

SECTION 2.1 QUALITY ASSURANCE

QUALITY ASSURANCE

A quality assurance system must be in place that provides for ongoing evaluation of personnel and services. All agencies must develop and implement a plan for internal program review and evaluation of its services to assure the provision of quality services and compliance with basic standards and policies. (Program Guidelines 10.4, p.30)

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.

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
 - 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

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- c. Financial Risk Management System (FRMS)**
- d. 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
- 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 committee meetings and minutes
- r. Progress reports on agency work plan objectives
- s. Insurance policies and requirements
- t. Emergency plans and incident reports
- u. Consultation with the Medical Director

*Refer to Section 1.11 - Risk Management/Quality Assurance Policy, pages 1-5 in the Nursing Manual for more information.

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DELEGATE AGENCY ANNUAL WORK PLAN

All agencies must submit an annual work plan and progress reports. The work plan goals and objectives are based on the Goals and Objectives from the Colorado Department of Public Health and Environment's Title X Grant Application. Work plan activities describe how each agency will attain a desired outcome objective while taking into consideration their specific community's needs.

Colorado Department of Public Health and Environment (CDPHE) Family Planning Program staff will provide agencies with a work plan template for the contract year in the summer. Progress reports are due to the CDPHE Family Planning Program in January (covering July-December) and July (covering January - June) each year.

The work plan should be available to all staff upon request.

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MEDICAL POLICY ADVISORY COMMITTEE (MedPAC)

Definition

Title X requires that the Colorado Department of Public Health and Environment (CDPHE) provide an opportunity for maximum participation by existing or potential sub-grantees in the ongoing policy decision making of the project, including input into establishing standards and guidelines [42 CFR 59.5(a)(10)(ii)]. The CDPHE Family Planning Program Medical Policy Advisory Committee, hereafter referred to as MedPAC, is a standing advisory committee that provides continuous support and recommendations to the CDPHE Family Planning Program, its service providers and consumers. MedPAC is staffed by the CDPHE Family Planning Program Administrative and Nursing Consultants.

Advisory Role

While MedPAC does not set policies or administer programs, the CDPHE Family Planning Program will consider all committee recommendations in making decisions.

Confidentiality

MedPAC participants are subject to the same rules of confidentiality as department personnel. Information shared with the committee may be confidential or sensitive in nature and should not be disclosed.

Conflict of Interest

Participants of MedPAC who have a personal and/or financial interest in organizations which would benefit from any committee action, or recommendation, must disqualify themselves from discussion on those actions.

Communication and Education

MedPAC participants are expected to communicate community attitudes and needs to CDPHE Family Planning Program staff, to recommend changes in program policies and procedures, and to otherwise make recommendations during the CDPHE Family Planning Program's decision-making process. After decisions have been made, MedPAC participants may be asked to help the CDPHE Family Planning Program to effectively communicate with and educate providers, consumers, and the public.

Committee Composition

The CDPHE Family Planning Program believes that diversity is essential to an effective committee. Delegate agencies should be represented geographically and by delegate type to the extent possible. Participation in MedPAC is open to staff members from all delegate agencies.

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Meetings

MedPAC meetings will be held quarterly. The length of the meeting will be determined by the agenda requirements. Participants may attend meetings either in person or via a conference call. **Attendance at quarterly MedPAC meetings is strongly encouraged, but not required.**

Co-Chairs

MedPAC shall have two co-chairs. The co-chairs shall be elected from MedPAC participants. They shall be kept advised of the general affairs of the program and will be asked for input into MedPAC meeting agendas. They may be asked to provide additional input into program activities and policies outside of meetings. Term of office for co-chairs shall be two years, and co-chairs may serve no more than two terms. Elections will be held each year, and the terms of each co-chair will be staggered, not running concurrently.

Minutes

CDPHE Family Planning Program staff is responsible for taking the minutes of each MedPAC meeting and for distributing to members all appropriate correspondence and materials.

MedPAC Objectives

1. To help the CDPHE Family Planning Program and delegates analyze problems and develop recommendations to improve the effectiveness of the CDPHE Family Planning Program in serving clients, and the efficiency and responsibility with which it uses public funds;
2. To advise on existing and future state and local family planning program needs and plans to meet those needs;
3. To promote and generate public interest and support for family planning services;
4. To provide information and feedback to state staff and MedPAC participants concerning rural and urban needs and current developments relevant to family planning at the local level.

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**CDPHE FAMILY PLANNING PROGRAM POLICY ON RESPONDING TO CONSUMER
COMPLAINTS**

The CDPHE Family Planning Program welcomes feedback from consumers. Staff is expected to respond quickly to complaints or concerns received by telephone; preferably by the end of the business day the call was received. If a consumer wishes to submit the complaint in writing, it should be addressed to the Director of the Family Planning Program. Procedures are as follows:

- When a complaint is received by the CDPHE Family Planning Program, the standard form must be completed by the complainant or the information can be taken over the telephone.
- The Director of the Family Planning Program or a designee will investigate the complaint and respond to the complainant within five working days.
- If a complaint is investigated and it is determined that the delegate agency or special project is out of compliance with federal or state law or Title X regulation, the agency must submit a compliance plan within six weeks.

The following is a sample of a Consumer Complaint Form. This form can be downloaded from the CDPHE Family Planning Program website at:

<http://www.colorado.gov/cs/Satellite/CDPHE-PSD/CBON/1251618366665>

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CONSUMER COMPLAINT FORM

NAME: _____ **DATE:** _____

ADDRESS: _____ **ZIP CODE:** _____

DAY TIME PHONE: _____ **EVENING PHONE** _____

NATURE OF COMPLAINT (continue on back of form if needed)

Name/address of the clinic where you were seen: _____

What name did you use when you were seen at the clinic? _____

Have you been seen as a client in that clinic before? No Yes

What name(s) have you used before? _____

What service did you receive related to the above complaint? _____

What day and time did you receive that service? _____

Did you pay for that service? No Yes What was the fee? _____

What were the names of the clinic staff that served you, related to the above complaint?

Please return this form by _____ to:

**Family Planning Unit Manager
Women's Health Branch
PSD-WHU-A4
Colorado Department of Public Health & Environment
4300 Cherry Creek Drive South
Denver, Colorado 80246**

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ADMINISTRATIVE AND NURSING CONSULTANTS

The objectives of having administrative and nursing consultants are as follows:

1. To improve communication and cooperation between the central office and delegate agency staff by providing one primary contact at the State level for administrative issues and medical/nursing issues.
2. To assess delegate agencies' needs for administrative or medical consultation, training and technical assistance, and to coordinate the provision of these services.
3. To provide Title X program orientation to new delegate agency staff.

ADMINISTRATIVE CONSULTANT RESPONSIBILITIES

- Determine and coordinate training, consultation, and technical assistance needs of the delegate agency staff.
- Review annual budgets, Expenditure Revenue Reports and client volume with the delegate's coordinator, if requested.
- Assist delegate agency staff in performing cost analysis and analyzing the results.
- Provide general orientation to the Family Planning Program to new delegate agency staff, as requested.
- Assist delegate agency staff in developing marketing and outreach plans as needed.
- Assist delegate agency staff in developing and completing activities for the Work Plan.

ADMINISTRATIVE SITE VISIT

The purpose of the administrative site visit is to determine whether delegate agencies are managed effectively and comply with Title X, federal, and state requirements, as well as with the terms, conditions and specifications of the contract. [45 CFR Part 74.41 & 74.47; 45 CFR 92.37]

The Administrative Consultant conducts an administrative site visit every third year, alternating with medical site visits and medical chart audits. Fiscal site visits will be conducting on a separate cycle. Please see Section 1.11 Risk Management/Quality Assurance Policy of the Nursing Manual for more information on medical site visits.

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ADMINISTRATIVE SITE VISIT PROCEDURES

1. The Administrative Consultant should arrange a date with the delegate agency's Family Planning Coordinator approximately 6 weeks in advance for the site visit. Generally, it is best to schedule an Administrative Site Visit on a non-clinic day. Copies of a confirmation letter should go to the coordinator and the coordinator's supervisor.
2. The pre-visit form should be sent to the coordinator at least six weeks prior to the scheduled visit. It should be completed by the coordinator and returned to the consultant 2 weeks before the visit. The list of materials to be reviewed on site should always be sent with the pre-visit tool. Prior to the visit, it is the responsibility of the consultant to review recent semi-annual expenditure reports submitted to central office; review the most recent funding formula amount; review data regarding clients served; review the agency's work plan; and be familiar with the agency file and previous correspondence between the agency and central office.
3. At the beginning of the site visit, an entrance interview should be held with the appropriate delegate 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.
4. The consultant should spend most of the day with the Family Planning Coordinator to review the completed pre-visit tool, materials requested, and to complete the site visit tool. Whenever possible, the consultant should confirm compliance by observation vs. report (e.g., if the Bill of Rights for Clients is posted and visible to clients).
5. The consultant should tour the clinic and observe the interactions of the front desk staff with clients, if possible.
6. The consultant should review approximately 10 charts, checking for documentation of income, charges, collections, and donations, and comparing select chart information to data reported in IRIS.
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.
8. A final report should be completed and emailed to the delegate agency within four weeks of the visit. Copies should be circulated among CDPHE Family Planning Program staff, sent to the local coordinator's supervisor, and to the public health nurse consultant from the CDPHE Office of Planning and Partnerships. The report, completed site visit tools, and subsequent follow-up correspondence should be placed together in the agency's file in the state's 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.

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ADMINISTRATIVE PRE-VISIT MATERIALS CHECKLIST

Agencies are asked to prepare the following items for assessment at the Administrative Site Visit.

- Schedule of clinic hours that is made available to clients, i.e. wall chart or handout
- Agency organizational chart
- One copy of any publications (brochures, educational materials, small print media, or flyers) produced by the agency's family planning program. If creation of the publication was funded, in part, by the family program, please ensure the following language is included: "This brochure was developed (in part) with federal funds from the Office of Population Affairs grant FPHA080079."**
- Family Planning Program sliding fee/charge schedule currently in use
- Federal Poverty Guidelines currently in use
- Most recent Cost Analysis documentation
- Written procedure and policy manuals for agency/program staff (general, fiscal, personnel, etc.), including the following. (These policies may exist at a program, agency or county level):
 - Written policy that no person is denied treatment that is available and medically indicated on the basis of religion, age, sex, race, color, creed, national origin, handicap, number of pregnancies, marital status, contraceptive preference, or the source of payment of his/her care (this is covered in the CDPHE Family Planning Program's Bill of Rights for Clients, if used by the agency)
 - Written policies and procedures for any required family planning services provided by referral as well as written agreements for such services with referral providers (if applicable)
 - Written policy/policies that establishes safeguards to prevent employees, consultants, members of the governing board, and advisory committees from using their positions for the purposes of personal gain
 - Written personnel policies
 - Written plans and procedures for the management of emergencies/disasters
 - HIPAA policies and procedures
 - Written policies and procedures for overall fiscal management of the program/agency
 - Written policies and procedures for billing and collecting client fees
 - Written purchasing policies and procedures
 - Written policy for aging outstanding accounts
- Orientation and in-service training materials used with new staff
- CDPHE Family Planning Program Administrative Manual **with completed signature sheets. These should be signed initially and when updates are circulated.**
- CDPHE Family Planning Program Nursing Manual

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- ❑ Minutes/determinations from the agency's Information and Education (I&E) Committee, including a list of current committee members
- ❑ Minutes from the agency's Advisory Committee (if separate from the I&E Committee)
- ❑ Ten client records from a recent clinic and corresponding log/charge sheets/"super bills" to ascertain income codes and charges
- ❑ Proof of most recent financial audit
- ❑ Letter used to collect outstanding balances from clients
- ❑ **Policy or description of the agency's cash management procedure.**

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The following is a sample of the Administrative Site Pre-Visit Tool. This form can be downloaded from the CDPHE Family Planning Program website at:

<http://www.colorado.gov/cs/Satellite/CDPHE-PSD/CBON/1251618366665>

STATE OF COLORADO

John W. Hickenlooper, Governor
Christopher E. Urbina, MD, MPH
Executive Director and Chief Medical Officer

Dedicated to protecting and improving the health and environment of the people of Colorado

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Denver, Colorado 80246-1530 8100 Lowry Blvd.
Phone (303) 692-2000 Denver, Colorado 80230-6928
Located in Glendale, Colorado (303) 692-3090
<http://www.cdphe.state.co.us>



Colorado Department
of Public Health
and Environment

**FAMILY PLANNING PROGRAM
ADMINISTRATIVE SITE PRE-VISIT TOOL**

Please fill out this form and return it, along with a copy of the organizational chart for your agency, if available, to the Administrative Consultant at least 2 weeks prior to the site visit.

Date:	
Name of person completing this form:	
Agency:	

1. List all Family Planning Clinic Sites

Clinic Location:	Average number of visits per month at each site:

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2. For each Family Planning Clinic Site listed in #1, please provide the following:

First Clinic Site:

a. Clinic Site:		
b. List clinic days and regular hours of operation for this site		
<i>Day of the week:</i>	<i>Hours:</i>	
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		
c. List staff members that work in the family planning program at this site and the approximate amount of time (%) spent doing family planning:		
<i>Staff Member:</i>	<i>Percent of time doing family planning:</i>	
d. For this site, does your agency provide any required family planning services (i.e., IUD insertion, etc.) off-site or by referral?:		
Please list this site's family planning referral providers and subcontractors below. These contractors may include individual practitioners who come into the clinic to provide services, physicians/practitioners who provide services such as IUD/Implanon insertions, vasectomies, Essures, HSGs, etc.		
Name of Subcontractor	Brief description of Services Provided	Written Agreement in place? (yes/no)

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Second Clinic Site (if applicable):

a. Clinic Site:		
b. List clinic days and regular hours of operation for this site		
Day of the week:	Hours:	
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		
c. List staff members that work in the family planning program at this site and the approximate amount of time (%) spent doing family planning:		
Staff Member:	Percent of time doing family planning:	
d. For this site, does your agency provide any required family planning services (i.e., IUD insertion, etc.) off-site or by referral?:		
<p><i>Please list this site's family planning referral providers and subcontractors below. These contractors may include individual practitioners who come into the clinic to provide services, physicians/practitioners who provide services such as IUD/Implanon insertions, vasectomies, Essures, HSGs, etc.</i></p>		
Name of Subcontractor	Brief description of Services Provided	Written Agreement in place? (yes/no)

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Third Clinic Site (if applicable):

a. Clinic Site:		
b. List clinic days and regular hours of operation for this site		
Day of the week:	Hours:	
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		
c. List staff members that work in the family planning program at this site and the approximate amount of time (%) spent doing family planning:		
Staff Member:	Percent of time doing family planning:	
d. For this site, does your agency provide any required family planning services (i.e., IUD insertion, etc.) off-site or by referral?:		
<i>Please list this site's family planning referral providers and subcontractors below. These contractors may include individual practitioners who come into the clinic to provide services, physicians/ practitioners who provide services such as IUD/Implanon insertions, vasectomies, Essures, HSGs, etc.</i>		
Name of Subcontractor	Brief description of Services Provided	Written Agreement in place? (yes/no)

Attach additional pages for additional clinic sites, if needed.

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3. For the clinic site that will be visited, please choose one week in the last three months that is most typical of your usual clinic process.

a. How many scheduled clients were seen?	
b. How many walk-ins?	
c. How many no-shows?	

4. For the clinic site that will be visited, if a client called today, how soon would she/he get an appointment for:

Type of Visit:	Length of time to get in:
a. Pregnancy Test	
b. Initial Exam	
c. Annual Exam	
d. Problem Visit (Medical)	
e. Supply Visit	
f. Repeat Pap Smear	
g. Delayed Exam	
h. Emergency Contraception	

5. Do you feel it takes too long for clients to get an appointment?

Yes	No

6. Do you use any of the following to remind clients of upcoming visits?

	Yes	No
a. Mailed Reminder		
b. Telephone Reminder		
c. Other Reminder (please specify below)		

Specify here:

7. Is (are) your clinic(s) close to public transportation?

Yes	No

If applicable, please describe proximity of bus lines or other means of public transportation (in box below):

8. To whom does the Program Coordinator report?

a. What kinds of decisions relative to the program are made by this next level of administration?	
b. Who does the program planning?	
c. Who does the budget?	

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<i>9. List the most important accomplishments of the last year:</i>	
<i>a. What major barriers or problems did you encounter this past year?</i>	
<i>b. What changes are planned for the next year?</i>	

<i>10. Would you like consultation or technical assistance regarding:</i>	<i>Yes</i>	<i>No</i>
<i>a. Decreasing your no-show rate</i>		
<i>b. Scheduling</i>		
<i>a. Program planning/evaluation</i>		
<i>b. Budgeting/financial management</i>		
<i>c. Clinic/Client Flow</i>		
<i>d. Training (if yes, specify in the box below)</i>		
<i>e. Other (if yes, specify in the box below)</i>		

SAMPLE

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11. Is your agency currently participating in any human subjects research projects involving Title X clients or resources?
 No (no further information is needed) Yes (please fill out the following table):

Title of research project	Institutional Review Board (IRB) approved (yes/no)	Which IRB	IRB number	Funder	Notified CDPHE Family Planning Program? (yes/no)
<i>EXAMPLE: Video intervention to prevent STDs</i>	<i>Yes</i>	<i>COMIRB</i>	<i>10-123</i>	<i>CDC</i>	<i>Yes (9/8/10)</i>

SAMPLE

**SECTION 2.1
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The following is a sample of the Administrative Site Visit Tool. This form can be downloaded from the CDPHE Family Planning Program website at:

<http://www.colorado.gov/cs/Satellite/CDPHE-PSD/CBON/1251618366665>

STATE OF COLORADO

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Colorado Department
of Public Health
and Environment

**FAMILY PLANNING PROGRAM
ADMINISTRATIVE SITE VISIT TOOL**

Delegate Agency: _____

Consultant: _____

Delegate Staff in Attendance: _____

Date of Visit: _____

Items marked with an asterisk ("*") are program requirements or "musts" for compliance. Items not marked with an asterisk are recommendations or "shoulds" for the program.

The "[42 CFR 59.5]" citation refers to the location of the requirement/recommendation in the Title X federal law (Code of Federal Regulations).

References such as "(6.5 p.5)" indicate the location of the requirement/recommendation in the *Program Guidelines For Project Grants For Family Planning Services*.

The "Federal Program Review Tool" indicates requirements outlined in the federal program review tool that were not clearly outlined elsewhere.

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CONSULTANT PRE-SITE VISIT REVIEW	YES	NO	REMARKS
*1. a) The delegate agency has a written work plan that relates to the CDPHE Family Planning Program's Title X goals and objectives.			
*b) It is renewed and updated at least annually and is used to monitor and evaluate the program.			
2. The site visit pre-tool was completed and returned prior to the visit as requested.			
3. The following have been submitted in a timely fashion:			
*a) FTE report by January 31 of each year. (On time in the last 3 years?)			
*b) Semi Annual expenditure reports by February 7 and August 7 of each year. (On time in the last 3 years?)			
*c) Work plan progress report by June 30 and work plan by January 31 of each year. (On time in the last 3 years?)			
*d) Independent medical audits by the specified due dates. (On time in the last 3 years?)			
*e) The sliding fee scale by September 1 st every year. (On time in the last 3 years?)			
*f) Client satisfaction survey summary results by October 31 of each year. (On time in the last 3 years?)			
*g) Family Planning data quarterly reports have been signed and submitted on time. (On time in the last 3 years?)			
h) Cost reimbursement statements.			
i) Their current timely submission percentage is above 75%. (What is their %?)			
j) They have never missed out on being part of a method buy due to tardy submissions.			
4. The agency is on track to meet their contracted number of target clients. (The agency has seen 90% of contract goal for time period)			
CLIENT RIGHTS AND SERVICES	YES	NO	REMARKS
*1. The program has a policy, in writing, that no person is denied treatment that is available and medically indicated on the basis of religion, age, sex, race, color, creed, national origin, handicap, number of pregnancies, marital status, contraceptive preference, or the source of payment of his/her care [42 CFR 59.5 (a) (4)] or uses the CDPHE Family Planning Program's Bill of Rights for Clients.			
*a) The program has a written Client Bill of Rights that includes the points on the recommended Bill of Rights for Clients.			
*b) It is posted or given to clients in writing.			
*2. Services are provided without a residency requirement or a physician referral [42 CFR 59.5, (b)(5)].			
*3. Clients voluntarily choose to receive services and their contraceptive method of choice without coercion (5.1 p.5) [42 CFR 59.5 (a)(2)].			

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CLIENT RIGHTS AND SERVICES (cont.)	YES	NO	REMARKS
*4. Agency personnel have been informed that they may be subject to prosecution if they coerce or they try to coerce any person to undergo abortion or sterilization procedures (5.1, p.5) [42 CFR 59.5(2)]			
5. *a) Clients are informed that fees for services are based on their income and family size and that they will be charged according to a fee scale (6.3 p.7) [42 CFR 59.5 (a)(8)].			
* b) Clients are informed that no one is denied services because of an inability to pay (6.3 p.7).			
*c) Clients whose income is at or below 100% of poverty are not charged or billed for required services (6.3 p.7-8) [42 CFR 59.5 (a)(7)].			
*d) Fees for minors requesting confidential services are based on their own income (6.3 p.7; OPA Program Instruction Series 97-1). (What is the methodology for determining if clients are seeking confidential services?)			
*e) #4 a-d are posted or given to clients in writing (CDPHE). (Do they use the CDPHE Family Planning Program's "Dear Family Planning Client" letter?)			
6. a) The agency takes reasonable steps to ensure that clients with limited English proficiency have meaningful access to services. (If a client had a language need, how would they address it?) [Title VI, Civil Rights Act, 1964 and 45 CFR 80.3(b)(2)]			
*b) Consent forms and education materials (including HIPAA notices and consents) are available in the primary language of all clients; or interpreters are available for non-English speaking clients (8.1 p.17).			
c) Are bilingual staff members formally trained in medical interpretation and/or translation?			
7. *a) When required services are provided by referral, the policies and procedures are in writing, including a description of the services provided (6.1 p.6; 7.4 p.16) [42 CFR 59.5 (b)(9)]. <i>Delegates must have their own policy.</i>			
*b) A written agreement exists between the delegate agency and the referral agency or provider (7.4 p.16)			
*c) There is a mechanism for reimbursement of costs to a referral agency providing required services (7.4 p.16).			
*d) The agreement specifies fiscal responsibility for unexpected follow-up/complications (CDPHE).			
8. The program provides family planning services to males.			
9. The program provides care to walk-in clients.			
10. Evening and/or weekend hours are available (6.4 p.9).			
*11. If there is a waiting list for appointments, target clients are given priority for services (8.7 p.25) [42 CFR 59.5 (a)(6)].			
*12. Client's acceptance of family planning services is not a prerequisite to eligibility or receipt of a non-Title X service (5.1 p.5) [42 CFR 59.5 (a)(2)].			
*13. a) The agency has an after hours phone message to instruct clients what to do in case of emergency.			

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CLIENT RIGHTS AND SERVICES (cont.)	YES	NO	REMARKS
*b) If a significant proportion of clients speak a primary language other than English, the message is also in the primary language of that population.			
*14. The agency notifies the CDPHE Family Planning Program of human subjects research projects in which family planning clients are subjects and the agency adheres to legal requirements governing human subjects research. (5.5 p. 6) [HHS Grants Policy Statement p.II-9]			
COMMUNITY OUTREACH AND MARKETING	YES	NO	REMARKS
1.*a) The agency establishes and implements planned activities to make their services known to the community (6.9 p.12) [42 CFR 59.5 (b)(3)].			
*b) The agency makes special efforts to make their services known to the target population (6.9 p 12) [42 CFR 59.5 (b)(3)].			
2. Written information about services and clinic hours is available to clients and agencies referring clients to family planning (pamphlet, referral card, etc.).			
3.*a) The agency conducts community education programs regarding reproductive health (6.9 p.12) [42 CFR 59.5 (b)(3)].			
b) Presentation records/evaluations are kept on file.			
4.*a) The agency has an Information and Education (I&E) Committee that approves educational materials prior to their distribution [42 CFR 59.6 (a)]. This committee is made up of 5-9 members [42 CFR 59.6 (b)(1)] who broadly represent the client population [42 CFR 59.6 (b)(2)] and review materials according to Title X guidelines (Consider educational and cultural background of the recipient; Consider community standards and appropriateness for community served; Are factually accurate) (6.8 p.10)[42 CFR 59.6 (a)].			
*b) There are written records of I&E committee determinations on file (6.8 p.11) [42 CFR 59.6(b)(3)(v)].			
5.*a) The agency has an Advisory Committee that participates in the development, implementation, and evaluation of the project, or uses the I & E Committee for these purposes. This committee meets annually (6.9 p.11) [42 CFR 59.5 (b)(10)].			
b) There are minutes of these meetings on file.			
*c) The committee is broadly representative of the population served [42 CFR 59.5 (b)(10)].			
*d) Members are knowledgeable about community needs [42 CFR 59.5 (b)(10)].			
*6. Delegate publications acknowledge federal support (6.10 p.12).			
* 7. The federal government has unrestricted use of publications funded by Title X.			

**SECTION 2.1
QUALITY ASSURANCE**

PERSONNEL	YES	NO	REMARKS
1. There is a written organizational chart for the agency, which defines lines of authority and responsibility; is revised as necessary; and is available to agency personnel (HHS OASH Grant Application; OPA/OFPP Guidelines for Title X Grant Application Preparation).			
2.*a) Written personnel policies exist which detail procedures for equal employment opportunities [Title VI Civil Rights Act]. <i>Delegates/Agencies/Counties must have their own policies.</i>			
b) Written personnel policies exist which detail procedures for staff recruitment; selection; performance evaluation; promotion; termination; compensation; benefits; and discipline (6.5 p.9). <i>Delegates/Agencies/Counties should have their own policies.</i>			
*c) A formal grievance mechanism is available for all staff (6.5 p.9 and Federal Program Review Tool).			
3. a) Project staff is broadly representative of the population served (6.5 p.9) [42 CFR 59.5 (b)(10)].			
b) Project staff is sensitive to and able to deal effectively with the cultural characteristics of the client population (6.5 p.9) [42 CFR 59.5 (b)(10)].			
4.*a) Employee compensation is reasonable and comparable to that paid for similar work in the area [Title VI Civil Rights Act]. (Do they do a salary survey?)			
b) Resources allow coverage when there is turnover, vacation, or illness.			
*5. The agency maintains confidential personnel records for each employee (6.5 p.10).			
*6. There is an established procedure for orientation and training for all staff that includes family planning and Title X specific training (6.6 p.10; OPA Program Instructions 11-01) [42 CFR 59.5 (b)(4)].			
7. a) There is ongoing training and continuing education available to all staff (6.6 p.10).			
b) Attendance at workshops/training is documented and kept on file in the employee's personnel file (6.6 p.10).			
c) A plan and a process is in place that evaluates the scope and effectiveness of staff training program.			
d) Staff routinely attends training on Federal and state requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as human trafficking (OPA Program Instructions 11-01, 06-01 and 99-1).			
8. All state and local program policy and procedure manuals are available to all staff (6.5 p.9).			
9. *a) All family planning program staff have reviewed Part 1 of the Administrative Manual and have signed the signature sheet.			
*b) The Family Planning Coordinator has reviewed Part 2 of the Administrative Manual and has signed the signature sheet.			
10. Written job descriptions are available for key personnel (HHS OASH Grant Application; OPA/OFPP Guidelines for Title X Grant Application Preparation).			

**SECTION 2.1
QUALITY ASSURANCE**

FACILITY	YES	NO	REMARKS
1.*a) The facility meets applicable standards for the management of emergencies established by the Federal, state and local government (e.g., local fire, building & licensing codes) (6.4 p.9).			
*b) Fire evacuation routes are prominently posted, and staff understand assigned emergency escape routes [29 CFR 1910.37 and 1910.38].			
*c) Exits are recognizable and free from barriers [29 CFR 1910.37].			
3.*a) The agency has written plans and procedures for the management of emergencies/disasters (6.4 p.9) [29 CFR 1910.38]. <i>Delegates/Agencies/Counties must have their own policy.</i>			
*b) Staff has completed training and understands their role in an emergency or natural disaster [29 CFR 1910.38].			
4. The traffic flow through the clinic is such that unnecessary embarrassment to the client is avoided and staff can function efficiently (6.4 p.9).			
5. There is adequate space for private consultation and interviews, to protect confidentiality (6.4 p.9).			
6. There are adequate bathrooms, changing areas, and exam areas (6.4 p.9).			
*7. The agency's location and facilities are accessible to handicapped visitors and clients (6.4 p.9).			
ADMINISTRATION	YES	NO	REMARKS
*1. The agency is properly organized and incorporated according to law, as a public or non-profit agency. 501(c) approval has been given by the IRS for non-profit agencies (3.1 p.2).			
2. Materials that were requested on the pre-visit checklist were available for the site visit.			
*3. Program has policies and procedures that address all applicable HIPAA regulations [65 FR 82462, 50312]. <i>Delegates/Agencies/Counties must have their own policy.</i>			
*4. The program has a policy in writing that establishes safeguards to prevent employees, consultants, members of the governing board, and advisory committees, from using their positions for the purposes of personal gain. (5.3 p. 6) [45 CFR 74.42; 45 CFR 92.36; HHS Grants Policy Statement p. II-7] <i>Delegates/Agencies/Counties must have their own policy.</i>			

**SECTION 2.1
QUALITY ASSURANCE**

FINANCIAL MANAGEMENT	YES	NO	REMARKS
1.*a) There are written accounting policies and procedures for overall fiscal management of the program (i.e. determining reasonableness, allocability and allowability of costs). (6.3 p.7-8) [45 CFR 74.21; 45 CFR 92.20] <i>Delegates/Agencies/Counties must have their own policy.</i>			
*b) There are written policies and procedures for billing and collecting client fees. <i>Delegates/Agencies/Counties must have their own policy.</i>			
*c) There are written purchasing policies and procedures [42 CFR 74.44; 45 CFR 92.36]. <i>Delegates/Agencies/Counties must have their own policy.</i>			
*2. There is an adequate chart of accounts that includes at a minimum, Expenditure Revenue Report (ERR) required line items [45 CFR 92].			
*3. A double entry system is used that balances income and expenditures [45 CFR 74.21; 45 CFR 92.20].			
*4. The agency has been audited by an auditor who has met established criteria for qualifications and independence (when?) (6.3 p.8) [OMB A-133, 500(a), GAGAS Standards].			
*5. There is adequate documentation of time and effort designated to Title X program (example: Continual time sheet showing program time) (OMB A-87 and A-122).			
*6. Family Planning income, including client fees and donations, are used only for program purposes [42 CFR 59.9; 45 CFR 74.24; 45 CFR 92.25]. (How are they sure?)			
*7. Payroll is prepared by someone other than the timekeeper [GAGAS Standards].			
8.*a) Separation of Duties: No one person has complete control over more than one key function or activity (e.g., authorizing, approving, certifying, disbursing, receiving, or reconciling) [OMB A-133, 300; 45 CFR 74.21; 45 CFR 92.20].			
*b) Custodial and security arrangements: Responsibility for physical security/custody of assets is separated from record keeping/accounting for those assets [OMB A-133, 300; 45 CFR 74.21; 45 CFR 92.20].			
*c) Unauthorized access to assets and accounting records is prevented [OMB A-133, 300 and 45 CFR 74.21]. (How?)			
9. a) Agency reconciles Title X cash receipts/collections to accounting system on either a daily or monthly basis. [45 CFR 74.21; 45 CFR 92.20]			
b) Receipts are completed and given to clients for all donations or payments. (What is the process?)			
c) Receipt amounts can be verified via billing software or numbered receipts.			
10. If an accountant does not maintain the system, the agency has accounting consultation available.			

**SECTION 2.1
QUALITY ASSURANCE**

FINANCIAL MANAGEMENT (cont.)	YES	NO	REMARKS
11. Dual signatures are required for check signing or there is a series of approvals required.			
12. There is a properly documented and administered petty cash fund limited to \$100.			
13. Bank accounts are reconciled promptly by persons not involved in disbursement functions [OMB A-133, 300 and 45 CFR 74.21].			
14. Central records are maintained which include purchase requisitions and receipts. [45 CFR 74.21 & 74.41; 45 CFR 92.20 & 92.36(b)(9)]			
15. a) The program purchases from bulk purchasing agreements [45 CFR 92.36 (5)].			
*b) Supplies purchased through the Federal Drug Pricing program (340B) are provided only to clients served in the Title X project. [Veterans Health Care Act of 1992]			
*c) The program has established controls over access to medications and supplies [45 CFR 74.21; 45 CFR 92.20]			
16. a) The agency has an inventory system to control purchase, use, reordering of medications and supplies. [45 CFR 74.21; 45 CFR 92.20]			
*b) The agency has documented equipment purchased with Title X funding in accordance with 45 CFR 92.32 or 45 CFR 74.34 (6..3 p.7). (Per Title X, equipment is any single item over \$5000)			
17. There is a comprehensive liability insurance policy in place that covers all segments of the project funded by the grant, including members of the governing board. (5.4 p. 6) (CDPHE contract).			
18. *a) The agency uses the most recent federal poverty guidelines to determine the client's charges [42 CFR 59.5 (a)(8)].			
*b) The fees for services are based on a local cost analysis (6.3 p.7 #1) [42 CFR 59.5(a)(8)].			
19. a) Client income is assessed and/or verified at least annually (6.3 p. 8).			
*b) Documentation of income, family size and income code are recorded (6.3 p. 8 #4). (Do they take self-declaration or written verification?)			
*20. Clients are asked about Medicaid eligibility and referred appropriately (6.3 p.7 #1) [42 CFR 59.5 (a)(9)].			
21. *a) In cases where a third party is responsible, bills are submitted to that party (6.3 p.7 #1) [42 CFR 59.5 (a)(9)].			
*b) Bills to third party payers show total charges without applying any discount unless there is a contracted reimbursement rate that must be billed per the third party agreement (6.3 p.8 #5) [42 CFR 59.5 (a)(9)].			
*c) Third parties authorized or legally obligated to pay for clients at or below 100% FPL are properly billed (6.3 p8 #3).			
22. *a) Efforts are made to collect past due accounts when confidentiality is not jeopardized. (6.3 p.8 #9).			
*b) There is a system to determine how much money is owed by clients and how long the debt is outstanding and not yet paid. (What is their system?)			

**SECTION 2.1
QUALITY ASSURANCE**

FINANCIAL MANAGEMENT (cont.)	YES	NO	REMARKS
*c) Statements are given to clients at the time of services and show total charges less any allowable discounts (6.3 p.7-8 #1&7).			
*d) A written policy for aging outstanding accounts is in place (6.3 p.8 #10). (What is their methodology for writing off overdue accounts?) <i>Agencies must have their own policy.</i>			
*e) Methods for collection of past due accounts are not coercive (6.3 p.7). (look at sample collection statement)			
23. *a) Donations from clients and program supporters are encouraged (6.3 p.8 #11).			
*b) Donations from clients are documented. (6.3 p.8 #11).			
*c) Clients are not pressured to make donations. Donations are not a prerequisite to the provision of services or supplies (6.3 p.8 #11). (What do they say?)			
*d) Billing requirements are not waived because of client donations (6.3 p.8 #11).			
24. Ongoing efforts are made to secure financial support from city, county or private organizations in the community.			
DATA MANAGEMENT	YES	NO	REMARKS
1. Data reports are routinely reviewed by program staff.			
2. Data reports are utilized in clinic management and long-range planning.			
3. Organization has written Information System policies and procedures to maintain and secure electronic and hard copy records.			

SECTION 2.1 QUALITY ASSURANCE

ADMINISTRATIVE SITE VISIT CHART REVIEW

Review at least ten charts from recent clinic days for which data has been entered/submitted to IRIS. Compare information in the chart to what was recorded in IRIS.

CHART # (IRIS #)	DO REVIEWED DEMOGRAPHICS AND PROCEDURES RECORDED IN IRIS REFLECT INFO IN CHART?	WAS CLIENT ASSIGNED THE CORRECT INCOME CODE?	WHERE IS INCOME CODE RECORDED? IS IT CURRENT?	WERE CHARGES FOR SERVICES COMPLETE & ACCURATE?	WERE CHARGES, COLLECTIONS, BALANCE DUE, & DONATIONS DOCUMENTED AND RECORDED?	LIST OTHER PROBLEMS THAT NEED DISCUSSION OR FOLLOW-UP.