

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

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.

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
 - c. Periodic medical chart audits and medical 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. Continuing education and training records
 - h. Review of site visit reports, plans for correction
 - i. **List of common compliance findings on medical and administrative site visits**
 - j. **Medical Policy Advisory Committee (MedPAC) meetings**
 - k. Evaluation and audits of the family planning data system
 - l. Progress reports on grant objectives
 - m. Insurance requirements and policies
 - n. Emergency plans
 - o. Job descriptions
 - p. Consultation with the Medical Director
 - q. **Contract Monitoring System evaluations**
2. At the local level, quality assurance activities include the following:
 - a. Medical chart audits, including Internal Medical Audits (IMAs)
 - b. Medical, 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

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

- j. **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.**
- k. **Documentation of the running of controls for CLIA waived tests according to the manufacturers' recommendations (generally with each new lot number of a CLIA waived test).**
- l. **Documentation of instrument maintenance as directed by the manufacturer (examples: devices used for CLIA waived tests, autoclave to include spore testing, microscope, refrigerator including temperature log).**
- m. **Documentation of an infection control policy (cleaning of exam rooms, instruments, lab, autoclave, and devices) and blood borne pathogens/Occupational Safety and Health Administration (OSHA) staff training and proficiency.**
- n. **Documentation of pharmacy protocols and procedures.**
- o. Peer review
- p. Bill of Rights for clients
- q. Advisory council meetings and minutes
- r. Progress reports on grant objectives
- s. Insurance policies and requirements
- t. Emergency plans and incident reports
- u. Consultation with the Medical Director

C. MEDICAL CHART AUDIT AND ON SITE VISITS

1. A medical 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 nurse practitioner. Delegates scoring below 90% on any criteria in the Medical Chart Audit will be asked to re-audit those criteria within the following year. (See **Letter F below** for the Audit Criteria.)
3. Medical site visits and administrative site visits are made on a three year rotation. (See Section 2.1 - Quality Assurance of the Administrative Manual for more information on administrative site visits)
4. Those sites that have implemented electronic medical records (EMRs) will have the chart review conducted on site.

D. SEMI-ANNUAL INTERNAL MEDICAL AUDITS (IMAs)

1. The **CDPHE Family Planning Program** requires Internal Medical Audits on a twice/year basis.
2. The topics for these audits will be determined by the Family Planning Nurse Consultant, with input from the MedPAC Committee. The Nurse Consultant will mail out the audit forms and results will be forwarded 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 Medical Chart audit scores, as to a topic for another Internal Medical Audit (IMA).

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

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 (Letter F).
2. This could be done after three months of working in his/her new capacity.
3. Program Coordinators or Nursing Directors can ask for help with this from the Nurse Consultant at **CDPHE Family Planning Program**. 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

1. Vital Signs
 - a. Blood pressure
 - b. Weight and BMI
 - c. Height
 - d. Last menstrual period
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. Hematocrit/hemoglobin
 - g. Urine screening (protein, sugar, leukocytes, nitrites, etc.)
 - h. Special chemistries
3. Appropriate Physical Exam
 - a. Standards for routine visits met
 - b. Appropriate exam for problems
4. Health Issues Addressed
Evidence that medical history was complete and reviewed by the provider
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

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

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
 - d. Appropriate referral made if applicable
10. Method Noted
 - a. OCP/contraceptive patch/contraceptive vaginal ring prescription correctly written and dispensed
 - b. Diaphragm type and size written
 - c. IUD type and expiration date written
 - d. DMPA site of injection, correct prescribing regimen
 - e. Implanon®
 - 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 chart
13. Consent forms
Appropriate consent forms (complete and in ink) related to client visit in chart
14. Income information
Complete
15. Education
 - a. All methods discussed, at the initial exam as indicated. Emergency contraception must be discussed at initial and annual exams for any client who is sexually active and using a temporary method of contraception, with the possible exception of IUDs or implants.
 - b. Nutrition education, specific to history, physical findings, and birth control method, including calcium information for Depo users. **Weight loss education if BMI \geq 25.**

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

- c. Self Breast Exam (SBE), if desired by the client
- d. Testicular Self Exam (TSE) for male clients
- e. **HIV/AIDS** education (See Section 1.13 – HIV/AIDS Education of the Nursing Manual regarding content)
- f. **STI education**
- g. Reproductive A&P, at initial exam and as indicated
- h. Folic acid education for all women of reproductive capability
- i. Appropriate other education given as indicated by history and physical exam to include but not be limited to:
 - 1) Rubella immunity
 - 2) Importance of yearly Flu vaccine**
 - 3) HPV vaccine
 - 4) DES exposure, if born 1940 - 1970
 - 5) Vaginal infection or STI's, including treatment
 - 6) UTI
 - 7) Substance use
 - 8) Domestic violence
 - 9) Sexual coercion of minors
 - 10) Family involvement for minors
 - 11) Preconception counseling
 - 12) Abstinence counseling for clients under 18 years old.**

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

COLORADO DEPARTMENT OF HEALTH • FAMILY PLANNING PROGRAM

CHART AUDIT CHECK LIST

Item	Audit Requirement	Completed (✓)
1	Photocopied <u>de-identified</u> charts of clients with new/annual client visit in following range:	
2	Send list of chart numbers with charts.	
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.	

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

SOME DO'S TO BEAR IN MIND WHEN CHARTING

1. DO be sure that chart contains an emergency contact mechanism.
2. DO be sure that every page contains sufficient information to identify client.
3. DO write in blue or black ink for copying purposes.
4. DO write legibly.
5. DO have clients complete self-history in ink.
6. DO document all contacts with clients (including phone calls) and all services rendered.
7. DO chart immediately.
8. DO ensure that each entry describes:
 - a. Mode of contact; i.e., telephone call, visit, etc.
 - b. Reason for contact.
 - c. Procedures done or information given.
 - d. Outcome of contact.
 - e. Plan for future care.
9. DO sign every entry.
10. DO date every entry.
11. DO fill in every blank - negatives as well as positives.
12. DO note charting errors by drawing single lines through the entries, and initialing and dating them.
13. DO make legible corrections on charts, or referenced attachments, and sign and date them.
14. DO chart only what has been done, not what has not been done.
15. DO use only clinic-approved abbreviations and symbols.
16. DO draw a line through the empty space at the end of an entry.
17. DO date each page.
18. DO use a supplemental page if necessary to record missed notes and indicate as late entry.
19. DO use objective rather than subjective observations and language.
20. DO chart what you do to protect the client.
21. DO chart what the client's response to treatment was.

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

SOME DON'T'S TO BEAR IN MIND WHEN CHARTING

1. DON'T use white out or pencil; don't scribble over, or in other manner obliterate any entry.
2. DON'T use names without describing their functions in relation to the client (e.g., don't write: "referred to Sally Smith").
3. DON'T file the chart without ensuring completeness.
4. DON'T place in the chart any information about the clinic's liability insurance or the name of the insurance company.
5. DON'T omit medical information from the chart, even though it might be regarded as potentially embarrassing to the client.
6. DON'T use ditto marks or vertical lines drawn through multiple categories.
7. DON'T squeeze in extra words on a line and/or write between the lines.
8. DON'T use "none of the above" in the Medical History. Use "Yes" or "No" columns, or check off boxes.

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

MEDICAL 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 medical site visit every third year, alternating with administrative site visits and medical chart audits.

A. MEDICAL SITE VISIT PROCEDURES

1. The Nurse Consultant should arrange a date with the delegate'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 should be 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.
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 should review approximately 10 charts for criteria determined at the start of each year. This information will then be compared to the Integrated Registration and Information System II (IRIS) record when the consultant returns to her office.
6. An additional activity on the Medical Site Visit is the collection of data for the Regional Quality Indicators Project (RQIP). The Nurse Consultant reviews the Facility Audit Tool (sent out with the confirmation letter and completed by the Family Planning Coordinator ahead of time), as well as the Chart Audit Tools for the number of medical charts as determined by John Snow, Inc. (JSI). The third RQIP tool is the client survey. The clinic staff distributes and collects this tool over a period of time. The number of surveys collected is also determined by JSI. Once the surveys are completed, they are returned to the Nurse Consultant, who sends them in with the other two completed tools.
7. An exit interview should be 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 should be emphasized before deficiencies.

SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY

8. A final report should be completed and mailed 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 in the CDPHE Family Planning Program central files. Compliance issues should be clearly outlined in the report. Delegate agencies will be 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.

B. MEDICAL SITE VISIT MATERIALS CHECKLIST

Please prepare the following items for assessment at the medical site visit.

- CDPHE Nursing Manual with appropriate signatures; other protocols in use
- Pharmacy protocols
- Laboratory logs
- Referral policy and list of referral resources
- Tracking and follow up written policy/procedure and logs
- Licenses (copies are fine) for nurses and physicians serving as family planning staff
- CLIA license and written lab quality assurance procedures
- Infection control policy
- Ten client records from the previous few months (so that the lab reports are back) plus a number (to be designated in the site visit confirmation letter) of records for clients presenting only for pregnancy tests. If this is a third party data site, then make sure the client visits reviewed occurred in the most recent upload of data, i.e., from the previous completed quarter.

The following pages contain a sample of the medical/nursing site visit Evaluation Form. This form can be downloaded from the CDPHE Family Planning Program website at:
<http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html>

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

**COLORADO DEPARTMENT OF PUBLIC
HEALTH AND ENVIRONMENT**

FAMILY PLANNING PROGRAM

MEDICAL/NURSING SITE VISIT EVALUATION

Agency	
Address	
Program Coordinator/Clinic Manager	
Provider of Clinic Services	
Consultant Physician	
Evaluator	
Date of Evaluation	
Date of Report	

SAMPLE

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
A. GENERAL			
*1. No charge for services is made to any person from a low income family except to the extent that charges can be billed to a third party (check medical records) (Part I, 6.3 p.7).			
*2. This program does not provide abortion as a method of family planning (Title X sec 1008, 300a-b).			
B. FACILITIES AND ACCESSIBILITY			
1. The services of this program are made available in a manner that protects the dignity of the individual. The design of the program's facilities ensures privacy, confidentiality, and regard for self respect and dignity of the served individual during personal interviews, consultations, medical examinations, and treatment (observe facilities) (Part I, 6.4).			
2. Walk-in hours available.			
3. Evening/weekend hours available (Part I, 6.4).			
C. PERSONNEL			
*1. Nurses are licensed to practice in the state with current nursing license (review nursing license number and expiration date) (Part I, 6.5 p.10).			
*2. Physicians providing supervision of personnel are currently licensed to practice in the state (review license number and expiration date) (Part I, 6.5 p.9).			
D. MEDICAL SERVICES			
1. *Family planning services are performed under the direction and responsibility of a physician with special training or experience in family planning (name specialty of physician) (Part I, 6.5 p.9).			
*a. Medical policies, procedures and protocols are in written form (Part I, 6.5			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
p.9; Part II, 7.1 p.13).			
b. Medical policies (protocols) are reviewed and signed by the supervising physician (Part II, 7.1 p.13).			
c. Medical policies are reviewed and signed by personnel in clinic area.			
*d. There is a written agreement with the physician describing responsibilities and functions (Part II, 7.1 p.13).			
2. Medical services are provided by nurse practitioners and/or physician's assistants			
a. collaboration according to appropriate act.			
b. NPs have prescriptive authority			
c. Contract NPs have liability insurance			
*3. Programs provide laboratory services, contraceptive supplies, and referrals to other facilities/providers when indicated (Part II, 8.3 p.22, 7.0 p.13, 7.4 p.16).			
*4. The female examination, if required, emphasizes pelvic and breast examination. The pelvic examination includes visualization of the cervix, and bimanual. Rectal-vaginal is done as indicated. At the time of the breast examination, instruction in breast self-examination may be reviewed (review client medical records) (Part II, 8.3 p.21).			
*5. Facility has CLIA license appropriate for the testing it conducts (CLIA).			
*6. Proficiency testing is done as indicated by type of license (CLIA). (site visit report from CLIA?)			
*7. The laboratory services for all initial clients may include a Pap smear and Chlamydia test, according to screening guidelines. (8.3 p.21).			
a. Gonorrhea and Chlamydia tests are done on all clients requesting IUD insertion; all clients with PID; other clients as indicated by current screening guidelines.			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
b. Pap smears are done according to ACOG screening intervals and are done with dacron swabs/spatulas, cytobrushes/ spatulas, or sampler recommended by lab (per C.A.P.).			
c. If using CDPHE lab, site is using correct IPP requisition (#271)			
d. Site is reporting IPP data			
e. Site reports STD treatments to the CDPHE STD registry			
8. Lab log is maintained for tracking all labs performed (per CLIA).			
a. all results are dated and initialed upon receipt			
b. lab log reflects receipt of results			
*9. Additional laboratory services are available as indicated or requested (Part II, 8.3 p.22)			
a. Gonorrhea screening			
b. Pregnancy testing			
c. Serology for syphilis			
d. Hepatitis B screening			
e. HIV testing			
f. Wet preps for diagnosis of vaginitis			
g. Urinalysis			
h. Blood sugar or cholesterol test for women who are potentially at high risk for oral contraceptive use			
i. Hemagglutination test for rubella			
j. Colorectal screening for female clients over 50 years old.			
*10. All clients in this program are treated or referred for continuing care when their laboratory tests show abnormal findings (review written procedures). All such abnormal labs, i.e., Pap smears, Chlamydia tests, lipid screens, etc., are followed through a tracking system which includes (Part II, 8.3 p.20):			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
*a. Recommendations for follow-up (Part II, 8.3 p.22).			
b. Documentation that client received follow-up or documentation that client refused follow-up			
*11. The program has written procedures and time frames for follow-up of all referrals made by staff, and procedures are sensitive to client's concerns for confidentiality and privacy (7.4 p.16).			
*12. This program provides for the use of a broad range of medically approved FP methods on site or by referral (Part II, 8.3 p.22)			
a. Barrier methods (male & female)			
b. IUD			
c. Hormonal contraceptives			
d. Fertility awareness methods including NFP			
e. Emergency contraception			
13. In determining the appropriate method of contraception, the personal preference of the client receives prime consideration unless the method selected has medical contraindications. *Contraindications are explained to the client (review client medical records) (Part II, 8.2 p.18).			
14. Clinic utilizes Delayed Exam protocol for COC/DMPA/Evra.			
a. %age of clients who return			
15. A pharmacy protocol is utilized (Part II, 10.2 p28).			
a. Protocol is reviewed and signed annually by a Registered Pharmacist and the FP Program Coordinator (review protocol to assess review procedure) (per state law).			
b. Expiration dates are checked regularly and out-of-date supplies are removed from the shelves in the presence of the pharmacist (check pharmacy cupboard)			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
(per state law).			
c. All clinic locations are individually licensed (per state law).			
d. Treatment medication for non-clients is dispensed from separate stock not purchased with 340B discounts.			
16. Registered nurses dispense medications per chart order, which must be co-signed by the practitioner); nurse practitioners dispense medications following protocols or according to prescriptive authority (per state law).			
*17. In order to provide services for emergencies that arise outside of clinic hours, the program has medical back-up through liaison with a hospital clinic or physician. Arrangements for emergency care after program hours are (Part II 1, 7.3 p15):			
a. In effect			
b. Posted (English and Spanish)			
c. After hours phone message in English/Spanish			
c. Explained to new clients			
*18. Agency has policy/procedure for Infection Control that includes cleaning of room, instruments, and other equipment. (Part II, 10.1 p.27).			
19. CPR Training is available to staff (Part II, 7.3, p. 15)			
20. Agency maintains a sterilization log or record which includes all clients referred for sterilization and			
a. Documentation of whether the procedure was completed			
b. If not completed, the reason the procedure was not completed			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
c. Documentation of follow up for each procedure i.e. HSG/sperm count			
d. Documentation that the Provider was paid for the procedure and F/U testing			

E. CLIENT REVISITS

1. Oral Contraceptive/Evra/Nuvaring/Implanon clients (per package insert):			
a. Are scheduled to return no later than 3 months after initial prescription and no less frequently than every year thereafter.			
b. During revisits, an interim history is taken, including but not limited to:			
1) Pain, especially in arms and chest			
2) Headaches & visual problems			
3) Mood changes			
4) Leg complaints			
5) Vaginal bleeding and/or discharge			
6) Sexually Transmitted Disease history			
7) Satisfaction with method			
c. Blood pressure and weight are checked.			
d. Laboratory procedures are performed as indicated.			
2. IUD clients (per IUD insert):			
a. Are scheduled to return no later than 3 months following insertion			
b. During 3 month recheck, an examination is made including visualization of the cervix and bimanual examination			
c. During any revisits an interim history is taken including but not limited to:			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
1) Review of lower abdominal pain, chills, fever, and abnormal vaginal bleeding and/or discharge			
2) Other complaints client has about the device			
3) Satisfaction with method			
d. During any revisits lab procedures are performed as indicated			
3. Diaphragm/cap clients are scheduled to return within 2-4 weeks after initial fitting to confirm that they know how to position the diaphragm/cap correctly, to ascertain whether it fits and to determine satisfaction with method (per method insert).			
4. All clients return at least every 2 years for total evaluation.			
5. IUD users and hormonal contraceptive users return annually for examination and appropriate labs (per IUD/OCP/Evra/NuvaRing/DMPA/Implanon insert).			
*6. All clients receive counseling on STD/HIV risks, prevention and referral services (Part II, 8.2 p.19).			

F. ADDITIONAL SERVICES

*1. This program has, by prior arrangement, a group of agencies to whom clients may be referred, because of problems noted at the time of the history and physical examination or laboratory testing, or because of problems arising as a result of the contraceptive method, or because the client requested an additional evaluation (check list of referral agencies which includes name, specialty, address and telephone number) (Part II, 7.4 p.16).			
*2. This program provides follow-up, either directly or by referral, for the following specific conditions:			
a. Medical problems beyond the scope of the treatment facility (Part II, 7.4 p.16).			
b. Positive STD (Part II, 9.2 p.26).			
c. Abnormal cervical cytology (Part II, 9.1			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
p.26).			
d. Lack of immunity to rubella/Hepatitis B			
e. Pregnancy related services when appropriate (Part II, 8.6 p.24)			
f. Infertility work-up and/or therapy of an extensive nature (Part II, 8.5 p.24).			
g. Clients or partners of clients requesting information about and/or operation for sterilization if that service is not available on site (Part II, 8.4 p.23).			
h. Genetic counseling (Part II, 9.4 p.27).			
i. Mental health issues, i.e., domestic violence, past or present physical/sexual/emotional abuse (Part II, 9.3 p.27).			
j. Substance use, i.e., drug/alcohol/smoking (Part II, 9.3 p.27).			
k. Nutrition services (Part II, 9.3 p.27).			
l. Referral regarding Medicaid eligibility and enrollment			
3. Interpreters are available as indicated.			

G. MEDICAL RECORDS

*1. This program maintains complete medical records for every client in accordance with accepted professional standards. The medical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling of information (check client medical records) (Part II, 10.3 p.28).			
*2. All information obtained by program personnel from participants is held confidential (Part II, 10.3 p.28). No client information obtained by staff is disclosed without written consent, unless information is disclosed in summary, statistical or other form when the information does not disclose the client's identity (Part I, 5.2 p 5). Client's			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
sign a Notice of Privacy Practices, (review this notice – available in other languages?).			
*3. Records are secured by lock when not in use (Part II, 10.3 p.28).			
*4. All client contacts, including phone calls, are documented in the medical record (Part II, 10.3 p.28).			
H. CLIENT INTERVIEW AND EDUCATION SESSION			
1. This program provides information on the effective usage of contraceptive devices and practices through individual and/or group education sessions which includes:			
*a. Information on all contraceptive methods, their benefits, risks, effectiveness and potential side effects			
b. Information about basic female and male reproductive anatomy and physiology (Part II, 8.1).			
c. Information on the value of fertility regulation in maintaining individual and family health (Part II, 8.1).			
*d. Information on clinic services and procedures (Part II, 8.1).			
*e. An explanation of the physical/pelvic exam, if one is required. (Part II, 8.1).			
f. An explanation of breast self exam/testicular self exam when indicated.			
*2. Post-exam interviews include:			
a. Instructions on correct usage of the method selected and signs and symptoms of any method-related problem (written and verbal) (Part II, 8.2).			
b. An explanation of procedures for emergencies and complications (written and/or verbal) (Part II, 8.2).			
c. A discussion of the history, physical exam, and any laboratory studies in relation to the client's health and contraceptive plans (Part II, 8.3).			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
d. An explanation of the return visit schedule and instructions to make an appointment at an appropriate interval (Part II, 8.3).			
e. An explanation of any referral recommendations (Part II, 8.3).			
f. Discussion of increased nutritional needs for IUD and Depo users .			
g. Instructions for treatment and follow-up of any additional services as needed (Part II, 8.3).			

I. SPECIAL COUNSELING

1. Pre-conception counseling is provided regarding future pregnancies.			
*2. Counseling is provided regarding pregnancy management, sterilization, and other individual problems, as indicated (Part II, 8.1 p.17, 8.2 p.18-19, 8.4 p.23).			
3. Counseling is provided regarding the benefits of folic acid supplementation.			
4. Counseling is provided on osteoporosis prevention, e.g., calcium for Depo users			
*5. Adolescents are counseled and encouraged to discuss their visit with a parent (Part II, 8.7 p.25).			
*6. Adolescents are counseled about sexual coercion. (Part II, 8.7, p.25)			
*7. Adolescents are counseled about abstinence			

J. CONSENT FORMS

*1. Program and method-specific informed consents are signed by the client before receiving medical services/methods, are part of the client record, and are (Part II, 8.1 p.17-18):			
a. Written in a language easily understood by the client			
b. Available in other than English if			

**SECTION 1.11
RISK MANAGEMENT / QUALITY ASSURANCE POLICY**

SUBJECT	YES	NO	COMMENTS
applicable			
c. Inclusive of a statement that the client has been counseled, read the appropriate informational material and understands the content of both			
d. Reviewed and updated when there is a change in contraceptive method.			
e. Cosigned by translator if indicated.			

K. QUALITY ASSURANCE

1. Results of internal twice-yearly audits from last three years are on file at CDPHE (Part I, 6.3 p.8).			
2. There is follow-up on the results of these audits (Part I, 6.3 p.8).			
3. Comparison of data elements in 10 charts vs. the IRIS records results in a score of \geq 90%.			
4. Periodic review of client records is done by clinic staff to assure completeness and legibility. (Part II, 10.4 p.30).			
5. Policy is in place re the percentage of charts cosigned by the medical consultant. (Part II, 10.4 p.30).			

L. MANDATORY REPORTING

*Agency follows state statute regarding mandatory reporting of child/sexual abuse and domestic violence			
Internal written mandatory reporting policy			

Describe observed clinic flow: