

**ILLINOIS DEPARTMENT OF
HUMAN SERVICES**



**FAMILY PLANNING
PROGRAM
GUIDELINES**

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Mission Statement

The mission of the Illinois Department of Human Services Family Planning Program is to provide voluntary comprehensive family planning services to low-income individuals of reproductive age including information and means to enable personal choice in determining the number and spacing of their children, if and when pregnancy is desired. Through this effort, the program seeks to improve the well-being of communities by lowering the incidence of unintended pregnancy, improving maternal and infant health, and reducing the incidence of abortion.

Preface

The IDHS funded family planning service network, comprised of more than 100 geographically diverse clinical sites, is specifically created to address the unmet family planning needs of individuals in Illinois below poverty, as well as those slightly above poverty, and to provide access to those with special needs (such as adolescents). At these sites, no one is denied family planning care because of the inability to pay. The service network includes health departments, hospitals, private not for profit agencies, federally qualified health centers and community based organizations dedicated and trained for the provision of confidential reproductive health care.

Illinois Department of Human Services

Family Planning Program Guidelines

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PART I: GUIDELINES FOR DELEGATE AGENCY PROGRAM MANAGEMENT AND ADMINISTRATION

SECTION 1.0: INTRODUCTION TO THE IDHS FAMILY PLANNING PROGRAM GUIDELINES

The Illinois Department of Human Services (IDHS) Family Planning Guidelines have been revised and updated to reflect changes in the Federal policy, law and program priorities under Title X of the Public Health Services Act (42 U.S.C. 300, *et seq*), Illinois State regulations under the Illinois Family Planning Program Services Code (77 Illinois Admin. Code 635), Region V Infertility Prevention Project service guidelines, as well as Illinois State law that is applicable to the provision of family planning services. These Guidelines have been reviewed by the IDHS Family Planning Program Administrator, members of the Family Planning Advisory Council, representatives of delegate agencies, and the Family Planning Program staff and will be issued to family planning program staff at each service site. Any additions or revisions will be distributed as needed.

This document is organized into three major parts: Part I (Sections 1.0 through 6.11) contains guidelines for delegate agency program management and administration; Part II (Sections 7.0 through 10.4) includes guidelines for client services and clinic management; and Part III (Sections 11.0 through 11.3) consists of the evaluation criteria and monitoring components, as well as the evaluation methodology, used by IDHS for ongoing program review. These guidelines and criteria are included in this manual for delegate agency self-evaluation and to assure delegate compliance with the program requirements.

1.1 PURPOSE OF THE GUIDELINES

The IDHS Family Planning Program Guidelines have been developed to direct program personnel, including physicians, mid-level clinicians, and other clinic staff on the program requirements and recommendations for the effective delivery of family planning and related reproductive health care in the local setting. As a quality assurance mechanism, this manual is designed to assure compliance with program regulations, to serve as a resource for staff orientation and continuing education, and to ensure the continuity and quality of care for all clients receiving reproductive health care in the Illinois family planning service network.

These Guidelines reflect the minimum acceptable level of care. The IDHS does not permit deviation from the requirements set forth by its funding agencies and governmental regulations. IDHS also expects family planning services to comply with other pertinent regulations, such as those required by the CDC STD Guidelines, CLIA, OSHA and HIPAA requirements.

1.2 DEFINITIONS

Throughout this document, the words “**required**” or “**must**,” indicate mandatory program guidelines, services or requirements. The word “**should**” indicates recommended program guidelines. The words “**can**” and “**may**,” indicate suggestions for consideration by delegate agencies.

“**Evaluation**” refers to review criteria, instruments and activities that can be used to examine family planning administration and clinical operations. Meeting the standards established in these evaluation criteria will demonstrate compliance with program guidelines/requirements and existence of a particular service.

The “**grantee**” is the entity that receives the federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The Illinois Department of Human Services Family Planning Program is a Grantee of Title X funds in Illinois.

“**Delegate agencies**” are those entities that provide family planning services with Title X funds under a negotiated, written agreement with the grantee. The terms “delegate agency” and “delegate” are used interchangeably in this document.

“**Service (clinic) sites**” are those locations where services actually are provided by the delegate agencies.

SECTION 2.0: THE LAW, REGULATIONS, GUIDELINES, AND PROGRAM PRIORITIES

The Illinois Department of Human Services has the primary responsibility in Illinois to receive and administer state and federal funds for family planning services. In this capacity, the IDHS Family Planning Program is guided by both Federal and State law, regulations, guidelines, program instructions and program priorities.

Law: At the Federal level, Congress enacted the Family Planning Services and Populations Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs" to the Public Health Service Act to enable persons voluntary access to family planning services. Section 1001 of the Act (as amended) authorizes grants to "assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services and services for adolescents)." The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

Illinois law addressing birth control services provided to minors is called the "Birth Control Services to Minors Act " (410 ILCS 305/) found under tab 6 "Federal and State Rules and Regulations."

Regulations: The regulations governing Title X [42 CFR Part 59, Subpart A] set out the requirements of the Secretary, U.S. Department of Health and Human Services, for the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act.

Guidelines: To interpret the law and regulations the US Department of Health and Human Service, Office of Public Health and Science, Office of Population Affairs (OPA), Office of Family Planning has issued *Program Guidelines for Project Grants for Family Planning Services*, revised in January 2001.

Program Instructional Memos: To provide further clarification, interpretation and/or explanation of the law, regulations, guidelines or program changes, OPA will issue program instructional memos as needed. These memos, called *Program Instruction Series* are dated and catalogued serially each calendar year. The instructional guidance(s), and any corresponding attachments, are distributed to grantees for further distribution to delegate agencies.

Program Priorities: Federal Program Priorities, which include Legislative Mandates and Key Issues, are revised annually and distributed to Grantees with their Notice of Grant Award (NOGA). IDHS prepares an annual work plan based on these priorities. Delegate agencies are required to address Priorities and Key Issues as identified in the IDHS annual grant application packet.

State Code: In addition to Title X, the IDHS family planning program operates under policies and guidelines authorized by the State of Illinois through the Illinois' Family Planning Services Code (77 Illinois Adm. Code 635), implemented in 1991 with minor revisions in 1994. All funding sources used by the Illinois Family Planning Program are administered in accordance with Title X law and guidelines.

Copies of the Federal and State issued program requirements are included for reference and clarification as Tab 6 and additional program instructional guidance as Tab 7 of this manual.

SECTION 3.0: THE APPLICATION AND GRANT AWARD PROCESS

3.1 APPLICANT ELIGIBILITY FOR DELEGATE AGENCY STATUS

Specific eligibility criteria have been established to ensure that any delegate agency funded by IDHS with Title X resources is able to meet the program requirements set forth by law. Any agency meeting these criteria is eligible to make a written application to IDHS for consideration as a delegate agency. The eligibility criteria are as follows:

- The applicant is a public or private non-profit entity located in the State of Illinois. Non-profit organizations must provide proof of their non-profit status.
- The applicant organization is able to offer the full scope of family planning and related services and offer all contraceptives, as defined and required by IDHS.
- The applicant organization has a governing board and/or advisory board that is representative of its community and the service population.

If an applicant ceases to meet any of the above criteria, the agency must notify IDHS in writing.

3.2 NEEDS ASSESSMENT

A new organization applying for delegate agency status must conduct a needs assessment of their service area to ensure that services are being delivered in an area that is not served or is under-served by other medical and/or social welfare facilities. Currently funded delegate agencies are periodically required to provide an assessment of need. The needs assessment must include the following:

1. Description of the geographic area including a discussion of potential geographic, topographic, and other related barriers to service;
2. Demographic description of the service area including objective data pertaining to individuals in need of family planning services, maternal and infant mortality/morbidity rates, birth rates and percentage of unintended pregnancies by age groups, poverty status of the population to be served, cultural and linguistic barriers to service, etc.;
3. Description of existing services and the need for additional family planning services to meet community/cultural needs;
4. Need indicators that include rates of STDs and HIV prevalence (including perinatal infection rates) in the service area;
5. Identification and description of linkages with other resources related to reproductive health; and,
6. Identification and discussion of high priority populations and target areas.

Any current delegate agency considering expanding their service area or the services provided by their agency must also submit a needs assessment justifying this expansion. This must be approved by IDHS prior to implementation to assure Title X requirements have been met.

3.3 THE APPLICATION REQUIREMENTS FOR NEW AND CONTINUING DELEGATE STATUS

Currently funded delegate agencies will be sent an application package each year prior to the new State fiscal year and may reapply for funding as family planning delegate agencies. IDHS determines the schedule for the periodic bidding of funds through a Request For Proposal (RFP) process. A complete application contains the following materials for new or continuing applicants:

NEW APPLICATIONS

CONTINUING APPLICATIONS

Signed Title X Assurance of Compliance	Signed Title X Assurance of Compliance
Provider Directory Information	Provider Directory Information
Clinic(s) Schedule	Clinic(s) Schedule
Services Provided Checklist	Services Provided Checklist
Organizational Requirements	Organizational Requirements
Information and Education Committee	Information and Education Committee
Needs Assessment	Needs Assessment, as required
Geographic Service Area	Geographic Service Area
Health Care Plan	Health Care Plan (condensed: every three years)
Work Plan	Work Plan
Sterilization Waiver Letter, if applicable	Sterilization Waiver Letter, if applicable
Schedule of Discounts	Schedule of Discounts
Sliding Fee Scale	Sliding Fee Scale
Financial Status Baseline Report (Budget)	Financial Status Baseline Report (Budget)
Revenue Analysis of Patient Fees (estimated)	Cost Center Report
	Cost Analysis
	Revenue Analysis of Patient Fees

Applications cannot include activities that cannot be funded under Title X, such as abortion, fundraising or lobbying.

All applicants are required to submit the required application materials by the application deadline. Funding awards will be made only to those organizations or agencies that have met all applicable requirements and deadlines and demonstrate the capability of providing the proposed services. Based on evaluation of the application materials and the service area needs, the IDHS will determine which family planning projects to fund in Illinois, as well as determine the funding allocations.

Funding provided to delegate agencies might include funds from Federal Title X (Public Health Service), Title XX (Social Services Block Grant), Title V (Maternal and Child Health Services Block Grant) and from State General Revenue funds. Funding will be allocated to delegate agencies based on the quality and comprehensiveness of the application, demonstrated capability and compliance, as well as the meeting of program priorities. Additional funds may be directed toward targeted priorities.

New applicants will receive formal notice of the approved application. All new and continuing agencies will receive a contract agreement for the funding period. Successful applicants will be responsible for the overall management and reporting of activities within the scope of the approved project plan.

A sample continuing application package, including detailed information, instructions and required forms, is located in Appendix A of this manual.

Delegate agencies earn the allocated award based on a capped, fee-for-service mechanism. Reimbursement rates are established annually using current Medicaid rates. Use of an award monitoring form is recommended to ensure that the full award is expended. Documentation of the amount billed is provided monthly through the Billed Procedure Listings provided by the DHS data contractor. A sample Reimbursement Rate Schedule and Award Monitoring Form are attached to Appendix A.

3.4 TERMINATION OF DELEGATE STATUS

IDHS may terminate the delegate agency status for chronic non-compliance with the following contract requirements:

- Lack of compliance with the Program's administrative and clinical requirements as evaluated through program reviews and follow-up on cited deficiencies.
- Failure to establish and/or report progress on an approved work plan.
- Failure to notify the Program of delegate agency changes in key personnel, scope of services, or clinic location changes.
- Delinquent submission of required reports, including: Family Planning Annual Report, the Financial Status Report, and all other reports listed in Section 6.7.
- Failure to submit the Financial Audit.

Delegate agency status will not be terminated without formal written notification by IDHS.

Delegate agencies will be given advance notice to allow them the opportunity to respond to a change in status prior to termination of funding.

SECTION 4.0: GRANT ADMINISTRATION

All projects must comply with IDHS and Federal grants administration requirements as detailed throughout this manual. Family Planning Coordinators must be familiar with the DHHS/OPA *Program Guidelines for Project Grants for Family Planning Services*, January, 2001, the Title X law and regulations and the Illinois Administrative Code for Family Planning (Refer to Tab 6).

Delegate agencies must understand the legal issues and legislative mandates associated with the provision of family planning as defined in Section 5.0.

Delegate agencies must have a system for project management that includes a Family Planning Governing Board and/or an Advisory Board to review general program/policy issues and make recommendations to the agency on the organization, as well as the management and operation of its family planning program. Program management systems must meet administrative requirements for personnel and training, financial and progress reporting, approval of education materials, community participation, program promotion, publications and discoveries. (Refer to Section 6.0 this manual).

Delegate agencies must provide all Title X required services as defined in this manual in Sections 7.0 and 8.0 and may provide related services as described in Section 9.0.

All projects receiving Title X funds must provide services efficiently and assure they are of high quality. (Refer to Section 10.0 and Part III Program Evaluation included in this manual).

SECTION 5.0: LEGAL ISSUES

All family planning program services must be provided in a manner that protects the dignity and privacy of the individual, and without regard to religion, race, color, national origin, residency, creed, handicap, sex, number of pregnancies, marital status, age, sexual orientation, or contraceptive preference.

Delegate agencies are required to have written protocols and operating procedures that meet the standards of the legal issues described in 5.1 through 5.6.

5.1 VOLUNTARY PARTICIPATION

Any individual using family planning program services must do so solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use, or not use, any particular method of family planning.

Acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or participation in, any other program of the IDHS.

Project personnel must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

5.2 CONFIDENTIALITY

All personnel working in the IDHS family planning program must assure and respect client confidentiality and provide safeguards to protect against any invasion of personal privacy as required by the Privacy Act/Health Insurance Portability and Accountability Act (HIPAA). No information obtained by the delegate agency staff about clients receiving services may be disclosed without the client's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Otherwise, information may only be disclosed in summary, statistical, or other form that does not identify the individual.

At all times, personnel must preserve the confidentiality of all clients in every aspect of their family planning care, including within the clinic setting and with billing transactions. Every effort should be made to have all written and verbal exchanges between clients and office/clerical staff kept private, so that other clients in the waiting room or other uninvolved staff do not know who is visiting the clinic or the reason for the visit.

Personnel must inform clients fully about the limits of confidentiality in a given situation, when confidentiality may be broken, the purposes for which information is obtained, and how information may be used within the confines of the program. Clients must be advised that they have the right to specify how the family planning program staff may contact them. Clinics may establish a code system with the client to be used for contact purposes (e.g., "tell her 'Judy' would like for her to call back."). Clients have the right to designate themselves as a "no contact" client, however they must be advised about the possibility of abnormal test results and the need for further confidential contact to ensure the health of the client.

Minors must be assured that all aspects of their care are confidential and that if follow-up is necessary, every effort will be made to assure their privacy and confidentiality. (See also Section 5.6 regarding Mandatory State Reporting).

Confidentiality of information must be assured by the inclusion of confidentiality statements on consent forms and through postings in the clinics. Delegates must have confidentiality policies that are included in policy manuals and which are verbalized to clients. All staff, volunteers, students, auditors and program consultants must be required to sign confidentiality statements prior to working with the delegate agency. (Refer to Appendix B for a Confidentiality Statement).

Personnel must obtain written consent from the client prior to the photocopying of and/or the releasing of medical records. Staff should make efforts to assure confidentiality of the client's family planning record while it is being photocopied. In addition, staff should be aware of confidentiality issues and policies of other agencies and providers when releasing documents and/or discussing client information, e.g., school nurse/school health clinics.

Other issues of importance:

- The client's written consent must also be obtained prior to photographing, taping or recording any family planning activities.
- The client's verbal consent is required before permitting third party observation of a clinic visit.
- The client must be informed that she/he has the right to have his or her partner participate or not participate in the process of providing services to the client. If the partner participates, the client must also have some time alone with the clinician.

See also Section 10.3 Medical Records for information on confidentiality of client records.

5.3 CONFLICT OF INTEREST

Delegate agencies must ensure that all employees, consultants, or members of advisory/governing bodies associated with the IDHS Family Planning Program will not use their positions for the purposes of private gain for themselves or for others.

5.4 LIABILITY COVERAGE

Delegate agencies must ensure the existence of adequate liability coverage for all segments of the project funded under the grant (medical malpractice, general liability, disaster coverage and fidelity bonding). If contractual staff are not covered under the delegate policies, the agency must maintain evidence of current insurance in personnel files. Liability insurance coverage should be considered for members of the Governing Board and/or Advisory Boards. Agencies claiming Tort Immunity must provide evidence with each annual grant application.

5.5 HUMAN SUBJECTS CLEARANCE AND RESEARCH PROJECTS

The IDHS Family Planning Program adheres to the legal requirements governing human subjects research of 45 CFR Part 46, as applicable.

All delegate agencies considering clinical or sociological research must adhere to legal requirements governing human subjects research, specifically with regard to informed consent.

Delegates must meet the following criteria for research activities:

- All delegate agency requests for research approval must be submitted in writing to the IDHS. No research may be conducted until a federally certified Institutional Review Board (IRB) has reviewed and approved the project. Delegate agencies are required to submit to DHS Family Planning Program Administrator a copy of the study protocol, materials submitted to the IRB, and the IRB letter of approval. When all proposal

components are in place, IDHS will forward requests to the Region V DHHS office and the Office of Population Affairs for final approval. Delegates must be notified by IDHS in writing of approved research projects prior to initiation of any research activities.

- Informed consent to participate in the research must be obtained from each client prior to their enrollment or participation in research efforts.

Refer to Appendix C for the IDHS Application Form and Checklist for Human Subjects Research Proposals.

5.6 LAWS ON SEXUAL COERCION AND COMPLIANCE WITH MANDATORY STATE REPORTING

The fiscal year 1998 appropriation's bill for the Departments of Labor/HHS and Education (Public Law 105-78) contains language governing the use of Title X funds with respect to counseling minors about sexually coercive relationships. Specifically, the language states:

“None of the funds appropriated in the Act may be made available to any entity under

Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.”

Additionally, the Fiscal Year 1999 Omnibus Appropriations bill (Public Law 105-277) contains language specific to Title X providers on compliance with State mandatory reporting laws. Specifically section 219 states:

“Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification, or reporting of child abuse, child molestation, sexual abuse, rape, or incest.”

Delegate agencies must comply with this appropriations language and with the Office of Population Affairs issued Program Instruction Series, OPA 98-1 and OPA 99-1, and must provide written assurance of compliance to the Illinois Department of Human Services Family Planning Program annually. In addition, delegate agencies are required to provide annual staff training for counseling on sexual coercion and the mandatory reporting of abuse. A resource prepared for Illinois Title X delegate agencies, called *Minor Consent, Confidentiality, and Child Abuse Reporting in Title X Funded Family Planning Settings* is included as Appendix D of this manual and is available online at the National Center For Youth Law website at www.youthlaw.org. Refer also to Section 8.8 in this manual for Guidelines for Counseling on Sexual Coercion.

Guidelines for the Mandatory Reporting of Abuse:

The IDHS Family Planning Program recognizes the legal responsibilities that a family planning professional has with respect to reporting suspected cases of child abuse and neglect as mandated by Federal law and the State of Illinois.

In Illinois, abuse and neglect are legally defined in the Abused and Neglected Child Reporting Act (ANCRA). ANCRA was interpreted by the Illinois Department of Children and Family Services Children's Justice Task Force into the *Manual for Mandatory Reporters*, revised in September 2005.

According to ANCRA, and as described in the *Manual for Mandatory Reporters*, all family planning program staff members are considered mandatory reporters. Mandated reporters are professionals who may work with children in the course of their professional duties. There are six groups of mandated reporters as defined in the ANCRA, sec.4, including Medical Personnel, such as physicians, LPNs, RNs, medical social workers, emergency medical technicians, nurse practitioners, and hospital administrators.

Mandated reporters are required to report suspected child maltreatment immediately when they have “reasonable cause to believe” that a child known to them in their professional or official capacity may be an abused or neglected child” (ANCRA sec.4). Reporting is done by calling the DCFS Hotline at 1-800-252-2873 or 1-800-25ABUSE. The hotline worker will determine if the information given by the reporter meets the legal requirements to initiate an investigation.

Criteria needed for a child abuse or neglect investigation include:

- The alleged victim is a child under the age of 18.
- The alleged perpetrator is a parent, guardian, foster parent, relative caregiver, paramour, any individual residing in the same home or any person responsible for the child's welfare at the time of the alleged abuse or neglect.
- There is a specific incident of abuse or neglect or a specific set of circumstances involving suspected abuse or neglect.
- There is demonstrated harm to the child or a substantial risk of physical or sexual injury to the child.

Information the reporter should have ready to give to the DCFS Hotline:

- Names, birth dates (or approximate ages), races, genders, etc. for all adult and child subjects.
- Addresses for all victims and perpetrators, including current location.
- Information about the siblings or other family members, if available.
- Specific information about the abusive incident or the circumstances contributing to risk of harm—for example, when the incident occurred, the extent of the injuries, how the child says it happened, and any other pertinent information.

If this information is not readily available, the reporter should not delay a call to the DCFS Hotline.

As professionals who work with children, mandated reporters are assumed to be in the best position to recognize and report child abuse and neglect as soon as possible. Mandated reporters are the state's “early warning system” to identify probable abuse early enough to avoid serious and long-term damage to a child. The State's primary goal is to protect the child and, whenever possible, to stabilize and preserve the family so that it may remain intact.

The Abused and Neglected Child Reporting Act places several requirements on mandatory reporters, including:

- Mandatory reporters are required to report suspected child abuse or neglect immediately.
- Privileged communication between professional and client, including communication in the Title X setting, is not grounds for failure to report. Willful failure to report suspected incidents of child abuse or neglect is a misdemeanor. Further, professionals may be subject to penalties by their regulatory boards.
- Mandatory reporters may have to testify regarding any incident reported if the case becomes the subject of legal or judicial action.

- State law protects the identity of all mandated reporters and they are given immunity from legal liability as a result of reports made in good faith.
- Reports must be confirmed in writing to the local investigation unit within 48 hours of the DCFS Hotline call.

Upon hire, and then annually, all Title X staff must be oriented to the State of Illinois Mandated Reporting Act.

All abuse and mandatory reporting definitions, requirements, reporting hotlines and forms are included in the Illinois Department of Children and Family Services Manual for Mandatory Reporters and the IDHS requires that a copy of the manual must be kept on site at every family planning clinic. Specific required reporting forms are included in Appendix E of this manual.

SECTION 6.0: PROGRAM MANAGEMENT

6.1 STRUCTURE OF THE GRANTEE

As a Grantee of Title X funds in Illinois, IDHS is responsible to the Federal government for the quality, cost, accessibility, reporting, and performance of the family planning services provided by its delegate agencies under the Title X grant. As such, IDHS will provide delegate agencies with the materials, resources, technical assistance, and consultation that will assure that each individual agency has all the information required to meet all applicable Federal and State regulations. All requests for onsite technical assistance should be forwarded to IDHS in writing.

The IDHS must have a written agreement for services with each delegate agency. It is the responsibility of the delegate to ensure that every effort is directed to total compliance with regulations. If the delegate agency wishes to subcontract any of its responsibilities or services, a written negotiated agreement that is consistent with Title X requirements must be approved by IDHS prior to the execution of the subcontract. (To subcontract means that a significant part of the program is being performed by another agency through a negotiated agreement and IDHS approval is necessary). If a delegate agency uses a single referral source for the provision of a particular clinical service (example: insertion of an intrauterine device), a formal agreement must be signed, but it does not require prior approval by the IDHS.

Administrative, clinical, community outreach and financial reviews of each delegate must be performed by IDHS annually. For additional information about the evaluation activities of the family planning program, refer to Part III of this manual.

6.2 DELEGATE AGENCY PROGRAM PLANNING

All delegate agencies receiving Title X funds must provide services of high quality and be competently and efficiently administered. In addition, the delegates must work with IDHS to address the Title X Program priorities and Key Issues impacting Title X, established by the Department of Health and Human Services/ Office of Population Affairs. IDHS has also established statewide program goals and objectives. To assist in meeting these requirements, each delegate must prepare an annual Work Plan for their family planning program that identifies specific activities to meet the Program's measurable objectives for the coming year. The Work Plan must also include evaluation measures and define indicators by which the delegate agency intends to evaluate itself. The Work Plan is a major component of the annual grant application in an ongoing monitoring process. Refer to Section 3.3 and Appendix A of this manual for more information on the Work Plan, the grant application and its required elements.

6.3 FINANCIAL MANAGEMENT

Delegates must maintain a financial management system that meets Federal and State regulations and complies with Federal standards to safeguard the use of funds. Written fiscal policies and procedures must be in place within the delegate agency. Documentation and records of all income and expenditures must be maintained.

The financial management systems of the delegate agencies must meet the following standards:

- Financial reporting must be accurate, current and ensure complete disclosure of the financial results of supported activities in accordance with contract requirements;
- Accounting records must adequately identify the source and application of funds and contain information pertaining to grant awards, obligations, unobligated balances, assets, liabilities, expenditures and income;
- Effective internal control and accountability must be maintained to safeguard all cash, property, inventory and other assets assuring that assets are used solely for authorized purposes; and

- Actual expenditures must be compared with budgeted amounts.

Delegate agencies are required to submit an annual budget with their grant application. Budget revisions are required for the following conditions:

- Changes in award are issued (contract amendments)
- Changes in the budget initiated by the delegate

All financial records of expenditures, third party reimbursements, CVR billed procedures listings, and other program income, as well as inventory records of equipment purchased with project funds, must be kept for a minimum of three years, or as local legal counsel advises.

Delegate agencies are required to submit the following financial reports. Refer to Section 6.7 for detailed information on all reporting requirements.

1. FPAR Revenue Report
2. Financial Status Report

Tracking systems must be in place to monitor funds and ensure accurate reporting. Forms were developed to assist delegate agencies with tracking, including the Grant Monitoring and Cash Received Report forms.

Payments to the delegate agencies are based on a capped “fee for service” system and are limited to the lesser of the dollar amount of services documented or the actual costs reported on the Financial Status Report.

Delegate agencies must assure that an annual audit is conducted and complies with Federal OMB Circular A-133. Audits of delegate agencies must be conducted in accordance with provisions of 45 CFR Part 74, Subpart C, and 45 CFR Part 92, Subpart C, as applicable. External auditors meeting established criteria for qualifications and independence must conduct the audits, which are to be submitted annually to DHS.

6.3a CHARGES, BILLING AND COLLECTIONS

Delegates are responsible for the development and implementation of written policies and procedures for charging, billing, and collecting funds for services that are in compliance with Federal and State guidelines. Clients must not be denied family planning services or be subjected to any variation in quality of services because of inability to pay. Billing and collection procedures must include:

1. Charges are based on a cost analysis of all family planning services provided by the delegate agency.
2. A schedule of discounts and sliding fee schedule must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 0 (zero)% and 250% of the federal poverty level. Fees may be waived for individuals who, as determined by the service site project director, are unable, for good cause, to pay for family planning services. The determination of fees and notice of any applicable waiver should be made prior to the delivery of services. (Refer to Appendix A for additional information on the development of a schedule of discounts and fee schedules).
3. Clients with income below 100% of poverty are not assessed a fee. Fee schedules must include a zero fee category.

4. Individual eligibility must be documented in the client chart. Income verification may be requested but cannot be required. Language used to request income verification must not establish barriers to care. Income must be reassessed with annual July 1st revised poverty guidelines or more frequently if indicated.
5. Third party payers must be billed using total charges without applying any discount. Total charges represent the maximum fee (“customary and reasonable”) on the sliding fee scale.
6. Where reimbursement is available from Title XIX or Title XX of the Social Security Act, delegate agencies must have either a written agreement with the Title XIX or Title XX State agency or have evidence of the authority to bill the state agency through an approved provider/billing number.
7. Bills (receipts) to clients must show total charges less any allowable discount. All clients must receive a receipt at the time of service.
8. Eligibility for discounts for minors who request confidential services must be based on the income of the minor. Income actually available to the minor, such as wages from part-time employment or stipends paid directly to the minor, should be considered in determining the minor’s ability to pay for services. Those services normally provided by parents/guardians, e.g., food, shelter, transportation, tuition, etc., should not be used in determining the minor’s income. It is not allowable to have a general policy of flat fees for minors or a fee schedule that is different for minors than for other clients.

When considering charges to minors for services, several conditions must be taken into account:

- a) If the minor is not emancipated and confidentiality is not a concern, the family’s income must be considered in determining the charge.
 - b) If the minor has not requested confidentiality but the parent refuses financial support, charges must be based on the minor’s income.
 - c) If the minor requests confidential services, without the involvement of a principal family member, charges must be based on the minor’s income.
 - d) If the minor is in the situation where confidentiality is restricted to one family member (e.g., one parent is aware of the minor seeking services, but the other is not, because of a disagreement regarding the minor’s right to receive family planning services), the charges shall be based on the minor’s income if the minor’s confidentiality would be breached.
 - e) If the minor presents evidence of parent’s insurance, but requests confidential services, charges must be based on the minor’s income. (An insurance company may submit Explanation of Benefits to the minor’s parent and thereby breach confidentiality).
9. Reasonable effort to collect charges without jeopardizing client confidentiality must be made. Example: Collection agencies cannot be used for clients requesting confidential services.
 10. A method for aging of outstanding accounts must be in place.
 11. Voluntary donations from clients are permissible, however:
 - Clients must not be pressured to make donations;
 - A specific amount must not be suggested;
 - Donations must not be a prerequisite to the provision of services or supplies; and
 - Donations cannot establish an “amount due” on the client’s account.

- Donations from clients do not waive the billing requirements set above.

12. Client income must be re-evaluated annually. Reassessment should occur at a minimum during the client's first visit after July 1 to correlate with Federal Poverty Level changes, and periodically as needed. When client income changes, eligibility documentation must be complete and consistent across records.

Delegate agencies are allowed to revise their sliding fee schedules, under certain circumstances, such as to adjust for a cost increase in contraceptive methods or laboratory services, or for the addition of new services. If revisions are made to fee schedules, a revised budget must be submitted and approved by the Program.

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

The IDHS requires that all of its family planning service sites are safe, geographically accessible, comfortable, efficient for service provision and designed to ensure that privacy, dignity and confidentiality are maintained for the client throughout all aspects of the family planning visit including interviewing, counseling, dressing, examination and billing transactions.

Family planning facilities must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap.

All IDHS family planning service sites must be clean and attractive and meet the following requirements according to the Federal Government, the State of Illinois, and local municipal codes:

- Accessible for patients with disabilities
- Adequately equipped examination rooms
- Adequate seating in waiting room area(s) for patients and visitors
- Adequate heating, ventilation and electrical systems
- Adequate space for administrative functions and maintenance of medical records
- Current certificate for elevator inspection available, if applicable
- Fire protection that meets local codes (e.g. smoke alarms, fire extinguishers, etc.)
- Fire/emergency evacuation plan that is posted and available to staff and clients
- Fire drills conducted and documented annually, at a minimum
- Geographic accessibility and located along public transportation routes
- Adequate restrooms
- Lighting for all areas
- Visible identifying sign(s)
- Written procedures for the management of non-medical and medical emergencies

If the delegate performs surgical procedures, such as sterilization, onsite, the facility must be accredited by the State of Illinois and meet US DHHS, Ambulatory Health Care Standards.

In addition, facilities should have hours of operation that are scheduled at times that are convenient to those seeking services. In an effort to assure accessible and acceptable client services, it is strongly encouraged that each delegate agency offers late afternoon, evening, and/or weekend clinic hours.

Delegate agencies must notify the IDHS Family Planning Program well in advance of any clinic moves, additions or closures. Refer to Appendix F for the IDHS procedures regarding facility changes.

6.5 PERSONNEL

Personnel working in the IDHS delegate agencies should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to and able to deal effectively with the language and cultural needs of the client population.

Delegate agencies, and/or their organizing bodies, must establish and maintain written personnel policies that comply with Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title I of the Americans with Disabilities Act. These personnel policies must include the following elements:

1. Nondiscrimination in hiring employees
2. Staff recruitment and selection methods
3. Job descriptions of duties, responsibilities and qualifications for each staff position
4. Compensation and benefits
5. Methodology for annual performance evaluation
6. Staff promotion
7. Staff termination
8. Staff orientation that is specific to the Family Planning Program
9. Grievance procedures
10. Client confidentiality issues

IDHS further requires that delegate agency personnel policies cover the use of contractual consultants for providing care, the use of volunteers, and a system for replacing key staff in cases of illness, vacation or unexpected absence.

Delegates must ensure that:

- The family planning project is administered by a qualified project director;
- Licensure of applicants for positions requiring licensure are verified prior to employment and that there is documentation that licenses are kept current (use of a credentialing service is recommended as a risk management tool);
- The medical care component of the project operates under the supervision of a medical director who is a licensed and qualified physician with training or experience in family planning;
- Physical assessment, diagnosis, treatment, and provision of medication and devices must be performed by a physician or licensed and/or certified mid-level (non-physician) clinician. Mid-level clinicians shall include nurse practitioners, certified nurse midwives, and physician assistants. Clinicians other than physicians performing medical functions must do so under protocols and/or standing orders approved by the medical director. All clinicians employed in the family planning program must agree to follow the appropriate clinic procedures and/or standing orders and protocols;
- All Advance Practice Nurses must maintain current licensure, certification and have a signed collaborative agreement by the standards defined by the 225 ILCS 65/, the Illinois Nursing and Advanced Practice Nursing Act; and that other health professionals and para-professionals may be utilized to perform non-medical responsibilities, or assist in medical functions as approved by the medical director;
- Organizational charts and personnel policies are available to all personnel;

- Job descriptions are available for all positions, reviewed annually, and updated as needed;
- All personnel, students, volunteers, auditors and program consultants and reviewers must sign a written confidentiality agreement. (Refer to Appendix B for a Confidentiality Statement);
- Written annual performance evaluation is discussed with the employee and is kept in the employee's personnel files;
- Personnel are knowledgeable about the agency's compliance with OSHA regulations;
- Family planning personnel must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure;
- Personnel records are kept confidential; and,
- The organizational chart and personnel policies are reviewed annually and updated as needed.

Agencies must submit provider directory information, listing key personnel and means of contact, annually with the grant application and promptly as changes occur. Refer to Appendix A for the Provider Directory Information form.

6.6 TRAINING AND TECHNICAL ASSISTANCE

Delegate agencies must provide for orientation and in-service training specific to family planning for all project personnel. All project staff should participate in continuing education related to their job duties. They should be offered the opportunity to attend targeted family planning training programs, such as the Region V training programs and IDHS sponsored training events. Delegate agency staff members should make every effort to attend Regional Family Planning update meetings and Family Planning Advisory Council meetings. Delegate agencies must send staff to all mandated program trainings.

To fulfill the training needs of its staff, delegates should annually conduct: (1) an assessment of the training needs of their staff; and (2) an evaluation of the scope and effectiveness of all educational programs offered. As a result of these assessment and evaluation activities, delegates should:

- Develop educational opportunities to assist in meeting identified needs;
- Plan future in-service training programs;
- Evaluate staff response to any in-service training offered;
- Determine any changes needed in established training programs; and,
- Report training needs to the IDHS.

Delegates should have one person assigned to develop in-house training capabilities. Funding for training and continuing education should be included in each year's operating budget.

New staff participating in the delegate's family planning program must be provided with an appropriate orientation by experienced family planning staff. The orientation must include a thorough review of the materials specified in the IDHS New Employee Orientation Material for Family Planning Checklist (Refer to Appendix G).

Family planning staff must receive or have previously had training in the following areas, as indicated:

- The unique social practices, customs and beliefs of under-served or minority populations of the service area, and those with Limited English Proficiency (LEP).
- Prevention, transmission and infection control in the health care setting of sexually transmitted diseases, including HIV
- Specialized Services to adolescents
- Pregnancy options counseling
- Illinois' Mandated Reporting Requirements and Sexual Coercion Resistance Training
- Compliance with regulatory entities such as, OSHA, CLIA and HIPAA

Program medical directors and physicians must provide evidence of annual continuing medical education in reproductive health. Advance Practice Nurses shall maintain evidence of continuing education to comply with their licensure/certification process.

Delegate agencies are required to report attendance at training sessions and continuing education programs on a semi-annual basis using the Training Attendance Form. (Refer to Section 6.7 Reporting Requirements).

6.7 REPORTING REQUIREMENTS

Annual reporting is required for family planning service delivery projects authorized and funded under Title X of the Public Health Service Act. The submission of the Family Planning Annual Report (FPAR) is required of all Title X family planning service Grantees for purposes of monitoring and reporting program performance (45 Code of Federal Regulations [CFR] Part 74 and 45 CFR Part 92). The FPAR is the only source of annual, uniform reporting by all Title X family planning service grantees. It provides consistent, national-level data on the Title X Family Planning Program and its users. Information from the FPAR is important to OPA for several reasons:

- FPAR data are used to monitor compliance with statutory requirements, regulations, and operational guidance set forth in the *Program Guidelines for Project Grants for Family Planning Services*
- FPAR data are used to comply with accountability and federal performance requirements for Title X family planning funds as required by the 1993 Government Performance and Results Act (GPRA).
- FPAR data guide strategic and financial planning, are used to monitor performance, and to respond to inquiries from policymakers and Congress about the program.

Grantees are further responsible to OPA for annual program monitoring, compliance and progress reporting and must periodically compete for continued grant funds. Therefore, Grantees may require supplemental reporting, in addition to the FPAR, from their delegate agencies.

Delegate agencies must comply with the IDHS Program's required reporting schedule. At the start of every fiscal year, a Family Planning Program Report Calendar is provided to delegate agencies with specific timelines outlined for each report. Refer to Appendix H for the general schedule of reporting requirements and copies of required reporting forms

Required Report	Report Period	Purpose of the Report
Community Education/Outreach Report	Jan-June; July-Dec	Reporting on activities and accomplishments toward community awareness, education and program promotion.
CVR Clean Up Run	Jan-June; July-Dec	Final submission of all patient services data and billings for the six-month period.
Equipment Inventory Report	July-June	Reporting on purchased items with values equal to or greater than \$500.00 and with an estimated life greater than one year.
Family Planning Annual Report (FPAR)	Jan-June; Jan-Dec	Reporting data on program users, service providers, utilization of services and sources of other revenue that complement Title X funds.
Family Planning Staff Training Attendance Report	Jan-June; July-Dec	Documenting compliance with training requirements for staff working in the family planning program.
Financial Status Report (FSR)	Jan-June; July-Dec	Reporting to assure that family planning income is expended according to the program guidelines, including grant-related income.
Information & Education Committee Meeting Minutes	Jan-Dec	Reporting on the review and approval of all informational and educational materials developed and/or distributed.
Sterilization Semi-Annual Report (if applicable)	Jan-June; July-Dec	Reporting on procedures completed during the specified time period.
Work Plan Progress Report	July-Dec; July-June	Report to summarize and evaluate progress against the work plan in achieving the stated objectives for the specified project period.

Additional reports, surveys, and any other identified program priorities reporting may also be required from delegates.

For delegate agencies arranging for DHS payment of sterilization procedures, all sterilization reporting requirements must be met. All projects must be in compliance with Title X regulations on minimum age, waiting period between signing of consent and surgical procedure and informed consent. Documentation that these requirements have been met should be found in the client's chart and/or the sterilization log. Refer to 8.4 of this manual for specific standards and evaluation criteria relating to sterilization. Agencies electing to waiver out of arranging for sterilization procedures must submit the Waiver Letter as specified in the annual grant application.

6.8 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

All delegate agencies must have an Information and Education Advisory Committee of at least five and no more than nine members who are broadly representative of the community served and who are knowledgeable about family planning services. Broad representation can include, but is not limited to, the following: teachers, clergy, health educators, parents, clients, medical professionals, and community leaders. Ethnic and racial representation must be considered. It is advisable to utilize the expertise of this committee as often as feasible to update and enhance the agency community education plan and activities to meet work plan objectives. The agency's family planning advisory committee or governing board, if appropriate, may assume the functions of this committee.

The Information and Education Advisory Committee must:

- Prior to their distribution, review and approve all information and educational materials to be used for family planning clients or for community information or education. This applies to all materials, whether purchased or developed.
- Assure that materials are consistent with the purpose of Title X and reflect Title X policies (re. Section 59.5 of 42CFR) regarding:
 - Client eligibility
 - Client fees
 - Coercion
 - Confidentiality
 - Education about all methods of contraception and program services
 - Managing unplanned pregnancies by appropriate referrals
 - Intimate partner and domestic violence
 - Non-discrimination
 - Provision of required services
 - Abortion is not included as a method of family planning
 - Voluntary services
- Periodically review the content of all materials to assure that the information is factually correct. (The committee may delegate responsibility for review of technical materials to appropriate persons or groups, but final responsibility and authority for approval rests with the committee).
- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed.
- Consider the standards of, and determine whether the material is suitable for, the population or community to be served.
- Assure that all materials developed acknowledge Federal grant support (Refer to Section 6.10 for additional publication information).

The delegate should elicit client input in the development of educational materials. Clients should be asked to evaluate new brochures, pamphlets, etc., and client questionnaires may be utilized to determine perceived educational needs.

The Information and Education Advisory Committee must meet at least once in the calendar year. There must be a written record, such as minutes, of all Information and Education Advisory Committee meetings. (See Recommended Format for I&E Committee Meeting Minutes in Appendix H.) Copies of the Information and Education Advisory Committee meeting minutes must be kept on file at the delegate agency and submitted annually to the IDHS.

6.9 COMMUNITY PARTICIPATION, EDUCATION AND PROJECT PROMOTION

Community Participation:

Delegate agencies must provide an opportunity for community participation in the development, implementation and evaluation of the project by establishing an advisory board or committee. The composition of the community participation board or advisory committee must include:

1. Broad representation of all significant segments of the population to be served; and
2. Persons knowledgeable about the community's need for family planning.

Each delegate agency should develop guidelines or by-laws for its community participation activities. The agency governing board or program specific family planning advisory committee (or the information and education sub-committee) may be used to fulfill the community participation requirement provided this group meets the above two requirements.

The delegate agency's annual plan must include a component for community participation in its project. The role of the committee is:

- To review the delegate program plan, assess accomplishments and suggest future program goals and objectives;
- To review the agency's progress toward meeting the needs of the priority population(s) in the service area, as well as the plan for making the clinic services and policies more responsive to the client needs and preferences.

The committee fulfilling the community participation function must meet annually, or may meet more often, as appropriate. Minutes must be kept of all meetings.

Community Education:

Delegate agencies must have a formal, written plan for community education that is based on an assessment of the needs of the community and contains an implementation and evaluation strategy. Delegate agencies must budget for community education activities and Cost Center Reports must identify funds spent for community education activities.

The community education objectives must be delineated in the agency's annual plan. The following are examples of the type of community education objectives the IDHS expects delegates to develop in their annual plans:

- To develop and maintain a positive community climate for program activities;
- To coordinate with other community agencies to avoid duplication of services and to eliminate gaps in service;
- To reach out to clients of agencies or institutions which are likely to serve individuals in need of family planning care;
- To orient professional staff of agencies or institutions likely to counsel or refer clients for family planning services.

A variety of strategies should be used for community education based on the objectives of the program and the intended audience. These may include:

- Distribution of educational materials;
- Educational sessions to schools, community groups, and/or professionals;
- Assisting community schools and groups in the development of family life and human sexuality curricula;
- System for handling telephone requests for information;
- Family planning library.

Community education activities should be directed toward priority target groups, one of which must be adolescents. Other groups targeted for community education may include parents, teachers, school counselors, school nurses, school principals and school board members, clergy, medical professionals and workers in health settings; members of minority populations, members of the media, community leaders in business and/or government, workers in youth service agencies, community service offices, drug rehabilitation centers, crisis centers and mental health centers.

The community education program should provide information on the following:

- Need for family planning services in the community
- Services provided by the agency
- Contraceptive methods, including emergency contraception
- Human sexuality and family life education
- Parent-child communication
- Parental involvement
- Sexually transmitted diseases
- HIV/AIDS
- Health promotion
- Availability of other related community services
- Teen issues

The agency should have a system in place to evaluate the quality and effectiveness of the community education program. Evaluation should take place annually. Community education activities must be documented and include the following elements:

- Number of educational sessions
- Type of audience addressed at sessions
- Number of participants at each activity
- Classification of participants at each activity
- Number of pamphlets, brochures, etc. distributed

Community Education Reports must be submitted semi-annually to the IDHS.

Program Promotion:

To facilitate community acceptance of and access to their family planning services, delegate agencies must establish and implement planned activities whereby their services are made known to the community. Program promotion is a component of the agency's community education plan. Low-income women and teens must be included in the target groups the agency has identified for program promotion activities.

In planning for program promotion, delegates should review a range of strategies and assess the availability of existing resources and materials. A variety of approaches should be used for promotional activities based on the goals of the program and the intended audience. Suggested approaches include:

1. Distribution of posters and brochures.
2. Distribution of a newsletter to: clients (provided there will be no breach of confidentiality); board and committee members; community leaders; elected officials; and local school boards.
3. Providing information to the public through mass media: websites; television; radio; newspaper and/or magazines;
4. Providing information to the public through open houses; distribution of family planning fact sheets; or a speaker's bureau.
5. Providing information to professionals working with the agency's target population in order to help them better counsel and/or refer potential family planning clients, including, health and social services agencies, local physicians, youth service groups and clergy.
6. Assisting community schools and groups in developing curricula in family life and human sexuality that includes, but is not exclusive to, the importance of preventing pregnancy and disease through abstinence. The delegate should assign a family planning staff member to serve on these groups.

7. Maintaining a teen advisory or peer counseling group. Part of the function of this group should be to deliver family planning information to their peers.

6.10 PUBLICATIONS AND COPYRIGHT

Federal grant support must be acknowledged in any publication developed by delegate agencies as follows: ***“Program funding includes a grant from the US Department of Health and Human Services (DHHS) Title X.”*** The word “publication” is defined to include computer software. Publications developed under Title X may not contain any information that is contrary to program requirements or to acceptable medical practice and must be approved by the delegate's Information and Education Advisory Committee prior to distribution.

Any copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable license or right to the government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

6.11 INVENTIONS OR DISCOVERIES

Delegates must comply with government-wide regulations 37 CFR Part 401, regarding any inventions or discoveries made by any activity that is federally funded.

PART II: GUIDELINES FOR CLIENT SERVICES AND CLINIC MANAGEMENT

SECTION 7.0: CLIENT SERVICES

Delegate agencies funded under Title X must provide clinical, informational, educational, social and referral services to family planning clients seeking such services. Policies and procedures must be in place to address the needs of clients with limited English proficiency (LEP). All delegate agencies must offer a broad range of acceptable and effective medically approved family planning methods and services. Exceptions must be approved by IDHS.

Part II of this Guidelines Manual has been developed to assist the delegate agencies in determining those services that must be provided to fulfill the mission and requirements of Title X and the IDHS.

- Delegates must provide the services stipulated in the law or regulations, or which are required by the Title X Program Guidelines or by the IDHS for the provision of high quality family planning services.
- Delegates may also provide services that are intended to promote the reproductive and general health care of the family planning client population.

All delegate agencies must have a process in place to inform all clients of their rights and responsibilities related to the delivery of family planning services. Suggested approaches include:

1. Use of a consent form that delineates the client rights and responsibilities.
2. Posting of a "Patient Bill of Rights" in common areas within the clinic.
3. Providing each client with an informational brochure explaining his or her rights and responsibilities.
4. A verbal explanation followed by a signed statement indicating that the client's rights and responsibilities

7.1 DELEGATE AGENCY HEALTH CARE PLANS AND PROTOCOLS

The health care plan, developed by the delegate agency's medical director and clinical staff, identifies the clinical services to be provided as well as the plan for client education. Plans must be written in accordance with Title X program guidelines and current medical practice and must cover the services provided at initial visits, annual visits, and other visits, including supply and problem revisits. The health care plan is periodically requested as part of the annual grant application process.

The health care plan should include a description of the facility, including its location, accessibility and general description. Refer to Section 6.4 for items to be included. The plan should also include a facility floor plan and description of the pattern of clinic flow.

All delegate agencies must have written protocols, which detail specific procedures for the provision of each service offered. The service/clinical protocols must be signed and reviewed annually by the medical director, and must include, but are not limited to the following:

1. Client education and counseling
2. Client eligibility
3. Confidentiality
4. Informed consent and method specific consent
5. Contraceptive education and counseling for all FDA approved methods, (including permanent and temporary methods and emergency contraception)

6. Specialized adolescent services
7. Mandatory reporting of child abuse
8. History and/or physical examination procedures for each type of visit (e.g. specific procedures to be performed for the initial visit; annual visit; deferred exam and other revisits, including supply visits, medical problem visit and education visits such as pregnancy testing/counseling or provision of emergency contraception)
9. Laboratory testing
10. Pregnancy diagnosis and options counseling
11. HIV/AIDS education and counseling, including risk assessment
12. Sexually transmitted diseases counseling, screening, and treatment
13. Management of contraceptive services including emergency contraception
14. Management of reproductive diseases/disorder and abnormal test follow-up, including the management cervical cancer screening
15. Colorectal cancer screening
16. Management of high-risk contraceptive clients
17. Level I Infertility services
18. Special counseling on topics such as sexual coercion, sexual abuse, sexual concerns, domestic violence, genetics, nutrition, preconception health, and substance abuse
19. Medical follow-up
20. Referral procedures
21. Supply distribution
22. Emergency procedures, both medical and environmental
23. Management of medical records and release of records
24. Medical supervision
25. Pharmaceuticals management
26. Clinic Management, including appointment and scheduling standards and clinic flow procedures
27. Telephone procedures
28. Equipment and supplies management and inventory
29. Facilities requirements
30. Quality assurance
31. Standing orders
32. Clinic personnel policies, job descriptions and responsibilities
33. Additional protocols dictated by the services that are provided by the program

As clinical issues, research findings and standards of care evolve over time, the IDHS distributes either mandatory protocols or guidelines for protocol development.

7.2 PROCEDURAL OUTLINE

Services provided to a client at a family planning visit, and the sequence in which they are provided, will depend on the type of visit and the services requested/needed by the client. According to the Title X guidelines and Illinois mandates, there are certain services that must be offered and provided to family planning clients. The required services are listed below, grouped by visit types. The delegate agency must make every effort to promote client acceptance of services required with the provision of a prescription contraceptive method. However, the client has the right to refuse any service. Refusal and the reason for refusal must be carefully documented.

Initial Visit:

The following services must be provided and documented for all clients at the initial visit:

Education: Present individualized relevant information and educational materials based on the client needs and knowledge. Education materials may be used in addition to support verbal

discussion and may include pamphlets and brochures and audio-visual materials. (Refer to Section 8.1 for the content requirements of Client Education).

Counseling: Conduct an interactive process in which the client is assisted in making an informed choice. Refer to Section 8.2 for the content requirements of Counseling.

Informed Consent: Explain all procedures and obtain general consent covering examination and treatment and, where applicable, a method specific consent. Refer to Section 8.1 for requirements related to obtaining Informed Consent.

History: Obtain a comprehensive personal and family medical and social history. Refer to Section 8.3 for the requirements of a complete History.

Laboratory Testing: Perform routine testing and other lab tests as indicated. Refer to Section 8.3 for the requirements for Laboratory Testing.

Examination: Perform a complete physical assessment and any necessary clinical procedures as indicated. New clients may elect to defer the initial exam under certain program guidelines. Refer to Section 8.3 for the requirements of a complete Physical Assessment and Examination Deferrals.

Follow-up and/or Referrals: Plan for a mechanism for client follow-up (e.g., how a client will be notified of abnormal test results, how a client will be contacted if she/he misses a follow-up/referral appointment, etc.); performance of any other clinical procedures; provision of medications and/or supplies as needed; and provision of referrals as needed. For clients who request “No Contact” status, an alternative mechanism for emergency contact must be established. Refer to Section 7.4 for the requirements for Referrals and Follow-Up.

Return Visits:

Return visits (annual, problem, and routine) should include an assessment of the client’s status, current complaints, and evaluation of the birth control method, as well as an opportunity to change methods. The exception is routine supply visits. The following components must be offered and documented for all clients at the return visit:

Counseling: Determine the nature of the follow-up visit. Discuss the client’s use of and proficiency with the contraceptive method, any side effects, satisfaction with the method, and change of method, if necessary. Counseling at annual visits is not billable except in documented non-routine situations (e.g., method change or problem).

History: Update the personal and family medical and social history.

Examination: Perform either a complete physical assessment or a focused exam based on the reason for the visit, plus any necessary clinical procedures, if indicated.

Laboratory Testing: Perform routine and other indicated lab tests.

Follow-up and/or Referrals: Review the mechanism for client follow-up; discuss additional laboratory test(s) and/or referral(s) to appropriate outside medical resources as necessary; provide medications and/or supplies as needed; inform client of the follow-up return visit schedule and offer any additional counseling based on the client needs.

Regardless of the purpose of the visit, service delivery to all clients must include:

- Courteous service and treatment that is provided with dignity and respect;
- The opportunity for clients to participate in the planning of their medical treatment;

- Encouragement for clients to voice any questions or concerns;
- Materials and/or interpreters available for those with limited ability to read or understand English and for those who may be blind or hearing impaired.

A summary of the required IDHS Minimum Requirements for Routine Health Care is presented in the Table 1 below:

TABLE 1: IDHS Minimum Requirements for Routine Reproductive Health Care		
	Y= required ("MUST" per guideline) (Y)= required as indicated	X= recommended ("SHOULD" per guideline) (X) = recommended as indicated
	Initial Visit Female Clients	Annual / Revisits Female Clients
		Individualized based on need for clinical education & counseling
History – Section 8.3		
Complete Medical History:	Y	Update
Personal, Family, Social and Partner	Y	Update
Reproductive Function	Y	Update
Colo-rectal Cancer Risk Assessment >40	Y	Y
Written Informed Consent-Section 8.1		
Consent for Services	Y	Update if changes
Method Specific Consent	Y	Update if changes
Physical Assessment - Section 8.3		
General including: Thyroid/Heart/Lungs/ Extremities/Abdomen	Y ^{1,2}	Y ²
Ht, Wt, Blood Pressure	Y ²	Y ²
External Genitals	Y ^{1,2}	Y ²
Pelvic exam (includes bi-manual)	Y ^{1,2}	Y ² - Y within 3/mo - IUD
Breast exam	Y ^{1,2}	Y ²
Laboratory Tests - Section 8.3		
Specific tests if required in the provision of a contraceptive method.		
Pap test	Y ^{1,2, per protocol}	(Y-per protocol) ²
HGB &/or HCT	Y ²	Y ²
Chlamydia test	(Y) ²	(Y) ²
Gonorrhea test	(Y) ²	(Y) ²
Vaginal wet mount	(Y) ²	(Y) ²
Diabetes testing (fasting glucose)	(Y) ²	(Y) ²
Total cholesterol and lipids	(Y) ²	(Y) ²
Syphilis test	(Y) ²	(Y) ²
Urinalysis	Y ²	(X) ²
Fecal occult blood >50	Y ²	Y ²
Counseling & Education - Section 8.2		
Contraceptives, STD, HIV	Y	Y(Update)
Breast self exam	Y	Y
Preconception (Routine Required)	Y	Y
Minors - abstinence, family involvement, relationship safety	Y	Y
Health Promotion - smoking cessation, nutrition, exercise, substance abuse, etc.	(X)	(X)
Follow-up and Referrals - Section 7.4		
	Y	Y
1 = may be deferred 3 mos., maximum 6 mos., unless compelling reason		2 = on-site or by referral

7.3 EMERGENCIES

Emergency situations involving clients and/or staff may occur any time; therefore, all agencies must have written plans and operating procedures to cover the following emergency situations:

- After hours management of contraceptive-related emergencies
- Anaphylaxis
- Cardiac arrest
- Fainting (syncope)
- Hemorrhage
- Respiratory distress
- Shock
- Vaso-vagal reactions
- Emergencies requiring ambulance services or hospital treatment
- Fire, natural disaster, robbery, power failure, violence, harassment, and bioterrorism

Staff should be trained in emergency procedures and must be familiar with the plans. All licensed medical staff must be trained in CPR and hold current certification.

There must be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.

All client medical emergencies requiring referral to another provider should have referral results documented in the client's medical record.

7.4 REFERRALS AND FOLLOW-UP

Delegate agencies must provide all services listed in Section 8.0 under "Required Services" either on-site or by referral (unless specified as required on site by IDHS). For required services provided by referral, the project must have in place formal arrangements regarding the provision of services and reimbursement of cost with the referral organization, as appropriate.

For services determined as necessary, but which are beyond the scope of the family planning project, the client must be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies must:

- Make arrangements for the provision of pertinent client information to the referral provider. Agencies must obtain the client's consent to such arrangements, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality;
- Advise the client on their responsibility in complying with the referral; and
- Counsel the client on the importance of such referral and the agreed upon method of follow-up.

Agencies should provide for the coordination and use of referral arrangements with other providers including health care providers, local health and human services departments, hospitals, voluntary agencies and health service projects supported by other Federal and State agencies.

- Referral providers must be selected by procedures that assure fairness in the selection process and that identify providers of high quality.
- Referral provider lists must be updated annually.

Delegates must have written protocols and operating procedures for referrals and follow-up. These written procedures must include referrals and follow-up that is needed as a result of abnormal physical examination or laboratory test findings. These procedures must be sensitive to clients' concerns for confidentiality and privacy.

Delegate agencies referral procedures must include a description of the arrangements for:

- Emergency referrals, which require immediate referral to the provider;
- Urgent referrals, which should be followed-up with the client in a brief, specified period (e.g. 2 weeks);
- Essential referrals, which are followed-up with the clients within a timeframe determined by the clinician;
- Discretionary referrals, which are followed-up with the client as necessary;
- Client consent for the release of pertinent information to another provider;
- The appropriate documentation that the referral was made and the follow-up has taken place, as needed; and
- The system for obtaining feedback from the client about referral providers.

Additionally, follow-up system should include procedures that document:

- A method to identify clients in need of follow-up;
- The action taken to follow-up on referred clients (e.g., confirming that the referral appointment was kept);
- The client information was received from the referral provider and placed in the medical record;
- The action taken to implement the recommendations from the referral provider or the reasons why the recommendations were not implemented;
- The client has been given a complete explanation of the referral and the need for follow-up including:
 - The reason for the referral;
 - The services to be received from the referral provider;
 - Directions to the referral agency;
 - When to return to the family planning clinic;
 - Any instructions needed to help insure the client will follow through with the referral and follow-up; and
 - An assurance of confidentiality.

SECTION 8.0 REQUIRED SERVICES

The services contained in sections 8.1 through 8.8 must be provided by all delegate agencies funded by the IDHS Family Planning Program. Required services must be provided on site by the delegate or through formal contractual referral agreements, as approved by the Program.

The client's written informed voluntary consent to receive services must be obtained prior to the client receiving any clinical services. In addition, if a client chooses a prescription method of contraception, a method specific consent must be obtained and reviewed at annual visits to reflect current information about that method.

8.1 CLIENT EDUCATION AND INFORMED CONSENT

Client Education:

Delegate agencies must have written education plans for client education that include goals and content outlines to ensure the consistency and accuracy of the information provided. Education protocol should include detail on the educational focus for initial, annual, other revisits and supply visits.

A method to assess the client's educational needs should be performed at each visit. The education provided should be appropriate to the client's age, level of knowledge, language, and socio-cultural background and be presented in an unbiased manner. Clinic staff should use a client-centered approach to education, assessing each client's knowledge, circumstances and risks. A mechanism to determine that the information has been understood should be established. An example would be asking the client to repeat information in her/his own words.

Education services must provide clients with the information needed to:

- Make informed decisions about family planning;
- Use specific methods of contraception and identify adverse effects;
- Perform breast self examination or testicular self examination;
- Reduce the risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV), beginning with a risk assessment;
- Understand the importance of recommended screening tests and other procedures involved in the family planning visit;
- Understand the range of available services, the purpose and sequence of the clinic visit, and procedures and agency fees and financial arrangements.

Family planning education must include face-to-face instruction with the individual client. Additionally, film or videotape, pamphlets, and/or group discussion may be used. A variety of printed educational materials may be given to clients. Printed educational materials in languages prevalent in the community should also be available in the common areas or waiting areas of the clinic.

Initial clients should be offered information about basic female and male reproductive anatomy and physiology, and the value of fertility regulation in maintaining individual and family health. On subsequent visits, clients should be given information on reproductive health and health promotion/disease prevention, as appropriate.

Additional education should include information on preconception counseling, nutrition, exercise, smoking cessation, alcohol and drug abuse, partner and family violence, sexual abuse and sexual coercion.

Information on all contraceptive choices must be given to clients. Details on the safety, effectiveness, benefits, risks, potential side effects, complications and instructions on how to use the methods must be given for each contraceptive method prior to the client making an informed choice of method. See Appendix J for a Contraceptive Options Chart. The contraceptive education should be offered to clients on the following contraceptive choices:

Female Methods

Abstinence
Contraceptive Sponge
Contraceptive Transdermal Patch
Contraceptive Vaginal Ring
Diaphragm/Cervical Cap
Female Condoms
Female Sterilization
Fertility Awareness Method
Hormonal Implant
Hormonal Injectables
Intrauterine Device/System
Oral Contraceptives
Spermicides

Male Methods

Abstinence
Male Condoms
Male Sterilization

In providing contraceptive information to clients, staff should consider and discuss with the clients the methods for both their contraceptive effectiveness and their effectiveness in preventing STDs and HIV. Education on emergency contraception must be provided and emergency contraception must be available on site. See Appendix I for a Client Information Fact sheet on Emergency Contraceptive Pills.

Clinics must use any appropriate opportunity to provide all clients with information on the following high priority topics: emergency contraception and STD and HIV risk and prevention. This education must be done annually at a minimum.

Delegate agencies must develop procedures for evaluating the quality and effectiveness of the educational component. Evaluation of the client education services must occur annually.

All required client education must be documented in the client medical record. An education checklist will document coverage of all required education components. Topics on the checklist must be detailed in the education protocols.

Informed Consent and Method Specific Consent:

Informed consent is a process between the staff and client. The consent form exists to document the process.

The client's written voluntary informed consent must be obtained prior to the receipt of any clinical services. A written consent for general services must be executed at the initial visit. The consent form should inform the client of all routine clinic procedures that will be provided and should be reviewed and explained to the client.

Before signing the consent form the client must receive the appropriate education, and have the opportunity to ask and receive answers to any and all questions. This includes questions about the consent form or any services, supplies or procedures. Staff must make every effort to assure that clients understand all information presented verbally and/or in writing and be confident that clients understand the content of both the education and the consent form.

Staff signature as a witness on the form is not proof of client understanding, but attests the authenticity of the client's signature.

A method specific consent form must be executed if the client chooses a prescription method of contraception. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen.

The method specific consent form must be updated and executed again when there is a change in the client's health status or a change to a different prescription contraceptive method. It should be routinely reviewed and updated at subsequent visits to reflect any changes in current information about that method.

Separate consent is also required for certain other procedures, including but not limited to, pregnancy testing and counseling visits and for sterilization. If the agency is a contracted IDHS sterilization provider, Federal sterilization regulations [42 CFR Part 50, Subpart B], which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for through Title X.

All consent forms must contain statements acknowledging that consent is voluntarily given, that counseling and education were provided, that all of the client's questions have been satisfactorily answered and that the client has understood the content of all information given.

All consent forms must include the signature of the client, the signature of the person obtaining consent and the date. Consent forms must be written in a language that is understood by the client or translated and witnessed by an interpreter. In the case of clients with visual impairment or unable to read, the consent form should be read in its entirety to the client prior to obtaining the client's signature.

Parental or partner consent cannot be requested in order for the client to receive services; however, all clients should be encouraged to discuss their decisions with their partners, and in the case of teens, with their parents or an adult family member.

If staff believes that the client is unable to give informed consent (for example, because of a mental disability), then written informed consent must be given by the parent or legal guardian if the client is a minor, or by a legal guardian, if the client is an adult.

All consent forms must be kept in the client medical record.

8.2 COUNSELING

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The counseling process involves the mutual sharing of information and offers more than education and providing information. Counseling assists clients in dealing with their feelings about the information. The staff role is to help clients:

- Explore, express and manage feelings;
- Define alternatives;
- See circumstances realistically;

- Cope with anxieties and pain;
- Mobilize for action on a decision;
- Recognize and draw on her/his own strengths and the support system of her/his environment.

Persons who provide education/counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware, and able to create an environment in which the client feels comfortable discussing personal information.

In some cases, the type of counseling that the client needs is beyond the scope of that which can be provided on a short term basis in the family planning clinic. The clinic staff, therefore, must maintain a list of referral resources for meeting the client's long term counseling needs.

Method Counseling:

Method counseling refers to an individualized, face-to-face, dialogue with a client that covers the following:

- Results of the physical examination and lab studies;
- Effective use of the contraceptive method chosen and the benefits, risks, safety, limitations and efficacy of the method;
- Warning signs and complications to report to the provider;
- Possible side effects of the methods;
- How to discontinue the method selected;
- Information regarding back-up method use;
- Use of emergency contraception;
- Planned return visit schedule;
- Emergency 24-hour telephone number;
- The location where emergency services can be obtained when the clinic is closed; and
- Appropriate referral for additional services as needed.

STD and HIV Counseling:

All clients must receive thorough and accurate counseling on STD's and HIV. This counseling is an individualized, face-to-face, dialogue with a client in which there is a discussion of personal risks for STD's and HIV.

A risk assessment must be completed. Clients with behaviors that put them at risk for STD's and HIV must be given advice regarding risk reduction and must be advised whether clinical evaluation is necessary.

Family planning staff/counselors must offer STD and HIV counseling that includes, at a minimum, the following:

- Education about STD's, HIV infection and AIDS, including the modes of disease transmission and behaviors that place clients at risk;
- The relationship between HPV and cervical cancer;
- STD symptoms or absence of symptoms;
- The relationship between CT/GC and infertility;
- Information on risks and infection prevention;
- Risk reduction strategies;
- HIV testing availability; and
- Ways to inform partner(s) of potential risk.

All clients must be encouraged to use condoms, in addition to another method of contraception, for the prevention of STDs and HIV.

Preconception Health:

Since roughly half of the U.S. pregnancies are unintended, the agency must provide basic preconception health education to clients at key visits, such as initial visits, annual visits, and negative pregnancy test visits. Though ever under time constraints, clinic staff can use the rapport and trust they establish over time to help the client desirous of, or at risk for, pregnancy.

At a minimum, all clinics must provide information on the topics below. In addition, they must provide a handout on preconception health, with opportunities for discussion. The topics to be included in routine preconception education are:

- Key messages: Half of pregnancies are unintended. Be healthy in your “childbearing” years. As you set life goals for education and employment, make planning for any future pregnancy a key to your success.
- Use highly effective methods to prevent, plan or space a pregnancy.
- Stop or greatly reduce smoking, alcohol and street drugs.
- Practice safer sex. Use condoms.
- Know your HIV status. Be tested unless you are sure.
- Know your rubella, tetanus, and hepatitis immunization status.
- Eat a variety of healthy foods.
- Engage in regular weight bearing exercise.
- Maintain a healthy body weight.
- Practice good oral health.
- Finish all medication if diagnosed with any STD. Make sure partner(s) are treated.
- Take 400 mcg folic acid daily. Check the dosage on a multi-vitamin you take now.

Documentation of all counseling provided must be included in the client’s medical record. Refer to Appendix I for Routine Preconception Education guidance and checklist.

8.3 HISTORY, PHYSICAL ASSESSMENT AND LABORATORY TESTING

History:

At the initial comprehensive clinical visit, a complete medical history must be obtained on all female clients. Pertinent changes in the client’s health history must be updated at subsequent clinical visits. The history must be taken in a language understood by the client, whether directly or through an interpreter.

The history must include:

- Significant illnesses, e.g., cardiac disease, embolic disease, cancer, pelvic infection, hospitalizations, surgeries, blood transfusions or exposure to blood products, and chronic or acute medical conditions;
- Allergies/drug reactions;
- Current use of prescription and over-the-counter medications;
- Extent of use of tobacco, alcohol and other drugs;
- Immunizations, including rubella, tetanus and hepatitis status;
- Review of systems;
- Pertinent history of immediate family members;
- For women 40 years or above, screening history for colorectal cancer risk
- Depression or other mental health problems;
- Family or intimate partner violence;
- Coercion of minors to engage in sexual activity; and

- Partner history, including injection drug use, multiple sexual partners, risk history for STDs and HIV, and bisexuality.

Histories of reproductive function in female clients must include at least the following:

- Menstrual history;
- Sexual history;
- Obstetrical history;
- Gynecological conditions;
- Sexually Transmitted Diseases;
- HIV;
- Pap test history (date of last pap, any abnormal pap and treatment);
- History of blood transfusion prior to 1984;
- In utero exposure to diethylstilbestrol (DES), if born between 1940 and 1970. (Clients with prenatal exposure to exogenous estrogens should receive information/education and special screening either on site or by referral);
- Past and current contraceptive use, including adverse effects and reason for discontinuation, as well as the method desired; and
- Assessment of contraindications for use of contraceptive methods.

The health history may be a self-administered form that must be completed by all new clients prior to the physical examination. The client should be instructed on how to fill out the form and staff should answer any questions the client may have. Clients should sign and date the form in the appropriate spaces. After reviewing the form, questioning the client appropriately, and charting any additional information, the clinician must sign and date the form in the appropriate spaces.

A medical history update must include the following:

- Recent illness, medical problems or surgery;
- Pregnancy;
- Contraceptive method problems;
- Changes in smoking or drug use behaviors;
- Changes in medications used;
- Changes in sex partner risk history; and
- Pertinent changes in health of first order relatives

Physical Assessment:

For many clients, family planning programs are their only source of continuing health information and clinical care. Therefore, all female clients should have a complete physical assessment at the initial and annual return visits.

For all clients the complete physical examination includes:

- Height and weight;
- Blood pressure evaluation;
- Thyroid palpation;
- Auscultation of the heart and lungs;
- Examination of extremities;
- Clinical breast examination and instruction for the client in breast self examination;
- Abdominal palpation;
- Pelvic examination that includes visualization of the genital area, vagina and cervix and bimanual examination;

- Laboratory specimen collection for pap tests and STD screening, as indicated. (Refer to Laboratory Testing below for additional information); and
- Rectal examination and fecal occult blood test for individuals over 50. (Women 40 years or older must be assessed for colorectal cancer risk. If at risk, the fecal occult blood test must be offered annually.)

All physical examination and laboratory test requirements stipulated in the prescribing information for specific methods of contraception must be followed.

Following counseling about the importance of prevention services, if a client chooses to decline or defer a service, this must be documented in their medical record. Counseling must include information about the possible health risks associated with declining or delaying preventative screening tests or procedures.

Physical examination and related prevention services should not be deferred beyond 3-6 months after the initial visit, and in no case may be deferred beyond 6 months, *unless in the clinician's judgment, there is a compelling reason for extending the deferral.* All deferrals, including the reason(s) for deferral, must be documented in the client medical record. No deferral may extend beyond 12 months. All exams deferred beyond six months must be documented in a log for the IDHS annual clinical review.

IDHS has developed detailed guidance for protocol development, sample fact sheets and an assessment form for the provision of hormonal contraception without a pelvic exam for delegate agency use. These documents are included in Appendix I of this manual.

Laboratory Testing:

Laboratory tests can be important indicators of client health status and useful for diagnostic purposes. Certain laboratory tests are required for the provision of specific methods of contraception. Counseling should inform clients about the recommended tests as well as the limitations of specific tests (for example, false negatives or positives). The following lab procedures must be made available to clients on site or by formal referral, provided to clients if required in the provision of a contraceptive method, and may be provided for the maintenance of health status and/or diagnostic purposes:

1. Chlamydia Test
2. Gonorrhea Test
3. Fasting Glucose Test
4. Fecal Occult Blood test
5. Hemoglobin or Hematocrit
6. Herpes Test
7. HPV/DNA Test
8. Pap Test
9. Pregnancy Test
10. Sickle Cell Test
11. Syphilis Test
12. Total Cholesterol
13. Urinalysis, as indicated (for initial visit clients)
14. Vaginal Microscopy

Pregnancy Testing:

The pregnancy test is a standard service for family planning clients and must be provided on site. Clients should be encouraged to have the results confirmed by a pelvic examination scheduled within two weeks. Appropriate pregnancy test counseling must be provided. Clients who are

pregnant must be offered options counseling and provided with information on prenatal care, adoption and pregnancy termination, as requested. (Refer to section 8.6 “*Pregnancy Diagnosis and Counseling*” in this manual for detailed information). Those clients who are not pregnant should be provided with contraceptive counseling.

STD Testing and Treatment:

At the initial and annual visits, clients must have a thorough health history and physical assessment that includes screening for risk of STD infection and sexually active women less than 25 years of age will be tested for Chlamydia and Gonorrhea. Risk assessment may indicate the need for more frequent screening than yearly. Clients may also be screened for Chlamydia and Gonorrhea according to the one or more of the following criteria:

- The client has signs or symptoms of infection, such as vaginal discharge, mucopurulent cervicitis, pelvic inflammatory disease;
- The client’s sex partner was diagnosed with Chlamydia or Gonorrhea;
- In the past three months, the client has had a new sex partner, more than one sex partner, and/or sex partner with another partner; or
- The client has a history of an STD in previous three years.

In addition, clients who receive IUD/IUS must be screened for Chlamydia and Gonorrhea per protocol.

Clients who are symptomatic of other STDs should be screened and treated in accordance with the most current Centers for Disease Control and Prevention Sexually Transmitted Diseases Treatment Guidelines.

Refusal of Laboratory Services:

The client has the right to refuse any laboratory test/procedure. If the test is a prerequisite for a procedure or prescription, the client shall be informed that unless the test is done, the procedure cannot be performed or the prescription cannot be given. The client’s refusal should be documented in the medical record.

Laboratory Testing Protocol and Quality Assurance:

The IDHS has issued written protocol guidance for Cervical Cancer Screening, Colorectal Cancer Screening and Sexually Transmitted Diseases Screening and Treatment. Delegate agencies must have written laboratory protocols and operating procedures in place for all laboratory testing and follow-up procedures for all abnormal test results. The delegate protocol must reflect the IDHS issued protocol (Refer to Appendix I). A system must be in place to track abnormal findings. The best practice approach is to keep an abnormal log to ensure follow up protocol is observed.

Delegate agencies are required to conduct quality control, equipment maintenance and proficiency testing for on-site lab testing. All family planning clinics must also be in compliance with CLIA regulations, effective September 1992, that apply to their CLIA certification type. A current CLIA certificate should be displayed on site.

When contracting and utilizing the services of an off-site lab the delegate must establish systems to assess the credentials of the contracted lab and to assure high quality lab testing. Cytology services must be provided by laboratories that are compliant with CLIA and State licensure regulations.

Notification, Referral and Follow-Up for Abnormal Test Results:

A procedure must be in place that addresses client confidentiality, notification of test results, and adequate follow-up of abnormal laboratory test results. Clinic staff must establish a mechanism

for contacting all “no contact ” clients in the event of abnormal lab test results and must document this contact in the medical record where applicable.

Referral and follow-up for abnormal tests must include:

- Documentation of the appropriate management for abnormalities;
- All follow-up with the client regarding significant lab results;
- Referrals for additional necessary services, if not provided on site;
- Documentation of reasonable attempts to contact the client that is consistent with the severity of the abnormality. (For example: documentation of 3 contacts within 6 weeks, 2 of which will be in writing).

8.4 FERTILITY REGULATION (CONTRACEPTION)

All FDA approved methods of contraception must be available to family planning clients on site or by formal referral. All reversible contraceptives must be FDA approved, except for fertility awareness methods and abstinence. Written protocols and procedures must be in place for all reversible contraceptive methods. Current FDA guidelines regarding method contraindications should be followed when prescribing contraceptives.

For all methods of contraception, appropriate client education must be provided and should be client focused. The goals of client education are to ensure the consistency and accuracy of information provided, to present information in an unbiased manner and to present education that is appropriate to the client’s age, level of knowledge, language, and socio-cultural background.

More than one method of contraception may be used simultaneously by a client and may be particularly indicated to minimize the risks of STD, HIV and pregnancy. Consistent and correct use of condoms should be encouraged for all persons at risk for STDs and HIV.

Reversible Contraception:

Delegate agencies must offer the following currently available reversible methods of contraception to clients enrolled in the family planning program:

- Abstinence
- Hormonal Methods:
 - Oral Contraceptives
 - Implant
 - Injectables
 - Transdermal contraceptive patch
 - Vaginal Contraceptive Ring
 - Emergency Contraception
- Intrauterine Device/System (IUD/IUS)
- Barrier Methods (female and male condoms, cervical cap, sponge, diaphragms, spermicides)
- Fertility Awareness Methods

Emergency Contraception (EC):

To maximize the reduction of unintended pregnancies, delegate agencies’ protocols are required to include the on site provision of emergency contraception. The protocol must comply with the FDA recommendations for the administration of drugs or devices for emergency contraception.

EC is more effective the sooner it is taken and the FDA recommended window is within 72 hours of intercourse. Recent studies indicate effectiveness up to 120 hours. EC acts by delaying or

inhibiting ovulation and/or altering tubal transport of sperm and/or altering the uterine lining thereby inhibiting implantation. These mechanisms are basically the same as occur with the routine use of standard oral contraceptives.

Emergency contraception should not be confused with abortion. EC pills are not effective if the woman is pregnant. Family Planning Programs are prohibited from providing abortions using Title X funds.

Appointments, physical exams, and routine pregnancy testing can be barriers to effective provision of EC. A pregnancy test may be indicated in some instances by the client's history. Thorough birth control counseling must accompany or follow use of emergency contraception to discourage clients from considering this a routine method of contraception. Refer to Appendix I for IDHS EC Client Information Fact Sheet on Emergency Contraceptive Pills.

Non-Reversible Contraception-Sterilization:

The consent and counseling process for sterilization must assure that clients making the decision to undergo sterilization do so completely voluntarily and that the decision is made with the full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures.

All Federal regulations for sterilization must be met if the procedures are performed or arranged by the delegate, including the following:

- The individual must be at least 21 years of age;
- The individual is mentally competent;
- The individual has voluntarily given informed consent in accordance with the procedures of 50.201, Subpart B, 42 CFR *Sterilization of Persons in Federally Assisted Family Planning Projects*; and
- At least 30 days, but not more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. Consent to be sterilized at the time of premature delivery or emergency abdominal surgery may be given if at least 72 hours have passed after the informed consent is obtained. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

Refer to Appendix K for the Illinois Sterilization Program Procedures and the required payment forms.

8.5 INFERTILITY SERVICES

Delegates must make basic infertility services available to women and men desiring such services and must establish written protocol and procedures for its infertility services. This protocol must meet the program requirements and define the scope of the infertility services, and whether those services will be provided on site and/or by referral.

All family planning clinics must provide Level I infertility services at a minimum. Level I infertility services include an initial infertility interview, including an informed consent, complete medical, menstrual and sexual history, a complete physical and pelvic examination, lab testing (including Hgb/Hct, Pap, Gonorrhea and Chlamydia testing) education and counseling, and appropriate referral. The education and counseling should include:

- A basic discussion about male and female anatomy and the physiology of conception as it relates to the client's needs or concerns;
- Reassuring the client that infertility does not relate to sexuality;

- The benefits and risks of any proposed diagnostic and therapeutic measures;
- A description of how the infertility study may proceed. (Clinics must advise the client that the infertility investigation will consider both partners because there may be more than one contributory factor); and
- Referral to a physician with training and experience in infertility.

Level II and Level III infertility services are considered beyond the scope of the Illinois Family Planning Program. Level II services may only be provided by clinicians who have special training in infertility. Level II services include semen analysis, assessment of ovulatory function and post coital testing. Level III infertility services include more sophisticated and complex testing and procedures than both Levels I and II.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Pregnancy testing is one of the most common reasons for a first visit to a family planning clinic. It is important to use this opportunity as an entry point for providing education and counseling about family planning and reproductive health. Personnel involved in pregnancy diagnosis and counseling should have knowledge of:

- Pregnancy testing procedures
- Preconception education
- Prenatal care and delivery
- Infant care, foster care and adoption
- Pregnancy termination
- Availability of referral services
- Methods of contraception
- Federal, state and local requirements
- Non-directive counseling skills and techniques
- Required documentation

The client's response to counseling should be documented in the medical record.

All family planning delegate agencies must provide pregnancy diagnosis and counseling to all clients in need of this service. However, if a pregnant woman is seeking proof of pregnancy simply for evidence of eligibility for other public services, agencies should seek support from sources of funds other than Family Planning grants.

Pregnancy cannot be accurately diagnosed and staged through lab tests alone. Pregnancy diagnosis consists of:

- Informed consent;
- History;
- Pregnancy testing; and
- Physical assessment, including a pelvic examination, when appropriate.
 - If the medical evaluation cannot be performed in conjunction with the pregnancy test, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 14 days.
 - If the pregnancy test is negative but the physical examination and history are indicative of probable pregnancy, the client must be encouraged to schedule a repeat pregnancy test within an appropriate time frame. Prescriptive methods of contraception should not be given if a pregnancy is suspected.
 - For clients with a negative pregnancy diagnosis, the cause of the delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and treatment. Clients with a history of PID (due to Chlamydia and other STDs) are at high risk for ectopic pregnancies. Follow-up with these clients must occur and must be documented in the medical record.

Pregnancy Options Counseling:

Family planning clinics must offer pregnant clients the opportunity to be provided with information and counseling regarding each of the following options:

- Prenatal care and delivery;
- Infant care, foster care and adoption; and
- Pregnancy termination

All pregnancy options must be named. All materials provided to clients on the pregnancy options should be balanced. A referral sheet that provides 2-3 referrals for each pregnancy option is highly recommended. If requested to provide information and counseling, family planning counselors must provide neutral, factual information and non-directive counseling on each of the options and referral upon request, except with respect to any option(s) about which the pregnant client indicates she does not wish to receive information and counseling.

1. Counseling Content: Unplanned Pregnancy and a Positive Test Result:

Clients with an unplanned pregnancy may be unsure about their pregnancy options. Provide them with the following information to assist them in making an informed choice:

a. Prenatal Care and Parenting:

Provide clients considering the choice of carrying their pregnancy to term and parenting with information about good health practices during early pregnancy, and stress the medical, social and financial aspects of prenatal care and parenting, such as:

- the need for early and ongoing prenatal care;
- the importance of proper nutrition and exercise;
- the significant benefits of knowing her HIV status early in the pregnancy;
- the negative impact of smoking, drugs, and/or alcohol consumption, lead and other toxic chemicals/substances and exposure to x-rays;
- the need to check with her physician before taking any medications or over the counter products;
- the financial aspects of pregnancy and parenthood; and
- her relationship with the father of the baby.

When a prenatal referral is appropriate, encourage the client to schedule an appointment within two weeks of the pregnancy diagnosis. If appropriate, refer the client to other services, such as screening for Medicaid eligibility and/or Women, Infants and Children and Family Case Management (WIC/FCM), at the time of the pregnancy diagnosis.

b. Prenatal Care and Infant Care, Foster Care and Adoption:

When clients are considering the choice of this option, additional counseling may be required. In such cases, refer the client for prenatal care and counseling services. Along with these referrals and the counseling outlined above in Prenatal Care and Parenting, other important medical, social or financial areas for discussion include:

- discussion of the different types of adoption that are available;
- birthparent rights, termination of parental rights and finalization of adoption;
- discussion of the procedural aspects of licensed adoption agencies, such as placement directly after birth with adoptive parents, foster care until after termination of parental rights, availability of housing for the birthmother, and input by birthparents in the matching

- process;
- legal, medical or other costs.

c. Pregnancy Termination:

Provide clients requesting information about pregnancy termination with medical, social and financial information about this option, such as:

- the timetables for medical and surgical terminations;
- general information about medical and surgical termination procedures. The client will receive in-depth, extensive counseling from the abortion provider;
- safety/risks of the procedure;
- the cost of the procedure;
- the importance of the follow-up examination following the procedure; including obtaining an effective contraceptive method.

Referrals for medical or surgical pregnancy termination may be given to clients upon request. Termination referrals should be made relative to the client's LMP. It is important to note that Title X family planning clinics may provide referral information such as the name, address, telephone number, and fees for abortion providers. A Title X family planning clinic may NOT provide services that directly help a client secure pregnancy termination services such as to negotiate a reduced fee, make an appointment for the client or provide transportation to the procedure.

If the client with an unintended pregnancy is in need of additional information/counseling to make a pregnancy options choice, the client must be referred to other community based social service or medical facility that will provide her with the additional assistance and counseling to make an informed decision.

2. Counseling Content: Planned Pregnancy and a Positive Test Result:

Counseling information will deal with the importance of early prenatal care, proper nutrition, and the cessation of smoking and drug/alcohol intake. Referral should be made to an appropriate prenatal care provider. Prenatal vitamins may be given to the client at the time of this visit. See also the previous section on Prenatal Care and Parenting above.

3. Counseling Content: Unplanned Pregnancy and a Negative Test Result:

No options counseling is indicated. However, clients who are found not to be pregnant and not seeking pregnancy should be provided with counseling about their feelings about the test results. Counselors should define the limitations of the pregnancy test and stress the need for a follow-up appointment if menses does not occur within two weeks. Also, preconception health, contraception information, contraceptives, and/or prophylactic emergency contraception should be discussed and/or dispensed. A follow up family planning clinic appointment should be scheduled at the time of the pregnancy test visit. If not, document referral to the chosen provider in the client record.

4. Counseling Content: Planned Pregnancy and a Negative Test Result:

No options counseling is indicated. Preconception health messages should be reviewed. Provide counseling on fertility awareness, fertility determination and infertility and provide a referral for infertility services, if indicated.

8.7 ADOLESCENT SERVICES

Adolescents are a special segment of the population and attention should be given to their individual needs. Adolescent clients require skilled counseling and age appropriate information. Clinic staff working with adolescents should have at least a basic understanding of adolescent development as the adolescent's stage of development plays a significant role in how they make decisions.

Delegate agencies must address service delivery to adolescents in their annual work plan. The plan must include the total number of teens the agency anticipates it will serve and written protocols must address adolescent services. Specialized services for adolescents must include:

- Priority scheduling of appointments for counseling and clinical services for teens.
- Assurance of confidentiality, including:
 - All minors receiving any services funded by Title X are entitled to confidentiality and the parents/guardians of minors cannot access their minor children's medical records unless the minor agrees. This confidentiality also includes not confirming the client's clinic attendance.
 - Family planning services shall be provided to minors with no requirement of consent from a parent or guardian.
 - No notification will be made to a parent before or after a minor has requested or received family planning services.
 - If follow-up to the clinic visit is necessary, every attempt must be made to assure the privacy of the adolescent. Adolescents must be informed that their confidentiality will be maintained whenever possible; however situations may arise where it is necessary for contact (such as an abnormal pap report). An alternative method of contacting a "no contact" minor must be established at the time of the initial visit. Adolescents must also be informed that in special cases (e.g., sexual coercion or abuse) reporting to authorities is required.
- Adolescents should be fully informed of all of the procedures usually performed at the first clinic visit prior to their examination. Clinics must create an atmosphere in which teens are comfortable asking questions.
- **Adolescents seeking contraceptive services must be informed about all methods of contraception. Abstinence, as well as all other contraceptive options to reduce risks for pregnancy, must be discussed with all adolescents. Abstinence is defined as the decision not to have sex (vaginal, oral or anal). As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively. Adolescents should be advised to contact the provider if they are dissatisfied with their contraceptive method before stopping the method.**
- **Because adolescents are at high risk for STD and HIV infection, delegate services must encourage adolescents to undergo examination and testing and treatment, as indicated, either on site or by referral.**
- **During the initial visit, the physical examination for adolescents may be deferred for 3-6 months, if necessary. Refer to Section 8.3 in this manual for further information on examination deferrals.**

Additional services with a specialized teen focus should be available. These services should include one or more of the following:

1. **Teen peer counselors;**
2. **Special clinic hours for teens;**
3. **Community education programs;**
4. **Representation from delegate agencies on local advisory committees or to school districts on teen sexuality issues, teen pregnancy programming, or adolescent health issues.**

It is important for clinic staff members not to assume that adolescents are sexually active simply because they have come for family planning services. The decision to become sexually active should be discussed with the adolescent. If the adolescent is not sexually active, the family planning staff should provide support for that decision. Refer teens to the IDHS Abstinence Only programs, as appropriate.

If the adolescent client is sexually active, the current sexual relationship must be assessed for behavior that reflects sexual coercion. Family planning staff should avoid assuming that the adolescent is completely comfortable with being sexually active. All adolescent clients must be provided with counseling on resisting attempts to coerce minors into engaging in sexual activities. Refer to Section 8.8 for detailed information. If the adolescent shares that she/he is not freely choosing to be sexually active, the family planning staff should assist in the clarification of the relationship and explore family involvement. Refer also to Appendix L for the IDHS Adolescent Care Mandates Policy.

Family Involvement Counseling:

Adolescents requesting family planning services should be counseled about involving their parent(s), caregiver(s) or other significant adult(s) in their decision to use contraception or about a pregnancy or sexually transmitted diseases. The minor's feelings about parental involvement should be explored, and every effort should be made to encourage them to involve their parent(s), caregiver(s) or other significant adult(s). If parental involvement is not possible, the adolescent must not be denied services and the adolescent client must know that family involvement is not a requirement to receive services.

Counseling sessions, which include the adolescent and his/her parent(s), caregivers(s) or significant other adult(s) should be offered.

Counseling to involve families in decisions about family planning services and counseling to resist sexual coercion must be documented in the client's medical record.

8.8 GUIDELINES FOR COUNSELING ON SEXUAL COERCION AND ABUSE

In the IDHS Family Planning Program, coercive sex is defined as:

A sexual relationship in which a partner possesses an unhealthy dominance that causes submissive behavior, not consensual behavior. Elements of coercion may be deception, bribery, manipulation, violence or threat of violence, which control when, where and how to have sex.

The IDHS Family Planning Program supports the belief that sexual relationships between individuals should be established and maintained in a mutually respectful and healthy context. IDHS recognizes that individuals who are uncomfortable with or feel that harm may result to themselves from a sexual relationship should have the opportunity to express these concerns during a visit to a family planning clinic and should receive appropriate counseling and referrals. This opportunity should be available to clients regardless of their age, gender, sexual orientation, marital status, or race/ethnicity. Adolescents, in particular, are a population that may need additional information about consensual sexual relationships and strategies for resisting coercive encounters.

The IDHS Family Planning Program requires the following of its family planning clinics to assure that clients receive information and counseling about coercive relationships:

1. Include general questions about abuse and sexual practices that may be indicative of an abusive or coercive relationship on intake questionnaires that are administered to all

- clients. This information should be reviewed during the individual education and counseling session with the client and documented in the client's record. Documentation should also include any referrals and follow-up information.
2. Offer adolescents, and other clients, as appropriate, information that presents strategies for avoiding and/or resisting coercive sexual situations. Documentation that adolescents have been given this information must appear in the medical record.
 3. In each family planning clinic there should be at least one staff person who has advanced training in screening, interviewing, documenting and reporting suspected minor victims of sexual coercion. Upon hire and then annually, all Title X staff must be oriented to the State of Illinois Department of Human Services Family Planning Program's Sexual Coercion Training Module.
 4. Clinic staff members are required to have thorough training opportunities to ensure that the staff is aware of the legal reporting requirements, as well as confidentiality concerns, and how these may affect counseling encounters with clients.
 5. Each family planning clinic must maintain a directory of local resources to which clients may be referred and assure that staff are trained on the appropriate use of this directory. All referrals should be followed-up to be certain that a client's needs are being appropriately addressed through the referral process.
 6. Adolescents should be counseled about the potential benefit of involving their parents, caregivers, and/or other appropriate adult family members in supporting their efforts to establish non-coercive sexual relationships.

Client Education On Sexual Coercion:

All clients who visit an IDHS family planning clinic for an initial or annual visit, regardless of age or gender, should be offered appropriate written education materials on sexual coercion. Family planning staff should briefly review the material with the client and explain the term "coercive sexual relationship." The discussion with the client should also provide techniques to prevent or resolve coercive sexual situations.

Client Clinic Services and Counseling:

At each initial and annual visit to a family planning clinic, a client, regardless of age or gender, should be evaluated for her/his risk of being in a coercive/abusive sexual relationship. The visit intake process must include a mechanism to reveal abusive or coercive relationships. One suggested way of eliciting this information is by asking, "Have you ever been forced to have sex?" If the answer is yes, the client should receive appropriate counseling and referral. If the answer is no, prevention information may be given. This discussion may also elicit a client's concern about safety in a current relationship. Refer to Appendix M for *Is Your Relationship Healthy?*. This checklist may be used with clients to assist them in determining sexually coercive relationships.

All information should be documented in the client's medical record. On the physical exam section of the visit form, include a check box or other flag for the examiner to assess for physical, verbal or behavioral indicators of coercion and abuse, and a place for documentation of findings and follow-up needed.

Referral Requirements:

In the event that a family planning clinic is unable to provide a service, such as professional counseling, medical services related to abuse or rape, or other victim service, to a client who has revealed information about a coercive relationship or incident, the client should be provided with a written referral. Wherever possible, clients should be offered a choice of referral service providers. Each clinic site must develop a referral resource guide, which will be maintained and updated annually.

Pertinent information must be forwarded in written form to the referral provider with the appropriate written client consent. This must be documented on the medical record along with copies of the written documents and the reason for the referral. Any written information received from the referral provider must be filed in the client's medical record. Any verbal communication should be recorded in the medical record as well.

Referral Follow-up Requirements:

Determination of the extent of the follow-up should be based on the nature of the problem referred. Family planning staff should consider telephone follow-up with clients who are extremely nervous, upset, depressed, victims of abuse and other cases where additional support in completing the referral may be useful. Family planning staff may arrange for the client to call in to report that the referral contact is complete or have the referral provider make the report. If a pre-arranged follow-up visit or contact is missed, staff may call the client within a reasonable time to ascertain if the client needs further assistance.

8.9 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

Children of women who received diethylstilbestrol (DES) or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. Women born between 1940 and 1970 must be asked if their mothers took estrogens during pregnancy. Clients with prenatal exposure to exogenous estrogens must receive information/education and special screening either on site or by referral.

Suggested approaches for identifying and treating estrogen-exposed offspring include:

- History includes screening questions for in-utero exposure to estrogen.
- Counseling for female clients who had prenatal exposure to DES should include information about the risks of developing a rare cervico-vaginal tumor and pregnancy complications. A referral for colposcopy should be made.
- Counseling for male clients who were exposed should include information that they are at risk of certain lesions of the genital tract and for decreased fertility.

SECTION 9.0: RELATED SERVICES

The following family planning related services, which can improve quality of care, may be offered if skilled personnel, equipment and funding are available.

9.1 GYNECOLOGIC SERVICES

Family planning should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of health care for clients with these conditions.

Immediate clinical diagnosis and treatment should include:

- Vaginitis/vaginosis
- Urinary tract infections

More complex procedures may be offered to family planning clients, provided that clinicians performing these services have specialized training.

9.2 SEXUALLY TRANSMITTED DISEASES (STDs) AND HIV/AIDS

Refer to Section 8.2 and 8.3 for STD and HIV/AIDS counseling and testing requirements. STD diagnosis and treatment, and HIV/AIDS testing beyond the scope of Program requirements may be offered if personnel and funding are available.

9.3 SPECIAL COUNSELING

Clients should be offered appropriate counseling and referral, as indicated, regarding future pregnancies, the management of a current pregnancy, and other individual concerns (e.g. substance use and abuse, family and intimate partner violence, genetic issues, nutrition, sexual concerns, etc.).

9.3a Preconception Education

See Section 8.2 for required basic preconception education for all clients. Advanced level preconception counseling should be provided if the client's history indicates a desired pregnancy in the future. At the client's request, a health risk appraisal should be provided to help promote a healthy future pregnancy. Appraisal forms and educational materials must be in place if this service is offered. If a delegate agency has an IDHS approved preconception counseling protocol, they may be reimbursed for this counseling service.

9.3b Nutritional Counseling

Nutritional counseling should include problem identification, basic nutritional information, screening and medical care to clients at high risk of nutrition problems or those requiring nutritional management of disease. All women of childbearing age will be educated on folic acid intake in prevention of neural tube defects in the infant. Each client having a low hematocrit/hemoglobin should be interviewed to determine if the cause could be a nutritional deficiency. Information on dietary source of iron should be given as appropriate. If indicated, follow-up testing for anemia must be provided.

9.3c Substance Use and Abuse

The health history should include assessment for substance use and abuse. Referral for substance abuse evaluation must be provided if indicated by the client's history.

9.3d Male Counseling

Provision of any services to males (e.g. supply pick-up, sterilization counseling, individual or couple education) presents the opportunity to provide education on the following:

- Proper use of condoms
- STD and HIV risk
- Testicular self exam (TSE) and breast self exam (BSE)
- Health relationships
- Family and partner abuse
- Supporting partner health (fertility awareness, female breast self exam)
- Sexual concerns

9.3e Family and Intimate Partner Violence

The health history should include key assessment questions to identify intimate partner or family violence. Referral for further evaluation, shelter, or support must be provided if indicated by the client's history.

Refer to Appendix N for an intervention resource for intimate partner violence.

9.4 GENETIC INFORMATION AND REFERRAL

Extensive genetic counseling and evaluation is beyond the scope of the DHS family planning program. However, basic information regarding genetic conditions and referral should be offered to clients who request it or to those who are in need of such services. Some delegates may be located in or near local health departments with genetic nurse educators available. The Illinois Department of Public Health may be contacted for the nearest genetic services.

Initial genetic screening consists of a careful family history of the client and the client's partner.

- More complete screening and counseling may be offered directly (by a genetic counselor who functions in association with clinical genetics team capable of providing comprehensive services) or indirectly (through referral to a comprehensive genetic service program).
- Linkages should be established with a comprehensive genetic service program for client referral.

In-service training in genetics should be arranged for project staff to enable them to provide basic genetic information.

Literature and informational materials regarding the availability of genetic services, including but not limited to prenatal diagnosis, should be available in the appropriate language to all clients on request. Information on IDPH's statewide genetic screening program should be available to all clients.

9.5 HEALTH PROMOTION AND DISEASE PREVENTION

For many clients, family planning programs are their only continuing source of health information and medical care. Projects should, therefore, assess the health problems prevalent among their service population and develop strategies to address these problems. Projects should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease. Refer to Section 8.0 Required Services.

9.6 POSTPARTUM CARE

Family planning programs may provide postpartum care in collaboration with local agencies or institutions that provide prenatal and/or intrapartum care.

If a family planning program assumes responsibility for postpartum care, then they should include the following:

- Assessment of the woman's physical health
- Initiation of contraception
- Postpartum depression education and screening. Special attention should be given to assessment of and referral for depression.

If time and staff skills permit, also include the following:

- Counseling and education about parenting
- Breastfeeding and resources for support
- Infant care anticipatory guidance
- Family adjustment

SECTION 10.0: CLINIC MANAGEMENT

10.1 EQUIPMENT AND SUPPLIES

Equipment and supplies shall be safe, adequate, and appropriate to the type of care offered by the family planning project.

It is the responsibility of the medical director to assure the proper selection and maintenance of equipment and supplies. A written log must be established to document equipment maintenance and calibration checks. Delegates are expected to follow applicable Federal and State regulations regarding infection control.

Appropriate IDHS procedures must be followed for the purchase and disposition of equipment costing \$500.00 or more, if purchased with Family Planning funds (grant or grant-related).

Equipment inventory reports must be submitted annually.

10.2 PHARMACEUTICALS

Delegate agencies must operate the family planning program in accordance with Federal and State laws relating to security and record keeping for drugs and devices.

The Illinois Title X Family Planning Program operates under the auspices of the Illinois Medical Practice Act. It is, therefore, the interpretation of the program that the physician must insure the patient is aware they have the option to have their prescriptive medications filled by a provider of his or her choice. It is further the interpretation of the IDHS that this does not require that a written prescription be extended to each client. Compliance is judged through standard DHS annual clinical evaluation measures including review of written protocols and direct observation of clinic practices.

The Medical Practice Act indicates that all persons licensed under this Act shall maintain a book or file of prescriptions as required in the Pharmacy Practice Act of 1987. This file has been determined to be the client's medical record. A separate file of the original written prescription is not required. Refer to Appendix I for DHS interpretation regarding prescriptive medications. The written prescription must include all standard prescription components.

It is essential that each delegate facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. A listing (formulary) of all drugs must be kept and annually revised. Purchase and use of generic drugs should be based on therapeutic equivalence as published by the FDA or in the Formularies of Therapeutic Equivalence accepted by the State Board of Pharmacy.

Delegates must have written protocols and operating procedures for the distribution, security and record keeping of all pharmaceuticals and supplies that include the following elements:

- The medical director of the family planning program is responsible for all policies and procedures pertaining to the general handling of pharmaceuticals.
- Prescription of pharmaceuticals is done under the direction of a physician as directed by the Medical Practice Act (who must have a drug control license to dispense medications). The physician may dispense indirectly under his/her delegated authority to a R.N. via standing orders or an APN via collaborative agreement and standard protocols. Pre-labeled, pre-packaged oral contraceptives may be distributed by trained staff, if so delegated by a dispensing prescriber.
- All medications must be prepackaged. Refer to the Pharmacy Practice Act related to repackaging of medications.

- All prescriptions vials/packages (including samples) must be labeled and contain the following information:
 1. Name/address of dispensing agency
 2. Date dispensed
 3. Name of client
 4. Name, dosage and quantity of drug dispensed
 5. Directions for use, including frequency of use
 6. Prescriber's name.
 7. Expiration date
 8. Lot number
- All clients must receive verbal and written instructions for each drug. The nature of drug education should be documented in the medical records.
- At a minimum, each site that provides medical services must have the following:
 - Emergency drugs and supplies for treatment of vasovagal reaction.
 - Emergency drugs and supplies for treatment of anaphylactic shock.
- There must be documentation that in-service education pertaining to the nature and safety aspects of pharmaceuticals is provided to staff involved in the provision of medications to clients.

Prescriptive Methods for Transfer Clients:

1. Title X agencies are not allowed to operate as a pharmacy. Clients who received a full exam within the last six months at another provider, may request that records be sent to the Title X clinic. A new client history must be completed and an informed consent form must be obtained. If the client does not return for the next annual exam, the prescription may not be extended without a full annual exam by the delegate agency. If the clients' last exam occurred over six months ago, the client should be treated as a new client with clinical protocols followed accordingly.
2. Delegate agencies must insure that all Title X education, counseling and clinical service requirements were met and provide any required services not documented in the records received from the previous provider. The clinician will review the transfer records and decide if current prescription can be continued. The clinician must document the prescription in the client's record.

Pharmaceutical Purchasing and Inventory:

The purchasing, inventory, supply and provision of pharmaceuticals may be delegated to an appropriately qualified health professional, however, all family planning staff members are to be trained in all aspects of pharmaceutical and supply distribution. Delegate policies for purchase, inventory and storage of pharmaceuticals must include the following:

- Contraceptive and therapeutic pharmaceuticals must be kept in a secure place, either under direct observation or locked.
- Access to pharmaceuticals must be limited to health care providers responsible for distributing these items.
- A system must be in place to monitor the expiration date on drugs and ensure disposal of all expired drugs. Check with pharmaceutical companies to see if outdated stock may be exchanged.
- A system must be in place for client notification in case of drug recall must be in place.

340 B Drug Pricing Program:

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of drugs to federal purchasers and to certain grantees of federal agencies. Significant savings on pharmaceuticals may be seen by those entities that participate in this program.

Delegate agencies contracted for family planning by IDHS are eligible to participate in the 340B Drug Pricing Program and benefit from reduced costs for supplies for their family planning program. IDHS Family Planning is directly responsible for sign-up with and notification to the Office of Pharmacy Affairs when there are clinic additions, moves, or deletions. IDHS must also forward written approval of new and moved sites to DHHS Region V prior to such notification by the delegate agency. See Appendix O for IDHS Policy and Procedure for 340B Drug Pricing Registration. Visit the 340B website at <http://bphc.hrsa.gov/opa/howto.htm>.

Family Planning Cooperative Purchasing Program (FPCPP):

The family planning purchasing cooperative has been in existence since 1992 and assists Title X funded agencies in managing their higher cost/higher usage products and services. The Cooperative strives to:

- Maximize cost savings and increase participant buying power through combined purchasing contracts
- Standardize specifications and encourage consistent quality in product availability
- Provide a single location for vendor sales presentations, contract negotiations and general information.

Delegate agencies contracted for family planning by IDHS are eligible to participate in the Family Planning Cooperative Purchasing Program and benefit from reduced costs for clinical supplies, office supplies and other services for their family planning program. Delegate agencies must keep their address current with the FPCPP. For more information, visit the FPCPP website at <http://www.fcpp.org>.

10.3 MEDICAL RECORDS

General Guidelines:

Client medical records must be maintained in accordance with accepted medical standards and State laws with regard to record retention. Delegate agencies must establish written protocols and operating procedures for medical records that include the following:

- Each client who receives medical services must have a medical record (this must include all pregnancy testing/counseling clients).
- Medical records must be available to the client upon request.
- Medical records of clients must be maintained in accordance with the accepted medical standards. Medical records must be:
 1. Complete, legible, accurate, and written in ink;
 2. Uniform in content and format;
 3. Signed by the physician or other appropriately trained health professional making the entry, including name, title and date;
 4. Readily accessible;
 5. Systematically organized and in chronological order to facilitate retrieval and compilation of information;
 6. Confidential;

- 7. Safeguarded against loss or use by unauthorized persons; and
- 8. Secured by lock when not in use.
- HIPAA regulations regarding medical records must be followed.

Medical Record Content:

Delegate policies regarding the content of the medical records must include:

- Complete and accurate information to identify the client;
- Indicate where and how the client can be contacted;
- Confidentiality assurance statement;
- Informed consent for services and method specific consent per IDHS guidelines;
- Documentation of medical telephone encounters;
- Date and signature of the clinician or other appropriate health care provider making the entry:
 1. Signature contains name and title, and
 2. A signature log must be used if full name and title is not used in medical record
- Personal data:
 1. Name
 2. Address, phone number, and how to contact
 3. Age
 4. Sex
 5. Income eligibility (income information should not be a barrier to service)
 6. Number of pregnancies, abortions, live births
 7. Unique client number
 8. Race and ethnicity
 9. Need for an interpreter or other special consideration (e.g. accommodation for disability)
- Medical history;
- Allergies and untoward reaction to drug(s) recorded in a prominent and specific location;
- Results of physical exam;
- Reports of clinical findings, diagnostic and therapeutic orders;
- Laboratory test results and follow-up done for abnormal results;
- Treatments initiated and special instructions and scheduled revisits;
- The contraceptive method chosen by the client;
- Documentation of all counseling, education, and social services given;
- Refusal of any service;
- Problem list at the front of the chart listing identified problems to facilitate continuing evaluation and follow-up; and
- Documentation of continuing care, referral, follow-up and scheduled revisits.

Client financial information, other than income eligibility information, should be kept separate from the client medical record. If financial information is included in the medical record, it must not be a barrier to client services.

Confidentiality and Release of Medical Records:

A system must be in place at the clinic to assure the confidentiality of client records. A release of the client's medical record information can occur only with client's written consent, except as may be necessary to provide services to the client, or as required by law. Adolescents have the same rights to confidential services as any client.

Delegates must have a consent form for the release of medical records. Prior to the release of records, the consent form for release of information must be signed by the client and must specify

to whom information may be disclosed and what specific information may be disclosed. Only the specific information requested may be released.

Prior to the release of any information in response to the serving of a subpoena, the delegate agency must contact their agency's legal counsel for guidance.

HIV, mental health and substance use information should be handled according to law and released only with the specific consent of the client.

Delegate agencies must have a policy and procedure for allowing the client access to their own record.

Information collected for reporting purposes is disclosed only in summary or statistical form.

Medical Records Security:

Medical records are confidential and must be safeguarded against loss or use by unauthorized persons. All personnel, students, volunteers, auditors and program consultants and reviewers must execute a written confidentiality agreement before obtaining access to medical records. Refer also to Section 6.6 on training new or volunteer staff on confidentiality.

Medical records must be kept locked in secure files unless they are under the supervision of an employee who has a business need to see the medical record.

Medical records rooms will be locked after regular working hours.

Medical records must be secured in locked cabinets during the time the janitorial service cleans the area where records are stored.

Medical records being used by staff over a period of time must be kept in locked cabinets after regular working hours.

Fax machines must be placed in an area where staff may supervise and safeguard the medical record information that is sent from other providers regarding clients.

Records not filed after clinic hours, to be reviewed by employees the next day, must be kept in locked files.

Medical Records Retention:

The agency must have policies in place regarding the retention and destruction of medical records. For advice on record destruction, agencies are to contact agency legal counsel, or in the case of public entities, the Illinois Secretary of State's Illinois State Archives. Family planning clinics must retain all records, documents and correspondence relative to medical services for a period determined by agency legal counsel. Records may be stored in inactive or closed files per agency policies.

Records of minors shall be retained for a period past majority determined by agency legal counsel. Records of clients receiving contraceptive devices (implants, IUD/IUS) shall be kept indefinitely.

Record Monitoring:

Monitoring of client medical records must be periodically performed. (Refer also to Section 10.4, Quality Assurance, on quality monitoring of medical records).

Concurrent medical record monitoring should be performed after each clinic session by consistently assigned staff. There should be a system in place to identify medical record deficits and to resolve identified problems.

Periodic medical record audits must be conducted. Audits should randomly sample records of new patients, continuing patients, teens or method specific users for compliance to medical practice and documentation standards.

Family planning clinics must comply with audits of medical records and documents that may be conducted at any reasonable time by State and Federal personnel or other persons duly authorized by IDHS. This may include the review of client medical records, delegate policies and procedures, personnel records, job descriptions, and meeting minutes. All reviewers and auditors accessing delegate agency records must sign a confidentiality agreement.

10.4 QUALITY ASSURANCE

Delegate agencies must develop a quality assurance system that provides for the continued development and evaluation of their clinical and educational services and performance.

The quality assurance system must include written protocols and operating procedures and include the following:

1. An approved health care plan that is based on an on-going community needs assessment specifying all services to be routinely provided by the delegate, as well as the additional services provided for specific population groups.
2. A tracking system that identifies clients in need of follow-up and/or continuing care.
3. Medical audits to determine conformity with the program guidelines, standards and current acceptable medical practice that are conducted on an on-going basis. The medical audits should include:
 - A review of a reasonable number of randomly selected medical records by the medical director at least once a month.
 - A review of a minimum of 20 medical records, per clinic site per month, by the quality assurance personnel. A minimum of five medical records from each clinician should be reviewed at this time.
 - Medical audits should address completeness and accuracy of the medical record
 - Topic-specific audits are strongly recommended.
4. Annual performance evaluations for all family planning program staff, including the medical director.
5. Ongoing peer review by the medical director of all physicians and mid-level practitioners is recommended. This should include evaluation of both clinical skills and documentation practices. Re-certification in a relevant area of practice constitutes evidence of maintaining current skills in the field.
6. Annual update of clinic procedures and clinician protocol manuals reflecting current acceptable medical practices.
7. Infection control policies and procedures reflecting CDC recommendations and current acceptable medical practice.
8. A periodic patient flow analysis.

9. Periodic client satisfaction surveys for input on services provided both on-site and by referral. Satisfaction must be evaluated annually at a minimum, with programmatic changes responsive to client feedback, as indicated.
10. Regularly scheduled staff meetings, with minutes, to update and/or review medical or service delivery topics.
11. Equipment maintenance checks and calibration of equipment conducted on a regular basis.
12. Laboratory audits, including but not limited to the following:
 - Evidence of internal compliance with periodic laboratory proficiency testing procedures, according to the level of CLIA certification and/or tests being performed;
 - An annual review of credentials of contracted laboratories;
 - An annual pap test results audit, reviewing results of ACS or higher (refer to FPAR, Table 9 instructions); and
 - Routine monitoring for the accuracy of laboratory testing equipment and materials via the running of control tests; and
 - Evidence of staff skills in test performance.
13. Annual review of educational materials used in both the clinic setting and community education activities.
14. Annual review of all forms used by the delegate for completeness and applicability.
15. Routine monitoring of critical incident/occurrence reports.
16. Annual review of adequacy of provider liability insurance coverage.
17. CPR certification of clinic staff, as appropriate.
18. Documentation that drugs and supplies are checked routinely.
19. A process for monitoring the reliability and accuracy of the local client data system and that the data system assures program performance, quality care, and maximizes program revenues. The following components should be monitored:
 - Missing user data
 - Coding error editing
 - Data outcome
20. Annual external financial audit.
21. Ongoing and systematic documentation of the quality assurance activities.

Delegate agencies should have a quality assurance committee in place. This committee should meet monthly/quarterly to discuss quality assurance issues and to make recommendations for corrective action when deficiencies have been noted.

- If a formal quality assurance committee is in place, minutes should be kept of all quality assurance committee meetings.
- An in-house nursing or medical advisory committee may assume the function of the quality assurance committee.

PART III: PROGRAM EVALUATION AND MONITORING

Part III of the Family Planning Guidelines consists of the program evaluation criteria and review components, as well as the evaluation methodology, used by IDHS for program review. **It is suggested that delegate agencies utilize this section for self-evaluation to assure compliance with the program requirements.**

SECTION 11.0: INTRODUCTION TO THE IDHS PROGRAM REVIEW

The purpose of the IDHS Family Planning Program Review is to determine whether IDHS supported family planning delegate agencies are managed effectively and comply with the intent of Title X and the IDHS program requirements. The Family Planning Program Review is part of an overall State effort to strengthen and improve the administrative and clinical performance of delegate agencies. The Program Review should also be regarded as a mechanism to assist projects in assessing their own performance and identifying strengths and weaknesses. The review incorporates: (1) an annual clinical review, including observation; (2) a periodic administrative review; (3) an annual grant application; (4) annual and semi-annual required reports, including semi-annual progress reports on the previous year's objectives; (5) periodic monitoring of client visit and services data; and (6) periodic technical assistance visits.

The general parameters of the program review include:

1. Evaluation of Administrative Management
 - a. The delegate agency demonstrates the capability to make decisions based upon clearly stated goals and objectives approved by the IDHS.
 - b. The delegate agency operates under a well functioning family planning governing board. The board must adhere to the standards put forth in Section 4.0 of this Manual in regard to their composition and function.
 - c. There is a management information system in place that generates timely and accurate client and financial data, which interfaces with IDHS's contracted data vendor. These data provide useful information for planning and management and meet the Family Planning Annual Report (FPAR) requirements.
 - d. The personnel management system includes appropriate policies and procedures for employee orientation, job descriptions, staff recruitment and selection, performance evaluation, promotion, grievances, termination, compensation, benefits, employee discrimination and affirmative action.
 - e. The delegate agency financial management system is in compliance with Title X and the IDHS guidelines regarding cost of operations, billing, and collections.
2. Evaluation of Clinical Management
 - a. High quality health care is consistently made available to clients by the delegate agency. Providers are licensed and certified as required.
 - b. Medical and laboratory services comply with program requirements.

- c. Major conditions (birth control method management, abnormal paps, STDs, etc.) are cared for according to the written policies, procedures, protocols and standing orders as approved by the agency's medical director.
 - d. The delegate agency provides drugs and supplies that are safe, appropriate, and as cost effective as possible.
 - e. The delegate maintains systems that support good health care delivery (e.g., medical records, tracking systems, referral systems, quality assurance systems, etc.).
3. Evaluation of Client and Community Education
- a. The delegate agency is evaluated for compliance with Title X and IDHS guidelines regarding review of educational materials, client education, community education, program promotion and community participation according to Sections 6.8, 6.9 and 6.10.
 - b. The delegate agency has an approved and established plan and process for community education and program promotion based on community needs assessment.
 - c. Although the IDHS maintains a Family Planning Advisory Council to assist in program guidance and an Information and Education (I & E) sub-committee to guide the Program on clarification of delegate agency I & E and Community Education policies, the primary responsibility for Information and Education resides with the delegate agencies.
 - d. Delegate agencies must have an I & E committee and must submit I & E Committee minutes at least annually to the IDHS.

SECTION 11.1: IDHS COMPREHENSIVE PROGRAM REVIEW COMPONENTS

The IDHS comprehensive program review of delegate agencies consists of six major components. Each component utilizes standardized review processes and/or review instruments. The elements of the family planning program that are reviewed correspond directly to the guidelines issued in this manual. Questions on the review instruments are posed to be answered in the affirmative and any negative responses indicate delegate noncompliance with a particular guideline.

Clinical Review: The MCH Nurse Consultants conduct annual onsite clinical reviews for Title X compliance utilizing designated audit tools. The Nurse Consultants evaluate all clinical services, including certain personnel and financial sections that relate to client services. The evaluation/audit instruments include:

- Family Planning Delegate Agency Clinical Review Criteria
- Family Planning Delegate Agency Clinical Review Tool
- Medical Chart Audit/CVR Billable Services Audit Tool
- Illinois Title X Family Planning Clinic Infertility Prevention Project Chlamydia and Gonorrhea Screening Criteria Chart Audit Tool (as required)
- Sterilization Audit Tool (if applicable)
- Separation of Title X Family Planning and Abortion Services (when applicable)

(Refer to Appendix P for the IDHS Family Planning Delegate Agency Clinical Review Criteria and Tools).

Administrative Desk Audit: The IDHS's administrative review process for delegate agencies is conducted to ensure all other requirements not evaluated during the clinical audit and grant application process are being met. These include:

- Community Education Plan;
- Personnel Management, including the orientation outline specific to family planning, current job descriptions, and personnel policies; and
- Financial Management, including charges, billing and collection policies; cash handling policies; fiscal policies and chart of accounts.

The Administrative Desk Audit procedures outline a tiered schedule (6 months, 2, 3, or 4 years) for audits based on compliance with program requirements. (Refer to Appendix Q for the Administrative Desk Audit).

Delegate Agency Grant Application: The IDHS requires an annual grant application that includes:

- Signed Title X Assurance of Compliance
- Provider Directory Information
- Clinic(s) Schedule
- Services Provided Checklist
- Organizational Requirements
- Information and Education Committee
- Geographic Service Area
- Needs Assessment, when applicable
- Health Care Plan, when applicable
- Work Plan
- Sterilization Waiver Letter, if applicable
- Schedule of Discounts
- Sliding Fee Scale
- Financial Status Baseline Report (Budget)
- Revenue Analysis of Patient Fees
- Cost Center Report
- Cost Analysis

Required Reporting: As outlined in Section 6.7, Required Reporting, delegates must submit required reports for review by IDHS staff on an annual or semi-annual basis. Included in these required reports are the following, which are considered key elements for program evaluation:

- Community Education/Outreach Report
- Equipment Inventory Report
- Family Planning Annual Report (FPAR)
- Family Planning Staff Training Attendance Report
- Financial Status Report (FSR)
- Information & Education Committee Meeting Minutes
- Sterilization Semi-Annual Report (if applicable)
- Work Plan Semi-Annual Progress Report

All of the above listed grant application documents and plans, along with all of the annual and semi-annual reports, are used for delegate program evaluation by the IDHS staff and for Federal

reporting compliance. Refer to Appendix A for all Grant Application Required Materials and Appendix H for Required Reports.

Client Visit and Services Data Monitoring:

The IDHS data reporting system contributes to service site monitoring by providing detailed reports on the client population and the services provided. From these data reports, IDHS staff determines if services are meeting the needs of the community and meeting the approved service objectives of the delegate agencies. Specifically, the IDHS reviews the data reported for the Family Planning Annual Report, as well as data from the IDHS Program Objectives Monitoring Report and the IDHS User, Visit and Extended Exam Comparison Report such as:

- Total unduplicated users;
- Low income users;
- Medicaid clients;
- Adolescents; and
- STD and HIV education/counseling encounters.

Minimally, the IDHS reviews these data every six months, at the mid point and the end of the program year. Delegate agencies are also responsible for data monitoring and should evaluate the quality of their data input quarterly.

Technical Assistance Visits: IDHS provides onsite technical assistance to any Title X funded site. Most often, technical assistance is provided to improve operations and assure compliance with guidelines. But technical assistance may also be provided to meet the specific request or need of a particular site or delegate agency.

The focus of technical assistance visits generally fits into the following four categories:

- a) *Clinical Operations:* including assistance with medical policies, standards or procedures, standing orders, clinic staff orientation, implementation of new clinical services, clinical in-service training, client scheduling, patient flow, clinic efficiency, etc.
- b) *Management Development:* including assistance with training of new site managers, staff scheduling, personnel issues, data analysis, facility management, operational efficiency, cost effectiveness and outreach planning.
- c) *Data Operations:* including assistance with pertinent systems enhancements, software changes, and training on FPAR reporting and CVR completion.
- d) *Finance:* including assistance with budget preparation, billing and collections, cash management, cost analysis and fee schedule development and inventory management and control.

IDHS program and field staff conduct the technical assistance visits. IDHS also utilizes professionals outside of the department through the availability of the Title X Technical Assistance support.

SECTION 11.2: CLINICAL EVALUATION METHODOLOGY

The clinical evaluation methodology has both clinical and administrative components and includes a review of client records, policy and procedure manuals, and selected administrative documentation, as well as direct observation of clinical services. It is designed to establish the procedure and protocol for outside reviews and to assist the delegate agencies to conduct self-

reviews of their own programs. The clinical evaluation should provide information about the strengths and weaknesses of the delegate agency's current operations, which can be used for ongoing management and service improvement.

Evaluation/Reporting Coordination:

IDHS Regional MCH Nurse Consultants will conduct the IDHS Family Planning Program Clinical Review annually.

1. It is important that all of the clinical evaluation activities be conducted with minimal disruption of delegate agency project operations. The MCH Consultant should schedule the review four to six weeks in advance at a mutually agreeable time, date and location.
2. Delegates will receive a confirmation letter along with all audit criteria and tools that will be used in advance of the clinical evaluation date.
3. MCH Nurse Consultants should recognize that special circumstances may preclude an agency's exact adherence to an established program standard, and this should be noted in their comments. For example, a delegate agency may not be prescribing IUD/IUS onsite. This may be due to the untrained personnel; thus, an off-site clinician referral source must be identified in order for the agency to be in compliance with the Section 8.4 of the Title X guidelines.
4. After the clinical evaluation activities are completed, an exit conference will be conducted to share preliminary or pertinent findings/comments with the delegate agency staff. Delegate agency personnel may provide immediate feedback to IDHS review team members regarding negative findings and any recommendations made as a result of the program review.
5. The final written report will contain the completed indicators and required actions, along with recommendations for enhancing or improving practice, if indicated. The final report will be sent to the delegate agency within four weeks. As directed, the agency will respond with corrective action in writing within four weeks. MCH nurses may also provide additional technical assistance to assure compliance with the Title X or IDHS guidelines. The delegate agency will receive an acceptance letter from the Nurse Consultant approving the agency response to any required action.
6. IDHS Program Coordinator (Clinical) will facilitate the IDHS internal approval processes for the program review documentation.
7. Final approval of the program review resides with the Project Medical Director. This final approval may indicate the need for additional technical assistance or continued monitoring.

SECTION 11.3: ADMINISTRATIVE DESK AUDIT METHODOLOGY

The Administrative Desk Audit assures compliance with administrative requirements not reviewed through the clinical audit and grant application processes. The timeframe for the frequency of the desk audits is based on a tiered schedule (6 months, 2, 3, or 4 years) for audits based on each delegate's compliance with program requirements.

Desk Audit Coordination:

1. Depending on the scheduled timeframe for review, each delegate agency will receive notification and a checklist of all materials that must be submitted to IDHS for the Administrative Desk Audit.
2. The delegate will have four weeks to prepare and submit the requested documents to the IDHS program staff.
3. The IDHS staff will conduct and complete the desk audit review, including a written report with recommendations for each delegate agency within four weeks.
4. The delegate will be given an approval/disapproval status of the Administrative Desk Audit. If approved the delegate will be scheduled for the next Desk Audit in two to four years, depending on whether the audit was rated as acceptable, accomplished or exceptional. If the desk audit is not approved, the delegate will be asked to either submit more information and/or will be scheduled for a technical assistance visit within 6 months.