with the index client for the partner, use non-340B purchased medication.

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## 6. Education

- a. Provide the client information about the STI and the medication prescribed for treatment.
- b. Inform the client of complications of untreated STIs, including PID, hospitalization, and infertility for women and epididymitis and prostatitis for men, increased risk of HIV transmission, disseminated GC, reactive arthritis.
- c. Clients should be instructed to abstain from sexual intercourse until therapy is completed and they and their partners no longer have symptoms. If one day treatments have been used, advise refraining from intercourse for 7 days following treatment. In cases where compliance is doubtful, recommend condom use and provide a supply of condoms.

## 7. Follow up

- a. Clients with uncomplicated CT or GC who have been treated with any of the recommended regimens need not return for a test of cure. However, advise the client to be retested in 3 months after treatment. If client does not seek retesting in 3 months, encourage retesting if client presents to the clinic within the next year.
- b. Clients who have symptoms that persist after treatment should be further evaluated.
- c. Appropriate resuscitation equipment must be available in the clinic and clinic personnel must be up to date in its use if parenteral medications are used.

## 8. Reporting procedures

- a. State law requires that positive STI tests be reported by the provider to the Colorado Department of Public Health and Environment (CDPHE) Registry. Clinic staff members are responsible for completing the state reporting form, including treatment information and faxing it to the STD Registry. See form for instructions.
- b. Clinic sites using a lab other than the state lab must report both positive and negative CT and GC test results to the CDPHE STI-HIV Section for prevalence monitoring.

## D. CT/GC Screening

1. The USPSTF recommends screening for Chlamydia and gonorrhea in sexually active women aged 24 years or younger and in older women who are at increased risk for infection. Grade: B Recommendation.
2. The CDC recommends annual screening for Chlamydia and gonorrhea for all sexually active women aged less than 25 years old and screening of older women at increased risk for infection.
3. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for Chlamydia and gonorrhea in men. Grade: I statement.  
<http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/chlamydia-and-gonorrhea-screening?ds=1&s=> (September 2014)
4. According to the USPSTF " ... risk factors for [CT/GC] infection include having a new sex partner, more than 1 sex partner, a sex partner with concurrent partners, or a sex partner who has an STI; inconsistent condom use among persons who are not in mutually monogamous relationships; previous or coexisting STI; and exchanging sex for money or drugs. Prevalence is also higher among incarcerated populations, military recruits, and patients

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receiving care at public STI clinics. There are also racial and ethnic differences in STI prevalence. In 2012, black and Hispanic persons had higher rates of infection than white persons. Clinicians should consider the communities they serve and may want to consult local public health authorities for guidance on identifying groups that are at increased risk. Gonococcal infection, in particular, is concentrated in specific geographic locations and communities.”

5. 2014 USPSTF CT/GC screening recommendations:  
<http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/chlamydia-and-gonorrhea-screening>
6. All female clients 24 years old and younger must have a screening CT/GC test annually. If the test is not done at the discretion of the provider or client, there must be documentation as to the reason. Annual screening is to be charged on a sliding scale fee schedule that slides to zero. Clients who present for revisits should be tested as indicated. All screening at revisits may be charged as non-required services. Clinics are advised to waive the fee if it is a barrier to testing.

## **E. Incorporation of ACOG’s Primary and Preventive Care: Periodic Assessment Guidelines in to STI screening and treatment care**

1. Colorado Family Planning Program clinic providers have incorporated ACOG annual woman’s health care and well woman recommendations (<http://www.acog.org/wellwoman>) in to practice. A pelvic examination (including visualization and inspection of external genitalia, vagina, and cervix, and bimanual exam) is not recommended for women until age 21, unless indicated by medical history. Female clients also are seen in the clinic for express visits in which the women are provided contraceptive counseling and a method of contraception without the provision of an exam. Asymptomatic male clients are also provided an opportunity for an express visit for contraceptive counseling and STI screening. Clients are asked to return to the clinic at a later date for a comprehensive history and an exam as indicated by the client’s age or health history. Clinics have the capability of providing genital Chlamydia and gonorrhea screening for asymptomatic clients without the necessity of performing an exam with the use of urine based or vaginal self collected swabs for women and urine based testing for men.
2. Providing Chlamydia and Gonorrhea screening to asymptomatic clients without requiring an exam helps reduce barriers to screening. Colorado Family Planning clinic sites have adopted the practice of treating asymptomatic clients who have had screening Chlamydia or gonorrhea testing without an exam and a positive test without performing an exam prior to treatment.
3. Clients who have received Chlamydia and gonorrhea test screening without the performance of an exam and who have a positive Chlamydia or gonorrhea test must be questioned regarding complaints or reports of STI symptoms and the possibility of pregnancy before treatment is provided. A physical exam should be provided to clients who report STI symptoms. An exam is particularly important to rule out complications of Chlamydia and gonorrhea infections such as pelvic inflammatory disease (PID). Symptoms may include recent pelvic pain, pain with intercourse, or unusual discharge or bleeding.
4. Clients who have a positive Chlamydia or gonorrhea tests, who received a screening Chlamydia or gonorrhea test without an exam being performed and continue to be asymptomatic for STIs may be provided treatment without an exam being performed prior to treatment. Follow the CDPHE STI Testing and Treatment protocol.
5. Clients’ partners should be treated as outlined in the CDPHE STI Testing and Treatment protocol.

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6. Clients should be counseled regarding STI prevention.
7. Clients should be counseled regarding the signs and symptoms of STIs and told to return to the clinic if any develop.
8. A repeat Chlamydia or gonorrhea test should be offered 3 months after treatment to rule out re-infection. (2015 CDC STD Treatment Guidelines)

## F. Expedited Partner Therapy

1. The use of EPT in Colorado is done with the approval of both the Board of Pharmacy (Policy 40-4, July 19, 2007) [https://www.colorado.gov/pacific/dora/Pharmacy\\_Laws#Policies](https://www.colorado.gov/pacific/dora/Pharmacy_Laws#Policies) and the Board of Medical Examiners (Policy 40-10, May 1, 2001, revised 7-1-2010; 8/20/2015) [https://www.colorado.gov/pacific/dora/Medical\\_Laws#Policies](https://www.colorado.gov/pacific/dora/Medical_Laws#Policies).
2. Client selection: client has a lab confirmed positive CT and/or GC and partners of heterosexual client.
3. Contraindications: CT or GC infections in men who have sex with men (MSM), STI other than CT/GC.
4. Client should be counseled to encourage her/his partner to present to clinic or private provider for testing and treatment; however, if partner(s) is not willing or able to be evaluated, then client should be encouraged to use EPT. If the client selects EPT, then the client should be counseled to tell the partner(s) to read all the information in the partner pack before taking the medication
5. EPT is carried out with the use of "partner packs." A client may be offered up to 3 (three) partner packs. Partner packs contain the appropriate treatment drug for either Chlamydia, gonorrhea, or both, information about the infection, and information about the medication(s) and how to take it.
6. Any medication dispensed as EPT must be properly labeled and logged out in the clinics pharmacy log. If possible, collect the partner name, date of birth, and phone number. If unable to collect this partner information, use "Partner #1," "Partner #2," or "Partner #3" for the log book and the label. Assign an Rx number as per usual, as well as provider name, lot #, expiration date, and instructions for use. Label is placed on the medication container. Please remember that if the partner is not a client of the clinics and has no record at your clinic the use of drugs purchased at 340B pricing is not permitted according to 340B regulations. Partner pack treatment drugs for non-clients should be dispensed from separate stock that was not purchased at 340B discounts.
7. Documentation in the client record must include whether EPT was offered, whether it was accepted, and how many and what type of EPT were given. If an agency chooses to use such a checklist, then documentation in the client record should also indicate that this checklist was completed and signed.

- G. **The Denver Prevention Training Center provides a STD Clinical Consultation Network, providing STD Clinical Consultation services within 1-3 business days, depending on urgency, to healthcare providers in the states of Colorado, Montana, New Mexico, North Dakota, South Dakota, Texas, Utah and Wyoming. The Clinical Consultation "Warm Line" can be reached at 1-855-4-STD-CCN (1-855-478-3226) or online at: <https://www.denverptc.org/Consultation.html> . The phone line is staffed from Monday to Friday, 7 AM - 5 PM Mountain Time and 8 AM - 6 PN Central Time.**

## H. National HIV Recommendations

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1. Title X program priorities include HIV prevention education, testing, and referral in accordance with Title X program requirements and nationally recognized standards. The incorporation of CDC's "Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings" (CDC Revised Recommendations for HIV Testing), published in 2006, into family planning clinical services is a key issue for the federal Title X program. (Centers for Disease Control and Prevention. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. MMWR 2006;55 (No. rr-14 [1-17]) See the following link for the full report: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>)
2. The CDC Revised Recommendations for HIV Testing include the following:
  - a. Routine screening for HIV infection for all clients aged 13-64 years unless the prevalence of undiagnosed HIV infection is documented to be less than 0.1 %.
  - b. In the absence of existing data for HIV prevalence, health care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is less than 1 per 1,000 clients screened, at which point such screening is no longer warranted. Subsequently, health care providers should test clients who are at high risk for HIV at least annually.
  - c. All pregnant women in the US should be tested for HIV infection as early during pregnancy as possible (CDC STD Treatment Guidelines 2010 and CDC Revised Recommendations for HIV Testing).
3. In April 2013, the US Preventative Services Task Force (USPSTF) published updated HIV screening recommendations, which also recommend expanded screening for HIV infection. See the following link for the full report: <http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm>

The USPSTF recommends that:

- a. Clinicians screen for HIV infection in adolescents and adults ages 15-65 years. Younger adolescents and older adults who are at increased risk should also be screened.
  - b. Clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown.
  - c. An approach to screening intervals, since there is not sufficient evidence to determine optimum testing intervals, is one-time screening of adolescents and adults to identify clients who are HIV positive, then provide repeat screening for clients at risk for HIV infection. Individuals at very high risk for HIV infection should be screened at least annually.
4. It is imperative that the clinic staff be educated about HIV/AIDS prior to instituting any counseling, education, or referral. This is to avoid any misinformation, as well as to ensure sensitivity and confidentiality.
    - a. The Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immune Deficiency Syndrome (AIDS), is transmitted by blood and body fluids.
    - b. The HIV antibody test is a test for the presence of HIV antibody, not a test for AIDS.
    - c. The body will produce HIV antibodies three weeks to six months after infection with HIV.
    - d. Due to this time frame, it is important to consider the client's risk when interpreting HIV antibody test results.

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- e. The type of exposure, the length of time since last exposure, and previous test history are all important factors.
  - f. Return visits for HIV testing are recommended at 1 month and 3 months post exposure.
5. HIV infection leads to immune dysfunction and deficiency. In untreated individuals, the time between HIV infection and the development of AIDS varies from a few months to many years, with an estimated median time of approximately 11 years. (2015 CDC STD Treatment Guidelines)
  6. Early diagnosis of HIV infection, prompt referral, and ensuring linkage to care and support services can help improve the health of the individual tested, and reduce the risk of HIV transmission to others.
  7. The family planning and prenatal settings provide a climate conducive to HIV risk reduction counseling and HIV/AIDS prevention messages.

### I. Recommendations for Testing

1. Each new family planning client must be offered HIV education, including information about pre-exposure prophylaxis (PEP) and post-exposure prophylaxis (PrEP) for HIV prevention, and HIV testing information. Family planning clinic staff should provide community resources for the provision of PrEP and PEP for clients in need of these services.
2. All family planning clients should receive an educational handout on HIV and HIV testing.
  - a. All family planning clients should be offered a one-time screening HIV test. Repeat screening should be based on client risk for HIV infection.
  - b. The client may be tested at the family planning clinic site, or referral may be made to an HIV testing site or medical provider, with staff experienced in HIV testing.
3. Testing resources
  - a. Denver Public Health is funded to lead a consortium of counties to conduct HIV testing. For information see:  
<http://denverhealth.org/PublicHealthandWellness/PublicHealth/ClinicsandServices/HIVCareandPrevention/OurServices/Testing.aspx>
  - b. For testing sites see:  
<http://www.denverhealth.org/public-health-and-wellness/public-health/clinics-and-services/std-and-family-planning-services/our-services/community-based-testing>
  - c. Pueblo City and County Health Department is funded by the Colorado HIV and AIDS Prevention Grant Program (CHAPP) to provide HIV testing, as is the Boulder County AIDS Project, which subcontracts HIV testing at Boulder County Health Department.
  - d. Each of the Colorado AIDS Projects, the Denver HIV Resources Planning Council, and the Boulder County AIDS Project include information on where clients can go for HIV testing on their web sites.
  - e. CDC National HIV and STD Testing Resources <https://gettested.cdc.gov/>
4. The CDC has published new testing guidelines for laboratories.

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<http://www.cdc.gov/hiv/testing/laboratorytests.html>. Many labs are moving to a 4th generation HIV test. Discuss the specifics of testing with the lab the clinic uses.

5. Point of Care (POC) testing using FDA-approved rapid HIV tests is recommended so that clients receive their test results on the day of their clinic visit.
6. The CDC Revised HIV Testing Recommendations contain the following provisions:
  - a. Voluntary HIV screening is recommended for clients in all health care settings after the client is notified that testing will be performed unless the client declines (opt-out screening).
  - b. Oral or written information should include an explanation of HIV infection and the meaning of positive and negative results. The client should be offered an opportunity to ask questions and to decline testing.
  - c. Persons at high risk for HIV infection should be screened for HIV at least annually.
  - d. Repeat screening of persons not likely to be at high risk for HIV should be performed based on clinical judgment.
  - e. Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass HIV testing.
  - f. Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health care settings.
  - g. Easily understood informational materials should be available in the clinic.
  - h. If a client declines an HIV test, this decision should be documented in the medical record.
  - i. HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
7. The USPSTF concurs with the CDC's recommendations that:
  - a. HIV screening should be voluntary and done only with the client's knowledge and understanding;
  - b. Clients should be informed orally or in writing that HIV testing will be performed unless the client declines;
  - c. Clients should receive an explanation of HIV infection and the meaning of positive and negative results.
8. The following procedure should be used with clients who are pregnant or considering pregnancy and are assessed to be at high risk for HIV infection:
  - a. Encourage HIV counseling and testing prior to pregnancy or as soon as possible if already pregnant.
  - b. The American College of Obstetrics and Gynecology, the American Academy of Pediatrics, and the CDC recommend the opt-out approach, meaning that women should be informed that an HIV test will be conducted as a routine part of prenatal care unless they opt to decline the test.
  - c. If the client is living with HIV and currently pregnant, refer for expert counseling and care. Inform client of the benefits of antiretroviral therapy in pregnancy.

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- d. The risk for perinatal HIV transmission can be reduced to <2% if antiretroviral regimens and obstetrical interventions (elective Cesarean section at 38 weeks gestation) are used, and by avoiding breastfeeding. (See CDC Sexually Transmitted Diseases Treatment Guidelines, 2015 and American College of Obstetrics and Gynecology [ACOG] [Committee Opinion Number 635](#), June 2015).
- e. If individual living with HIV and considering pregnancy, family planning providers must refer the client for expert counseling and care with a provider experienced in conception related services for individuals living with HIV (see linkage to care information below). Discuss delaying pregnancy until client receives expert counseling and information. Provide birth control information and contraceptives if the client wishes to start a contraceptive method.
- f. The following is provided as resources for staff. Providers should be aware that there are safe(r) conception opportunities for individuals living with HIV, including treatment of the index individual and PrEP for the uninfected person.

Resources for staff:

Prevention with Persons with HIV <http://www.cdc.gov/hiv/prevention/programs/pwp/rpc.html>  
 Preconception Counseling and Care Women of Childbearing Age. Reproductive Options for HIV-Concordant and Serodiscordant Couples <https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/153/reproductive-options-for-%20hiv-concordant-and-serodiscordant-couples>

- g. Provide appropriate (internal or external) referral for further counseling and testing to at-risk clients or upon request.

### J. Assessing Client Risk

1. The CDC recommendations indicate that prevention counseling should not be required as a part of HIV screening programs in health care settings. Prevention counseling, though, is strongly encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely, but should not be linked to HIV testing.
2. Risk assessment questions should be asked, in a non-judgmental manner, about the following behaviors:

Client History	Sexual Exposure With a(n):
Injection drug use	Person with HIV infection/AIDS
Receiving blood transfusion or products before 1986	Man who has sex with men or bisexual male
Sexual abuse or assault	Injection drug user
Receiving money or drugs in exchange for sex	Person who receives money or drugs in exchange for sex
Occupational exposure to body fluids (as a health worker)	Person with hemophilia
Syphilis, Gonorrhea, Herpes, Chlamydia, or Hepatitis B or C Recipient of artificial insemination, bone or tissue transplant	
Multiple sexual partners	

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3. Also see the Clinical Guideline for HIV Screening in Colorado which includes the [Denver HIV Risk Score](#) tool. Obtain copies of the guidelines from the Denver Prevention Training Center.
4. Responses to questions should be explored with the client. Any information the client can provide about the context of the potential exposure should be used to help the client determine her/his level of risk. A risk reduction plan tailored to the client's skills and motivation should be documented, if appropriate, and followed-up on subsequent visits.

### K. Education

Education of health care personnel regarding all facets of AIDS and HIV antibody testing, including the legal, ethical, and psychological ramifications is critical.

1. According to the CDC, client risk reduction behaviors include (see <http://www.cdc.gov/hiv/basics/index.html>):
  - a. Know your HIV status;
  - b. Abstain from sexual activity or be in a long term mutually monogamous relationship with an uninfected partner;
  - c. Limit the number of sex partners;
  - d. Correct and consistent condom use;
  - e. Get tested and treated for STIs and insist that your partners do, too;
  - f. Male circumcision has also been shown to reduce the risk of HIV transmission from women to men;
  - g. Don't use IV drugs; If you are using IV drugs don't share needles, syringes or other injection equipments;
  - h. Obtain medical treatment immediately if you think you were exposed to HIV. Sometimes HIV medications can prevent infection if they are started quickly – within 72 hours of a possible exposure. This is called post exposure prophylaxis, or PEP. PEP is the use of antiretroviral drugs after a single high-risk event to stop HIV from making copies of itself and spreading through your body. <http://www.cdc.gov/hiv/basics/pep.html>
  - i. Pre-exposure prophylaxis, or PrEP, is a prevention option for people who are at high risk of getting HIV. It is meant to be used consistently, as a pill taken every day, and to be used with other prevention options such as condoms. <http://www.cdc.gov/hiv/basics/prep.html>
2. Provide information about harm reduction programs in the community for individuals using IV drugs, such as needle exchange programs. Examples: Denver's Harm Reduction Action Center <http://harmreductionactioncenter.org/>, Boulder County The Works Program <http://www.bouldercounty.org/family/disease/pages/syringeexchange.aspx>, Western Colorado AIDS Project <http://www.ncaids.org/western-colorado-aids-project/syringe-exchange>
3. Documentation in the client's chart of the HIV/AIDS educational component will indicate that this protocol was used to inform the client about HIV screening and testing availability at the clinic or by referral.

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## L. Linkage to care for individuals who are HIV positive (Including case management and counseling)

1. Treatment as prevention - treating persons living with HIV improves their health, reduces viral load in blood and genital fluids and reduces the risk of transmission to others <http://www.cdc.gov/hiv/prevention/research/tap/>
2. Linkage to Care is a free and confidential service offered by the Colorado Department of Public Health and Environment that links people with HIV into care. The service is available to Colorado residents who are newly diagnosed or have been out of care. The HIV Linkage to Care Coordinator works with individuals to provide assistance and ensure connection to a provider based on area of residence, insurance status and personal preference. For more information please contact the Linkage to Care Coordinator, phone: 303-692-2734 or [maria.chaidez@state.co.us](mailto:maria.chaidez@state.co.us) Spanish language help also available.
3. Denver Metro Area
  - a. HIV Resources Planning Council, <http://dhrpc.org/default/index.cfm>
  - b. Denver Metro Area Counties, [DenverHealth.org/LinkageToCare](http://DenverHealth.org/LinkageToCare) 303-602-3652
  - c. Denver Colorado AIDS Project, <http://www.denvercap.org/>
4. Other resources outside the Denver Metro Area
  - a. Boulder County AIDS Project (BCAP) (Boulder, Broomfield, Clear Creek, and Gilpin Counties) <http://bcap.org/>
  - b. Northern Colorado AIDS Project (NCAP) (Larimer, Logan, Morgan, Philips, Sedgwick, Washington, Weld, and Yuma Counties) <http://www.ncaids.org/>
  - c. Western Colorado AIDS Project (West-CAP) (Archuleta, Delta, Eagle, Dolores, Garfield, Grand, Gunnison, Hinsdale, Jackson, Lake, La Plata, Mesa, Moffat, Montezuma, Montrose, Ouray, Pitkin, Rio Blanco, Routt, San Juan, San Miguel, and Summit Counties) <http://www.westcap.info/>
  - d. Southern Colorado AIDS Project (S-CAP) (Alamosa, Baca, Bent, Chaffee, Cheyenne, Conejos, Costilla, Crowley, Custer, El Paso, Elbert, Fremont, Huerfano, Kiowa, Kit Carson, Las Animas, Lincoln, Mineral, Otero, Park, Powers, Pueblo, Rio Grande, Saguache and Teller) <http://www.s-cap.org/>
5. CDPHE Services for individuals living with HIV web page: <https://www.colorado.gov/pacific/cdphe/sti-hiv> Information about case management services, drug assistance, health insurance assistance, navigating care
6. Post test results counseling (negative and positive results) <http://www.aids.gov/hiv-aids-basics/prevention/hiv-testing/post-test-results/>
7. Just Diagnosed: Next Steps After Testing Positive for HIV <http://aidsinfo.nih.gov/education-materials/fact-sheets/21/65/just-diagnosed--next-steps-after-testing-positive-for-hiv>

## Section 16: Breast Cancer Screening

Breast cancer screening, a related preventative health service, is beneficial to reproductive health, is closely linked to family planning services, and is appropriate to deliver in the context of a family planning visit, but does not contribute directly to achieving or preventing pregnancy. Providing Quality Family Planning Services (QFP)

<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/qfp.htm>

Clinics must stress the importance of and provide for breast cancer screening as appropriate.

### A. Prevention

1. According to American College of Obstetricians and Gynecologists (ACOG) recommendations, a screening clinical breast exam should be performed every 1 to 3 years starting at 20 years of age, and as indicated. ACOG recommends annual breast exams starting at 40 years of age. Clients should be told about breast self-awareness and that any breast changes should be reported to her health care provider. The benefits and limitations of breast self-examination (BSE) should be explained. Clients choosing to do BSE should be given instruction and/or review on the technique for doing a BSE.

### B. Screening Mammography

Clients should be told about the benefits and limitations of routine mammograms.

1. Under age 35
  - a. Mammography is not indicated unless a woman has a first-degree relative diagnosed with breast cancer at age 35 or younger. Clients should be referred for MD consultation and follow-up. There is evidence to support a mammogram ten years before the age of diagnosis of the relative's breast cancer, but no sooner than the age of 25 years.
2. Age 35-39
  - a. Mammographic imaging should be limited to clients with a first-degree relative with a history of early breast cancer, unless signs or symptoms are present. Clients with a personal history of breast cancer should receive a diagnostic mammogram, as well as other follow-up determined by the physician in charge of her breast cancer care.
3. Women in their 40's should have mammogram screening based on their individual risk and preferences. Mammography recommendations may also depend on physical exam findings or a radiologist's recommendations.
4. Screening recommendations vary for women considered to be at average or high risk for breast cancer. Breast cancer risk can be calculated using a screening tool such as the Breast Cancer Risk Assessment Tool from the National Cancer Institute and based on the Gail Model <http://www.cancer.gov/bcrisktool/Default.aspx>
5. See ACS recommendations for women at higher than average risk for breast cancer <http://www.cancer.org/cancer/breastcancer/moreinformation/breastcancerearlydetection/breast-cancer-early-detection-ac-recs>
6. National screening recommendations/guidelines
  - a. **ACOG** recommends annual screening mammograms starting at age 40 <http://www.acog.org/About-ACOG/News-Room/Statements/2015/ACOG-Statement-on-Recommendations-on-Breast-Cancer-Screening>

## Section 16: Breast Cancer Screening

- b. **US Preventive Screening Guidelines (USPSTF)** Screening mammogram recommendations (2016) for woman at average risk for breast cancer. See the following link for more in-depth information.  
<http://www.uspreventiveservicestaskforce.org/BrowseRec/Search?s=breast+cancer>
- 1) Women age 50-74 years – biennial screening mammography (Grade B)
  - 2) The decision to start screening mammography before the age of 50 years should be an individual one.
  - 3) Women who place a higher value on the potential harms may choose to begin biennial screening between the ages of 40 and 49.
  - 4) Women with a parent, sibling or child with breast cancer are at higher risk for breast cancer and thus may benefit more than average risk women from beginning screening in their 40s.
- c. **American Cancer Society (ACS)**
- Recommendations for woman at average risk for breast cancer (([JAMA, 2015; 314\(15\): 1599-1614](#)))
- 1) Women ages 40 - 44 should have the choice to start annual screening mammograms if they wish to do so (qualified recommendation).
  - 2) Woman should start mammogram screening at age 45 (strong recommendation)
  - 3) Women ages 45 – 54 should get a mammogram every year (qualified recommendation).
  - 4) Women age 55 and older should switch to mammograms every 2 years or have the choice to continue yearly screening (qualified recommendation)

### C. Management

1. Clients with a family history of first-degree relatives with premenopausal breast cancer should be encouraged to have a baseline evaluation with a specialist. These clients should be counseled regarding risks, benefits, and limitations of monthly BSE and the importance of annual clinical breast exams.
2. Any breast pathology - a lesion, mass, cyst, lump, breast pain, nipple discharge, change in appearance or deviation from the normal breast of an individual requires careful follow-up.
3. Palpable mass/unusual or suspicious unilateral thickening:
  - a. Document complete description of mass. The client must be given a written referral to a physician. In women under 30 years of age with a well-circumscribed mass and no skin changes, it is acceptable to re-check the breast after the next menses for resolution of the mass.
  - b. A negative mammogram in the presence of a palpable mass is NOT sufficient to rule out pathology.
  - c. Follow-up contact, to document client compliance, should be made with the patient within two (2) weeks, per agency tracking and follow-up guidelines.
4. Nipple change or discharge:
  - a. Women with skin breakdown on the nipple or areola or skin changes, such as dimpling, puckering, or peau d'orange (orange peel-like skin) should be referred.
  - b. For women with nipple discharge, document the complete description and history, including use of any medications.

## Section 16: Breast Cancer Screening

- 1) Bloody discharge, unilateral discharge, a palpable mass, or abnormal mammogram increases the suspicion of malignancy.
- 2) If spontaneous galactorrhea is present, serum prolactin levels/ thyroid function tests may be drawn.
- 3) Referral should be made either in house or to an outside provider for:  
Galactorrhea with headaches, amenorrhea and/or involuntary infertility, or galactorrhea in the presence of an abnormal prolactin or thyroid function test result. Any non-milky discharge.
5. Breast pain: If the clinical breast exam is negative, reassure the patient; suggest an analgesic and a supportive bra. A follow-up breast exam may be done in two months. If conservative measures do not relieve symptoms, a referral is indicated. Any other undiagnosed, unilateral breast pain or non-cyclic breast pain should be referred.
6. Clients may be followed on hormonal contraceptives or hormonal replacement therapy for up to three months while the breast findings are investigated.
7. Please refer to Section 23 - Referral and Follow-Up of the Clinical Manual. Referrals for solitary breast masses are considered urgent, requiring follow-up within two weeks.
8. Breast Cancer Diagnostic Algorithms for Primary Care Providers 4<sup>th</sup> Edition 2011 from the California Department of Public Health Cancer Detection Section Breast Expert Work Group may be helpful to providers in assessing risk for breast cancer and determining follow up testing.  
<http://gap.sdsu.edu/screening/breastcancer/bda/index3.html>
9. Also included on the above noted web site are clinical tools including a CBE results documentation form, CBE skills reminder card, core competencies of CBE (video) and a lymph node exam guide.



## Section 17: Cervical Cancer Screening and Follow Up

USPSTF and ACS/ASCCP/ASCP	
Age to begin screening	Age 21, regardless of the age of initiation of sexual intercourse.
When to discontinue screening	At greater than 65 years old if the woman has had adequate negative prior screening. Women with a history of CIN2 or more severe diagnosis should continue routine screening for at least 20 years.
Screening intervals, Ages 21-29	Pap testing alone every 3 years.
Screening Intervals for women 30-65 years old	Pap testing alone every 3 years or Pap testing with high risk HPV testing every 5 years.
Screening intervals for women with total hysterectomy	No Pap test screening if the woman has had adequate negative prior screening and the woman does not have a cervix and does not have a history of CIN2 or a more severe diagnosis in the past 20 years or cervical cancer ever.
<p>Use of high risk HPV Testing in conjunction with Pap test screening and follow-up in specific circumstances.</p> <p><i>For further recommendations for the use of high risk HPV testing in the management of abnormal Pap or biopsy results, please refer to the American Society for Colposcopy and Cervical Pathology algorithms referenced in Section III below.</i></p>	<ul style="list-style-type: none"> <li>•Should not be used for screening in women under 30 years</li> <li>•HPV co-testing can be used in women 30 years old or older, every 5 years.</li> </ul> <ul style="list-style-type: none"> <li>•If co-testing HPV positive and Pap test negative then repeat co-testing in 12 months or do immediate HPV DNA typing for HPV16/18.               <ol style="list-style-type: none"> <li>1. If co-testing is repeated at 12 months:                   <ol style="list-style-type: none"> <li>a) If positive HPV or Pap <math>\geq</math>ASC refer to colposcopy.</li> <li>b) If Pap and HPV negative repeat co-testing in 3 years.</li> </ol> </li> <li>2. If HPV DNA typing                   <ol style="list-style-type: none"> <li>a) If HPV 16 and 18 negative, then repeat co- testing in 1 year.</li> <li>b) If HPV 16 or 18 positive, then refer for colposcopy</li> </ol> </li> </ol> </li> <li>•If co-testing HPV is negative and the Pap test is ASC-US, repeat co-testing in 3 years.</li> </ul> <p>(Source: ASCCP Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors © 2013)</p>

## Section 17: Cervical Cancer Screening and Follow Up

### **B. Follow-Up of Abnormal Cervical Cancer Screening Tests and Cancer Precursors**

NOTE: Please refer to the American Society of Colposcopy and Cervical Pathology Consensus Guidelines on the Management of Women with Abnormal Cervical Cancer Screening Tests and Cancer Precursors © 2013 algorithms found at the following website:

<http://www.asccp.org/Guidelines-2/Management-Guidelines-2>

1. Please note that the follow-up for women 21 to 24 years old may be different than for women 25 years and older.
2. Individual providers are permitted by copyright law to print these algorithms for use in the clinic.
3. Document all client contacts and attempted contacts regarding the abnormal cervical cancer screening tests and or colposcopy/biopsy results in the client's chart. Consider the use of a certified return receipt letter if the client is unresponsive to follow up contacts (if the client has previously indicated receiving mail is acceptable).

### **C. Patients Declining the Recommendation For Colposcopy Follow-Up**

1. Document the client's declining follow up in the patient's chart.
2. When a patient declines colposcopy, cryotherapy or LEEP, the case should be reviewed by a consulting physician.

### **D. Management of Patients Reporting Previously Abnormal Cervical Cancer Screening Tests:**

1. If a patient provides a verbal report of an abnormal cervical cancer screening test (or colposcopy, cryotherapy, conization, or laser ablation) within the last year, efforts should be made to obtain medical records. Do an initial exam or a delayed exam as appropriate.
2. If records cannot be obtained and the initial cervical cancer screening test is negative, patients should have a repeat cervical cancer screening test six to 12 months later.
3. If the initial cervical cancer screening test (through Family Planning clinic) is other than negative, the patient should be followed for the abnormality described, as outlined in the algorithms referenced in Section B. above.

### **E. Abnormal Pap Tests and Contraceptives**

1. An abnormal Pap test does not constitute a contraindication to hormonal contraceptives or IUCs.
2. Cervical cancer (awaiting treatment) is a category 4 (IUC is contraindicated) for initiating an IUC and a category 2 for continuing an IUC.

### **F. Management of Diethylstilbestrol (DES) - Exposed Women**

1. Women who were born between 1940 and 1971 who were exposed to DES should be counseled about the potential risks, provided with DES information, and offered a baseline colposcopic evaluation, with iodine staining.
  - a. Physiological changes that occur include circular ridges in the wall of the vagina, cervical hood, and cervical cockscomb, adenosis, or persistence of immature glandular epithelium in the vaginal walls and/or endocervix.

## Section 17: Cervical Cancer Screening and Follow Up

2. Pap test sampling should include a vaginal 4-quadrant technique in addition to cervical sampling. Using the spatula, scrapings are taken from the upper to the lower third of the vagina. These samples should be submitted on two slides. One slide should have the endocervical/ectocervical sample, and the rest of the four quadrant samples should be placed on the second slide. If using liquid-based media, the four quadrant vaginal specimen is put in one specimen container, and the endocervical/ectocervical sample in another specimen container. Label the slides or specimen containers appropriately, indicating cervical specimen and vaginal specimen. Send each specimen with a corresponding requisition noting a history of DES exposure. Examination of a DES exposed woman must include palpation of the vagina. Any unexplained vaginal or cervical mass or nodule detected on visual inspection or digital examination should be biopsied. Clear cell carcinoma of the cervix which occurs after DES exposure often originates along the anterior vaginal wall as opposed to vaginal cancer of older women which often occurs along the posterior wall.
  - a. A history of DES exposure or adenosis on a Pap test is not a contraindication to the use of hormonal contraceptives.
  - b. See the following links for more information. <http://www.cancer.gov/cancertopics/factsheet/Risk/DES>  
<http://www.cancer.org/Cancer/CancerCauses/OtherCarcinogens/MedicalTreatments/des-exposure>
  - c. Follow up
    - 1) DES-exposed daughters should have yearly gynecological exams with cervical and vaginal cytology, visualization and palpation of the vagina and cervix, and a bimanual exam.
    - 2) If the results of the exam, Pap tests, colposcopy, iodine staining, or biopsies are abnormal, the client should be referred to a provider experienced in evaluating DES exposed daughters.

## Section 18: Adolescent Services

Title X family planning services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)). Client confidentiality, including for adolescents, must be safeguarded. Adolescents are a priority population for Title X and adolescent services are addressed specifically in Providing Quality Family Planning Services pgs. 38-40. Family planning programs should take steps to make services youth friendly. (QFP pg. 40)

### A. Overview

1. Adolescent clients (defined as <18 years of age) have specialized needs when they come to a family planning program for services. Many need skilled counseling and detailed information to avoid contraceptive failure. Comprehensive information should be provided regarding how to prevent pregnancy and STIs.
2. While research shows most adolescent clients who come to a family planning program have been sexually active nine months to one year, some teenagers are seeking assistance in reaching a decision about sexual activity. Abstinence should be discussed with all teens as a valid and responsible option.
3. Family planning programs should take steps to make their services youth friendly.

### B. Contraceptive Services

1. Adolescents seeking contraceptive services must be informed about all methods of contraception, including abstinence. Education should include an explanation that LARCs are a safe and effective method for women who have not been pregnant, including adolescents.
2. Adolescents should be offered information about basic female and male reproductive anatomy and physiology.
3. All counseling and education must be documented.

### C. Confidentiality

1. Services provided to adolescents are confidential. Adolescents should be informed that contraceptive services are confidential and do not require parental consent.
2. However, adolescents must be encouraged to discuss their needs and decisions with family.
3. The family planning program recognizes the key role family members have to play in teenagers' lives and ideally as primary sex educators.
4. Adolescents must understand that there are certain reportable situations (e.g. positive STI, child abuse, child molestation, sexual abuse, rape, or incest) that supersede confidentiality. Please refer to the Mandatory Reporting and Human Trafficking Section for more information regarding Colorado mandatory reporting laws.
5. Inform teens with private insurance that an explanation of benefits will be generated and sent to the policy holder if services are billed to private insurance. Minors, those under 18 years old, may opt out of using their private insurance if confidentiality is a concern and they can be charged on a sliding fee scale. Individuals 18 -26 years old and covered under their parents' policy may contact their private insurance company and request that EOBs are only sent to the covered individual and not the policy holder. (Department of Regulatory Agencies, Division of Insurance, Amended Regulation 4-2-35)
6. Office of Population Affairs, Clarification regarding "Program Requirements for Title X Family Planning Projects", Confidential Services for Adolescents, OPA Program Policy Notice 2014 -01, release date June 5, 2014  
<http://www.hhs.gov/opa/pdfs/ppn2014-01-001.pdf>

## Section 18: Adolescent Services

### D. Encouraging Family Involvement

Family involvement includes, but is not limited to, parental awareness of an adolescent's decision to seek family planning services, discussion of family planning options, and encouragement of responsible sexual decision-making. By integrating encouragement of family involvement into the family planning visit, the staff may help adolescents develop the interpersonal skills necessary to involve their families. Provide adolescents information about contraception, safer sex, abstinence, teen pregnancy, STIs, and HIV/AIDS. Adolescents often need to be introduced to the concept of responsible decision-making as regards their sexuality.

Motivating adolescents to involve family should include the following:

1. A straightforward explanation of the confidentiality policy. This would include examples of what information would have to be shared, e.g., situations covered under the mandatory reporting laws, reporting of certain STIs, threats to the client's safety, etc.
2. Stating it is the clinic policy to talk to all adolescents about family involvement
3. Asking whether the adolescent has ever talked to his/her parent about sex, birth control, or STIs.
4. Being positive about the potential benefits of family involvement, while allaying any fears about requiring family involvement.
5. Getting the adolescent to verbalize what the hardest part about talking to a parent or family member would be; what the worst part of the parent's or family member's response might be; what the best part of involving the parent or family member might be.
6. Provision of the brochure, available from the CDPHE Family Planning Program or some other brochure on the topic of family involvement that has been approved by your agency's Information and Education (I & E) committee.

### E. Counseling on Resisting Sexual Coercion

Sexual coercion is the act of persuading or coercing a person, including an adolescent, into engaging in an unwanted sexual activity through physical force, threat of physical force, or emotional manipulation. It differs from rape in that the coerced individual feels it is easier to consent to sexual activity than to decline, because of an imbalance in power. Coercive situations may not be obvious, even to the coerced individual.

Education and counseling:

Information about sexual coercion must be provided to all new adolescent clients. It should be provided to any other client when there is suspicion of abuse or forced sexual activity. The imbalance of power can present itself through pressuring, intimidation, and threats; and it can be physical, emotional, psychological, or spiritual in nature.

Education should include, but not be limited to:

1. an explanation of what coercion is
2. the right to refuse sex at any time without negative consequences
3. the right to set limits
4. an awareness of the different kinds of peer pressure that might lead to sexual coercion and how the influence of drugs and alcohol can affect behavior and decision-making ability

## Section 18: Adolescent Services

5. the importance of self-esteem and self-respect in avoiding coercive relationships
6. a list of any available community resources written information on the topic of sexual coercion that has been approved by your agencies I & E committee.

### F. Documentation on Education/ Counseling

Education and counseling about family involvement and sexual coercion must be documented in the client chart. Use of a check off box is acceptable. If the topic is listed as “Adolescent Counseling” or “Teen Counseling” then marking it off would mean that the information listed under both ‘D’ and ‘E’ above has been covered. If the topics are listed separately, as “Family Involvement” and “Sexual Coercion” or “Partner Coercion,” then each topic would need to be marked, as indicated.

Please be sure that your education check-off list covers these topics.

Documentation of abstinence counseling is required.

### Resources:

- Refer to Section 25 for Mandatory Reporting/Human Trafficking information
- Refer to Section 20 Client Consent for Colorado minor consent information
- The Colorado Association for School-Based Health Care publication *Understanding Minor Consent and Confidentiality in Colorado* ©2011 National Center for Youth Law, Adolescent Health Law Project, [www.teenhealthlaw.org](http://www.teenhealthlaw.org)  
Topics covered include minor consent laws, confidentiality of adolescent medical information under Colorado law, mandated child abuse reporting, and the Family Educational Rights and Privacy Act (FERPA).  
<http://casbhc.org/Publications/Technical%20Assistance/Understanding%20Minor%20Consent%20and%20Confidentiality%20in%20Colorado.pdf>
- Guttmacher Institute, Adolescent Resources  
<http://www.guttmacher.org/sections/adolescents.php>
- Advocates for Youth, includes information and advice for parents  
<http://www.advocatesforyouth.org/index.php>
- StayTeen.org  
<http://stayteen.org/>
- Loveisrespect is a project of the National Domestic Violence Hotline and Break the Cycle with information about dating and healthy relationships  
<http://www.loveisrespect.org/>

## Section 19: Menopause

The following recommendations and educational information are provided to assist with the care of menopausal women transitioning from the need for contraceptive services. Services and supplies for menopausal women are not required by Title X and do not have to be offered. The sliding fee scale does not have to be applied.

### A. Definitions

1. Perimenopause - the interval of approximately 5-10 years that precedes and follows the last menses. It is characterized by fluctuating ovarian estrogen production secondary to decreased ovarian function. This transition may be relatively asymptomatic or can be associated with a wide variety of symptoms.
2. Menopause - the cessation of ovarian ovulatory function evidenced by the cessation of menses for a period of one year. Menopause may also be induced surgically (oophorectomy) or medically (chemotherapy or radiation treatment). The average age of menopause in the United States is 52. Smokers reach menopause 1.5 years earlier than non-smokers.
3. Premature ovarian failure/insufficiency – transient or permanent loss of ovarian function prior to age 40 resulting in cessation of menses and associated signs and symptoms of menopause.

### B. Perimenopausal / Menopausal Signs and Symptoms

The signs and symptoms associated with the perimenopausal period are primarily due to estrogen deficiency (and/or wide swings in estrogen levels) and can include:

1. Hot flashes or flushes
2. Insomnia / night sweats / poor quality sleep leading to fatigue
3. Mood changes / anxiety / depression
4. Memory impairment / difficulty concentrating
5. Irregular menses / vaginal bleeding
6. Vulvovaginal itching, pain, or dryness / vulvovaginal atrophy (usually a late sign)
7. Urinary symptoms such as frequency, urgency, dysuria, frequent UTIs
8. Dyspareunia / decreased libido
9. Loss of bone density / osteoporosis

### C. Assessment/Examination

Services and supplies for menopausal women are not required by Title X and do not have to be offered. The sliding fee scale does not have to be applied.

Comprehensive History - obtain a complete personal and family history including medical/surgical, family history of osteoporosis or hip fracture, personal history of fracture, Ob/Gyn history including menstrual, sexual, and contraceptive history, psychosocial history including lifestyle issues relative to nutrition, substance use, domestic violence, and vaccination history.

1. Physical Exam - complete
2. Laboratory / Screening Tests

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- a. Cervical cancer screening as indicated, according to ASCCP guidelines
  - b. Fasting lipid screen (total cholesterol, HDL, LDL, triglycerides) every 5 years beginning at age 45 (US Preventative Services Task Force 2008). The Task Force concluded that the optimal interval for screening is uncertain; reasonable options include every five years, or shorter for people who have lipid levels that are close to warranting therapy, or longer for low risk people with repeatedly low or normal values. An age to stop screening was not established; screening may be appropriate in older people who have never been screened, but repeated screening is less important in older people because lipid levels are less likely to increase after age 65.
  - c. Pregnancy test, if indicated
  - d. Baseline mammogram or negative mammogram result is recommended prior to initiation of menopausal hormone therapy (MHT). MHT may be started and a mammogram ordered within 3 months.
  - e. Fecal occult blood testing annually or sigmoidoscopy every 5 years or colonoscopy every 10 years after age 50; younger if risk factors are present.
  - f. Fasting blood sugar (FBS) should be considered in all clients  $\geq$  age 45. If normal, repeat every 3 years.
  - g. Bone mineral density (BMD) at age 65 or earlier if indicated by FRAX score assessment of risk factors.
3. Special circumstances lab testing:
- a. Serum follicle stimulating hormone (FSH) –This test is only helpful when evaluating for premature ovarian failure/insufficiency (<40 years old). An elevated FSH implies that the ovary is unable to produce sufficient estradiol (secondary to depletion of ovarian follicles) to provide negative feedback to the anterior pituitary where FSH is released. This is an expensive test and only reflects the “snapshot in time” when the test is drawn. Symptom resolution following estrogen treatment is a reliable indicator for diagnosis of perimenopausal status. Treatment, if indicated, should be started without drawing an FSH, unless the client is <40 years old. If an FSH is drawn, it should be drawn on Day 3 of the menstrual cycle, if possible.
  - b. Endometrial biopsy or ultrasound assessment of the endometrial thickness as indicated for irregular bleeding.

### D. Diagnosis

The diagnosis of menopause is usually made presumptively on the basis of amenorrhea (at least 12 months) and presence of menopausal symptoms in a woman at least 40 years of age. Perimenopause can be diagnosed with menopausal symptoms prior to complete cessation of menstrual periods and may also be an indication for treatment.

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## E. Treatment Alternatives

In July 2002, the Women’s Health Initiative announced that it was ceasing the estrogen/progestin arm of the trial (women with an intact uterus) because researchers found that patients who were assigned to the treatment group demonstrated risks that outweighed benefits. While the estrogen and progestin therapy (EPT) users in the study did have a reduced risk of colorectal cancer and fractures (including hip fractures), they also experienced more strokes, heart attacks, blood clots, and an increased risk of invasive breast cancer. Subsequent analysis of the data revealed that the risk of coronary heart disease was primarily in women who began EPT after age 60. In this and other more recent studies, EPT or ET appeared to decrease cardiac risk in women who initiated the therapy before age 60. This may open up a safer therapeutic window for younger women, who are the most likely to require MHT to control menopausal symptoms.

The estrogen alone (ET) treatment arm was stopped in March 2004 because it also showed an increase in the rate of strokes and deep vein thrombosis/venous thromboembolism. However, there appeared to be no increased risk of coronary heart disease in this group. Like the EPT arm, the ET arm of the study demonstrated a reduction in osteoporosis and the risk of hip and other fractures. And in the final analysis, ET appeared to be associated with an actual decrease in breast cancer risk.

Treatment of moderate to severe vasomotor symptoms is the primary indication for MHT. The benefits outweigh the risks for most healthy, symptomatic women aged younger than 60 or within 10 years of the final menstrual period (NAMS 2014). The scale tilts even more toward benefits in women who have had a hysterectomy and require only ET. A woman’s decision for therapy should be highly individualized based on her unique risk/benefit profile. The lowest dose necessary to relieve symptoms should be prescribed. ET/EPT is not recommended for long-term treatment to prevent cardiovascular or other chronic disease.

### 1. Menopausal Hormone Therapy (MHT)/Estrogen Therapy(ET)/Estrogen Progestin Therapy(EPT)

#### a. Contraindications

- 1) Known or suspected pregnancy
- 2) Undiagnosed abnormal vaginal bleeding
- 3) History of deep vein thrombosis or venous thromboembolism
- 4) Known thrombophilic disorder
- 5) History of stroke or ischemic heart disease
- 6) Active liver disease, liver dysfunction
- 7) History of or suspected breast or other estrogen-sensitive cancer
- 8) Women with a history of malignant melanoma must have a consultation with an oncologist/dermatologist prior to receiving MHT

Note: ET/EPT is not contraindicated in women with hypertension, fibroids, diabetes, migraines, and/or varicosities.

#### b. Side Effects

- 1) Gastrointestinal – nausea/vomiting, bloating, abdominal cramping

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- 2) Breast tenderness/enlargement
  - 3) Vaginal bleeding/spotting
  - 4) Weight gain/changes, fluid retention
  - 5) Chloasma
  - 6) Headache
  - 7) Mood changes
  - 8) Gallstones, cholecystitis
- c. Benefits
- 1) Relief of menopausal symptoms
  - 2) Protection against bone loss and osteoporosis
  - 3) May decrease risk of coronary heart disease if begun before age 60
- d. Risks
- 1) Increased breast cancer risk in women using combination MHT (EPT) continuously for more than 3-5 years
  - 2) Increased coronary heart disease in women who begin EPT after age 60
  - 3) Increased risk of DVT/PE, primarily with oral therapy
  - 4) Increased stroke risk, may be higher with oral therapy
- e. MHT Regimens
- 1) Continuous Combined Regimen (for clients with an intact uterus):  
Estrogen and progestin/progesterone daily.
    - a) Withdrawal bleeding and spotting may occur for the first 6-12 months. However, most women on continuous HRT experience amenorrhea within 6 months - 1 year.
    - b) Any woman with irregular uterine bleeding who has risk factors for hyperplasia (obese, diabetic, hypertensive, history of taking unopposed estrogen) or any woman with bleeding that persists for 6 months, should receive an ultrasound evaluation of endometrial thickness or an endometrial biopsy. If the endometrial stripe is greater than 4mm on ultrasound, an endometrial biopsy is indicated.
    - c) Based on the apparent negative effect of medroxyprogesterone acetate in the EPT arm of WHI, clinicians may wish to consider prescribing regimens formulated with other progestins such as norethindrone acetate, levonorgestrel, drospirenone, norgestimate, or progesterone itself.

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### Equivalent Doses of Progestins

<i>Brand Name</i>	<i>Dosage</i>
Provera®, medroxyprogesterone acetate (generic)	2.5, 5.0 mg
Aygestin®, norethindrone acetate (generic)	2.5, 5.0 mg
Prometrium®, micronized progesterone (generic)	100, 200 mg

- d) Although off label for this use, the levonorgestrel containing intrauterine system is an excellent means of delivering progestin to the endometrium and protecting the patient from hyperplasia. Side effects of oral progestins are avoided with this treatment modality.
- 2) Cyclic Regimen (for clients with an intact uterus):
- Daily estrogen plus progestin/progesterone for the first 14 days of every month.
- Withdrawal bleeding can be expected during or after the completion of the progestin cycle, although some women experience very light or no bleeding.
  - Many clinicians start perimenopausal/newly menopausal women on a cyclic regimen, switching later to the continuous combined regimen.
- 3) Estrogen alone
- Post-hysterectomy, estrogen alone is taken every day. However, women with prior endometriosis and possible remaining endometriotic implants should consider adding progestin/progesterone.
  - With an *intact* uterus, estrogen alone requires yearly endometrial biopsy or ultrasound evaluation of endometrial thickness and is quite likely over time to lead to endometrial hyperplasia (which will necessitate higher-dose progestin therapy or even hysterectomy).

### Equivalent Doses of Estrogens

<i>Brand Name</i>	<i>Dosage</i>
Premarin®, Cenestin®, Enjuvia, Menest®, esterified or conjugated estrogens (generic)	0.3, 0.45, 0.625 mg
Estrace®, estradiol (generic)	0.5, 1.0 mg
Ogen®, Ortho-Est®, estropipate (generic)	0.625 mg
Vivelle®, Vivelle Dot®, Minivelle®, Climara®, Alora®, Estraderm®, or generic estradiol patch	0.025, 0.0375, 0.05 mg

Estradiol can also be prescribed in a systemic vaginal ring (Femring® .05 mg), creams, gels or a spray (Evamist®).

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Combination pills (e.g. PremPro®, Activella®, Angeliq®) and patches (Climara Pro®, Combipatch®) combine estrogen and progestin in one vehicle.

Note: Recent data suggests that transdermal delivery of estrogen may be safer than oral therapy. Because it avoids first-pass through the liver effects on coagulation factors, transdermal delivery appears to be associated with less risk of DVT/PE, and possibly stroke and MI. It is also less likely to decrease libido. Transdermal delivery should be considered for all women, but may be preferred for those with cardiovascular risk factors.

### 4) Other Regimens

- a) Duavee®, a combination of 0.45 mg conjugated equine estrogens and the SERM bazedoxifene taken orally every day, is an innovative hormonal treatment for menopausal symptoms and prevention of osteoporosis. The SERM inhibits endometrial growth so that a progestin is not required for women with a uterus. Contraindications are the same as those for EPT/ET.
- b) Low-dose vaginal estrogen is preferred for women experiencing only urogenital symptoms:
  - (1) Estring® one ring every 90 days
  - (2) Estradiol or Premarin® vaginal cream intravaginally 1/4 applicatorful qd x 1-2 weeks then twice a week as indicated
  - (3) Vagifem® vaginal tablets 1 tablet intravaginally qd X 2 weeks followed by maintenance of 1 tablet intravaginally twice a week
  - (4) A progestin is not required with this therapy, but all bleeding that occurs while using it should be investigated with endometrial biopsy or ultrasound of the endometrial stripe.
- c) Ospheña® (ospemifene), a SERM given orally 60 mg/day, is a newer option for management of vulvovaginal symptoms that may be particularly useful for women who are uncomfortable with vaginal application. Contraindications are the same as those for estrogen therapy, and as with vaginal estrogen, any bleeding should be thoroughly investigated.

### f. Follow Up

- 1) The first follow up visit should be scheduled in 3 months to assess symptom relief and evaluate side effects.
  - 2) Continue annual well-woman checks.
2. Low dose oral contraceptives are effective in controlling perimenopausal symptoms and re-establishing cycle control in women with fluctuating levels of estrogen. They can be continued for this purpose up to age 52, but should be used only in non-obese nonsmokers without cardiovascular risk factors.
3. Non-hormonal Options

SSRIs, SSNRIs (such as venlafaxine), gabapentin, and clonidine have all been shown to be effective alternatives for reducing hot flashes. Use of these medications for vasomotor symptoms is off label, with the exception of Brisdelle® 7.5 mg. qhs, a low-dose paroxetine that has been approved for this purpose. Most SSRIs, including Brisdelle®, should not be used in women taking tamoxifen, as they may compromise the efficacy of the tamoxifen.

## Section 19: Menopause

4. Artificial lubrication and/or vaginal moisturizers (e.g. Replens®, Luvena®) can help alleviate vaginal symptoms and dyspareunia.
5. Clinical trials generally demonstrate benefits of complementary and alternative treatments for menopausal symptoms to be no better than placebo. In addition, herbs and botanicals are not regulated by the FDA, so safety is not assured and efficacy information is not available.
6. Lifestyle recommendations for symptom relief include cooler environments, avoiding triggers (e.g. spicy foods, red wine), relaxation techniques such as meditation and yoga, aerobic exercise, weight loss, and discontinuing smoking.

### F. Counseling and Education

1. Emphasize that menopause is a normal physiologic event and discuss normal changes in body systems and sexuality associated with aging.
2. Inquire about symptoms that may need to be addressed. Ask about sexual problems in particular, since the client may be uncomfortable bringing them up.
3. Stress that the menopausal transition is an important time for women to implement behavioral changes to ensure healthy aging.
4. Discuss the importance of good nutrition and adequate calcium intake (1200 mg qd if not on ET/EPT; 1000mg if on ET/EPT) and vitamin D at least 600 IU/day. Dietary calcium should be assessed and supplements added if needed to reach the RDA.
5. Encourage regular exercise for heart health. Weight-bearing exercise also enhances bone density.
6. Promote a healthy lifestyle
  - a. Maintain normal body weight.
  - b. Stop smoking.
  - c. Decrease alcohol consumption.
7. Counsel regarding the need for preventive health screenings such as cervical cancer screening according to ASCCP guidelines, breast self-awareness, annual clinical breast exam, mammography, bone mineral density, colon, lipid and diabetes screens.
8. Discuss the importance of recommended immunizations, including a Tdap booster every 10 years, influenza immunization yearly, Zostavax® shingles vaccine at age 60, and pneumococcal vaccine at age 65.
9. Counsel regarding contraception if client has not experienced cessation of menses for 1 year. Serum levels achieved with EPT do not suppress ovulation and are **NOT** adequate for contraception. (Hormone levels are ~1/6 the levels of a pill containing 20 mcg of estrogen.)
  - a. Combined oral contraception (COC) or vaginal ring may be continued to the early 50s unless contraindicated. As noted above, combined hormonal methods may be used for non-obese, nonsmoker clients without cardiovascular risk factors. Women using COC or vaginal ring cyclically may experience hot flashes and difficulty sleeping at the end of the week of placebo pills because of lack of estrogen. They may choose to use the COC continuously, which will help control these symptoms, or they may transition to EPT if using a back up method of contraception. Intrauterine contraception, the subdermal

## Section 19: Menopause

implant, and depot medroxyprogesterone may be continued to the early 50s unless contraindicated.

- b. If a patient has a levonorgestrel IUS or is using depot medroxyprogesterone acetate, she may initiate estrogen therapy with her method serving as the progestin.

**G. Discuss issues pertinent to STI & HIV prevention as indicated.**

**H. Discuss treatment options for menopausal symptoms; refer to community and other supportive resources as needed.**

1. Assess client risk factors for osteoporosis, cardiovascular disease, breast cancer and other pertinent conditions.
2. Discuss risks and benefits of MHT and alternative treatments.
3. Assess client expectations/attitudes about menopause and symptom treatment.
4. Menopause.org is an excellent internet site maintained by the North American Menopause Society providing information for both patients and providers.

# Section 20: Client Consent

## A. Standard

1. Informed consent must be obtained from each client receiving any clinical service, including pregnancy test only visits, emergency contraception visits, express visits, STI visits which are expanded to qualify clients for family planning, etc.
2. If the consent is read and/or translated to the client, there must be a signed statement by clinic staff that to the best of her/his knowledge, the client understood the content of the consent.

## B. Consent for Service

1. At the time of admission to any clinical service, a signed informed consent must be obtained from the client for voluntary acceptance of services. All clients entered in to iCare as family planning clients must have a signed family planning program consent in their medical record.
2. Program consent forms should state that receipt of family planning services is not a prerequisite to receipt of any other services offered.
2. This form should be completed before the client is provided any clinical services, which may or may not include an exam.
3. This consent must contain a statement about the client's potential financial liability for services not covered by the program. This could include, but would not be limited to, non-Title X services such as colposcopy, HIV testing, Chlamydia screening for clients not at risk, as well as complications resulting from Title X-covered procedures, side effects from medications, etc.
4. The client should be given a copy of the consent and the original is kept in the chart.
5. This only needs to be obtained once, at the first visit.

## C. Consent for Sterilization Procedure

(See [Section 11: Sterilization](#) - in the Clinical Manual)

## D. Minors and Consent for Services

The following information is intended only for use as a reference. It is not legal advice. Consult your legal counsel for more information.

Minors may consent to contraceptive and STI services in Colorado. A lower age limit is not noted in Colorado statutes for these services.

Title X projects may not require written consent of parents or guardians for the provision of services to minors. Nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services. All Title X providers must comply with State laws requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape or incest. (Office of Population Affairs clarification (OPA Program Policy Notice 2014-01) regarding confidential services to adolescents in the Program Requirements for Title X Family Planning Projects. <http://www.hhs.gov/opa/pdfs/ppn2014-01-001.pdf> )

Consent for treatment for services beyond contraceptive and STI-HIV services:

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Defining the “line” between what services a teen versus the teen's parent may consent to when the teen has an adverse reaction may best be made on a case-by-case basis by the health care provider and with the agency’s legal counsel, taking into consideration the confidentiality and privacy concerns of the teen.

Serious adverse reactions to contraceptives are not common. Reactions may vary from person to person and in severity. This may make developing a blanket policy regarding when to seek parental consent for care difficult. For the above reasons, the CDPHE Family Planning Program cannot provide advice regarding when to seek parental consent for teens in need of care beyond family planning services and advise seeking legal counsel.

### Resources:

The Colorado Association for School-Based Health Care publication *Understanding Minor Consent and Confidentiality in Colorado* ©2011 National Center for Youth Law, Adolescent Health Law Project, [www.teenhealthlaw.org](http://www.teenhealthlaw.org)

Topics covered include minor consent laws, confidentiality of adolescent medical information under Colorado law, mandated child abuse reporting, and the Family Educational Rights and Privacy Act (FERPA).

<http://casbhc.org/Publications/Technical%20Assistance/Understanding%20Minor%20Consent%20and%20Confidentiality%20in%20Colorado.pdf>

Colorado Revised Statutes (CRS) <http://www.lexisnexis.com/hottopics/Colorado/>

A complete statute is not reproduced here if “In part” is noted after the statute title. Statute language may be amended or repealed at times. Statute language noted in these policies may not be the most current language. Please consult the Colorado Revised Statutes for current language.

Statutes applicable to minor consent include:

CRS §25-6-102 Policy, authority, and prohibitions against restrictions (in part)

- 1) All medically acceptable contraceptive procedures, supplies, and information shall be readily and practicably available to each person desirous of the same regardless of sex, sexual orientation, race, color, creed, religion, disability, age, income, number of children, marital status, citizenship, national origin, ancestry, or motive.

CRS §13-22-105 Minors – birth control services rendered by physicians.

Birth control procedures, supplies, and information may be furnished by physicians licensed under article 36 of title 12, C.R.S., to any minor who is pregnant, or a parent, or married, or who has the consent of his parent or legal guardian, or who has been referred for such services by another physician, a clergyman, a family planning clinic, a school or institution of higher education, or any agency or instrumentality of this state or any subdivision thereof, or who requests and is in need of birth control procedures, supplies, or information.

CRS §13-22-102 Minors – consent for medical care and treatment for addiction to or use of drugs.

Notwithstanding any other provision of law, any physician licensed to practice in this state, upon consultation by a minor as a patient, with the consent of such minor patient, may examine, prescribe for, and treat such minor patient for addiction to or use of drugs without the consent of or notification to the parent, parents, or legal guardian of such minor patient, or to any other person having custody or decision-making responsibility with respect to the medical care of such minor patient. In any such case the physician or any person acting pursuant to the minor's direction shall incur no civil or criminal liability by reason of having made such examination or prescription or having rendered such treatment, but this immunity shall not apply to any negligent acts or omissions by the physician or

## Section 20: Client Consent

any person acting pursuant to the physician's direction.

CRS §13-22-103 Minors – consent for medical, dental, and related care.

1) Except as otherwise provided in sections 18-1.3-407 (4.5), 25-4-402, and 12-34-104, C.R.S., a minor eighteen years of age or older, or a minor fifteen years of age or older who is living separate and apart from his or her parent, parents, or legal guardian, with or without the consent of his or her parent, parents, or legal guardian, and is managing his or her own financial affairs, regardless of the source of his or her income, or any minor who has contracted a lawful marriage may give consent to organ or tissue donation or the furnishing of hospital, medical, dental, emergency health, and surgical care to himself or herself. Such consent shall not be subject to disaffirmance because of minority, and, when such consent is given, said minor shall have the same rights, powers, and obligations as if he or she had obtained majority. Consent to organ or tissue donation may be revoked pursuant to section 12-34-106, C.R.S.

2) The consent of the parent, parents, or legal guardian of a minor described in subsection (1) of this section shall not be necessary in order to authorize organ or tissue donation or hospital, medical, dental, emergency health, or surgical care, and no hospital, physician, surgeon, dentist, trained emergency health care provider, or agent or employee thereof who, in good faith, relies on such a minor's consent shall be liable for civil damages for failure to secure the consent of such a minor's parent, parents, or legal guardian prior to rendering such care. The parent, parents, or legal guardian of a minor described in subsection (1) of this section shall not be liable to pay the charges for the care provided the minor on said minor's consent, unless said parent, parents, or legal guardian agrees to be so liable.

3) In addition to the authority granted in section 25-4-1704 (2.5), C.R.S., any parent, including a parent who is a minor, may request and consent to organ or tissue donation of his or her child or the furnishing of hospital, medical, dental, emergency health, and surgical care to his or her child or ward. The consent of a minor parent shall not be subject to disaffirmance because of minority, and, when such consent is given, said minor parent has the same rights, powers, and obligations as if he or she were of legal age.

CRS §13-22-103.5 Minors - consent for medical care – pregnancy.

Notwithstanding any other provision of law, a pregnant minor may authorize prenatal, delivery, and post delivery medical care for herself related to the intended live birth of a child.

CRS §13-22-106 Minors – consent – sexual offense.

1. Any physician licensed to practice in this state, upon consultation by a minor as a patient who indicates that he or she was the victim of a sexual offense pursuant to part 4 of article 3 of title 18, C.R.S., with the consent of such minor patient, may perform customary and necessary examinations to obtain evidence of the sexual offense and may prescribe for and treat the patient for any immediate condition caused by the sexual offense.

(a) Prior to examining or treating a minor pursuant to subsection (1) of this section, a physician shall make a reasonable effort to notify the parent, parents, legal guardian, or any other person having custody or decision-making responsibility with respect to the medical care of such minor of the sexual offense.

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(b) So long as the minor has consented, the physician may examine and treat the minor as provided for in subsection (1) of this section whether or not the physician has been able to make the notification provided for in paragraph (a) of this subsection (2) and whether or not those notified have given consent, but, if the person having custody or decision-making responsibility with respect to the minor's medical care objects to treatment, then the physician shall proceed under the provisions of part 3 of article 3 of title 19, C.R.S.

(c) Nothing in this section shall be deemed to relieve any person from the requirements of the provisions of part 3 of article 3 of title 19, C.R.S., concerning child abuse.

2. If a minor is unable to give the consent required by this section by reason of age or mental or physical condition and it appears that the minor has been the victim of a sexual assault, the physician shall not examine or treat the minor as provided in subsection (1) of this section but shall proceed under the provisions of part 3 of article 3 of title 19, C.R.S.
3. A physician shall incur no civil or criminal liability by reason of having examined or treated a minor pursuant to subsection (1) of this section, but this immunity shall not apply to any negligent acts or omissions by the physician.

### CRS §25-4-402 Sexually transmitted infections reported – physician immunity (in part)

(4) Any physician, upon consultation by a minor as a patient and with the consent of the minor patient, may make a diagnostic examination for sexually transmitted infection and may prescribe for and treat the minor patient for sexually transmitted infection without the consent of or notification to the parent or guardian of the minor patient or to any other person having custody of or parental responsibilities with respect to the minor patient. In any such case, the physician shall not be civilly or criminally liable for making the diagnostic examination or rendering the treatment, but the immunity from liability shall not apply to any negligent acts or omissions of the physician.

### CRS §25-4-1405 Disease control by the state department of public health and environment and county, district, and municipal public health agencies (in part)

(5) Any county, district, or municipal public health agency, state institution or facility, medical practitioner, or public or private hospital or clinic may examine and provide treatment for HIV infection for any minor if such physician or facility is qualified to provide such examination and treatment. The consent of the parent or guardian of such minor shall not be a prerequisite to such examination and treatment. The physician in charge or other appropriate authority of the facility or the licensed physician concerned shall prescribe an appropriate course of treatment for such minor. The fact of consultation, examination, and treatment of such a minor under the provisions of this section shall be absolutely confidential and shall not be divulged by the facility or physician to any person other than the minor except for purposes of a report required under sections 25-4-1402 and 25-4-1403 and subsection (8) of this section and a report containing the name and medical information of the minor made to the appropriate authorities if required by the "Child Protection Act of 1987", part 3 of article 3 of title 19, C.R.S. If the minor is less than sixteen years of age or not emancipated, the minor's parents or legal guardian may be informed by the facility or physician of the consultation, examination, and treatment. The physician or other health care provider shall counsel the minor on the importance of bringing his parents or guardian into the minor's confidence about the consultation, examination, or treatment.

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CRS §27-65-103 Voluntary applications for mental health services. (in part)

(2) Notwithstanding any other provision of law, a minor who is fifteen years of age or older, whether with or without the consent of a parent or legal guardian, may consent to receive mental health services to be rendered by a facility or by a professional person or mental health professional licensed pursuant to Part 3, 4, 5, 6, or 8 of Article 43 of Title 12 C.R.S. in any practice setting. Such consent shall not be subject to disaffirmance because of minority. The professional person or licensed mental health professional rendering mental health services to a minor may, with or without the consent of the minor, advise the parent or legal guardian of the minor of the services given or needed.

CRS §27-81-109 Voluntary treatment of alcoholics (in part)

(1) An alcoholic, including a minor, may apply for voluntary treatment directly to an approved treatment facility.

CRS § 27-81-110 Voluntary treatment for intoxicated persons and persons incapacitated by alcohol (in part)

(1) An intoxicated person or person intoxicated or incapacitated by alcohol, including a minor, may voluntarily admit himself or herself to an approved treatment facility for emergency treatment

Family Planning Program Consent Form:

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

# Section 21: Medical Emergencies

Each agency must have internal written procedures for management of medical emergencies that occur in the clinic. Take into account the types of procedures done on site and the qualifications and training of the personnel in the agency. Clients must be informed about resources for after hours emergencies and the process for accessing emergency care.

Medical emergency procedure examples:

## A. General Information

1. As a precaution, have assistant available when performing procedures that may result in client collapse, e.g., IUD insertion; Nexplanon insertion and removal.
2. Stop procedure.
3. Summon help by calling “HELP! STAT! ROOM \_\_\_\_!”
4. Stay with the client until help comes.
5. Immediately summon physician or RN for client management or call emergency ambulance.
6. Monitor vital signs frequently.
7. Make sure the following have been assigned to staff:
  - a. Record the client information, such as vital signs. This could be the same person who is doing the vital signs, or it could be a second person if staff is available.
  - b. Communicate with the partner or family member who may have accompanied the client to the clinic.
  - c. Guide the ambulance into the facility/the ambulance crew into the client’s procedure room.
  - d. Reschedule other clients, if needed.

## B. Vaso-vagal reaction (faint)

1. Signs and Symptoms
  - a. Pulse present SLOW (60 or less);
  - b. Blood pressure hypotensive;
  - c. Skin cool, clammy;
  - d. Pallor around mouth;
  - e. Client may be conscious or unconscious;
  - f. Client may be nauseated or vomit.
2. Management
  - a. Have client lie down;
  - b. Turn client on her/his side, so that if she/he vomits, she/he will not aspirate vomitus;
  - c. Snap ammonia capsule under client’s nose for her/him to breathe;
  - d. Raise feet above chest level;

## Section 21: Medical Emergencies

- e. Cover client to conserve body warmth without overheating;
- f. Watch for cardiopulmonary arrest;
- g. Monitor blood pressure and pulse frequently;
- h. If client recovers spontaneously within a few minutes, keep her/him resting quietly until stable and make sure she/he is completely OK before letting her/him go home WITH A FRIEND.
- i. If client does not recover within a few minutes, or if you are in any doubt about her/his recovery, call emergency ambulance.

### C. Shock/Hemorrhage

#### 1. Signs and Symptoms

- a. Pulse present, FAST, may be thready;
- b. Blood pressure – hypotensive;
- c. Skin cool, clammy;
- d. Pallor around mouth or cyanosis;
- e. Client may be conscious or unconscious.

#### 2. Management

- a. Cover client to conserve body warmth without overheating;
- b. Assess for bleeding; if present, employ control measures;
- c. Raise feet above chest level;
- d. Call emergency ambulance;
- e. Observe client closely for cardiopulmonary arrest;
- f. Monitor vital signs frequently.

### D. Cardiopulmonary arrest

IT IS EACH CLINIC'S RESPONSIBILITY TO ENSURE THAT CLINIC PERSONNEL ARE CURRENTLY TRAINED IN BASIC CPR.

IMMEDIATELY CALL EMERGENCY AMBULANCE

### E. Seizure

#### 1. Signs and Symptoms:

- a. Client unconscious;
- b. Client is often incontinent of urine or feces;
- c. Rhythmic movements of limb(s), jaw, and/or eyeballs may be present;
- d. Pulse is generally above 60.

# Section 21: Medical Emergencies

## 2. Management

- a. Be sure client does not hurt her/himself by falling off table or against objects;
- b. Seizures generally run their own course; wait it out;
- c. Following seizure, client may remain unconscious, be confused, or appear partially paralyzed. Keep client lying down. Call emergency ambulance if indicated.
- d. Monitor vital signs.

NOTE: Seizure-like activity may accompany cardiopulmonary arrest, shock, or vaso-vagal reaction. Check for these conditions.

## F. Anaphylaxis

### 1. Signs and Symptoms

- a. Agitated, flushed;
- b. Rapid pulse;
- c. Difficulty breathing;
- d. May have itching, tingling sensations, coughing and sneezing, throbbing in ears.
- e. Hypotension

### 2. Management

- a. Have someone call for an ambulance immediately. Client should be in recumbent position with the lower extremities elevated, ensure airway is clear (no foreign body, neck extended). Assess level of consciousness.
- b. Follow your agency internal anaphylaxis protocol.
- c. Consider supplemental oxygen
- d. Consider IV fluids

## Section 22: Pharmaceuticals

### A. Overview

1. Each agency registered with the Colorado State Board of Pharmacy must have its own “Other Outlet License” at each clinic location.
2. Each agency must comply with the Colorado Pharmacy Practice Act and pharmacy rules and regulations and Colorado medical and nursing legislation, rules and regulations.  
<https://www.colorado.gov/pacific/dora/Pharmacy>  
[https://www.colorado.gov/pacific/dora/Medical Board](https://www.colorado.gov/pacific/dora/Medical_Board)  
<https://www.colorado.gov/pacific/dora/Nursing>
3. A pharmacy protocol must be utilized. The protocol must be reviewed and signed annually by a Registered Pharmacist.
4. Services provided, including pharmacy services, operate within written clinical protocols that are in accordance with nationally recognized standards of care.
5. Advanced practice nurses with prescriptive authority must follow the Board of Nursing Rules and Regulations regarding Prescriptive Authority.
6. Registered nurses (RNs) give medications per chart order or physician authorized and signed standing orders.
7. RNs and advanced practice nurses without prescriptive authority work under a medical plan such as protocols or standing orders authorized and signed by a physician and practice under the responsible direction and supervision of the physician when administering or dispensing medications.

### B. Drug Stocks

1. Ordering (All delegate agencies are eligible to purchase drugs at the 340B Public Health Service (PHS) pricing):
  - a. A written order signed by the Program Coordinator is necessary when ordering prescription items. Prescription items may be ordered through:
    - 1) Arrangements with pharmaceutical supply companies or distributors.
    - 2) Wholesale distributors participating in the 340B Prime Vendor Program  
<https://www.340bpvp.com/controller.html>
    - 3) Maintain purchase records in program files for a period of two years from the last date of an entry. 340B guidelines reference maintaining records for at least 3 years.
2. Storage
  - a. Maintain all prescription items in cabinets or drawers that can be locked. Pharmaceuticals must be kept under continuous observation or locked.
  - b. Maintain proper temperatures and storage conditions applicable to individual prescription items.
  - c. Inventory drug stocks on a routine basis. Rotate stock at that time as well as on receipt of new supplies. Return out-of-date stock to pharmaceutical companies or have it destroyed by the consultant pharmacist, or his/her delegate with proper recording of destroyed medication.
  - d. In the event a recall of pharmaceutical supplies occurs, review program inventory stock for recalled items and return these to the pharmaceutical supply company. Clients who received any recalled

## Section 22: Pharmaceuticals

pharmaceutical supplies will be properly identified through the dispensing logs and notified as appropriate.

### 3. Controlled Substances

Controlled substances are not stocked or dispensed/administered by family planning programs.

### 4. Labeling: Label each prescription item with the following information:

- a. Lot number
- b. Expiration date of medication
- c. Name and address of clinic
- d. Date of prescription or dispensing
- e. Serial or Rx number
- f. Name of medication, strength, quantity
- g. Directions for use and cautionary statements, if any
- h. Client's name
- i. Name of physician/nurse practitioner with prescriptive authority

### 5. Repackaging

- a. Follow Colorado Pharmacy rules and regulations regarding repackaging of pharmaceuticals.
- b. Use child-proof containers.

## C. Consultant Pharmacist

Each program will have a consultant pharmacist whose responsibilities will be:

1. To serve as a consultant for any pharmaceutical related issue.
2. To review pharmacy protocols and sign annually along with the program coordinator.
3. To make on-site inspections quarterly to ascertain that there is compliance with the protocols and the Pharmacy Practice Act.
4. To make follow-up visits in the event of non-compliance until compliance is assured.

## D. Formulary

1. Agencies must provide and stock a broad range of acceptable and effective medically approved family planning methods, including IUCs, implant, DMPA, at least three varieties of OCs (e.g. monophasic, multiphasic and ultra low dose, a progestin only OC, extended cycle pill), vaginal ring and/or hormonal patch, and barrier methods such as male/female condoms and diaphragms.
2. Each agency should keep a list, on-site, of prescription medications maintained at the site.
3. Agencies no longer need to notify the Pharmacy Board of any drugs added to the formulary.
4. Prescriptions for contraceptives may be written if 3<sup>rd</sup> party insurers decline to reimburse the agency for contraceptives dispensed from the clinic.

## Section 22: Pharmaceuticals

Sample Pharmacy On-Site Evaluation Form

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

Sample 340B Policy and Procedure Manual developed by Apexus 340B PVP on the CDPHE Family Planning web site:

<https://www.colorado.gov/pacific/cdphe/title-x-links-and-other-resources>

### E. 340 Discount Drug Program

- a. Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Program. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration (HRSA) Department of Health and Human Services. Only nonprofit health care organizations that have certain federal designations or receive funding from specific federal programs are eligible organizations (covered entities) that can register, be enrolled and purchase discounted drugs through the 340B Program.
- b. Upon registration on the OPA database as a participant in the 340B Program, entities agree to abide by specific 340B program statutory requirements, prohibitions and policies, including:
  - 1) Assuring the agency's information on the HRSA 340B database is complete, accurate, and up to date.
  - 2) Changes to Medicaid billing decisions on the OPA database are allowed on a quarterly basis.
  - 3) If an agency requests reimbursement from Medicaid for 340B discount purchased pharmaceuticals, the agency assures against duplicate discounts and rebates under Medicaid by keeping the 340B database up to date with the Medicaid/NPI numbers used to bill Medicaid for 340B purchased pharmaceuticals. All drugs billed under this Medicaid/NPI provider number must be consistently purchased through 340B.
  - 4) The agency assures that Medicaid is billed appropriately. Contact Colorado Department of Health Care Policy and Financing for information and instruction in Medicaid billing.
  - 5) The agency assures that drugs purchased under 340B are not provided to anyone other than patients or clients of the agency, and maintains a medical record for clients receiving 340B purchased pharmaceuticals.
  - 6) Definition of patient from the 340B web site: "An individual is a patient of a 340B covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:
    - a. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; *and*
    - b. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other

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arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; *and*

- c. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or
  - d. Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.”
- 7) The agency maintains separate stock/records for all 340B purchasing and dispensing to reasonably ensure ongoing compliance with all 340B requirements.
  - 8) The agency maintains internal policies and procedures and auditable records for all 340B purchasing and dispensing. It is recommended that agencies have a routine 340B self audit process in place. Please note that tracking the drug National Drug Code (NDC) to a client is part of the HRSA audit process.
  - 9) Additional 340B information and tools, including a sample family planning 340B policy and procedure manual can be found on the Apexus 340B Prime Vendor Program web site at <https://www.340bpvp.com/controller.html> (see below for more information about the Apexus 340B PVP and on the HRSA Office of Pharmacy Affairs web site at <http://www.hrsa.gov/opa/>
  - 10) It is highly recommended that the Apexus “Sample 340B Policy and Procedure Manual – A Guide for Family Planning Entities” be used to develop an internal 340B manual at each Title X agency.
- c. Covered entities are subject to audit by manufacturers or the federal government. Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts obtained or cause the covered entity to be removed from the 340B Program. See the HRSA 340B Program Integrity web pages for more information.
  - d. Recertification Procedure

OPA requires entities to recertify their information listed on the 340B database annually. An Authorizing Official annually recertifies information by following the directions in the recertification email sent from the OPA to the Authorizing Official by the requested deadline.
  - e. Enrollment Procedure: New Clinic Sites

The Authorizing Official completes the online registration process during the registration window:

    - January 1 - January 15 for an effective start date of April 1;
    - April 1 - April 15 for an effective start date of July 1;
    - July 1 - July 15 for an effective start date of October 1; and
    - October 1 - October 15 for an effective start date of January 1.

Online registration process: <http://opanet.hrsa.gov/340B/Default>
  - f. Change Request

An online change request is submitted to OPA for changes to information outside of the annual recertification timeframe. A change form is submitted to OPA as soon as the entity is aware of

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the need to make a change to its database entry. The entity can expect changes to be reflected within about 2 weeks of submission of the changes/requests.

- g. Enrollment in the Apexus 340B Prime Vendor Program (PVP)
- 1) The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract awarded by Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program. The Apexus 340B PVP is a free service for 340B eligible entities.
  - 2) The Apexus 340B PVP negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals among other services.
  - 3) Apexus publishes a quarterly 340B and sub-340B pricing drug list for Title X agencies.
  - 4) Complete the online Apexus PVP registration (<https://www.340bpvp.com/register/secure-website-access/>).
  - 5) Apexus offers 340B Program training for Title X agency staff through the 340B University and online training.
  - 6) Questions about the 340B Program can be directed to Apexus via [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com)  
Phone 1-888-340-2787  
Live chat [www.340bpvp.com](http://www.340bpvp.com)

## Section 23: Referral and Follow Up

### A. Referral Services

1. Agencies must provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, social services, hospitals, voluntary agencies, and health services supported by other federal programs (Program Requirements pg.15). A written list of referral services should be maintained and updated annually. It is recommended that this list be dated so it is easy to tell when it was last updated. On site or referral for ACA related insurance or Medicaid coverage should also be available.
2. Providers of family planning services must be trained and equipped to offer all family planning and related preventative health services (breast and cervical cancer screening in women) so that they can provide optimal care to clients, with referral for specialist care, as needed. "Other preventative health services" should be available either on-site or by referral. Examples of "other preventative health services" are screening for lipid disorders, skin cancer, colorectal cancer, or osteoporosis. These services are not addressed in the QFP. (QFP pg. 5).

### B. Inform clients that the treatment or follow up of the following conditions are available by referral or on site:

1. Medical problems beyond the scope of the treatment facility. Provide referral to appropriate provider or hospital.
2. Problems noted at the time of the history taking, physical exam, or laboratory testing
3. Problems arising because of contraceptive method
4. Other preventative health services
5. STI treatment.
6. Cervicitis, vaginitis, and minor gynecologic problems.
7. Positive or suspicious cervical cytology.
8. Hemoglobinopathies (e.g., sickle cell).
9. Positive tuberculin tests.
10. Pregnancy related services, when appropriate, including testing and counseling.
11. Sexual dysfunction and human sexuality counseling.
12. Infertility work-up and/or therapy of an extensive nature.
13. Clients or partners of clients requesting information about, and/or procedure for sterilization, if that service is not available on site.
14. Clients request additional referrals to other providers
15. Social services and social casework not appropriately handled by project personnel.
16. Linkage to care for individuals living with HIV
17. PrEP and PEP community providers.
18. Natural family planning counseling.
19. Nutrition counseling and WIC services.

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20. Colorado Department of Health Care Policy and Financing <https://www.colorado.gov/hcpf>
21. Colorado PEAK <https://coloradopeak.secure.force.com/>
22. Colorado Connect for Health <http://connectforhealthco.com/>

### C. In-Patient Services

1. The program must maintain a liaison with hospital backup facilities.
2. Either directly or by referral, the program must maintain a referral mechanism for hospitalization of clients with complications arising from contraceptive methods.

### D. General Referral Policy

1. Every client has the right to elect or refuse treatment.
2. If during the examination, conditions are found which indicate that further treatment is necessary, the condition is fully explained to the client. When possible give up to three referral provider options.

### E. Services for Special Populations

1. Physically/Developmentally disabled:
  - a. Services provided by the agency must be in compliance with ADA regulations.
  - b. It is up to the staff to develop sensitivity to the needs of this population.
2. Minors:
  - a. Minors requesting family planning services must be encouraged, whenever possible, to consult with their parents with respect to family planning services.
  - b. However, services must not be denied when this is not possible.

### F. General Follow-up Policy

1. This program has a responsibility to follow-up in any situation that may be, or is known to be, life- or health-threatening.
2. Follow-up measures are directed towards informing the client about her/his health risks and providing the client with appropriate referral sources for treatment/resolution.
3. Provide a written referral to the client. This information should include recommendations of the clinic.
4. Informing a client she/he is at risk:
  - a. When information (Pap or other lab test) is received indicating a client is at risk and the client is not in the clinic. All attempts to contact a client should be made with regard for the confidentiality of the client, whether by phone or letter.
  - b. Attempts to contact the client may be made by phone or mail, with all attempts documented in the chart. Use of certified letters with "Return Receipt Requested" early in the course of follow-up can expedite the notification process.

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- c. Referrals for conditions which are not urgent or life-threatening require written documentation in the chart noting that the client is aware of her/his need for follow-up, i.e., the return receipt of a certified letter or a note in the client's handwriting.
- d. Urgent or potentially life-threatening conditions require on-going attempts to assure follow-up.

### **G. Referral**

1. Internal - The client may be asked to return to the family planning clinic at a later date for further evaluation or follow-up. Documentation should be made in the chart, including the time frame for and purpose of this return visit.
2. The request to return should be logged in whatever manner is usual in the local clinic, and the log will be checked at intervals to assure that persons asked to return to clinic have done so.
3. External - If the client is referred to an outside agency or health care provider, the client should be given a referral form that identifies the reason for the referral. Client should give consent for transfer of medical records as indicated.
4. The referral should be logged in whatever manner is usual in the local clinic, and the log will be checked at intervals appropriate to the nature of the referral to assure that the clients have obtained further care. The name may be checked off if and when the return copy of the referral is received.
5. Clinics must develop/have in place a written mechanism for tracking all internal and external referrals. Time frames for referral follow-up are dependent upon the urgency of the client's problem. Agency policy should address time frames for follow-up. Suggested time frames can be found at the end of this policy.
6. When follow-up reports are returned to the program, they will be checked off on the log, reviewed and initialed by the provider, and filed in the client's chart.

### **H. Provision of Services to Clients Referred for Follow-up Care:**

1. Any client for whom follow-up care has been requested must have written follow-up information from the physician providing care in order for the program to continue providing services. All attempts to obtain this follow-up information must be documented in the client's chart. When clients fail to obtain the indicated follow-up or the clinic is unable to obtain the documentation of the follow-up care, the decision to provide ongoing care should include consideration of the risk to the client (unintended pregnancy from loss of contraceptive services) vs. the risk to the agency (liability claims).
2. This applies especially to situations in which ongoing provision of services (i.e., hormonal birth control methods or IUD) may result in aggravation of the condition for which the client has been referred.

### **I. Financial Responsibility for Referrals**

1. Referrals for required Family Planning services through an outside contractor, such as IUC or implant insertions, must be provided on the sliding fee scale developed by the agency and reviewed annually by the Family Planning Program at CDPHE.
2. Referrals for non-required services (including but not limited to such services as colposcopy, HIV testing, hypertension evaluation) or for complications resulting from procedures or medications provided by the

## Section 23: Referral and Follow Up

program are the financial responsibility of the client. The delegate agency is not expected to assume part or all of this financial liability. It is recommended that the delegate agency help the client identify available resources.

Sample referral form and referral feedback form

<https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

### EXAMPLES OF TIME FRAMES FOR REFERRAL AND FOLLOW UP POLICIES

This is an example of how to set up time frames for referral and follow up of abnormal findings.

1. Emergency – follow up in 12-48 hours or sooner, some examples are:
  - a. Possible ectopic
  - b. Severe PID
  - c. Complicated GC/CT
  - d. Malignant hypertension
  - e. Severe UTI or pyelonephritis
2. Urgent – follow up within 2-4 weeks or sooner, some examples are:
  - a. Initial episode of herpes
  - b. Solitary breast nodule, depending on risk factors
  - c. Hypertension
  - d. Positive GC/CT or other screening for infections
3. Essential – follow up in 1-2 months or sooner, some examples are:
  - a. Hematocrit above 55% on repeat, or anemia after trying increased iron
  - b. Hypertension
  - c. Abnormal Pap
  - d. Enlarged thyroid
  - e. Solitary breast nodule, low risk for cancer
4. Discretionary – referrals made at the request of the client, follow up at the next clinic visit. Further follow up may not be necessary, but should be based on professional judgment.

# Section 24: Mandatory Reporting & Human Trafficking

## A. Mandatory Reporting

Agencies must be compliant with all applicable state laws regarding the mandatory reporting of child abuse, child molestation, sexual abuse, rape, incest, or domestic violence. Agencies must have written procedures in place demonstrating compliance.

Family Planning Coordinators must assure that all staff members are trained and familiar with Colorado law regarding mandatory reporting / human trafficking (summarized below).

Family Planning agencies must develop written internal procedures for staff on how to address mandatory reporting incidents. It is expected that the Family Planning Coordinator will solicit input from local agencies involved in the issue before writing up a local procedure. Local agencies include law enforcement, child protective services, etc. Your clinic's procedure must detail how you will respond to any reportable or potentially reportable situation as outlined in this policy. All Family Planning Program staff must be familiar with the policy and procedures outlined in this section.

The Colorado Department of Human Services (CDHS) provides the Child Welfare On-line Training System at <http://www.coloradocwts.com/community-training>. This is a valuable resource for introducing staff members to mandatory reporting requirements.

References are made to various Colorado statutes in the information below. Statutes are noted for use as reference. This is not legal advice, consult legal counsel for legal advice. Staff should consult the Colorado Revised Statutes for the most current and complete wording of the child abuse and neglect reporting laws.

<http://www.lexisnexis.com/hottopics/colorado/>

### 1. Who are mandatory reporters?

Colorado law specifies the persons or professions that are required to report child abuse or neglect. Colorado mandatory reporters are listed in Colorado Revised Statute. (CRS 19-3-304).

Failure of a mandatory reporter to report suspected child abuse or neglect or to knowingly make a false report is a class 3 misdemeanor and punishable under Colorado law.

Mandatory reporters include:

- a. Physician or surgeon, including a physician in training
- b. Child health associate
- c. Medical examiner or coroner
- d. Dentist
- e. Osteopath
- f. Optometrist
- g. Chiropractor
- h. Podiatrist
- i. Registered nurse or licensed practical nurse
- j. Hospital personnel engaged in the admission, care, or treatment of patients

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- k. Christian science practitioner
- l. Public or private school official or employee
- m. Social worker or worker in any facility or agency that is licensed or certified pursuant to part 1 of article 6 of title 26, C.R.S. e.g. child care providers and employees
- n. Mental health professional
- o. Dental hygienist
- p. Psychologist
- q. Physical therapist
- r. Veterinarian
- s. Peace officer
- t. Pharmacist
- u. Commercial film and photographic print processor
- v. Firefighter
- w. Victim's advocate
- x. Licensed professional counselors
- y. Licensed marriage and family therapists
- z. Registered psychotherapists
- aa. Clergy member
- bb. Registered dietitian
- cc. Worker in the state department of human services
- dd. Juvenile parole and probation officers
- ee. Child and family investigators
- ff. Officers and agents of the state bureau of animal protection, and animal control officers
- gg. The child protection ombudsman
- hh. Educator providing services through a federal special supplemental nutrition program for women, infants, and children, as provided for in 42 U.S.C. sec. 1786;
- ii. Director, coach, assistant coach, or athletic program personnel employed by a private sports organization or program. For purposes of this paragraph (ii), "employed" means that an individual is compensated beyond reimbursement for his or her expenses related to the private sports organization or program.
- jj. Person who is registered as a psychologist candidate, marriage and family therapist candidate, or licensed professional counselor candidate
- kk. Emergency medical service providers.

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### 2. How is a report made?

Reporting procedures are detailed in CRS 19-3-307, 25-1-122 (4) (d) and 25-4-1404 (1) (d).

A report is made immediately to the county child protective service, local law enforcement agency, or through the child abuse reporting hotline followed by a written report prepared by the mandatory reporter.

Child protective services (CPS) personnel are required to assess reports of child abuse and/or neglect. CPS works with community professionals, who are mandated reporters, to prevent, identify, and respond to child abuse and/or neglect.

### 3. To whom should a mandatory report be made?

Generally, interfamilial abuse (includes abuse that occurs within a family context by a child's parent, stepparent, guardian, legal custodian, relative, spousal equivalent or any other person who resides in the child's home) is reported to the child protective services in the county where the victim lives. Third party abuse (includes abuse by any person who is not a parent, stepparent, guardian, legal custodian, spousal equivalent) is reported to law enforcement where the crime occurred. Local child protective services can provide guidance regarding to whom a report should be made. (Definitions from CRS 19-1-103)

### 4. Are there concerns about violating HIPAA privacy regulations when reporting child abuse or neglect?

HIPAA regulations permit covered entities to disclose certain types of personal health information, without an individual's authorization or giving an individual the opportunity to object or agree to the disclosure, if the law requires the disclosure. Reporting suspected child abuse or neglect by designated mandatory reporters is required by Colorado law and thus permitted by HIPAA regulations. The report of suspected child abuse or neglect must be made to the government authorities authorized by Colorado law to receive reports, child protection services or law enforcement agencies. (45 C.F.R. 164.512)

### 5. What information should be included in a mandatory report?

Reports of known or suspected child abuse or neglect, when possible, should include the following information (CRS 19-3-307 in part)

- a. The child's name, age, address, gender and race,
- b. The name and address of the person(s) responsible for the suspected abuse and/or neglect,
- c. The nature and extent of the child's injuries, including any evidence of previous cases of known or suspected abuse or neglect of the child or the child's siblings,
- d. The family composition,
- e. The source of the report and the name, address, and occupation of the person making the report.
- f. Any action taken by the reporting source.

Please note that CRS 25-1-122 (4) (d) (concerning epidemic and communicable diseases, morbidity and mortality, cancer in connection with the statewide cancer registry, environmental and chronic diseases, sexually transmitted infections, tuberculosis, and rabies and mammal bites) limits the information an officer or employee of the state department of public health and environment may provide when making a report. CRS 25-4-1404 (1) (d) (concerning HIV infection) limits the information an officer or employee of the county, district, or municipal public health agency or state department of public health and environment may provide when making a report.

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### 6. Assistance for mandatory reporters:

Staff should follow the reporting policies established by their local agency. A suspicion of abuse or neglect is adequate for reporting to child protective services. Staff should not attempt to further investigate or probe suspected child abuse or neglect. Staff making a report may find speaking with a fellow staff member or supervisor helpful but the mandatory reporter is ultimately responsible for complying with reporting laws. If staff are unsure about whether a report should be made, they should contact their local child protective services for guidance.

### 7. What happens when a report is made?

When a report of suspected child abuse and/or neglect is made, child protective services collects relevant information from the reporting party and screens the call to determine if a report will be accepted for assessment. Child protective services will prioritize accepted reports and assign them for assessment or for referral to other agencies, community services or another jurisdiction.

After a report is made, the county is required to notify the person who made the report within 30 days regarding whether or not the referral was assigned for assessment. A call may also be made to the county to follow-up to see if the report was assigned. If the referral was assigned, the person making the report may be contacted for additional information.

### 8. Applicable Colorado Revised Statutes include but are not limited to:

- a. Child abuse and neglect and sexual abuse  
CRS §19-1-103. Definitions – repeal (in part)

As used in this title or in the specified portion of this title, unless the context otherwise requires:

(1) (a) "Abuse" or "child abuse or neglect", as used in part 3 of article 3 of this title, means an act or omission in one of the following categories that threatens the health or welfare of a child:

(I) Any case in which a child exhibits evidence of skin bruising, bleeding, malnutrition, failure to thrive, burns, fracture of any bone, subdural hematoma, soft tissue swelling, or death and either: Such condition or death is not justifiably explained; the history given concerning such condition is at variance with the degree or type of such condition or death; or the circumstances indicate that such condition may not be the product of an accidental occurrence;

(II) Any case in which a child is subjected to unlawful sexual behavior as defined in section 16-22-102 (9), C.R.S.;

(III) Any case in which a child is a child in need of services because the child's parents, legal guardian, or custodian fails to take the same actions to provide adequate food, clothing, shelter, medical care, or supervision that a prudent parent would take. The requirements of this subparagraph (III) shall be subject to the provisions of section 19-3-103.

(IV) Any case in which a child is subjected to emotional abuse. As used in this subparagraph (IV), "emotional abuse" means an identifiable and substantial impairment of the child's intellectual or psychological functioning or development or a substantial risk of impairment of the child's intellectual

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or psychological functioning or development.

(V) Any act or omission described in section 19-3-102 (1) (a), (1) (b), or (1) (c);

CRS §18-3-402. Sexual assault. (In part)

(a) The actor causes submission of the victim by means of sufficient consequence reasonably calculated to cause submission against the victim's will; or

(b) The actor knows that the victim is incapable of appraising the nature of the victim's conduct; or

(c) The actor knows that the victim submits erroneously, believing the actor to be the victim's spouse; or

(d) At the time of the commission of the act, the victim is less than fifteen years of age and the actor is at least four years older than the victim and is not the spouse of the victim; or

(e) At the time of the commission of the act, the victim is at least fifteen years of age but less than seventeen years of age and the actor is at least ten years older than the victim and is not the spouse of the victim...

(Mandatory reporting laws also apply for minor victims of human trafficking. Child abuse or neglect includes unlawful sexual behavior as defined in CRS 16-22-102 (9) and includes sexual assault, trafficking in children, sexual exploitation of children, procurement of a child, procurement of a child for sexual exploitation, and inducement of child prostitution.)

CRS §19-3-304 Persons required to report child abuse or neglect. (in part)

(a) Except as otherwise provided by section 19-3-307 and sections 25-1-122 (4) (d) and 25-4-1404 (1) (d), C.R.S., and paragraph (b) of this subsection (1), any person specified in subsection (2) of this section who has reasonable cause to know or suspect that a child has been subjected to abuse or neglect or who has observed the child being subjected to circumstances or conditions which would reasonably result in abuse or neglect shall immediately upon receiving such information report or cause a report to be made of such fact to the county department or local law enforcement agency.

(b) The reporting requirement described in paragraph (a) of this subsection (1) shall not apply if the person who is otherwise required to report does not:

(I) Learn of the suspected abuse or neglect until after the alleged victim of the suspected abuse or neglect is eighteen years of age or older; and

(II) Have reasonable cause to know or suspect that the perpetrator of the suspected abuse or neglect:

Has subjected any other child currently under eighteen years of age to abuse or neglect or to circumstances or conditions that would likely result in abuse or neglect; or is currently in a position of trust, as defined in section 18-3-401 (3.5), C.R.S., with regard to any child under eighteen years of age.

### b. Intimate Partner Violence

Licensees have a duty to report injuries resulting from domestic violence/intimate partner violence.

CRS §12-36-135. Injuries to be reported - penalty for failure to report - immunity from liability.

(1)(a) (I) Every licensee who attends or treats any of the following injuries shall report the injury at once to the police of the city, town, or city and county or the sheriff of the county in which the licensee is located:

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(A) A bullet wound, a gunshot wound, a powder burn, or any other injury arising from the discharge of a firearm, or an injury caused by a knife, an ice pick, or any other sharp or pointed instrument that the licensee believes to have been intentionally inflicted upon a person;

(B) An injury arising from a dog bite that the licensee believes was inflicted upon a person by a dangerous dog, as defined in section 18-9-204.5 (2) (b), C.R.S., or

(C) Any other injury that the licensee has reason to believe involves a criminal act, including injuries resulting from domestic violence.

(II) Any licensee who fails to make a report as required by this section commits a class 2 petty offense, as defined by section 18-1.3-503, C.R.S., and upon conviction thereof, shall be punished by a fine of not more than three hundred dollars, or by imprisonment in the county jail for not more than ninety days, or by both such fine and imprisonment.

(b) (I) When a licensee or nurse performs a forensic medical examination that includes the collection of evidence at the request of a victim of sexual assault, the licensee's or nurse's employing medical facility shall, with the consent of the victim of the sexual assault, make one of the following reports to law enforcement:

(A) A law enforcement report if a victim wishes to obtain a medical forensic examination with evidence collection and at the time of the medical forensic examination chooses to participate in the criminal justice system;

(B) A medical report if a victim wishes to obtain a medical forensic examination with evidence collection but at the time of the medical forensic examination chooses not to participate in the criminal justice system. The licensee or nurse shall collect such evidence and victim identifying information, and the employing medical facility shall release the evidence and information to law enforcement for testing in accordance with section 24-33-113 (1) (b) (III), C.R.S., and storage in accordance with section 18-3-407.5 (3) (c), C.R.S.

(C) An anonymous report if a victim wishes to obtain a medical forensic examination with evidence collection but at the time of the medical forensic examination chooses not to have personal identifying information provided to law enforcement or to participate in the criminal justice system. The licensee or nurse shall collect such evidence, and the employing medical facility shall release it to law enforcement for storage in accordance with section 18-3-407.5 (3) (c), C.R.S. Law enforcement shall receive no identifying information for the victim. Law enforcement shall assign a unique identifying number to the evidence, and the licensee or nurse shall record the identifying number in the medical record and notify the victim that the identifying number is recorded. Additionally, the licensee or nurse shall provide the identifying number to the victim.

(II) Nothing in this section:

(A) Prohibits a victim from anonymously speaking to law enforcement about the victim's rights or options prior to determining whether to consent to a report described in this paragraph (b); or

(B) Requires a licensee, nurse, or medical facility to make a report to law enforcement concerning an alleged sexual assault if medical forensic evidence is not collected.

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(III) If the licensee's employing medical facility knows where the alleged sexual assault occurred, the facility shall make the report with the law enforcement agency in whose jurisdiction the crime occurred regarding preservation of the evidence. If the medical facility does not know where the alleged sexual assault occurred, the facility shall make the report with its local law enforcement agency regarding preservation of the evidence.

(IV) In addition to the report required by subparagraph (I) of this paragraph (b) to be filed by the employing medical facility, a licensee who attends or treats any of the injuries described in subparagraph (A) of subparagraph (I) of paragraph (a) of this subsection (1) of a victim of a sexual assault shall also report the injury to the police or sheriff as required by paragraph (a) of this subsection (1).

(1.5) As used in subsection (1) of this section, unless the context otherwise requires:

(a) "Domestic violence" means an act of violence upon a person with whom the actor is or has been involved in an intimate relationship. Domestic violence also includes any other crime against a person or any municipal ordinance violation against a person when used as a method of coercion, control, punishment, intimidation, or revenge directed against a person with whom the actor is or has been involved in an intimate relationship.

(b) "Intimate relationship" means a relationship between spouses, former spouses, past or present unmarried couples, or persons who are both the parents of the same child regardless of whether the persons have been married or have lived together at any time.

(2) Any licensee who, in good faith, makes a report pursuant to subsection (1) of this section shall have immunity from any liability, civil or criminal, that might otherwise be incurred or imposed with respect to the making of such report, and shall have the same immunity with respect to participation in any judicial proceeding resulting from such report.

(3) Any licensee who makes a report pursuant to subsection (1) of this section shall not be subject to the physician-patient relationship described in section 13-90-107 (1) (d), C.R.S., as to the medical examination and diagnosis. Such licensee may be examined as a witness, but not as to any statements made by the patient that are the subject matter of section 13-90-107 (1) (d), C.R.S.

### Resources:

- Futures Without Violence <http://www.futureswithoutviolence.org/> Provides resources such as small safety cards (Did you Know Your Relationship Affects Your Health?) in English and Spanish and Guidelines for Clinical Assessment and Intervention as a free download.
- Colorado Coalition Against Domestic Violence <http://ccadv.org/>
- Colorado Coalition Against Sexual Assault <http://www.ccasa.org/>
- Resource for youth regarding dating and relationships <http://www.loveisrespect.org/>

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- HHS Family Violence Prevention & Services Program <http://www.acf.hhs.gov/programs/fysb/programs/family-violence-prevention-services>
- CDHS Child Welfare On-line Training System <http://www.coloradocwts.com/community-training>
- CDHS - call 1-844-CO-4-Kids to report child abuse and neglect <https://sites.google.com/a/state.co.us/cdhs-dcw/reportchildabuse>
- Family Planning National Training Center <http://fpntc.org/>
- Mandated Child Abuse Reporting Law: Developing and Implementing Policies and Training <http://www.fpntc.org/event/mandated-child-abuse-reporting-law-developing-and-implementing-policies-and-training>
- National Domestic Violence Hotline <http://www.thehotline.org/help>

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### B. Human Trafficking

1. Family Planning Coordinators must assure that all staff members are familiar with Federal and Colorado human trafficking law. Family Planning agencies must develop written internal procedures for staff on how to address human trafficking incidents. It is expected that the Family Planning Coordinator will solicit input from various agencies and entities before writing a procedure regarding support and resources for victims of human trafficking.
2. Federal anti-trafficking laws include Victims of Trafficking and Violence Protection Act of 2000 and Trafficking Victims Protection Reauthorization Acts of 2003 and 2005, the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, and the Trafficking Victims Protection Reauthorization Act of 2013.
3. Human trafficking is defined as the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery; or sex trafficking in which a commercial sex act is induced by force, fraud, coercion, or in which the person induced to perform such act has not attained 18 years of age.
4. Colorado Revised Statutes also contain criminal statutes related to human trafficking. Please consult the Colorado Revised Statutes for the most current language.
5. Resources for staff and victims of human trafficking:
  - a. Colorado Resources:

**Colorado Organization for Victim Assistance (COVA)** manages the Office for Victims of Crime (OVC) federal human trafficking grant for the Denver Metro Area and the Northern Front Range in Colorado. Through this grant, COVA provides case management support for domestic and international human trafficking victims, documented or undocumented. COVA works with adults and minors; male, female, and LGBTQ community. COVA's human trafficking program has available multi-lingual staff (Spanish, German, Japanese, and Portuguese) to serve a diverse clientele.

Phone numbers: 303-996-8087 and 303-996-8084

<http://www.coloradocrimevictims.org/index.html>

#### **Colorado Network to End Human Trafficking (CoNEHT)**

CoNEHT represents a statewide network of service providers who work with human trafficking victims, foreign and domestic, and collectively provide an array of case management, interpreting/translation services, food, clothing, shelter, medical/dental services, legal advocacy, immigration services, mental health treatment, and transportation. CoNEHT will also provide information regarding training for clinic staff related to human trafficking

CoNEHT Hotline at 1-866-455-5075 (toll-free, 24 hours/day, 7 days/week).

#### **Laboratory to Combat Human Trafficking**

Provides training and educational sessions on the issue of human trafficking for law enforcement personnel, service providers, community members, and other potential first responders across Colorado. LCHT also conducts research around the state and provides technical assistance to community-based task forces; for more information about LCHT's research, visit <http://lcht.hotpressplatform.com/about/theproject>

Email: [info@combathumantrafficking.org](mailto:info@combathumantrafficking.org) Phone number: 303-295-0451

## Section 24: Mandatory Reporting & Human Trafficking

### Lutheran Family Services Rocky Mountains (LFS)

<http://www.lfsrm.org/>

LFS provides services to international adult and minor human trafficking victims who have received their Office of Refugee Resettlement (ORR) Certification Letter if an adult, or an Eligibility Letter if a minor. Victims of Human Trafficking (VOTs) can receive services up to 5 years after the date of their certification/eligibility letter. Depending on need and eligibility, services provided to clients may include: case management, employment placement services, health case management, pre-employment training, cash assistance, basic needs, and ESL, public assistance, physical and mental health and other referrals as needed. Services for adults are managed through the Refugee and Asylee Programs and services for minors are managed through the Unaccompanied Refugee Minor program. LFS also is a subcontractor to the National Human Trafficking Victim Assistance Program through the U.S. Committee for Refugees and Immigrants (USCRI) and can provide supplemental assistance to VOTs through this program as needed. LFS sits on the steering committee for CoNEHT. For more information please call (303) 217-5181.

**Prax(us)** <http://www.praxus.org/> 720-317-7009

Serves victims of domestic trafficking, particularly homeless youth.

b. National Resources:

### National Human Trafficking Resource Center

<http://www.polarisproject.org/what-we-do/national-human-trafficking-hotline/the-nhtrc/overview>

24 hour Hot Line 1-888-373-7888 or text BeFree (233733)

Email: [nhtrc@polarisproject.org](mailto:nhtrc@polarisproject.org)

The [National Human Trafficking Resource Center \(NHTRC\)](http://www.polarisproject.org/what-we-do/national-human-trafficking-hotline/the-nhtrc/overview) is a national, toll-free hotline, available to answer calls and texts from anywhere in the country, 24 hours a day, 7 days a week, every day of the year. The NHTRC is operated by Polaris, a non-profit, non-governmental organization working exclusively on the issue of human trafficking. NHTRC is not a government entity, law enforcement or an immigration authority.

**Polaris Project** <http://www.polarisproject.org/>

The Polaris Project provides human trafficking victim assessment tools for health care providers entitled “Identifying Victims of Human Trafficking – What to Look for During a Medical Exam/Consultation” and “Medical Assessment Tool” at <http://www.traffickingresourcecenter.org/audience/service-providers>

The Polaris Project also provides a range of social services to survivors of human trafficking including emergency services, comprehensive case management, group therapy, transitional housing, and victim outreach.

Email: [info@polarisproject.org](mailto:info@polarisproject.org) Telephone: (202) 745-1001

## Section 24: Mandatory Reporting & Human Trafficking

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**US Department of Health and Human Services, Office of Refugee Resettlement**

<http://www.acf.hhs.gov/programs/orr/programs/anti-trafficking>

The Anti-Trafficking in Persons Program (ATIP) identifies and serves victims of human trafficking, assisting foreign trafficking victims in the United States to become eligible for public benefits and services to the same extent as refugees. The program also raises awareness of human trafficking through the HHS Rescue & Restore Victims of Human Trafficking campaign.

Email: [Trafficking@acf.hhs.gov](mailto:Trafficking@acf.hhs.gov) Telephone: (202) 401-5510

## Section 25: Medical Records/Personal Health Information/Confidentiality

Agencies must maintain complete medical records for every client, in accordance with accepted professional standards. The medical records must be completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information. Each entry must be signed.

A record must be maintained of every client encounter with the staff. All staff, including non-medical workers, should record every encounter (including telephone calls), reason for encounter, and any action taken.

### A. Custody of Records

1. The agency is the legal custodian of client records. It is responsible for the provision of a safe place for storage of client records to prevent disclosure to unauthorized persons.
2. Client records should be kept in locked files when not in use and must not be left where individuals other than authorized persons have access to them. EMRs must be password protected and should have an automatic time out when not in use. Users should lock the EMR when not in use to ensure against unauthorized access. Also, consider that portable laptops should not be left in a room with a client. An additional layer of security can be provided with the use of biometrics.

### B. Confidentiality and HIPAA

1. Agencies must be compliant with HIPAA regulations. HIPAA covered entities are expected to have adequate administrative, technical and physical safeguards in place to protect personal health information under its control.
2. A summary of the HIPAA privacy rule is available at: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>
3. A summary of the HIPAA security rule is available at: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html>
4. In January 2013, HHS announced a final rule that implements a number of provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act to strengthen the privacy and security protections for health information established under HIPAA. See <http://www.hhs.gov/ocr/privacy/hipaa/administrative/omnibus/index.html> for the press release and a link to the final rule.
5. Clients must be informed of agency privacy practices and a signed acknowledgment of receipt of the notice must be part of the medical record. Model notices of privacy practices that reflect 2013 regulatory changes are available at <http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html>
6. The Colorado Department of Public Health and Environment (CDPHE) is not Covered Entity under HIPAA, as it does not meet the definition of a health plan, a healthcare provider billing electronically, a clearinghouse or a Medicare Drug Plan. However, the CDPHE Title X program does receive Personal Health Information (PHI) from its delegates. CDPHE has a privacy and security program designed to meet industry standards for safeguarding information under its control, and assuring that adequate physical, administrative and technical safeguards are in place. Inform clients about the statewide iCare database using the Family Planning Program Consent wording.

### C. Colorado's Open Records Law (See CRS §24-72-200.1 et al )

# Section 25: Medical Records/Personal Health Information/Confidentiality

**D. See CRS § 25-1-1202 Index of statutory sections regarding medical record confidentiality and health information**

**E. Other Considerations in Maintaining Confidentiality**

1. All staff must be oriented to the importance of safeguarding the confidential nature of the record and any other client information.
2. Privacy and confidentiality in gathering client information by interview or any other means is essential.
3. Office and clinic facilities should be such that client information is not inadvertently revealed to persons in the waiting room or any place else.
4. Use discretion in engaging a client in discussion in his home or on the street while neighbors, relatives, or other persons are present.
5. Electronic email exchanges with clients should be encrypted.

**F. Documentation**

1. Each entry must be signed by the person providing the information or service. If the full name of the signer is not used in the medical record, a signature sheet with full name, title, and signature of each individual making entries in the chart must be maintained.

For the purpose of quality assurance, a physician should also co-sign a percentage (10% is recommended) of the entries of an appropriately trained person for whom the physician is responsible (examples - an RN providing services under physician signed standing orders or APRN without prescriptive authority).

2. It is also recommended that the agency have an internal policy in place regarding the percentage of charts that are to be cosigned by the physician.

See the Colorado Medical Board Rules and Regulations for Licensure of and Practice by Physician Assistants (Rule 400 – Revised 8/19/10; Effective 10/15/10) for instruction regarding review and signature of a Physician Assistant’s (PA) charts by the PA’s supervisory Physician. The rule provides for a graduated plan depending on the PA’s experience and length of time at a particular practice.

3. All laboratory, X-ray, and referral follow-up reports should be reviewed, initialed, and dated by; (1) the provider (preferable); or (2) the clinic nurse/coordinator before filing in the chart. The provider(s) must be notified as soon as possible of any abnormal lab results for appropriate treatment, referral, or follow-up. This information must be documented in the medical record.
4. Document in the medical record when information is presented to the client either by means of translation or reading the information aloud to the client. Drug and food allergies alerts should be prominently noted in the medical record to inform the provider.

**G. Accessibility of medical records**

1. The records must be systematically organized to facilitate retrieval and compiling of information.
2. Funding agencies, such as the U.S. Department of Health and Human Services, have the right to review charts of those individuals whose care is supported by their funds.

## Section 25: Medical Records/Personal Health Information/Confidentiality

3. The original medical record is the property of the clinic. However, the client or her/his attorney, upon presentation of appropriate documentation, is entitled to copies of the record.

### H. Retention of records

1. Each agency should have an established written policy regarding the length of time for retention of records and the method of disposing of client records. This is usually done by obtaining a ruling from the agency or county attorney.
2. It is recommended that all client records be retained for a minimum of 7 years plus current year after discharge; or, in the case of a minor, 7 years after their 18th birthday. Resource: Colorado Medical Board Policy # 40-07 Guidelines Pertaining to Release and Retention of Medical Records (8/20/2015).

### I. Destruction of records

1. When materials no longer need to be retained, in order to ensure the confidentiality of records, they should be destroyed. Agencies that use EMRs should establish a business plan that addresses how and when records will be deleted or moved to a secure network drive.

### J. Content of client record

1. The medical record must contain sufficient information to identify the client, justify the diagnosis or clinical impression, and warrant the treatment and end results.
2. The record should contain the following:
  - a. Personal Data
    - 1) Client identification.
    - 2) Name, address, and telephone number.
    - 3) Name of someone who may be contacted to reach client.
    - 4) Name, address, telephone number, and relationship to client of a person who may be contacted in the event of a medical emergency. For the client under 18, the parent or guardian should be listed.
    - 5) Dates of visits.
    - 6) Identification of other sources of medical care.
  - b. Clinical data
    - 1) Medical history, which must be updated at least annually or more often as indicated.
    - 2) Documentation of physical examination.
    - 3) Documentation of laboratory tests ordered, results, and follow-up.
  - c. Diagnostic and therapeutic orders, observations, clinical findings, and action taken
    - 1) Indication of treatments and/or medications given, observations, and action taken.

## Section 25: Medical Records/Personal Health Information/Confidentiality

- 2) Progress notes.
- 3) Special instructions.
- 4) Follow-up contact when applicable.
- 5) Any telephone calls to or from a client regarding medical problems.
- 6) Referral forms.
- 7) Follow-up of referrals.
- 8) Whenever possible, a summary of relevant health-related encounters in other health facilities should be included in the client's family planning medical record.

### **K. Record audit**

- a. Internal record audits should be performed at least monthly, to determine completeness of records, e.g., blanks filled in, releases and consent signed appropriately, physician and staff signatures, etc.
- b. A full Clinical Chart Audit under the direction of Colorado Department of Public Health and Environment will be performed every third year by an independent auditor. (See Section 28 - Risk Management/Quality Assurance of the Clinical Manual).

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### A. Job Descriptions

The following are examples of job descriptions for staff working in Title X Family Planning Clinics. Each agency must have internal job descriptions that reflect the functions, duties, and responsibilities of the agency's employees and contracted personnel.

#### 1. Family Planning Nurse Practitioner/Certified Nurse Midwife

##### a. Definition of Position

- 1) A licensed health care provider (Advanced Practice Register Nurse (APRN)), specializing in the health needs of family planning clients.
- 2) Provides primary health care in the area of reproductive health, including initiation and maintenance of contraceptive methods.
- 3) Participates in an interdisciplinary approach to health care, being cognizant of and responsive to the experience of other disciplines and personnel involved with client services.
- 4) May also provide leadership in all aspects of the family planning program.
- 5) She/he maintains the right to refuse to examine and/or manage a client, based on professional judgment.
- 6) Collaborates with a physician.

##### b. Level of Responsibility

- 1) Directly responsible to the family planning program coordinator and/or nursing director in the local agency.
- 2) The Colorado Department of Public Health and Environment (CDPHE) Family Planning Nursing Consultant provides consultation and technical guidance, and participates in the evaluation process as appropriate.

##### c. Examples of Duties and Responsibilities:

- 1) Practices sound principles of nursing.
- 2) Participates in the decision-making processes concerning the delivery of family planning services.
- 3) Assesses the client's family planning needs by obtaining and/or evaluating a medical and social history.
- 4) Performs appropriate health assessment procedures, including but not limited to evaluation of the heart, lungs, thyroid, extremities, abdomen, breast, and pelvic area.
- 5) Develops and/or utilizes written protocols for the performance of activities related to initiation or modification of medical therapeutic regimens.
- 6) Provides counseling and teaching about family planning methods to include:
  - a) Hormonal contraceptive methods

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- b) Intrauterine devices
  - c) Diaphragm, FemCap
  - d) Foam, jelly, condom, and other over-the-counter methods
  - e) Natural family planning
  - f) Sterilization - male and female
  - g) Abstinence
  - h) Emergency contraception
- 7) Provides counseling and instruction about related health needs to include, but not be limited to:
- a) Infertility
  - b) Human sexuality
  - c) Nutrition
  - d) Breast and cervical cancer screening and follow-up
  - e) Sexually transmitted infections, including HIV/AIDS
  - f) Other minor gynecologic concerns
- 8) Performs appropriate laboratory screening tests.
- 9) Refers clients with suspected abnormal conditions to medical resources, when indicated.
- 10) Refers clients to other professionals or community resources as indicated.
- 11) Conducts family planning education sessions for professional, community, and client groups.
- 12) Maintains and reviews client records, including referral and follow-up systems.
- 13) Participates in the quality assurance component of family planning, e.g., chart audit of nursing/medical care standards.
- 14) Participates in in-service education for agency staff.
- 15) Allocates time regularly to update professional practice, e.g., reading, conferences, professional meetings, etc.
- 16) Adheres to the minimum medical guidelines as outlined in the Title X Clinical Manual.
- 17) Adheres to state statute regarding mandatory reporting of child abuse, child sexual assault, and domestic violence.
- d. Minimum Qualifications:
- See the Colorado Board of Nursing website for qualifications needed to be included on the Advanced Practice Registry and to use the Nurse Practitioner and Certified Nurse Midwife designation (<http://www.dora.state.co.us/nursing/>).

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- e. Desired Skills, Knowledge, Attitudes:
    - 1) Knowledge of needs of clients in regard to sexuality, family planning concepts, family and interpersonal relationships.
    - 2) Knowledge of public health nursing principles and practices.
    - 3) Knowledge of the clients' needs, psychosocial health, etc.
    - 4) Knowledge of clinic organization and its implementation.
    - 5) Knowledge and acceptance of family planning practices, philosophies, and concerns.
    - 6) Ability to maintain confidentiality
  - f. Special Requirements:
    - 1) Current license to practice as a registered nurse within Colorado.
    - 2) Advanced Practice Nurse Registration is required to use the NP/CNM designation.
2. Family Planning Physician Assistant (PA)
- a. Definition of Position
    - 1) A licensed health care provider specializing in the needs of the family planning client.
    - 2) Provides primary health care in the area of reproductive health, including the responsibility for the initiation and maintenance of contraceptive methods.
    - 3) Participates in an interdisciplinary approach to health care, being cognizant of and responsive to the experience of other disciplines and personnel involved with client services.
    - 4) May also provide leadership in all aspects of the family planning program.
    - 5) Maintains the right to refuse to examine and/or manage a client, based on professional judgment.
    - 6) Collaborates with a physician.
  - b. Level of Responsibility:
    - 1) Directly responsible to the family planning program coordinator for those duties not dictated by Colorado law. Otherwise responsible to the supervising physician in the local agency.
    - 2) The CDPHE Family Planning Nursing Consultant provides consultation and technical guidance, and participates in the evaluation process as appropriate.
  - c. Examples of Duties and Responsibilities:
    - 1) Practices sound principles of medical practice
    - 2) Participates in the decision-making processes concerning the delivery of family planning services
    - 3) Assesses the client's family planning needs by obtaining and/or evaluating a medical and social history

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- 4) Performs appropriate health assessment procedures, including but not limited to evaluation of heart, lungs, thyroid, extremities, abdomen, breast, and pelvic area.
- 5) Develops and/or utilizes written protocols for the performance of activities related to initiation or modification of medical therapeutic regimens.
- 6) Provides counseling and teaching about family planning methods to include:
  - a) Hormonal contraceptive methods
  - b) Intrauterine devices
  - c) Diaphragm, FemCap
  - d) Foam, jelly, condom, and other over-the-counter methods
  - e) Natural family planning
  - f) Sterilization - male and female
  - g) Abstinence
  - h) Emergency contraception
- 7) Provides counseling and instruction about related health needs to include:
  - a) Infertility
  - b) Human sexuality
  - c) Nutrition
  - d) Breast and cervical cancer screening and follow-up
  - e) Sexually transmitted infections, including HIV/AIDS
  - f) Other minor gynecologic concerns
- 8) Performs appropriate laboratory screening tests.
- 9) Refers clients with suspected abnormal conditions to medical resources, if indicated.
- 10) Refers clients to other professionals or community resources as indicated.
- 11) Conducts family planning education sessions for professional, community, and client groups.
- 12) Maintains and reviews client records, including referral and follow-up systems.
- 13) Participates in the quality assurance component of family planning, e.g., chart audit of nursing/medical care standards.
- 14) Participates in in-service education for agency staff.
- 15) Allocates time regularly to update professional practice, e.g., reading, conferences, professional meetings, etc.
- 16) Adheres to the minimum medical guidelines as outlined in the Title X Clinical Manual.

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- 17) Adheres to state statute regarding mandatory reporting of child abuse, child sexual assault, and domestic violence.
  - d. Minimum Qualifications:
    - 1) The Physician Assistant (PA) shall be certified by the State Board of Medical Examiners in the State of Colorado. In order to obtain certification, the Physician Assistant must have completed a Board-approved PA educational program and successfully passed a national certifying examination for Physician Assistants administered by the National Commission on Certification of Physician Assistants. See the Colorado Department of Regulatory Agencies Medical Board web site for Physician Assistant rules and regulations. (<http://www.dora.state.co.us/medical/> )
    - 2) The Physician Assistant should have at least one year of appropriate experience in the area of adult health, women's health, or family planning.
  - e. Desired Skills, Knowledge, Attitudes:
    - 1) Knowledge of needs of clients in regard to sexuality, family planning concepts, family and interpersonal relationships.
    - 2) Knowledge of public health principles and practices.
    - 3) Knowledge of the clients' needs, psychosocial health, etc.
    - 4) Knowledge of clinic organization and its implementation.
    - 5) Knowledge and acceptance of family planning practices, philosophies, and concerns.
    - 6) Ability to maintain confidentiality.
  - f. Special Requirements:
    - 1) Current certification to practice as a Physician Assistant in the state of Colorado
    - 2) Collaborative agreement with physician in accordance with Colorado law
3. Family Planning Coordinator
- a. Definition of Position:

Ensures the provision of family planning services, counseling, and education to clients served by the agency. This position may be assigned full or part time status, depending upon the size of the local program and may be assigned to a nurse or other staff according to the needs of the agency.
  - b. Level of Responsibility:

Within a local public health agency, may be directly responsible to the Nursing Director, Agency Director, or designee, and indirectly responsible to the CDPHE Family Planning Program Director.
  - c. Examples of Duties and Responsibilities:
    - 1) Supervises and schedules personnel for clinics where applicable.
    - 2) Initiates conferences with family planning and agency personnel relative to client services.

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- 3) Orients agency personnel to family planning services and duties within the program.
  - 4) Evaluates work performance of personnel assigned to the family planning services. Meets with staff and indicates modification of activity as needed for their continued education and supervision.
  - 5) Conducts in-service education for district community health nurses, community health workers, RN's and LPN's, as well as giving consultation and in-service to local agencies and groups such as schools and other agencies.
  - 6) Coordinates the family planning services with the generalized nursing program by establishing a communication system whereby a district community health nurse is informed about her clients and the needed follow-up.
  - 7) Assures that Family Planning Program goals and objectives, work plans, quality assurance activities, annual budgets and sliding fee scales are completed and submitted by respective due dates.
  - 8) In general, is responsible for all aspects of the local program, client care and education, and community development.
  - 9) Adheres to state statute regarding mandatory reporting of child abuse, child sexual assault, and domestic violence.
- d. Minimum Qualifications:
- 1) Graduation from a state/NLN approved school of nursing, and three years experience, at least one of which includes supervision. Family planning nursing experience is desirable;
- OR
- 2) A college degree and/or work experience within the social sciences or related field as deemed appropriate by the program personnel and the CDPHE Family Planning Program.
- e. Desired Skills, Knowledge, Attitudes:
- 1) Knowledge of needs of clients in regard to sexuality, family planning concepts, family and interpersonal relationships.
  - 2) Knowledge of public health principles and practices.
  - 3) Knowledge of the clients' needs, psychosocial health, etc.
  - 4) Knowledge of clinic organization and its implementation.
  - 5) Knowledge and acceptance of family planning practices, philosophy and concerns.
  - 6) Ability to maintain confidentiality.
- f. Special Requirements:
- Current license to practice as a registered nurse within Colorado, or other college degree or experience as described above.

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### 4. Clinic Nurse - Family Planning Services

#### a. Definition of Position:

Provides nursing counseling, physical assessment, and health history for clients seen within the family planning service of the local health agency.

#### b. Level of Responsibility:

Responsible to the family planning coordinator within the local agency. Technical and specialty nursing consultation available from the state nursing consultants.

#### c. Examples of Duties and Responsibilities:

- 1) Obtains health histories and identifies health needs of individuals and families, may provide parts of the physical assessments, and administers appropriate tests, i.e., Hct.
- 2) Teaches and counsels individuals on reproductive health issues, including various contraceptive methods.
- 3) Issues supplies.
- 4) Initiates referrals to other sources of health care if needed and provides follow-up.
- 5) Participates in quality assurance and program evaluation, as appropriate.
- 6) Adheres to state statute regarding mandatory reporting of child abuse, child sexual assault, and domestic violence.

#### d. Minimum Qualifications:

Graduation from NLN, state approved nursing program, with appropriate experience within an outpatient clinic service (one year).

#### e. Desired Skills, Knowledge, Attitudes:

- 1) Knowledge of needs of clients in regard to sexuality.
- 2) Knowledge of family planning concepts.
- 3) Knowledge of family and interpersonal relationships.
- 4) Knowledge of clinic function and ability to work in conjunction with other clinic personnel.
- 5) Knowledge of community health resources for alternate health services.
- 6) Acceptance and acceptance of family planning concepts, philosophy and practices.
- 7) Ability to maintain confidentiality.

#### f. Special Requirements:

Current license to practice as Registered Nurse within Colorado.

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### 5. Local Physician - Family Planning Services

#### a. Definition of Position:

The Physician is responsible for providing the medical care component to the local family planning program. The position may be full or part time, depending upon the size of the program.

#### b. Examples of Duties and Responsibilities:

- 1) Is familiar with the Title X medical guidelines as outlined in the Title X Clinical Manual and agrees to follow them.
- 2) Recommends the contraceptive method of choice after conferring with the client.
- 3) Records findings on client's chart and notes referrals for medical conditions.
- 4) Countersigns recommendations of the nursing personnel and/or mid-level providers.
- 5) Agrees to and signs CDPHE Family Planning Program policies and protocols which have been written and approved by the Medical Policy Advisory Committee (MedPAC).
- 6) Adheres to state statute regarding mandatory reporting of child abuse, child sexual assault, and domestic violence.
- 7) A physician agreement or job description for the agency's Medical Director/Medical Consultant should include
  - a) "Medical Director" in the job title
  - b) Clinical supervision of the Title X Family Planning Program and Title X Program staff
  - c) Physician will review and co-sign 10% of medical records

#### c. Minimum Qualifications:

Physician's license to practice in state of Colorado.

#### d. Desired Skills, Knowledge, Attitudes:

- 1) Obstetrician, gynecologist, or physician who has special training or experience in family planning.
- 2) Willingness to work with NP, CNM, and PA providers.
- 3) Knowledge and acceptance of family planning practices, concepts and philosophy.
- 4) Understanding of the role of the CDPHE Family Planning Program Medical Director as Medical Consultant in cases where consultation and additional medical expertise is needed. Willingness to work with same and accept recommendations.
- 5) Ability to maintain confidentiality.

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### 6. Clinic Aide/Community Health Worker - Family Planning Services

#### a. Level of Responsibility:

Responsible to the family planning coordinator.

#### b. Examples of Duties and Responsibilities:

##### *Clinic Aide*

- 1) Prepares examining room for clinic sessions, assuring an adequate supply of equipment needed for each client seen.
- 2) Prepares client for examination, assists practitioner/clinician with examination and treatment.
- 3) Collects and labels appropriate specimens.
- 4) Performs simple lab tests, e.g., urine dipstick.
- 5) Cleans equipment.
- 6) Arranges clinical area and/or interviewing area as needed.
- 7) May perform such duties as routine Depo injections according to local policy, if there is appropriate training and supervision according to the Board of Nursing Rules, (<http://www.dora.state.co.us/nursing/>) or the Board of Medical Examiner Rules (<http://www.dora.state.co.us/medical/>)

##### *Community Health Worker*

- 1) Informs individuals in community regarding existence of family planning services.
- 2) Explains methods of contraception and basic human reproduction to those requesting such information.
- 3) Informs individuals of other health and social services in the community.
- 4) Investigates transportation help for women/men who may not be able to drive to health services.
- 5) Serves as an interpreter or translator when there are language and cultural barriers that she/he can overcome.
- 6) Makes follow-up contacts to those clients not seen at clinic or agency.

#### c. Minimum Qualifications:

Graduation from high school, or having equivalent (GED diploma).

#### d. Desired Skills, Knowledge, Attitudes:

- 1) Knowledge about the community; may be bilingual.
- 2) Able to understand and communicate information about family planning services.

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- 3) Knowledge and acceptance of family planning practices, concepts, and philosophy.
- 4) Ability to maintain confidentiality.

### 7. Clerk/Secretary-Family Planning Services

#### a. Definition of Position:

Performs general clerical functions.

#### b. Level of Responsibility:

Works under the supervision of the Family Planning Coordinator.

#### c. Example of Duties and Responsibilities:

- 1) Acts as a receptionist; types correspondence and other communications; answers phones.
- 2) Maintains log sheets, ledgers; collects fees and donations.
- 3) Does inventory and replenishes office and nursing supplies.
- 4) Maintains client records and general office files.
- 5) Verifies accuracy of health worker's daily and clinic reports.
- 6) Pulls records for clients seen at clinic.
- 7) Prepares appointment lists and clinic roster for each clinic session.
- 8) Completes client data forms.
- 9) Makes appointments for needed referral services.

#### d. Minimum Qualifications:

- 1) Graduation from high school, or equivalent; business course desirable.
- 2) At least one year of general clerical experience.

#### e. Desired Skills, Knowledge, Attitudes:

- 1) Knowledge of simple bookkeeping practices; ability to organize files; do general office work.
- 2) Basic computer skills.
- 3) Ability to relate to the public and respect confidentiality of information.
- 4) Acceptance of family planning practices, concepts, and philosophy.

### 8. Clinic Health Educator - Family Planning Services

#### a. Definition of Position:

General responsibility for health education of individuals and groups in all aspects of family planning programs and concepts.

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- b. Level of Responsibility:  
Responsible to the family planning coordinator. Position may be full or part time.
- c. Examples of Duties and Responsibilities:
  - 1) Teaches family planning concepts in clinic, home visits, and/or community programs, e.g., schools.
  - 2) Educates clients during family planning clinics.
  - 3) Assists in preparation and dissemination of educational materials, such as reports, pamphlets, posters, news releases.
- d. Minimum Qualifications:
  - 1) Graduation from college or any combination of experience in training equivalent to a bachelor's degree.
  - 2) Work experience as deemed appropriate by program personnel
- e. Desired Skills, Knowledge, Attitudes:
  - 1) Knowledge and acceptance of family planning philosophy, concepts and practices.
  - 2) Ability to maintain confidentiality.

Sample Provider Agreement <https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

# Section 27: Risk Management / Quality Assurance/Quality Improvement

## A. Overview

1. Risk management is the system used to minimize the probability of events that have adverse effects and cause loss of human or financial resources.
2. It involves the prevention of circumstances that will lead to a loss of resources.
3. Errors are reduced through a comprehensive quality assurance plan that includes activities at both the state and local level.
4. Note that the Title X Federal Review Tool is incorporated by reference in the clinical manual, including implementation strategies that document compliance with Title X requirements. The review tool can be accessed on the CDPHE Family Planning Program web site <https://www.colorado.gov/pacific/cdphe/titlex-familyplanning>

## B. Activities

1. At the State level, quality assurance activities include the following:
  - a. Office of Population Affairs (OPA) Title X program reviews
  - b. State of Colorado audits (e.g. FRMS)
  - c. Periodic clinical chart audits and clinical and administrative site visits
  - d. Orientation to the department, division, and program
  - e. Annual work plans and objectives
  - f. Performance evaluations of state staff that can include input from delegate staff
  - g. Services provided according to national evidenced based recommendations and guidelines
  - h. Continuing education and training records
  - i. Review of site visit reports, plans for correction
  - j. Medical Policy Advisory Committee (MedPac) meetings
  - k. Evaluation and audits of the family planning data system
  - l. Quality improvement activities
  - m. Progress reports on grant objectives
  - n. Insurance requirements and policies
  - o. Emergency plans
  - p. Job descriptions
  - q. Consultation with the Medical Director
  - r. CDPHE Contract Monitoring System evaluations
2. At the local level, quality assurance activities include the following:

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- a. Clinical chart audits, including Internal Clinical Audits (ICAs)
- b. Clinical, administrative and fiscal site visits
- c. Data audits
- d. Independent financial audits
- e. Client satisfaction surveys
- f. Job descriptions
- g. Performance evaluations
- h. Documentation of staff orientation to the agency and program
- i. Continuing education and training records, including training on the QFP (e.g. training available from the Title X National Training Centers).
- j. Services provided based on national evidenced based recommendations and guidelines
- k. Quality improvement activities
- l. Documentation of staff training and proficiency testing related to the performance of CLIA waived laboratory procedures and provider performed microscopy. All CLIA waived tests must be performed following the instructions in the most current manufacturers' product insert, without modification.
- m. Documentation of the running of controls for CLIA waived tests according to the manufacturers' recommendations/package insert (generally with each new lot number or shipment of a CLIA waived test).
- n. Documentation of instrument maintenance as directed by the manufacturer (examples: devices used for CLIA waived tests, autoclave to include ensuring effective sterilization such as spore testing, microscope, refrigerator including temperature log).
- o. Clinic resources:  
MMWR Good Laboratory Practice for Waived Testing Sites  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>  
  
Ready? Set? Test!  
<http://wwwn.cdc.gov/clia/resources/waivedtests/pdf/readysettestbooklet.pdf>  
  
Family Planning web site  
<https://www.colorado.gov/pacific/cdphe/title-x-resources>
- p. Documentation of an infection control policy and measures (cleaning of exam rooms, instruments, lab, autoclave, and devices) and blood borne pathogens/Occupational Safety and Health Administration (OSHA) staff training and proficiency.

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### Clinic Resources:

Center for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. <http://www.cdc.gov/hicpac/pubs.html>

CDC Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care May 2011 <http://www.cdc.gov/hai/settings/outpatient/outpatient-settings.html>

Occupational Safety and Health Administration (OSHA) Blood Borne Pathogens and Needlestick Prevention <https://www.osha.gov/SLTC/bloodbornepathogens/>

### q. Management of BBP Exposure

- 1) Agencies must have written BPP policies and procedures for staff that clearly outline the steps the agency and worker need to perform if a worker has a possible BBP exposure.
- 2) Workers performing exposure prone procedures should discuss antiretroviral prophylaxis with their care provider in advance and decide if antiretroviral prophylaxis would be desired in the event of a possible exposure.
- 3) HIV and Hepatitis B post-exposure prophylaxis (PEP) and expert consultation in the management of health-care personnel who have occupational exposure to blood and other body fluids that might contain HIV/Hepatitis B should be provided within 2 hours of the exposure.
- 4) An incident report should be completed each time a worker has a potential exposure and full documentation of the event and the follow-up should be included.
- 5) See the following links for more information:

UCSF Clinician Consultation Center

<http://www.nccc.ucsf.edu/>

Information on HIV/AIDS treatment, prevention and research

<http://aidsinfo.nih.gov/guidelines>

HIV pre and post exposure prophylaxis

<http://www.cdc.gov/hiv/prevention/research/index.html>

Post exposure prophylaxis resources

<https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/>

- r. Documentation of pharmacy protocols and procedures.
- s. Peer review
- t. Bill of Rights for clients
- u. Advisory council meetings and minutes

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- v. Progress reports on grant objectives
- w. Insurance policies and requirements
- x. Emergency plans and incident reports
- y. Consultation with the Medical Director

### C. Clinical Chart Audit and on Site Visits

1. A clinical chart audit is required every three years.
2. This requirement is met by programs submitting charts to the family planning program to be audited by a contract provider. Delegates scoring below 90% on any criteria in the clinical chart audit are asked to provide a plan for correction.
3. iCare reports are provided annually. CDPHE IT staff pull specified demographic and clinical data from iCare to evaluate and compare clinic sites.

### D. Annual Internal Clinical Chart Audits (ICAs)

1. The CDPHE Family Planning Program requires Internal Clinical Audits annually.
2. The topics for these audits will be determined by the Family Planning Nurse Consultant, with input from the MedPac Committee. The Nurse Consultant emails the audit forms and results are emailed back to her.
3. These audit results should also be available at the delegate agency on request and during site visits.
4. Recommendations may be made by the Nurse Consultant, based upon the Clinical Chart audit scores, as to a topic for another Internal Clinical Audit (ICA).
5. All audits should contain a summary of results, and a plan of correction or follow-up, if applicable.

### E. New Employees

1. It is recommended that new employees, or employees with new functions, have ten charts audited, using the same criteria below.
2. This could be done after three months of working in their new capacity.
3. Program Coordinators or Nursing Directors can ask for help with this from the CDPHE Nurse Consultant. This would aid in identifying, in a timely fashion, any areas of client management or documentation that might need corrective action.

### F. Criteria for Chart Review (varies and may include but not limited to the following)

1. Vital Signs
  - a. Blood pressure
  - b. Weight and BMI
  - c. Height

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2. Lab Results - done as indicated and entered in chart
  - a. Pregnancy test
  - b. Pap test
  - c. Chlamydia screen
  - d. Gonorrhea test
  - e. Wet prep
  - f. HIV test
3. Appropriate Physical assessment
  - a. Standards for routine visits met
  - b. Appropriate assessment for problems
4. Health Issues Addressed
  - a. Evidence that medical history was complete and reviewed by the provider
  - b. Last menstrual period
5. Clinical Diagnosis/Impression/Assessment Recorded

Problem areas from history, physical examination, and interviewer's notes identified and recorded, including general health risks such as over/under weight, smoking and other substance use, partner violence or abuse.
6. Treatment Plan Outlined (excluding any birth control method)
  - a. Medication orders correctly written and dispensed
  - b. Other measures outlined - psycho-social follow-up
  - c. Referrals documented
7. Procedures described

IUD Insertion, Diaphragm Fitting, etc.
8. Follow-up Specified

Return to clinic, etc.
9. Clinical Judgment

(Based on client statements, laboratory, physical exam, etc.)

  - a. Accuracy of clinical impression
  - b. Appropriateness of prescription and person writing it
  - c. Appropriate consultation obtained and noted, as applicable

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- d. Appropriate referral made if applicable

### 10. Method Noted

- a. OCP/contraceptive patch/contraceptive vaginal ring prescription correctly documented and dispensed
- b. Diaphragm type and size documented
- c. IUC type and expiration date documented
- d. DMPA site of injection, correct prescribing regimen
- e. Contraceptive implant
- f. Emergency contraception, including specific brand and how dispensed
- g. Non prescriptive method, if applicable
- h. Continuation of a method noted
- i. Reason for any method change or reason method deferred

### 11. Signature and title (must be legible)

- a. Provider signature and title (at least one full signature in each chart)
- b. Co-signature and title as indicated

### 12. Subsequent follow-up

Medical referral response/report in medical record

### 13. Consent forms

Appropriate consent forms related to client visit

### 14. Education/counseling

- a. All methods, specific method, emergency contraception
- b. Weight loss education if BMI  $\geq$  25.
- c. Breast self awareness
- d. STI-HIV information and risk reduction
- e. Reproductive life plan
- f. Folic acid education
- g. Appropriate other education given as indicated by history and physical assessment to include but not be limited to:
  - 1) HPV vaccine
  - 2) Vaginal infection or STI's, including treatment

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- 3) Substance use
- 4) Intimate partner violence
- 5) Sexual coercion of minors
- 6) Family involvement for minors
- 7) Preconception counseling

### G. Chart Audit Check List

Item	Audit Requirement	Completed ( )
1	Photocopied (paper charts) <u>de-identified</u> charts of clients with new/annual client visit.	
2	Send list of chart numbers with charts. If EMR, select records for review prior to audit date.	
3	Protocols different than CDPHE FAMILY PLANNING PROGRAM are sent with charts, up-to-date and signed off. If protocols are the same, then just send the signature sheet with most recent signatures.	
4	Send list of providers used during the year audited.	

### H. Clinical Site Visit

The purpose of the site visit is to determine whether delegate agencies are managed effectively and comply with Title X, federal, and state requirements.

The Nurse Consultant conducts a clinical site visit every third year, alternating with administrative site visits and **clinical** chart audits.

### I. Clinical Site Visit Procedures

1. The Nurse Consultant arranges a date with the agency's Family Planning Coordinator approximately 45 - 60 days in advance for the site visit. It is important to schedule the site visit on a clinic day. Copies of a confirmation letter should go to the coordinator's supervisor.
2. At the beginning of the site visit, an entrance interview is held with the appropriate local agency staff to discuss the process involved and the day's agenda. Agency staff should have all of the materials requested for review available at this time.
3. The consultant will spend part of the day with the Family Planning Coordinator to review the site visit tool, and materials requested. Whenever possible, the consultant should confirm compliance by observation vs. report.

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4. The consultant will spend part of the day 'shadowing' several clients through the clinic, from check in to check out and all stops in-between. The purpose of this activity is to observe the flow of the clinic and the content of the visits.
5. The consultant will review approximately 10 charts of clients who have had a recent annual visit and 5 pregnancy test charts.
6. An exit interview is held with all appropriate agency staff, including, whenever possible, the supervisor of the Family Planning Coordinator. Discussion should include the preliminary results of the evaluation and possible recommendations. Strengths are emphasized before deficiencies.
7. A final report is completed and emailed to the delegate agency within four weeks of the visit. Copies should be circulated among State program staff, sent to the local coordinator's supervisor, and to the public health nurse consultant from the Colorado Department of Public Health and Environment (CDPHE) Office of Planning and Partnerships (OPP). The report, completed site visit tools, and subsequent follow-up correspondence should be placed together on the CDPHE Family Planning Program J Drive. Compliance issues should be clearly outlined in the report. Delegate agencies are given six weeks to submit a written compliance plan to the CDPHE Family Planning Program, with full compliance achieved within three months of the report. It is the consultant's responsibility to assure that a compliance plan has been received by the due date and that the agency has addressed all compliance issues in a satisfactory fashion.

### J. Clinical Site Visit Materials Checklist

A clinical site visit document check list will be sent to the Family Planning Coordinator at least 6 weeks before the visit to assist the Coordinator in collecting the documents and information that will be reviewed during the site visit.

Clinical Site Visit Evaluation Form and checklist <https://www.colorado.gov/pacific/cdphe/title-x-clinical-consents-and-forms>

# Section 28: Laboratory

## Guidance and Resources for Clinical Laboratory Improvement Amendments (CLIA) Waived Testing, Provider Performed Microscopy, and General Laboratory Practices

### A. Introduction

1. Clinic sites that perform CLIA waived tests are required to have a CLIA Certificate of Waiver. Anyone can serve as the lab director, but it should be someone who is knowledgeable of the testing performed and willing to provide oversight of the lab.
2. If mid-level and physician providers use a microscope to perform certain tests, such as wet preps, then a Certificate of Provider Performed Microscopy (PPM) is required. This Certificate also allows CLIA waived tests to be performed. Because PPM procedures are moderate complexity, the clinic lab must have a written quality assessment (QA) plan. QA plan elements, a sample QA plan provided by the State lab CLIA Certification Program along with other resources and forms can be downloaded from the CDPHE Family Planning Program web site: <https://www.colorado.gov/pacific/cdphe/title-x-resources>
3. Also provided and linked are CLIA regulations regarding PPM and Guidelines for Certificate of Provider-Performed Microscopy Procedures, a summary of CLIA PPM regulations.
4. The CDPHE Clinical Manual Sections Risk Management/Quality Assurance and Referral and Follow Up sections also address lab practices. Please see these sections for more information.
5. Please ensure that your clinic lab complies with CLIA regulations and regularly review and update your CLIA waived and provider performed microscopy (PPM) laboratory manuals.

### B. Laboratory quality assurance activities must include the following:

1. Documentation of staff training and proficiency testing related to the performance of CLIA waived laboratory procedures and provider performed microscopy.
2. All CLIA waived tests must be performed following the instructions in the most current manufacturers' product insert, without modification. The most current manufacturers' product insert must be available in the lab to staff members performing CLIA waived tests.
3. Documentation of the running of controls for CLIA waived tests according to the manufacturers' recommendations (generally with each new lot number or shipment of a CLIA waived test).
4. Documentation of instrument maintenance as directed by the manufacturer of the test or device (examples: devices used for CLIA waived tests, microscope, refrigerator including temperature log).
5. Provider performed microscopy proficiency testing or comparison testing must be performed and documented twice annually. A sample accuracy verification form is provided on with CLIA resources on the CDPHE family planning web site.
6. Proficiency testing should have a grading system that includes what a passing score is and what corrective action is taken if a staff member does not pass, described in the clinic lab policies and procedures.

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7. The clinic may do proficiency testing in house using client samples for double reads or by using photographs of potential elements in a wet prep in quiz form. Clinics may sign up for proficiency testing through an approved proficiency test provider (this is not required though) and receive a score for testing unknown samples. See below for contact information for proficiency test services. A more complete list provided by the CLIA Certification Program is on the family planning web site. See the written procedure examples for help with developing a written wet prep procedure for your clinic(s).
8. Clinics must have a lab procedural manual available for review by the CDPHE Family Planning Program Nurse Consultant and CDPHE Laboratory Services Division.

### C. Proficiency testing services and laboratory quality assurance programs:

The American Proficiency Institute (API) 800-333-0958

<https://www.api-pt.com/Default.aspx>

American Association of Bioanalysts (AAB) PTS Proficiency Testing Service 800-234-5315

<http://www.aab-pts.org/>

American College of Physicians (ACP) Medical Laboratory Evaluation 800-338-2746 option 5

[http://www.acponline.org/running\\_practice/mle/enroll.htm](http://www.acponline.org/running_practice/mle/enroll.htm)

Collage of American Pathologists (CAP) 800-323-4040

[http://www.cap.org/web/home/lab?\\_adf.ctrl-state=45x25auek\\_4&\\_afLoop=186789525778790](http://www.cap.org/web/home/lab?_adf.ctrl-state=45x25auek_4&_afLoop=186789525778790)

AAFP Proficiency Testing Program 800-274-7911

[http://www.aafp.org/practice-management/labs/about.html?cmpid=van\\_183](http://www.aafp.org/practice-management/labs/about.html?cmpid=van_183)

See a more complete list provided by Colorado CLIA Certificate Program.

<https://www.colorado.gov/pacific/cdphe/title-x-clia-and-ppm-guidelines>

### D. Wet Prep training:

Denver Prevention Training Center

<https://www.denverptc.org/>

### E. Resources:

CDPHE Laboratory Services Division – Lab certification

<https://www.colorado.gov/pacific/cdphe/lab>

Regulations and guidance regarding Clinical Laboratory Improvement Amendments (CLIA)

<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>

*Ready Set Test* Booklet from the CDC - great resource for performing CLIA waived tests in the clinic. Available at the following CDC web site <http://wwwn.cdc.gov/CLIA/Resources/WaivedTests/default.aspx>

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### F. General Laboratory Operations

1. All clinic sites must provide onsite pregnancy testing.
2. Agencies may make a business decision regarding the choice of outside lab the agency will use.
3. Clinic sites provide the following tests when required by the specific contraceptive method (FDA or prescribing recommendations) or according to screening recommendations in the QFP.
  - a. Chlamydia and gonorrhea
  - b. Diabetes
  - c. Syphilis serology
  - d. HIV
  - e. Hepatitis B
  - f. Cervical cancer screening
4. All clinic sites must have a tracking system for test specimens results sent to outside laboratories that includes test date and date test results are received back in the clinic or EMR.
5. All specimens must be properly labeled and lab requisitions must be correctly completed. Include private insurance or Medicaid information on requisitions so outside lab can bill the 3rd party payer directly.
6. Incoming test results must be signed off by clinic staff. Abnormal test results must be reviewed and signed by provider with a plan for follow up documented in the medical record.
7. All clinic sites must have a tracking system for abnormal lab results in need of follow up or continuing care.
8. Clients are notified of abnormal test results and the notification procedure maintains client confidentiality.
9. All positive STI and HIV tests must be reported to the CDPHE STI Registry using the form the Registry provides.
10. Agencies using a lab other than the State lab for CT/GC testing must send both negative and positive test results to the CDPHE STI Section for prevalence monitoring. Please contact Christen Lara [christen.lara@state.co.us](mailto:christen.lara@state.co.us) for more information and reporting requirements.