

Family Planning and Reproductive Health Manual

Bureau of Family Health
Kansas Department of Health & Environment

2016 -2017 Edition



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Family Planning and
Reproductive Health

**ADMINISTRATIVE
POLICY AND PROCEDURES
2016-2017**

Bureau of Family Health
Kansas Department of Health & Environment

Administrative Policy and Procedures

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ADMINISTRATIVE POLICY AND PROCEDURES

1. TITLE X FAMILY PLANNING SERVICES MISSION AND PROGRAM POLICY

Title X assists individuals and couples in planning and spacing births, contributing to positive birth outcomes and improved health for women and infants. The Office of Population Affairs (OPA) sets the standards for publicly funded family planning services in the U.S. The Title X statute, regulations and guidance offer patient protections by requiring that programs are voluntary, confidential and include a broad range of contraceptive methods. Program guidelines establish standards for the delivery of services based on the most current evidence. (www.hhs.gov/opa)

2. KANSAS FAMILY PLANNING SERVICES PROGRAM PURPOSE AND MISSION

The Family Planning Program in Kansas originated in 1965 with the passage of K.S.A. 23-501, 502. Subsequent to federal legislation in 1970, family planning services were broadened by providing federal funding and guidelines for services. The Kansas Title X Family Planning Program is viewed as a basic health service essential for the promotion of optimal family health throughout the life cycle.

The mission of the Kansas Title X Family Planning Program is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children and provide access to additional health services that lead to the overall improvement in the health of those individuals (prioritizing services to low-income and high risk individuals).

3. PURPOSE OF MANUAL

This Administrative Policies Manual contains information necessary for providing family planning and reproductive health services under federal Title X requirements. The KDHE Family Planning and Reproductive Health Manual has been developed to provide policies and procedures in line with the current federal regulations and guidelines for Title X funds, as well as additional information and guidelines that will assist sub-recipients in the management of their reproductive health care and family planning programs.

This manual outlines policies and procedures applicable to all sub-recipients. Some variations in management in the different sub-recipients providing services are anticipated and appropriate but many aspects of the program must be consistent and uniform throughout the state. Therefore, in addition to having this manual as a reference point for federal requirements, sub-recipient service site should use this manual as a guide in developing their own policy and procedure manuals specific to their local needs and goals.

4. SOURCES AND SUPPORTING DOCUMENTATION

This Administrative Policies Manual is based upon the following publications:

- 1) *Program Requirements for Title X Funded Family Planning Projects*, Version 1.0, April 2014 (<http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf>)

- 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, Vol. 63, No. 4, April 25, 2014
(<http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>)
- 3) Subsequent Policy Program Notices or PPN. Within this manual, those documents may be referred to as Title X Program Guidelines.

*Copies of 1 and 2 above are provided with this manual.

Sample documents and copies of some of the more relevant Kansas statutes and regulations are provided on the accompanying CD for which a Table of Contents is provided in the Administrative Appendix.

Any directives or instructions from the Program Guidelines that are not addressed in this document are still in effect and must be followed.

5. MANUAL CONTENT AND MAINTENANCE

The Administrative Policy and Procedure Manual contains sections dealing with the project management and administration, project services and clients, financial management, community participation, education, and project promotion, information and education materials review, and additional administrative requirements.

Every reasonable effort will be made to keep this manual current. If sub-recipients find errors in content they are encouraged to contact the staff at KDHE so that concerns can be addressed and changes may be made to the manual as needed.

6. CONTRACTS GRANT FUND USE, AND RECORDS RETENTION

Funds must be used in accordance with the Title X Family Planning Services Regulations, the terms and conditions of the award, and the Health & Human Services (HHS) grants administration regulations set out at 45 CFR parts 74 and 92. In addition, if a sub-recipient meets the federal threshold to require an OMB A-133 audit, the audit must be conducted in accordance with the HHS grants administration regulations (45 CFR parts 74.26 and 92.26), as applicable, by auditors meeting established criteria for qualifications and independence (OMB A-133).

KDHE will establish annual written agreements (called Aid-to-Local Contracts) with sub-recipients. Aid-to-Local (ATL) contracts will inform sub-recipients of the funding amount, the project period, and the applicable federal and state requirements that must be followed as a recipient of Title X family planning services funds. Funds received for the Title X family planning services may only be expended for the purposes for which the funds were awarded and in accordance with the approved application and budget.

All parts of the Title X Family Planning grant application submitted by the sub-recipient is part of the contract between the sub-recipient and KDHE. This includes budget, grant objectives, narrative and reported data. Any program or budget changes require a written revision to the application.

Program Adjustments

A request for approval of program changes (adjustments) must be submitted in writing to KDHE and approval must be granted before changes are implemented. The request should indicate what portion of the narrative or budget will be changed along with justification.

Budget Adjustments

A request for approval of budget changes must be submitted in writing KDHE if there is a 10 percent or more variance in the line item of the current budget. The deadline is June 20 to process the budget adjustment by June 30. Adjustments less than 10 percent of a line item may be made within the budget without prior approval. This includes moving less than 10 percent of the total budget amount for a program within the budget, revisions to the “other funds” categories and changes in a single category of personnel of less than .20 FTE. Examples of routine adjustments include replacing one full-time nurse with two part-time nurses or adjusting time between two programs. Year-end expenditures will be compared against the revised line item amount.

Records Retention

Sub-recipients generally must retain financial and programmatic records, supporting documents, statistical records and all other records considered pertinent to a grant for a period of 3 years from the submission date of the Quarter 4 (Final) Fiscal Report pertaining to the Family Planning Aid-to-Local Grant for a given State Fiscal Year.

A guideline for medical record retention and grant-related document retention is included in the Administrative Appendix.

7. DATA COLLECTION

KDHE must have program data reporting systems which accurately collect and organize data for program reporting and which support management decision making and act in accordance with other reporting requirements as required by HHS. To meet federal reporting requirements, minimum data elements must be collected and reported by each sub-recipient. Each sub-recipient must submit Detailed Client Encounter Data in a timely manner in accordance with the guidance provided by the KDHE Children and Families Section. The data collection software program used by KDHE for client level data is called DAISEY (Data Application and Integration Solutions for Early Years). DAISEY Solutions/KDHE website: <http://daiseysolutions.org/KDHE>

In addition, grant management is accomplished through the Catalyst/Grid 120 system. Applications, quarterly progress reports, and quarterly financial reports are done in this system

8. MANAGEMENT AND ADMINISTRATION

All Sub-recipients receiving Title X funds must provide services of high quality and be competently and efficiently administered.

8.1 Voluntary Participation

Prohibition of Coercion

Family planning services are to be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a)(2)). Clients cannot be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a)(2)).

Administrative policies used by service sites must include a written statement that clients may not be coerced to use contraception or service. Documentation at service sites must

demonstrate staff is informed at least once during the current project period that clients may not be coerced to use contraception or service. Personnel working within the family planning project must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).

Prohibition of Eligibility Prerequisite

A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).

Administrative policies used by service sites must include a written statement that client's receipt of family planning services may not be used as a prerequisite to receipt of any other services offered by the service site. Each client must sign a general consent form or other documentation that inform clients that receipt of family planning services may not be used as a prerequisite to receipt of any other services offered by the service site. Service site must have documentation (e.g., staff circulars, training, etc.) indicating staff has been informed at least once during the current project period that a client's receipt of family planning services may not be used as a prerequisite to receipt of any other services offered by the service site.

8.2 Prohibition of Abortion

Title X sub-recipients must be in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibit abortion as a method of family planning. Sub-recipients must have written policies that clearly indicate that none of the funds will be used in programs where abortion is a method of family planning.

Additional guidance on this topic can be found in the July 3, 2000, Federal Register Notice entitled *Provision of Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41281, and the final rule entitled *Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, which is available at 65 Fed. Reg. 41270.

8.3 Structure and Management

Family planning services under a Title X grant may be offered by sub-recipient agencies operating under the umbrella of a KDHE. Where core family planning services are provided by referral, the sub-recipient must submit a current copy of written agreements for the provision of services and reimbursement of costs as appropriate to KDHE.

If a sub-recipient wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements and approved by KDHE must be maintained by the sub-recipient (45 CFR parts 74 and 92). Sub recipients must include language specifying that all services are provided on a voluntary basis in all subcontracts.

The sub-recipient must ensure that services provided through a contract or other similar arrangement are paid for under agreements that include a schedule of rates and payment procedures maintained by sub-recipient. The sub-recipient must be prepared to substantiate that these rates are reasonable and necessary and provide a copy of the contractual document to KDHE.

All services purchased by sub-recipients must be authorized by the project director or his designee. (42 CFR 59.5(b)(7)). Documentation of purchases must demonstrate that the established policies and procedures established by KDHE are followed.

KDHE and each sub-recipient must maintain a financial management system that meets Federal standards, as applicable, as well as any other requirements imposed by the Notice of Award, and which complies with Federal standards that will support effective control and accountability of funds. Documentation and records of all income and expenditures must be maintained as required (45 CFR parts 74.20 and 92.20).

8.4 Charges, Billing, Collections and Income Verification

The sub-recipient will establish written fiscal management policies and procedures that shall include but are not limited to: payment of debts, payroll (including documentation of staff time and effort), record keeping, auditing, receivables/expenditures, as well as procurement of services, supplies and equipment and property management/inventory control system.

(See Administrative Appendix: *Billing and Collections Policy and Income Determination Policy*)

The sub-recipient is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the sub-recipient. Clients must not be denied project services or be subjected to any variation in quality of services because of inability to pay.

Sub-recipients should not have a general policy of no fee or flat fees for the provision of services to minors, or a schedule of fees for minors that is different from other populations receiving family planning services.

Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged, although sub-recipients must bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)).

- Service sites must develop and follow a written policy and procedure for verifying client income that is aligned with the Title X requirements.
- Assure service site policy and procedures for verifying client income does not present a barrier to receipt of services.
- Financial documentation at the service site indicates clients whose documented income is at or below 100% FPL are not charged for services.
- Financial documentation at the service site indicates that if a third party is authorized or legally obligated to pay for services, the sub-recipient has billed accordingly.

8.4.1 Income Determination

Within the parameters set out by the Title X statute and regulations, Title X sub-recipients have a large measure of discretion in determining the extent of income verification activity that they believe is appropriate for their client population. Although not required to do so, sub-recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients self-report.

(See Administrative Appendix: *Income Determination Guidelines*.)

8.4.2 Schedule of Discounts and Fees

A schedule of discounts, based on ability to pay, is required for individuals with family incomes between 101% and 250% of the Federal Poverty Level (FPL) (42 CFR 59.5(a)(8)).

The schedule of discounts must be updated annually to be in line with the most current FPL Guidelines. Service site documentation indicates client income is assessed and discounts are appropriately applied to the cost of services.

Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).

Sub-recipients should have a process to assess good cause and refer clients (or financial records) for families above 100% of the FPL to the service site director for review and consideration of waiver of charges. The site director's decision must be documented and the client informed of the decision.

For persons from families whose income exceeds 250% of the FPL, charges must be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR 59.5(a)(8)).

Sub-recipients are encouraged to conduct on a regular basis a cost analysis of their fee schedule to substantiate that the rates are reasonable and necessary.

Eligibility for discounts for unemancipated minors who receive confidential services must be based on the income of the minor (42 CFR 59.2). Service sites must have a process for determining whether a minor is seeking confidential services and stipulates that charges to adolescents seeking confidential services will be based solely on the adolescent's income. Client records must indicate appropriate implementation of policy.

(See Administrative Appendix: *Billing and Collections Policy and Income Determination Policy*)

8.4.3 Third Party Billing

Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all reasonable efforts must be made to obtain third party payment without the application of any discounts(42 CFR 59.5(a)(9)).

Family income should be assessed before determining whether copayments or additional fees are charged. With regard to insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

Clients with insurance cannot be asked to take a written prescription to a pharmacy when uninsured clients are provided with contraceptives at the time of the visit-- unless it is in the best interest of, or at the request of, the individual client.

Clients with a particular type of insurance are not to be subjected to a variation in services because that type of insurance won't reimburse the clinic. All efforts must be made to work with the company to insure reimbursement but even if the company refuses to contract with the clinic, those clients must still be treated and their fees determined on the sliding scale.

Sub-recipients must demonstrate that they have contracts with insurance providers, including public and private sources. Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a current written agreement with the state agency is required.

8.4.4 Collections and Confidentiality

Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Documentation at service sites demonstrate client services remain confidential when billing and collecting payments.

See Administrative Appendix: *Billing and Collections Policy and Income Determination Policy*

8.4.5 Voluntary Donations

Voluntary donations from clients are permissible; however, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies. On site documentation and observation must demonstrate that clients are not pressured to make donations and that donations are not a prerequisite to the provision of services or supplies. Observation may include signage, financial counseling scripts or other evidence.

8.5 Project Personnel

Title X sub-recipients must have approved personnel policies and procedures. Sub-recipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language. These policies should include, but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

Sub-recipient staff 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 cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)). Service site documentation should include records of cultural competence training, in services, client satisfaction surveys or other documentation that supports culturally competent services.

Sub-recipients must notify KDHE of changes in key family planning program personnel within 30 days so that KDHE may update the Family Planning program contact list and the OPA national database.

Sub-recipient service sites must provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning (42 CFR 59.5 (b)(6)).

Sub-recipients must provide evidence (e.g., medical advisory committee, board, and staff meetings) indicating involvement of the Medical Director in program operations. Clinical protocols must be approved by the Medical Director.

Sub-recipients must develop and have on file written local program policies and procedures for family planning services, based on the program standards and guidelines contained in the Kansas Family Planning and Reproductive Health Manual. The local policies and procedures and the Kansas Family Planning and Reproductive Health Manual shall be reviewed and signed by the physician advisor/consultant and the Family Planning staff on an annual basis.

8.6 Staff Training and Project Technical Assistance

Title X sub-recipients are responsible for the training of all project staff. Technical assistance may be provided by KDHE or the OPA Regional Office. Written records of orientation, in-service and other training attended by personnel. Policies should be in place and documentation provided that ensure staff received training on state-specific reporting/notification requirements.

KDHE will provide orientation for new sub-recipients and their service sites. Sub-recipients must provide orientation for new family planning personnel and in-service training for all family planning personnel (42 CFR 59.5(b)(4)). (See Administrative Appendix for Family Planning Orientation and Training for Clinical and Non-Clinical Personnel)

The sub-recipient training plan should provide for routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as human trafficking. (See "Training Checklist" in the Administrative Appendix.)

The sub-recipient's training plan should provide for routine training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.

9. SERVICES AND CLIENTS

Sub-recipients funded under Title X are to provide all persons who want to obtain family planning care access to such services. Sub-recipients must provide for comprehensive medical, informational, educational, social, and referral services related to family planning for clients who want such services.

Priority for project services is to persons from low- income families (Section 1006(c)(1), PHS Act; 42 CFR 59.5(a)(6)).

Services must be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a)(3)).

Written policy regarding provision of services without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b)(5)).

9.1 Nondiscrimination Requirement

Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)). Documentation (e.g., staff circulars, orientation documentation, training curricula) demonstrate that staff has been informed at least once during employment that services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status

9.2 Social Services and Referrals

Sub-recipients must provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).

Sub-recipients must provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services sub-recipients supported by other federal programs (42 CFR 59.5 (b)(8)). Medical records must indicate referrals were made based on documented specific condition/issues.

KDHE encourages current (within the last 12 months) written collaborative agreements with relevant referral agencies must exist, including: child care agencies, transport providers, WIC programs, emergency care, HIV/AIDS care and treatment agencies, infertility specialists, chronic care management providers, and providers of other medical services not provided on site.

9.3 Clinical Protocols

Sub-recipients should assure services provided within their service sites operate within written clinical protocols that are in accordance with nationally recognized standards of care, consistent with Title X guidelines, and signed by the physician responsible for the service site. The clinical protocols must be available for review by KDHE upon request.

(A copy of the *Providing Quality Family Planning Services* (QFP) is provided with this manual. In addition see: KSA 65-1626: Kansas pharmacy regulations. http://ksrevisor.org/statutes/chapters/ch65/065_016_0026.html)

All sub-recipients must provide current, written, clinical protocols for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)). This includes, but is not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but sub-recipients are not responsible for the cost of this care.

The determination of the amount and type of contraceptive supplies distributed to the client must be based on:

- medical guidelines
- the client's ability to maintain supplies safely
- a request made by the client pertaining to a pharmaceutical that is not regularly stocked in the clinic (*See following paragraph for details*)
- the availability of supplies, OR
- if it is in the best interest of the client.

If a client requests a contraceptive method not regularly stocked by the Title X service site, the clinical provider may provide a script to be taken to an outside pharmacy, provided the client has been counseled regarding the contraceptive methods available at the service site which could provide the same level of protection for the client. If the client still chooses a contraceptive method not available at the service site, the client must also be informed that 340 B pricing for the prescription will not be available outside of the service site.

Clinical protocols must show that the following services will be provided to female, male and adolescent clients as appropriate: contraception, pregnancy testing and counseling, services for achieving pregnancy, basic infertility services, STD services, and preconception health services.

9.4 340 B and Title X Program Requirements

Sub-recipients of Title X funding must be registered in the HRSA Office of Pharmacy Affairs 340B Drug Pricing Program and handle Family Planning pharmaceuticals purchased through this program in compliance with the program's guidelines. KDHE will confirm all Title X grant sub-recipients and their related service sites are updated and certified via the Office of Pharmacy Affairs' electronic forms system. In addition, sub-recipients must:

- Recertify annually any clinic sites where 340B purchased medications are used. Failure to recertify will result in the agency being unable to use 340B medications in any clinic sites that are not certified.
- Certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the Public Health Services Act that prohibit Drug Diversion and Double Discounts/Rebates.
- Have a policy clearly describing their safeguards for Drug Diversion and Double Discounts/Rebates in their family planning manual. Sub-recipients will describe how they will maintain control over their inventory of 340B medications.

Additional Information provided in the Appendix and is available at this link:

A list of Frequently Asked Questions (FAQ) for 340B: <https://www.340bpvp.com/resource-center/faqs/>

9.5 Range of Acceptable Family Planning Methods

All sub-recipients must provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services. (42 CFR 59.5(a)(1)). The medical record should document this.

9.6 Pregnancy Diagnosis and Counseling

Sub-recipients must provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a)(5)).

Written protocols regarding pregnancy testing and counseling are in accordance with QFP, including reproductive life planning discussions and medical histories that include any co existing conditions. See reproductive life plan, published by the CDC:

<http://www.cdc.gov/preconception/reproductiveplan.html>

Medical records should show pregnant women who wish to receive initial prenatal counseling were assessed regarding their social support and referrals were made as needed. Women who are not pregnant and who do not want to become pregnant must be offered same-day contraception, if appropriate.

Sub-recipient service sites must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options and document in the medical record that these options were offered:

- prenatal care and delivery;
- infant care, foster care, or adoption; and
- pregnancy termination.

If requested to provide such information and counseling, staff must provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicates she does not wish to receive such information and counseling (42 CFR 59.5(a)(5)). Staff training documentation must demonstrate staff have received training on pregnancy counseling recommendations presented in the QFP at least once during employment.

9.7 Title X Legislative Mandates

Sub-recipients must comply with applicable Title X legislative mandates set out in the HHS appropriations act. Sub-recipients must have written policies in place that address these legislative mandates and demonstrate staff training regarding these legislative mandates at least once per project period:

“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 of Health and Human Services 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.”

“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 the reporting of child abuse, child molestation, sexual abuse, rape, or incest.”

10. CONFIDENTIALITY

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. (42 CFR 59.11).

Each service site must have:

- documentation (e.g., staff circulars, new employee orientation documentation, training curricula) demonstrating that staff has been informed at least once during the current project period about policies related to preserving client confidentiality and privacy.
- clinical protocols and policies statements related to client confidentiality and privacy.
- safeguards in place to ensure adequate privacy for their electronic health records systems and security appropriate access to personal health information.

- HIPPA privacy forms which are provided to clients and collect signed forms.
- general consent forms or other documentation at service site which states that services will be provided in a confidential manner and note any limitations that may apply.
- third-party billing processed in a manner that does not breach client confidentiality, particularly in sensitive cases (e.g., involving adolescents or young adults seeking confidential services or individuals) for whom billing the policy holder could result in interpersonal violence.
- client education materials noting the client's right to confidential services are available to clients.

11. COMMUNITY PARTICIPATION, EDUCATION AND PROMOTION

Sub-recipients are expected to provide for community participation and education and to promote the activities of the project.

Sub-recipients must provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)). Sub-recipients must develop a community engagement plan which engages diverse community members including adolescents and current clients, and specifies ways community members will be involved in efforts to develop, assess, and/or evaluate the program. Evidence of implementation can be provided through reports, meeting minutes, etc.

Sub-recipients must establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b)(3)). Each family planning project must provide for community education programs (42 CFR 59.5(b)(3)). The community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

The community education and service promotion plan shall:

- enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage participation by persons to whom family planning may be beneficial (42 CFR 59.5 (b)(3));
- promote family planning;
- use appropriate range of methods to reach the community; and
- include an evaluation and documentation that this step was done.

12. INFORMATION AND EDUCATION (I & E) MATERIALS APPROVAL

Every sub-recipient is responsible for reviewing and approving local informational and educational materials. The Information and Education (I & E) Advisory Committee may serve the community participation function if it meets the requirements, or a separate group may be identified. An existing committee of the sub-recipient can also serve in this capacity if its membership includes the requirements stated in 11.

Title X sub-recipient agencies are required to have a review and approval process, by an Advisory Committee, of all informational and educational materials developed or made available under the project prior to their distribution (Section 1006 (d)(2), PHS Act; 42 CFR 59.6(a)).

12.1 Committee Membership Requirements

The committee must include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended (42 CFR 59.6 (b)(2)). Evidence of the review process and demographic representation on committee must be demonstrated through meeting minutes and list of board members

Each Title X sub-recipient must have an Advisory Committee of five to nine members, except that the size provision may be waived by the Secretary for good cause shown (42 CFR 59.6(b)(1)).

12.2 Committee Responsibilities

This Advisory Committee must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d)(1), PHS Act; 42 CFR 59.6(a)).

Any publications or other media developed by KDHE/sub-recipient using Federal Funds must acknowledge Federal Grant support. For example:

“This brochure was developed with funding from the Office of Population Affairs, grant # FPHPA076219. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Office of Population Affairs.”

The Advisory Committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff; however, final responsibility for approval of the I&E materials rests with the Advisory Committee.

The I & E Advisory Committee(s) must:

- consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- consider the standards of the population or community to be served with respect to such materials;
- review the content of the material to assure that the information is factually correct;
- determine whether the material is suitable for the population or community to which it is to be made available; and
- establish a written record of its determinations (Section 1006(d), PHS Act; 42 CFR 59.6(b)).

13. PROGRAM EVALUATION

Each agency must develop a quality improvement process that includes an evaluation plan to determine the impact of the program on local health outcomes, costs and client satisfaction. These local quality improvement programs will be evaluated during KDHE on-site monitoring visits.

13.1 Quality Assurance Policy and Procedure

Sub-recipients must have a quality assurance policy and procedure for ongoing evaluation of the quality of the services provided. Sub-recipient quality assurance procedures should include:

(Sub-recipient quality assurance procedures)

- administrative and clinical policies and procedures that define the agency's practices,
- a plan to audit both clinical and administrative agency record/documentation for conformity to stated policies,
- frequency of auditing to be determined,
- staffing responsibilities regarding auditing,
- determination of corrective measures if inconsistencies are found,
- a random sampling of client medical records (at least audited quarterly),
- audit form to be used to audit medical records,
- a summary of audit reports and corrective actions (should be available to KDHE during site visits),
- a system to track clients referred to an outside agency or managed onsite who were found to have either abnormal test results or abnormal findings on examination.

Additional information on developing a Quality Assurance Program may be found at: Family Planning National Training Center: <http://fpntc.org/training-and-resources/agency-self-assessment-providing-quality-services>

13.2 On-Site Visits

Site visits are conducted approximately every two years to evaluate the performance of sub-recipient service sites. Site visits are also a mechanism for State staff to receive feedback from the service site staff as well as provide technical assistance and training. Unless otherwise notified, all aspects (clinical, community outreach and information, managerial, fiscal and administrative) of the family planning program will be reviewed.

The Site Visit Tool will be sent to the local agency in advance. On the day of the visit this tool will be reviewed and discussed. In addition, the following items should be available for review:

- personnel policies/procedures;
- fiscal policies/procedures, including chart of accounts;
- documentation of staff time and effort;
- schedule of fees and discounts;
- client receipts/statements and charts;
- KDHE Family Planning/Reproductive Health Manual (acknowledged by staff by signature and date);
- evidence of review and approval of all Administrative Policy and Procedures and all Clinical Protocols, and APRN protocols, if applicable;
- signed contractual agreement with pharmacist and pharmacy license;
- written plans/procedures for management of medical and non-medical emergencies;
- written policy/procedures related to the HIPAA Privacy Act and HIPAA Security Rule
- written policy related to Limited English Proficiency (LEP);
- data collection information;
- Quality Improvement process;
- other items as requested.

A report will be sent to the local agency upon completion of the review. If deficiencies are noted, the local agency must submit a corrective plan of action

14. ADDITIONAL ADMINISTRATIVE REQUIREMENTS

This section addresses additional requirements that are applicable to the Title X program and are set out in authorities other than the Title X statute and implementing regulations.

14.1 Facilities and Accessibility of Services

Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (August 4, 2003) (HHS Grants Policy Statement 2007, II-23).

Title X service sites should be geographically accessible for the population being served. Sub-recipients should consider clients' access to transportation, clinic locations, hours of operation, and other factors that influence clients' abilities to access services. Service sites may not discriminate on the basis of disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR part 84).

Sub-recipients must take reasonable steps to ensure that people with limited English proficiency have meaningful access to health and social services and that there is effective communication between the service provider and individuals with limited English proficiency. Service site staff must be aware of policies and processes that exist to access language translation services when needed.

To clarify existing legal requirements, HHS published information for Providers of Health Care and Social Services: <http://www.hhs.gov/civil-rights/for-providers/index.html>.

(See CD included with manual: ADA checklist and LEP documentation)

14.2 Emergency Management

All sub-recipient service sites are required to have a written plan for the management of emergencies (29 CFR 1910, subpart E), and clinic facilities must meet applicable standards established by Federal, State, and local governments (e.g., local fire, building, and licensing codes).

Health and safety issues within the facility fall under the authority of the Occupational Safety and Health Administration (OSHA). Disaster plans and emergency exits are addressed under 29 CFR 1910, subpart E. The basic requirements of these regulations include, but are not limited to:

- disaster plans (e.g. fire, bomb, terrorism, earthquake, etc.) have been developed and are available to staff;
- staff can identify emergency evacuation routes;
- staff has completed training and understand their role in an emergency or natural disaster; and
- exits are recognizable and free from barriers.

14.3 Standards of Conduct

Sub-recipients are required to establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7).

14.4 Human Subjects Clearance (Research)

Research conducted within Title X sub-recipient service sites may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). The sub-recipient should advise KDHE of any research projects that involve Title X clients (HHS Grants Policy Statement 2007, II-9).

15. Other Applicable HHS Regulations, Statutes and Laws

Information about Title X Statutes and Regulations may be found at:

<http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/statutes-and-regulations/>

Attention is drawn to the following HHS Department-wide regulations that apply to grants under Title X. These regulations and statutes are provided on the enclosed CD for your reference.

- 45 CFR Part 74: Uniform administrative requirements for awards and sub-awards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments, and Indian tribal governments <https://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/xml/CFR-2011-title45-vol1-part74.xml>
- 45 CFR Part 80: Nondiscrimination under programs receiving Federal assistance through HHS effectuation of Title VI of the Civil Rights Act of 1964 <http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/program-guidelines/42-cfr-59-attachment-b.html>
- 45 CFR Part 84: Nondiscrimination on the basis of disability in programs and activities receiving or benefitting from Federal financial assistance <https://www.gpo.gov/fdsys/pkg/CFR-2015-title45-vol1/pdf/CFR-2015-title45-vol1-sec84-15-84-20.pdf>
- 45 CFR Part 91: Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance <https://www.gpo.gov/fdsys/pkg/CFR-2000-title45-vol1/pdf/CFR-2000-title45-vol1-part91.pdf>
- 45 CFR Part 92: Uniform administrative requirements for grants and cooperative agreements to State and local governments <https://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-part92.pdf>
- KSA 65-1626: Kansas pharmacy regulations. http://ksrevisor.org/statutes/chapters/ch65/065_016_0026.html

In addition, the following statutory and regulatory provisions may be applicable to grants under Title X:

- The Patient Protection and Affordable Care Act (Public Law 111-148) <http://www.dpc.senate.gov/healthreformbill/healthbill04.pdf>
- The Trafficking Victims Protection Act of 2000, as amended (Public Law 106-386) <http://www.state.gov/j/tip/laws/61106.htm>
- Sex Trafficking of Children or by Force, Fraud, or Coercion (18 USC 1591) <https://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap77-sec1591.pdf>
- The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). <http://www.hhs.gov/sites/default/files/privacysummary.pdf>