

Title X Family Planning Manual Administrative Policies FY2024-2025



Title X Family Planning - Administrative Policies Manual

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AI.I – PURPOSE

Purpose

The purpose of this manual is to provide key information necessary for providing family planning (FP) and reproductive health services as part of the Title X FP program.

The manual outlines federal and state policies and procedures as applicable. The Title X manual is based upon:

- 2021 Title X Final Rule,
- Title X Program Handbook, July 2022,
- Providing Quality Family Planning (QFP) Services: Recommendations of CDC and the U.S. Office of Populations Affairs. (April 25, 2014)
- Iowa Administrative Code Chapter 74 Family Planning Services
- Iowa Administrative Code Chapter 75 Family Planning Services

The Iowa Department of Health and Human Services (Iowa HHS) Title X FP manuals (administrative and clinical) will be reviewed and approved each project period by the contracted Medical Director and/or more frequently if needed. Iowa HHS will ensure if policy updates are made, Subrecipeients (SRs) will be notified, and updated documents shared.

Date Revised	September 2023
References	2021 Title X Final Rule (42 CFR § 59.5(a)(2))
	https://www.ecfr.gov/current/title-42/chapter-l/sub
	chapter-D/part-59
	Title X Program Handbook
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf)
Additional Resources	



A1.2 – FAMILY PLANNING PROGRAM DESCRIPTION

Purpose

The purpose of this policy is to describe the Iowa Department of Health and Human Services (Iowa HHS) Title X Program. The Title X Program is to assist individuals and/or families in identifying reproductive goals and developing a plan for the number and spacing of pregnancies. Title X family planning services are voluntary, confidential, and provided regardless of one's ability to pay. For many clients, Title X clinics are the only ongoing source of healthcare and health education. All direct services are provided by contracted subrecipients (SRs).

Policy

The Iowa HHS Title X Program (along with the contracted SRs) will ensure that family planning (FP) services are provided in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care. OPA priorities for Title X include:

- Advancing health equity through the delivery of FP services
- Improving and expanding access to Title X services, and
- Ensuring the delivery of the highest quality of care.

Procedure

The Iowa HHS Title X Program will ensure that all contracted SRs provide a broad range of medically approved family planning services, which includes all Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods for clients such as:

- Pregnancy prevention and birth spacing,
- Pregnancy testing and non-directive options counseling,
- Assistance to achieve pregnancy,
- Basic infertility services,
- Sexually transmitted infection (STI) services, and
- Other preconception health services.

Iowa HHS will work with each SR to determine what other services might be provided. Title X SRs may provide other reproductive health and related preventive health services that are considered beneficial to reproductive health such as HPV vaccination, provision of HIV pre-exposure prophylaxis (PrEP), breast and cervical cancer screening, and screening for blood pressure, obesity, smoking, drug and alcohol use, mental health, and intimate partner violence, among others.

Date Revised	September 2023
References	Title X Program Handbook, Provision of
	High-Quality Family Planning Services
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=18)</u>



Health and	
Human Services	

	2021 Title X Final Rule 42 CFR § 59.5(b)(5)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	bchapter-D/part-59#59.5)
Additional Resources	About Title X Services Grant)
	(https://opa.hhs.gov/grant-programs/title-x-service
	<u>-grants/about-title-x-service-grants</u>) – 9.22.23



AI.3 – ORGANIZATIONAL STRUCTURE

Purpose

The Iowa HHS partners with local public health, non-profit organizations, health care providers, policymakers, businesses and many others to protect and improve the health of lowans. The mission of lowa HHS is to provide high quality programs and services that protect and improve the health and resiliency of individuals, families, and communities. Additionally, Iowa HHS's guiding principles include: Data-Driven Initiatives, Accountability, Integrity, Equity, Communication and Collaboration. The Family Health Bureau along with the Title X Family Planning Program is part of the Iowa HHS Community Access Division.

Family Health Bureau

The Title X Program is administered by the Family Health Bureau on behalf of the Community Access Division. The Community Access Division includes Child Support Services, Eligibility, and Wellness and Preventive Health. The Family Health Bureau sits within Wellness and Preventive Health. The bureau uses the core public health functions to fulfill its responsibility for infrastructure building, population-based services, enabling services and direct health care services for the health of individuals and children. The bureau has the primary responsibility for system planning, program development and evaluation; developing and monitoring standards of care as well as coordinating health-related services between and among community-based entities serving lowans.

The bureau has multiple programs focusing on the health of individuals, children and families including: Maternal and Child Health Title V, Title X, Healthy Child Iowa Department of Health and Human Services **Community Access** Wellness and **Preventive Health Family Health** Maternal and **Reproductive Health Title X Family** Planning

Care Iowa (HCCI), Hawki, Iowa Maternal Mortality Review Committee, Iowa Maternity Quality Care Collaborative (IMQCC), and the Statewide Perinatal Care Program. Other programs include the Pregnancy Risk Assessment Monitoring System (PRAMS). The programs within the bureau work closely together and provide in-kind support to one another. Title X staff works closely with the staff of the Bureau of HIV, STD and Hepatitis.

In addition to the Core Public Health Functions (published in the 1988 Institute of Medicine Report) and the 10 Essential Public Health Services to Promote Maternal and Child Health in America, the bureau uses the Title X National Priorities to develop overall goals for oversight and management of the FP programs. Those goals can be found online at http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/program-priorities/.



The Iowa HHS Title X staff has had a long and collaborative relationship with the Family Planning Council of Iowa (FPCI). FPCI is the other Title X grantee in Iowa. The organizations continue to work together to maintain and expand access to FP services in Iowa.

Date	April 2024
References	
Additional Resources	



AI.4 – PROHIBITION OF PREGNANCY TERMINATION SERVICES

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs and service sites) that the project: 1.) will offer the pregnant clients the opportunity to be provided information and counseling regarding: prenatal care and delivery: infant care, foster care, or adoption; and pregnancy termination, and 2.) prohibit pregnancy termination (also called abortion) as a method of FP as part of the Title X project. (Section 1008, PHS Act; Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022); 42 CFR § 59.5(a)(5)).

Policy

- Pregnancy termination procedures are not provided as a method of family planning as part of the Title X project.
- Contracts with SRs will include language on the prohibition against providing pregnancy termination as a method of family planning as part of the Title X project.
- SRs have written policies and procedures that address this requirement.
- A referral system to another provider is in place for a person when a pregnancy termination is medically indicated because of the client's condition or the condition of the fetus.
- All SRs are required to provide non-directive, factual, and patient-centered counseling about pregnancy options and offer options of prenatal care and delivery: infant care, foster care, or adoption; and pregnancy termination

Procedure

Iowa HHS Title X Program will ensure that each SR/service site complies with the following:

- Pregnancy termination is not provided as a method of family planning as part of the Title X project.
 - o Each SR is responsible for signing an attestation as part of the RFP/RFA application.
- Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:
 - o Prenatal care and and pregnancy
 - o Parenting or adoption and
 - o Pregnancy termination.
- If requested, each SR CSP shall provide such information and counseling, to provide neutral, factual information, and nondirective counseling on each of the options, as well as referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling. (42 CFR § 59.5(a)(5), Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444.
 - o Referral for additional services (e.g., for prenatal care, delivery, infant care, foster care, adoption, or pregnancy termination) will be made upon request (42 CFR § 59.5(a)(5)).
 - o When a client requests referral for pregnancy termination, they may be given a name and relevant factual information.
 - Staff will not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the client (65 Fed. Reg. 41281 (July 3, 2000)).
 - o Where a referral to another provider who might perform a pregnancy termination is medically indicated because of the client's condition or the condition of the fetus (such as where the woman's life would be



endangered), such a referral by a Title X project is not prohibited by section 1008 of the Public Health Service Act and is required by 42 CFR § 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications (65 Fed. Reg. 41281 (July 3, 2000)).

- Ensure each SR is in compliance with the Title X Federal Review Tool, specific to the prohibition of abortion services. This will be monitored by Iowa HHS on an annual basis.
- For further guidance regarding state laws and legislation, contact the Title X Program Director.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Prohibition
	of Abortion #1, #6
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=27</u>)
	Section 1008, Public Health Service (PHS) Act
	(https://opa.hhs.gov/sites/default/files/2020-07/title
	<u>-x-statute-attachment-a_0.pdf</u>)
	2021 Title X Final Rule 42 CFR § Part 59.5(a)(5)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	bchapter-D/part-59#59.5)
	65 Fed. Reg. 41281 (July 3, 2000) Standards of
	Compliance for Abortion Related Services in
	Family Planning Services Projects
	(https://www.govinfo.gov/content/pkg/FR-2000-07
	<u>-03/pdf/00-16758.pdf</u>)
	Consolidated Appropriations Act, 2022, Pub. L.
	No. 117-103, 136 Stat. 49, 444 (2022)
	(https://www.congress.gov/117/plaws/publ103/PL
	AVV-117publ103.pdf)
Additional Resources	



AI.5 - VOLUNTARY PARTICIPATION

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs and service sites) with the expectation that projects provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning (42 CFR § 59.5(a)(2)); ensure that acceptance of services is solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the recipient (Sections 1001 and 1007, PHS Act; 42 CFR § 59.5(a)(2)).

Policy

- Family planning services are provided without subjecting individuals to any coercion to accept services or to employ, or not to employ, any particular methods of family planning.
- General consent forms or other documentation provided state that receipt of family planning services is not a • prerequisite to receipt of any other services offered by the service site.
- Services are not made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the recipient.
- Staff are informed that any officer or employee of the United States, officer or employee of any state, political • subdivision of a state, or any other entity, which administers or supervises the administration of any program receiving federal financial assistance, or person who receives, under any program receiving federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo pregnancy termination or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving federal financial assistance shall be fined more than \$1,000 or imprisioned for more than a year, or both. (42 U.S.C. § 300a-8, as set out in 42 CFR § 59.5(a)(2)).

Procedure

As part of the Iowa HHS Title X Program, each SR will have a:

- Process for ensuring family planning services, including contraception, are provided on a voluntary basis.
- Process for ensuring that staff are informed during their initial orientation and again, at a minimum of once per • project period, that:
 - o may not be coerced to use contraception, or to use any particular method(s) of contraception or services,
 - o 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, and
 - o they may be subject to prosecution if they coerce, or try to coerce, any person to undergo a pregnancy termination or sterilization procedure.
 - Iowa HHS will monitor through the Title X federal rules and regulations acknowledgment form provided by the Agency as well as the annual attestation form as part of the RFP/RFA application.
- Process for documenting that clients are informed that services are provided on a voluntary basis (such as the use of general consent forms or other documentation maintained in an electronic health record).



- Administrative policies used by all service sites that include a written statement that FP services are provided on a voluntary basis.
- All Title X staff and contracted SR's/staff are required to review the *Title X Requirements Acknowledgement Form.*
 - o This will be reviewed on an annual basis through auditing and/or site visits, as requested.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Program
	Administration #1, #2, and #3
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=16</u>)
	Sections 1001 and 1007, Public Health Service
	(PHS) Act
	(https://opa.hhs.gov/sites/default/files/2020-07/title
	-x-statute-attachment-a_0.pdf)
	2021 Title X Final Rule (42 CFR § 59.5(a)(2))
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	bchapter-D/part-59#59.5)
Additional Resources	



AI.6 - NON-DISCRIMINATION IN THE PROVISION OF SERVICES

Purpose

The purpose of this policy is to describe the lowa HHS process for ensuring compliance (including SRs and service sites) with the expectation that services are provided in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status. (42 CFR § 59.5(a)(4)).

Policy

Title X FP services will be provided without regard to religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.

Procedure

Iowa HHS will ensure that each SR has the following:

- Process by which SRs are informed of this expectation during their initial orientation and again, at a minimum of once per project period.
- Requirements of documentation that each SR needs to maintain to demonstrate compliance with this expectation (e.g., staff circulars, orientation documentation, training curricula).
- Process for monitoring SRs and service sites to ensure compliance with this expectation will include but not limited to site visits (in-person and/or virtually) and chart audit documentation.
- Policy updates will be shared with SRs as they are made. If policy updates are made, a revised policy will be sent outlining the changes.
- Each SR will be required to have a specific policy addressing non-discrimination that outlines how updates are shared within their agency if changes are made to the policy.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, #4
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=16</u>)
	2021 Title X Final Rule 42 CFR § 59.5(a)(4)
	(https://www.ecfr.gov/current/title-42/chapter-I/su
	bchapter-D/part-59#59.5)
Additional Resources	



A2.1 – FAMILY PLANNING RESPONSIBILITIES

Purpose

The lowa HHS Title X Program contracts with SRs to provide direct FP services. The purpose of this policy is to ensure job descriptions are available for all positions, or as specified by agency policy, and updated when necessary to reflect changes in duties. The list provided below of responsibilities serves as a guide for positions and can vary from agency to agency.

Procedure

These are suggestions only and positions are not limited to the roles and responsibilities listed below.

Project Director

Responsibility	Activities
Oversight of Provision of ongoing FP clinical services, which includes nursing and medical services. All services and operations, including services and operations provided by AGENCY	 Reads and adheres to Title X Administrative and Clinical Manual. This can be documented as part of the training log. Submits progress reports and other required documents,
NAME SRs, are provided in accordance with the laws and regulations of the state and Iowa HHS Title X requirements and regulations; Title X	as requested.3. Participates in required meetings (e.g. quarterly director meeting, site visits) and training.
clinical and administrative policies and procedures; and prevailing medical and nursing standards of care.	 Reads and shares the Title X communication including emails, training opportunities and policy changes among staff.
	 Participates in annual site visits including clinical, administrative, fiscal and participant chart record review.
	6. Participates in FP quality improvement activities, as applicable.
	 7. Provides orientation and in-service training of personnel. Topics to include: a. Requirements of reporting child abuse, child molestation, sexual abuse, rape, incest and human trafficking.
	 b. Involving family members in the decision of minors to seek FP services and counseling minors on how to resist being coerced into engaging in sexual activities. c. Cultural competency.



	 d. Care in compliance with QFP. e. Reproductive life planning/One Key Question®. 8. Maintains Title X staff orientation and training records. Ensures all Title X staff complete all required Title X training, including the quarterly Title X training hosted by lowa HHS. a. a. Training records are reviewed on an annual basis and lowa HHS will provide technical assistance where necessary. 9. Imbeds subcontractor requirements in subcontractor MOU, contracts and interagency agreements. 10. Maintains appropriate personnel to fulfill the Title X contract. 11. Ensures that all professional health care providers, including CSPs, consulting CSPs and contractors, have signed and agree to follow the Title X Clinical Manual and have completed the required training, as appropriate. 12. Ensures professional health care providers are in compliance with state licensing requirements and regulations. 13. Oversees the client satisfaction survey implementation and execution. 14. Ensures Title X services are performed under the direction of a CSP with special training or experience in FP. 15. Ensures that monthly Title X data is being inputted correctly in the FP database.
Ensure clinic(s) provide clients with the option of a broad range of FDA approved contraceptive methods and information with an emphasis on long acting, reversible contraceptive methods, along with related services on a voluntary basis. Provide core FP services of contraception, STI/HIV testing, treatment and referral, pregnancy testing and counseling; achieving pregnancy and basic infertility care; and preconception health with related preventive health services including breast and cervical cancer screening. All services are voluntary and confidential.	 Is familiar with and complies with the following: State Family Planning Program (FPP) Requirements QFP Document and eLearning File US Medical Eligibility Criteria (US MEC) for Contraceptive Use US Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016 CDC STD Treatment Guidelines CDC HIV Testing and Prevention Guidelines Related ASCCP, ACOG, USPSTF Recommendations 340B and State Pharmacy Laws and Regulations HIPAA Laws and Regulations



Ensures policy of nondiscrimination.	
Education and counseling services regarding FP, FP methods, child spacing, infertility, sterilization, nutrition, STIs, HIV/AIDS, adolescent counseling and other related health issues, as outlined in the Title X manual.	 Ensures Limited English Proficiency (LEP) services. Ensures client-centered counseling
Prioritize care for low income clients, those at 100% of Federal Poverty Level (FPL) and below, and adolescent clients and all persons with reproductive abilities who are 19 years of age or younger.	 Updates and reviews annually a sliding fee scale based on the most recent FPL guidelines. Completes a cost setting activity (i.e., cost analysis) that informs the fees presented in the sliding fee scale every three years, as requested by Iowa HHS.
Provide for follow-up and referral services, including referral services for pregnant clients.	I. Maintains list of referral sites and updates accordingly.
Revenue management activities that ensure billing and full clinical reimbursements are realized.	 Ensures implementation of safeguards for confidentiality and release of client health information.

Fiscal

Responsibility	Activities
Comply with all applicable Iowa HHS Title X regulations, Iowa HHS policies and procedures, any applicable fiscal or administrative policies, in addition to laws and regulations of the state or federal government, including client's confidentiality and privacy.	 Follows Title X Administrative Manual as it relates to fiscal policies. Performs a cost analysis every project period (more or less) for Title X FP services or as requested. In conjunction with the Coordinator/Director creates a sliding fee scale based on the most recent FPL guidelines and updates annually. Documentation of client income aligns with Title X requirements. Documentation that clients whose documented income is at or below 100% of the FPL must not be charged for FP services. Documentation of schedule of discounts for clients with incomes between 101% and 250% of FPL. Full charge for clients with income above 250% of FPL. Maintains documentation and records of all income and expenditures. Participates in the Title X fiscal review as necessary.



Adhere to contract budget and effectively manage cost.	 Submits monthly invoices for reimbursement in IowaGrants. Shows financial contribution of funds from local, regional, grant, client, Medicaid or other third party revenue. State FP funding cannot be the sole funder of any FP program.
Utilization of program income from client fee collections and donations are used for FP purposes only.	I. Maintains policy for aging accounts.
Revenue management activities that ensure billing and full clinical reimbursements are realized.	 Documentation that a third party authorized or obligated to pay for a service is billed accordingly. Documentation that private and public insurance are billed. Documentation of client donations and policy that client donations are not coerced.

Data Support

Responsibility	Activities
Compilation of Title X clinical visit data necessary for the data required for the Family Planning Annual Report (FPAR). Includes data collected in the data system and supplemental data.	 Collects and provides data monthly no later than the 12th business day of each month. Works with Iowa HHS staff to resolve outstanding issues with data for data cleaning in the FP data system. Reviews monthly QA Dashboard data reports (Title X data system and periodic emaisl from the department) to ensure the data that is reflected is accurate.

Clinical Staff

Responsibility	Activities
Oversight of ongoing FP clinical services, which includes nursing and medical services. All services and operations, including services and operations provided by SRs, are provided in accordance with the laws and regulations of the state governments, Title X requirements and regulations, Iowa HHS clinical and administrative policies and procedures, and prevailing medical and nursing standards of care.	 I. Ensure professional health care providers are in compliance with state and federal licensing requirements and regulations. a. Licenses of applicants for positions requiring licensure are verified prior to employment and documentation of licenses is kept current. CSPs comply with professional, licensing and if applicable, certifying organizations' policies, standards of



	 care, rules and regulations, and continuing education requirements. 3. FP services are performed under the direction of a CSP with special training or experience in FP. 4. Reads, signs and complies with the clinical manual annually. 5. Provides for medical services related to Title X and the effective usage of contraceptive devices and practices, including CSP consultation, examination and prescription, continuing supervision, laboratory examination, contraceptive supplies, as well as necessary referral to other medical facilities when medically indicated, including emergencies. 6. Participates in Title X quality improvement activities, clinical site visits and medical record reviews as requested.
Clients are provided the option of a broad range of FDA approved contraceptive methods and information with an emphasis on long acting reversible contraceptive methods, along with related services on a voluntary basis. Provide core FP services of contraception, STI/HIV testing, treatment and referral, pregnancy testing and counseling, achieving pregnancy and basic infertility care, preconception health with related preventive health services including breast and cervical cancer screening. All services are voluntary and confidential. Title X funds may not be used where abortion is a method of FP.	Is familiar with and complies with the following: I. QFP Document and eLearning File 2. US Medical Eligibility Criteria (US MEC) for Contraceptive Use 3. US Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016 4. CDC STD Treatment Guidelines 5. CDC HIV Testing and Prevention Guidelines 6. Related ASCCP, ACOG, USPSTF Recommendations 7. 340B and State Pharmacy Laws and Regulations 8. CLIA Laws and Regulations 9. HIPAA Laws and Regulations
Education and counseling services regarding FP, FP methods, pregnancy spacing, infertility, sterilization, nutrition, STIs, HIV/AIDS, adolescent counseling and other related health issues as outlined in the Iowa HHS Clinical and Administrative manuals.	 Provides LEP services. Provides client-centered counseling.
Uphold Iowa HHS Title X regulations that all adolescents, regardless of age, must be allowed services and may consent for their FP services. Title X service provision cannot be conditioned on parental consent or notification.	 Provides counseling that encourages family participation in the decision of minors to seek FP services. Provides counseling to minors on how to resist being coerced into engaging in sexual activities.



Provide for follow-up and referral services, including referral services for pregnant clients.	 Reports suspected child physical/sexual abuse following state law.
	2. Maintains referral list for health care concerns
	encountered in FP clinical setting, including mental health and social service providers.
	3. Maintains system for referral follow-up.

Date Revised	September 2023
References	Title X Program Handbook (https://opa.hhs.gov/sites/default/files/2022-08/title -x-program-handbook-july-2022-508-updated.pdf #)
Additional Resources	Colorado Family Planning Administrative Manual – State Funds Only September 2019, 2021



Purpose

The purpose of this policy is to ensure that Iowa HHS must establish and maintain personnel policies (along with SRs and service sites) that comply with applicable federal and state requirements.

Policy

These policies should include, but need not be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, training and grievance procedures. Title X staff should be broadly representative of all significant elements of the population to be served by Title X, and should be sensitive to and able to deal effectively with the cultural and other characteristics of the client population [59.5 (b)(10)].

Procedure

Iowa HHS Title X staff will ensure that each SR has the following in place:

- SRs are obligated to establish and maintain personnel policies that comply with applicable federal and state requirements.
- Title X staff should be broadly representative of all significant elements of the population to be served and should be sensitive to, and able to effectively collaborate with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).
- SRs must verify licenses of applicants for positions requiring licensure prior to employment and documentation • of licenses must be kept current and reviewed on an annual basis. The SR is responsible for assuring all persons, whether employees, contractors, subcontractors, or anyone acting on behalf of the SR, are properly licensed, certified, or accredited as required under applicable state law and federal program requirements
- SRs are responsible for ensuring that subcontractors have the required personnel policies • and procedures that comply with all applicable Federal, State and local requirements. SRs shall document the review of subcontractor personnel policies and procedures.
- All orientation, training, and continuing education shall be documented in the personnel file. •
- SRs shall ensure personnel records are kept confidential.
- SRs shall ensure confidential, secure, and appropriate guidelines for teleworking.
- lob descriptions must be available for all positions, or as specified by agency policy, and updated when necessary to reflect changes in duties.
- The clinical care component of Title X FP operates under CSPs who are licensed and qualified with special • training or experience in FP.

The items listed above will be monitored at least on an annual basis as part of the site visit using the federal review tool and/or as requested from the Iowa HHS Title X Program Staff.



Date Revised	September 2023
References	2021 Title X Final Rules 42 CFR § 59.5(b)(4)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	bchapter-D/part-59/subpart-A/section-59.5)
Additional Resources	IDPH Contract General Conditions for Service
	Contracts (<u>https://hhs.iowa.gov/contract-terms</u>)
	Title VI of the Civil Rights Act of 1964 (PL
	88-352), 45 CFR Part 80, Section 504 of
	Rehabilitation Act of 1973, the Americans with
	Disabilities Act of 1990 as amended, the lowa
	Civil Rights Act of 1965 as amended, Equal
	Employment Opportunity Act of 1973, the Age
	Discrimination Act of 1968 and 1975 and the
	OWBPA of 1990, 7 CFR Part 15, OSHA, the
	Drug Free Workplace Act of 1988, the
	Family and Medical Leave Act (FMLA),
	Certification of Compliance with Pro-Children
	Act of 1994, the Patient Protection and
	Affordable Care Act (ACA)



A3.2 – STAFF TRAINING & TECHNICAL ASSISTANCE

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring SRs are in compliance with the Title X FP requirements for staff training.

Policy

Title X staff are any employees that touch the Title X Program. *Refer to the Title X Training Log for required training by position.*

Procedure

Iowa HHS will ensure each SR has a process for the following:

Program Personnel

Iowa HHS Title X's SRs must have approved program personnel policies and procedures.

- SRs are obligated to establish and maintain personnel policies that comply with applicable federal and state requirements.
- Title X staff should be broadly representative of all significant elements of the population to be served and should be sensitive to, and able to effectively collaborate with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).
- Each SR must provide that FP medical services will be performed under the direction of qualified CSP.

Staff Orientation and Training

- Iowa HHS Title X Program will provide orientation on a quarterly basis.
- Iowa HHS Title X Program will work to onboard each new SR and/or staff individually to determine additional training/programmatic needs to support the new SR and/or staff in conjunction with the required Title X training.

All SRs must have an established orientation and training program for all staff, including specific Title X training. It is required that all staff be oriented to Title X.

- Provide time for orientation and in-service training for all project personnel. (42 CFR § 59.5(b)(4))
- Ensure 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 on human trafficking.
- Ensure 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.
- Continue training as noted above on an annual basis. In addition, the Office of Population Affairs recommends that Title X recipients provide routine training in accordance with the. <u>RHNTC Federal Title X Training</u> <u>Requirements Job Aid</u>
- All training and continuing education should be documented and readily available upon request and reviewed by Iowa HHS on an annual basis in conjunction with site visit.



Training Resources

The Reproductive Health National Training Center is supported by the Office of Population Affairs (OPA) targeting FP services and adolescent-centered health training.

- Administrative Training: https://rhntc.org/ •
- Clinical Training: https://rhntc.org/ and http://www.ctcfp.org/clinical-training/ •
- Relevant training resources are also available in the department training requirements document. For further ٠ information contact the Title X Team.
 - o Human Trafficking in Iowa. Reference Human Trafficking policy for additional resources.
 - o Mandatory Reporting in Iowa. Reference Mandatory Reporting policy for additional resources.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Staff Training #1, #2, #3,
	#4
	(https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-h
	andbook-july-2022-508-updated.pdf - page=27)
	2021 Title X Final Rules 42 CFR § 59.5(b)(4)
	(https://www.ecfr.gov/current/title-42/chapter-l/subchapter-D/pa
	rt-59/subpart-A/section-59.5)
Additional Resources	



A3.3 – EXCLUDED PROVIDERS

Purpose

The purpose of this policy is to describe the lowa HHS process for ensuring SR compliance with the expectation that if family planning services are provided by a contract, CSPs providing direct services under each SR are not listed as excluded providers under Medicaid and/or Medicare and state healthcare programs. SRs shall check the exclusion status of individuals/entities prior to entering into employment or contractual relationships and at least annually thereafter.

Policy

The effect of an exclusion (not being able to participate) is:

- No payment will be made by any federal health care program for any items or services furnished, ordered, or prescribed by an excluded individual or entity. Federal health care programs include Medicare, Medicaid and all other plans and programs that provide health benefits funded directly or indirectly by the United States (other than the Federal Employees Health Benefits Plan). For exclusions implemented prior to August 4, 1997, the exclusion covers the following federal healthcare programs: Medicare (Title XVIII), Medicaid (Title XIX), Maternal and Child Health Services Block Grant (Title V), Block Grants to States for Social Services (Title XX) and State Children's Health Insurance (Title XXI) programs.
- No program payment will be made for anything that an excluded person furnishes, orders or prescribes. This • payment prohibition applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider where the excluded person provides services and anyone else. The exclusion applies regardless of who submits the claims and applies to all administrative and management services furnished by the excluded person.
- There is a limited exception to exclusions for the provision of certain emergency items or services not provided in a hospital emergency room. See regulations at 42 CFR 1001.1901(c)

Procedure

The SR shall:

- Check the List of Excluded Individuals and Entities (LEIE) site prior to entering into employment or contractual relationships.
- Check the site at least annually for current employees and contractors. Contractors should search the HHS-OIG website to capture exclusions and reinstatements that have occurred since the last search.
- Document that the search was complete for all employees, subcontractors, and SR staff.

Iowa HHS will monitor this on an annual basis as part of the SR site visit and/or grant application submission.

Date Revised	September 2023
References	



Additional Resources	DHHS OIG Exclusions Program Background
	Information
	DHHS OIG Exclusions Program
	"Special Advisory Bulletin: The Effect of
	Exclusion From Participation in Federal Health
	Care Programs" State Medicaid Director Letter
	<u>dated January 16, 2009 (SMDL #09-001)</u>
	IME Informational Letter #1001 of April 8, 2011
	Section 1903(i)(2) of the Social Security Act (the
	Act);
	42 CFR section 1001.1901(b); section 1128B
	based on the authority contained in various
	sections of the Act, including sections 1128,
	<u>1128A, and 1156</u> .
	lowa Administrative Code 441-79.2.



A3.4 – DATA USE AND DATA SHARING

Purpose

The purpose of this policy is to describe the lowa HHS process for ensuring compliance (including the recipient, SR and service sites) with the expectation that recipients may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a federal award. The federal government reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so. The awardee is subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR § 401.

The federal government has the right to: obtain, reproduce, publish, or otherwise use the data produced under this award; and authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes. (43 CFR § 75.322).

Procedure

Family Planning Data System

- 1. Each SR must report client-level data through the online FP data system for all individuals who receive Title X FP services. As part of the data collected, data will be used to determine different QI/QA activities.
- 2. Iowa HHS will ensure that each SR has access to the online FP data system and each SR will be responsible to determine appropriate staff to have access. Individual client level data is required to be entered on a monthly basis as outlined in the program contract.

Family Planning Data

- 1. Title X data shall only be used for the purposes outlined within the contract and shall ensure that the minimum number of individuals has access to the information, as necessary, to complete program work.
- 2. Title X requirements state: "All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and 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 that does not identify particular individuals. Refer to Confidentiality Policy for additional detail and guidance.
- 3. Therefore, SRs may only release their own agency FP data in aggregate reports. No identifiable data may be released at any time. Identifiable data includes information that can directly or indirectly be used to establish the identity of a person, such as a name, address, or other information that can be linked to external information that allows for identification of the person. Aggregate data should generally not be reported if the count size or numerator is fewer than six or if the denominator is fewer than 100. Refer to Iowa HHS' Disclosure of Confidential Public Health Information Records or Data Policy #CO 01-16-002 for additional detail.
- 4. Any subcontracted entity hosting or maintaining clinical records or identifiable data and all IT staff with access to confidential or protected information must attest to the requirement of these safeguards in contract via the



Business Associate Agreement or an attestation document. Copies of the appropriate documentation will be available for review by Iowa HHS staff.

Date Revised	September 2023
References	Title X Program Handbook Additional Special
	Terms and Requirements and Standard Terms of
	the FY 22 Title X Notice of Award—Standard
	Terms Expectation #6
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=29</u>)
	37 CFR § 401 - Rights To Inventions Made By
	Nonprofit Organizations And Small Business
	Firms Under Government Grants, Contracts,
	And Cooperative Agreements
	(https://www.ecfr.gov/current/title-37/chapter-IV/p
	<u>art-401</u>)
	45 CFR § 75.322 Intangible property and
	copyrights.
	(https://www.ecfr.gov/current/title-45/subtitle-A/s
	ubchapter-A/part-75/subpart-D/subject-group-EC
	FR78b08d9c95aad03/section-75.322)
Additional Resources	HHS data sharing agreement (DSA) Policy #CO
	01-16-001, HHS Research Agreement and
	Research and Ethics Review Committee Policy #
	AD 07-12-004, HHS Disclosure of Confidential
	Public Health Information Records or Data Policy
	#CO 01-16-002, the Release of Information and
	Confidentiality of Records and Data Section
	within the HHS General Conditions, and any
	future revisions to any of these.



A4.1 – PROJECT SERVICES AND CLIENTS

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring each SR and service site is in compliance with the expectation that projects provide medical services related to family planning (including consultation by a CSP, examination, prescription and continuing supervision, laboratory examination, and contraceptive supplies), in person or via telehealth, and referral(s) to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices. (42 CFR § 59.5(b)(1)).

Policy

- Clients are provided appropriate medical services related to family planning, including consultation by a CSP, physical examination, prescription and continuing supervision, laboratory examination, and contraceptive supplies.
- Services are provided either in person or via telehealth. •
- Necessary referrals are made to other medical facilities when medically indicated, including if a client's method of choice is not available at this particular service site.
- Services are provided to ensure the effective usage of contraceptive devices and practices.

Procedure

- Provide priority for FP services to any client from low-income families.
- Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and • trauma-informed; protects the dignity of the individual and ensures equitable and quality service delivery consistent with nationally recognized standards of care.
- Provide services in a manner that does not discriminate against any client based on religion, race, color, national • origin, disability, age, sex characteristics, number of pregnancies, or marital status.
- Provide for social services related to FP, including counseling, referral to and from other social, medical, and any ancillary services, which may be necessary to facilitate clinic attendance.
- Provide coordination and use of referrals and linkages with primary healthcare providers, other providers of • healthcare services, local health and welfare departments, hospitals, voluntary agencies and health services supported by other federal programs, who are in close physical proximity to the Title X service site, when feasible, in order to promote access to services and provide a seamless continuum of care.
- Assure services provided within their Title X program operate within written clinical protocols that are in • accordance with providing quality family planning services that are consistent with nationally recognized standards of care.
- Provide medical services related to FP and the effective usage of contraceptive devices and practices (including • CSP consultation, examination and prescription, and continuing supervision, laboratory examination, contraceptive supplies), referrals to other medical facilities when medically indicated. 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 Title X is not responsible for the cost of this care.



- Provide a broad range of acceptable and effective medically approved FP methods and services (including, but not limited to, long acting reversible contraception (LARC), contraceptive pills/patches/rings, natural family planning methods, infertility services and services for adolescents).
 - o If a SR is unable to provide a client with access to a broad range of acceptable and effective medically approved FP methods and services, the SR must be able to provide a prescription to the client for their method of choice or referrals to another provider as requested.
- Provide medically accurate, nondirective counseling and referral to all pregnant clients. The options should include: prenatal care and delivery, infant care, foster care, or adoption, and pregnancy termination.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Referral
	for Social and Medical Services #I
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=21</u>)
	2021 Title X Final Rule 42 CFR § 59.5 (b)(1)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	bchapter-D/part-59/subpart-A/section-59.5)
Additional Resources	

Reference the FP Clinical Manual for guidance on clinical requirements.



A4.2 – CONFIDENTIALITY

Purpose

The purpose of this policy is to describe the process for Iowa HHS and SRs ensuring compliance with the expectation that 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. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipients must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client. (42 CFR § 59.10(a)).

Policy

- Confidentiality is safeguarded. •
- Medical record systems have safeguards in place to ensure adequate privacy, security, and appropriate access to • personal health information.
- Clients are informed of any potential for disclosure of their confidential health information to policyholders • where the policyholder is someone other than the client.
- General consent forms are provided in a confidential manner and note any limitations that may apply. •
- Third-party billing is processed in a manner that does not breach client confidentiality.

Procedure

Adolescents and Confidentiality

As part of Title X, family planning services need to be provided in a manner that is adolescent-friendly. Adolescents must be assured that services are confidential and, if follow-up is necessary, every attempt will be made to assure the privacy of the individual.

Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources. The Title X program shall encourage family participation to the extent practical, however, the SR/program may not require consent of parents or guardians for the provision of services to minors, nor can any Title X staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

Confidentiality and Release of Records

A confidentiality assurance statement must appear in the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality. When information is requested, agencies should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical or other form which does not identify specific individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care. SRs will be informed



annually of the requirement to safeguard client confidentiality and what that entails (charts, conversation, release of information, parental notification, for example). Documentation of the annual notification will be kept on file.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Project
	Administration #9
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=17)</u>
	2021 Title X Final Rule 42 CFR § 59.10(a)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	bchapter-D/part-59#59.10
Additional Resources	Health Insurance Portability and Accountability
	Act (HIPAA)
	(https://www.hhs.gov/hipaa/index.html)



A4.3 – LIMITED ENGLISH PROFICIENCY – USE OF INTERPRETERS

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs and service sites), that all persons with Limited English Proficiency (LEP) have meaningful access and an equal opportunity to participate in services, activities, programs and other benefits.

LEP Definition

Individuals who do not speak English as their primary language and who have a limited ability to read, speak, write or understand English can be LEP.

A person with LEP may have difficulty speaking or reading English. An organization and the individual with LEP will benefit from an interpreter (in-person, telephonic, video) who will interpret for the individual with LEP and provider.

Policy

- Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.
- Language translation services are readily provided, at no cost to clients, as needed.
- Project staff receive training in culturally competent care in order to be sensitive to, and able to deal effectively with, the needs of key populations, including LGBTQ, adolescents, individuals with limited English-proficiency, and people with disabilities
- Written educational materials are provided in a manner that is clear and easy to understand for clients with limited literacy skills and are provided in the commonly used languages of the client population served by the clinic. (i.e waivers of rights, consent to treatment forms, financial and insurance benefit forms, etc.)

Procedure

Iowa HHS will evaluate each SR on an annual basis for the following:

- Process that is used to provide translation services (e.g., language assistance line, on-site interpreters, or bilingual staff).
- Process for ensuring and documenting that staff are made aware of policies and processes to access language translation services.
- How clients are informed about availability of translation services at no cost (e.g., signage/posters in different languages).
- Process for ensuring that information presented in educational materials: 1. Clear and easy to understand, and 2. Tailored to literacy, age, and language preferences of client populations.
- Process for ensuring that information presented during counseling:
 - o Is culturally appropriate and reflects the client's beliefs, ethnic background, and cultural practices.
 - o Emphasizes essential points (e.g., limits the amount of information presented appropriately).



o Communicates risks and benefits in a way that is easily understood (e.g., using natural frequencies and common denominators).

Written Documents

An individual with LEP may also need documents written in English translated into his or her primary language so that person can understand important documents related to health and human services, such as vital written documents. Vital written documents include, but are not limited to, consent and complaint forms, intake and application forms with the potential for important consequences, written notices of rights, notices of denials, losses or decreases in benefits or services, notice of disciplinary action, signs and notices advising people with LEP of free language assistance services.

lowa HHS requires all SRs to have access to establish a language service provider, or providers, for interpretation (telephonic or on-site) and document translation. In addition, vital written documents, such as materials and intake forms, should be translated into widely encountered language(s) for the patient populations served.

Use of interpreters will be documented in the FP data system and a monthly QA report is available for missing data.

Date Revised	September 2023
References	2021 Title X Final Rule 42 CFR § 59.2
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	bchapter-D/part-59/subpart-A/section-59.2)
	2021 Title X Final Rule 42 CFR § 59.5(a)(3)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	<pre>bchapter-D/part-59/subpart-A/section-59.5)</pre>
	<u>Title X Program Handbook, Section 3, Provision</u> of High-Quality Family Planning Services #3 (https://opa.hhs.gov/sites/default/files/2022-08/title -x-program-handbook-july-2022-508-updated.pdf #page=18)
Additional Resources	National Standards for Culturally and
	Linguistically Appropriate Services (CLAS)
	(https://www.thinkculturalhealth.hhs.gov/)



A4.4 – INFORMATIONAL AND EDUCATIONAL (I&E) COMMITTEE

Purpose

The purpose of this policy is to describe the lowa HHS process for ensuring compliance (including SRs) with implementing and maintaining a statewide Information and Education (I&E) committee that reviews and approves print and electronic informational and educational materials developed or made available under the project, prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X. The project shall not disseminate any materials which are not approved by the advisory committee. (Section 1006(d)(1) and (2), PHS Act; 42 CFR § 59.6(a)).

Policy

- Iowa HHS will lead the committee and it will consist of no fewer than five members and up to as many members Iowa HHS determines appropriate.
- The committee will include individuals broadly representative of the population or community for which the materials are intended.
 - o In terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality), (Section 1006(d)(2), PHS Act; 42 CFR § 59.6(b).
- All I&E materials developed or made available under the Title X project are reviewed and approved by an I&E Statewide Committee prior to their distribution.

Procedure

Iowa HHS Title X Program will be responsible for the following:

- Maintain a roster of participants from each SR. At a minimum, the program coordinator or designee must participate along with 1-2 additional representatives in the SR service area.
- Schedule at least one meeting annually on a virtual platform and provide participants with at least a three week notice.
- Record attendance and meeting minutes at each meeting.
 - o Notes and a recording of the meeting will be available to all participants after each meeting.
- Collect all Review Summary forms and tally results and comments. Iowa HHS will be responsible for written records of its determinations.
- Follow-up with each SR regarding any action steps identified on the summary forms (if applicable).
- Ensure that any I&E materials developed by the SRs include:
 - o Citations of Title X as contributing to the development of the materials. Language should include the following:



- O This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with XX percentage funded by [PROGRAM OFFICE]/OASH/HHS and \$XX amount and XX percentage funded by non-government source(s). The contents are those of the author (s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].
- o When publishing materials, each SR is required to contact the Title X staff about the specific grant number and any additional grant requirements.
- Maintain a folder of all approved materials and a process for how SRs can order the approved educational materials.

Iowa HHS along with the SRs will ensure I&E Committee members are responsible for the following:

- Participate in the organized meetings by Iowa HHS which will be organized at least once per year. If additional meetings are needed, a calendar request will be sent out to each participant.
- Attend and/or view the Title X Program overview which will be part of the annual meeting
- All I&E materials developed or made available under the Title X project are reviewed and approved by the I&E Advisory Committee prior to their distribution.
- Provide the Iowa HHS Title X Program with a completed I&E Materials Review Summary Form for each material reviewed as part of the meeting requirement.
 - This form will include a complete summary of the reviewers' findings and recommendations, as well as the final recommendation on whether or not to distribute the materials to clients.

In reviewing materials, the Committee shall:

- Consider the educational, cultural and diverse 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.
- All I&E materials developed or made available under the Title X project are reviewed and approved by the I&E Committee prior to distribution.
- I&E materials shared on social media undergo an I&E Advisory Committee review and approval process, agency social media posts themselves do not require I&E approval
- Ensure the content of the material is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed.
- Determine whether the material is suitable for the population or community to which it is to be made available.

Date Revised	September 2023
References	Title X Program Handbook, Section 3,
	Information and Education (I&E) #1, #2
	(https://opa.hhs.gov/sites/default/files/2022-08/title



	<u>-x-program-handbook-july-2022-508-updated.pdf</u> <u>#page=26</u>) Section 1006(d)(1) and (2), Public Health Service
	(PHS) Act
	(https://opa.hhs.gov/sites/default/files/2020-07/title
	-x-statute-attachment-a_0.pdf
	2021 Title X Final Rule 42 CFR § 59.6(a)
	(https://www.ecfr.gov/current/title-42/chapter-I/su
	bchapter-D/part-59/subpart-A/section-59.6#p-59.
	<u>6(a))</u>
Additional Resources	


A4.5 – COMMUNITY PARTICIPATION, EDUCATION AND PROJECT PROMOTION

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance with SRs providing opportunities for community education, participation, and engagement.

Policy

Community education, participation, and engagement activities are conducted to: achieve community understanding of the objectives of the program; inform the community of the availability of services; and promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client centered, quality family planning services.

Procedure

Iowa HHS will collaborate with each SR to ensure:

- The agency provides community education, participation, and engagement to:
 - o inform the community of the objectives of the program to advance community understanding;
 - o inform the community of the availability of services; and
 - o promote continued participation in the project.
- The agency identifies diverse audiences for whom family planning services may be beneficial, such as by conducting a needs assessment.
- The agency engages diverse audiences for whom family planning services may be beneficial such as through developing a community education, participation and engagement plan that identifies objectives of engagement and intended audiences.
- SRs will create a process for educating staff about what is learned through community engagement efforts.
 - o SRs will ensure education is documented (e.g., statement signed by employee, staff circulars, training records, orientation checklist, etc.) at the recipient, subrecipient, and service site levels.

lowa HHS will ensure:

• A process is developed for monitoring subrecipients and service sites to ensure compliance with this expectation.



Date Revised

References

(https://opa.hhs.gov/sites/default/files/2022-08/title -x-program-handbook-july-2022-508-updated.pdf #page=25)

2021 Title X Final Rule 42 CFR § 59.5(b)(3) (<u>https://www.ecfr.gov/current/title-42/chapter-I/su</u> <u>bchapter-D/part-59#59.5</u>)

Additional	Pasaurcas
Auditional	Resources



A4.6 – PUBLICATION AND COPYRIGHT

Purpose

The purpose of this policy is to describe the process for Iowa HHS and SRs to ensure compliance with the expectation that the acknowledgment of federal funding.

Policy

- Federal funding is acknowledged when issuing statements, press releases, publications, requests for proposal, bid • solicitations and other documents-such as toolkits, resource guides, websites, and presentations (hereafter "statements")—describing the projects or programs funded in whole or in part with HHS federal funds.
- The federal award reflects total costs (direct and indirect) for all authorized funds (including supplements and • carryover) for the total competitive segment (project period) up to the time of the public statement. Any amendments to the acknowledgement statement are coordinated with the Office of the Assistant Secretary for Health (OASH) federal project officer and the OASH grants management officer.
- Press releases concerning the outcome of activities supported by this financial assistance include notifying the ٠ OASH federal project officer and the OASH grants management officer in advance to allow for coordination.
- Funding statements must clearly state the percentage and dollar amount of the total costs of the program or project funded with federal money and the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources

Procedure

- Iowa HHS and SRs will have a process when issuing statements resulting from activities supported by HHS financial assistance, acknowledgement of federal assistance using one of the following or a similar statement will be used:
 - o The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources: This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with XX percentage funded by [PROGRAM OFFICE]/OASH/HHS and \$XX amount and XX percentage funded by non-government source(s). The contents are those of the author (s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].
- Iowa HHS and SRs will have a process to ensure that the federal award total reflects total costs (direct and • indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement and that any amendments to the acknowledgement statement are coordinated with the OASH federal project officer and the OASH grants management officer.
- Iowa HHS and SRs will have a process for issuing press releases concerning the outcome of activities supported • by this financial assistance and Iowa HHS will notify the OASH federal project officer and the OASH grants management officer in advance to allow for coordination.



• Iowa HHS and SRs will have a process for identifying the percentage and dollar amounts of the total costs of the program or project funded with federal money and the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

Date Revised	September 2023
References	Title X Program Handbook Additional Special
	Terms and Requirements and Standard Terms of
	the FY 22 Title X Notice of Award – Standard
	Terms Expectation #7
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=29</u>)
Additional Resources	



A5.I – LIABILITY COVERAGE

Purpose

The purpose of this policy is to ensure that each SR shall procure and maintain such insurance as is required by applicable federal and state law and regulation. Such insurance should include, but not be limited to, liability insurance, fidelity bonding of persons entrusted with handling of funds, workers' compensation, unemployment insurance and professional liability.

Procedure

Iowa HHS will review liability coverage documents on an annual basis as part of the contract monitoring process. SRs will provide proof as part of the Iowa HHS Title X Family Planning Services grant application process as well as when site visits are conducted.

Date Revised	April 2024
References	https://hhs.iowa.gov/media/9494/download?inline=
	(Section 2.7, retrieved 4.4.24)
Additional Resources	



A5.2 – ACCESSIBILITY AND RESPONSIVENESS OF SERVICES

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs and service sites) making services as accessible as possible for clients. Iowa HHS and awarded SRs are required to identify and execute strategies for delivering services that are responsive to the diverse needs of the clients and communities served. (PA-FPH-22-001 NOFO, FY 22 Notice of Award Special Terms and Requirements).

Policy

- When selecting new service sites, geographic accessibility is considered to ensure client access to transportation, clinic location, hours of operation, and other factors that influence clients' abilities to access services.
- When viewed in their entirety, SR facilities and service sites are readily accessible to people with disabilities (45 CFR § 84).
- The clinic environment is arranged with inclusivity, accessibility, and a trauma-informed perspective, including colors, images, layout, etc.

Procedure

SRs will work along lowa HHS to comply with the following:

- Identify a process that is used to select new service sites.
- Meet all applicable standards established by the federal, state, and local governments (e.g., local fire, building, and licensing codes). In general, clinic locations should provide a comfortable gender-neutral waiting area, an adequate reception area, offer private areas for client interview, include sufficient number of enclosed single exam rooms to accommodate service needs and allow for private conversations, provide office space separate from client service areas for staff to make follow-up phone calls and complete documentation; and include a secure storage room/area for files and supplies.
- Comply with <u>45 CFR part 84</u>, which prohibits "discrimination on the basis of handicap in federally assisted programs and activities", and which requires among other things, that recipients of federal funds operate their federally assisted program so that when, viewed in their entirety, they are readily accessible to people with disabilities.
- Comply with any applicable provisions of the Americans with Disabilities Act (<u>Public Law 101-336</u>), compliance with the ADA and 504 requirements are evaluated as part of the on-site review.
- Comply with <u>ACA Section 1557</u> which prohibits discrimination based on race, color, national origin, sex, age or disability in health programs and activities that receive federal funds. Section 1557 assists populations that have been most vulnerable to discrimination in health care and health coverage, including: women, LGTBQ, individuals with disability, and individuals with LEP.





A5.3 – MEDICAL RECORDS

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs, and service sites) the process for ensuring compliance with statutes which regulate the way that medical records are handled and protected by the agency.

Policy

SRs must establish a medical record for every client who obtains Title X clinical services. SRs must maintain records in accordance with accepted medical standards and state record retention laws. Records must be:

- Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;
- Signed by the clinician and other appropriately trained health professionals making entries, including the professional's name, title and date;
- Readily accessible to Title X staff;
- Systematically organized to facilitate prompt retrieval and compilation of information; •
- Confidential; •
- Safeguarded against loss or use by unauthorized persons;
- Secured by lock or password protected when not in use; and •
- Available to the client upon request.

Procedure

Content of the Client Record

The client's medical record must contain sufficient information to identify the client, indicate where and how the client can be contacted, justify the clinical impression or diagnosis, and warrant the treatment and end results. The required content of the medical record includes:

- 1. Demographic information including gender, race, ethnicity, primary language, and if a translator is needed;
- 2. Medical history, physical exam, laboratory test orders, results, and follow-up;
- 3. Treatment and special instructions;
- 4. Scheduled revisits;
- 5. Informed consents initial and annual updates;
- 6. Refusal of services; and
- 7. Allergies and untoward reactions to drug(s) recorded in a prominent and specific location.

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, diagnoses and documentation of continuing care, referral and follow-up. The record must include entries by counseling and social service staff where appropriate. SRs should maintain a problem list listing identified problems to facilitate continuing evaluation and follow-up. Client financial information should be kept separated from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.

Health and Human Services

Records that are integrated with larger health systems or multiple program data systems (Electronic Health Records, etc.) must be able to be set up and maintained so that Title X Family Planning services can be extracted from the system, without compromising the client's confidentiality related to non-Title V services in the event of an audit or record transfer.

Contractors and subcontractors are prohibited from using personally owned electronic equipment (cell phones, tablets, computers, etc.), removable media and other devices to store, view, receive, or send records (medical, accounting, financial, programmatic, statistical, supporting documentation).

Confidentiality and Release of Records

A confidentiality assurance statement must appear in the client's record. The client's written consent is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality. HIV information should be handled according to law. When information is requested by the client, agencies should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical or other form, which does not identify particular individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care.

Each SR shall comply with Iowa Code 622.10(6)(a)-(d) regarding release for records and charges for release of records. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipients must inform the client of any potential for disclosure of their confidential health information to the policyholder is someone other than the client.

Iowa HHS HIPAA Statement

The effect of HIPAA privacy provisions on the release of protected health information to Iowa HHS.

lowa HHS, in conjunction with the Attorney General's Office, has completed a comprehensive review of its programs and has determined that neither the agency as a whole, nor any of its programs, are covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Iowa HHS is not a covered entity; many agencies and facilities in Iowa that are covered entities have questioned whether they can continue to disclose the protected health information of their patients or clients to Iowa HHS as they have in the past. The short answer is YES. Such disclosures may continue to occur under HIPAA.

First, HIPAA recognizes that if there is a statute or administrative rule that requires a specific disclosure of protected health information, a covered entity must obey that law. (Section 164.512). Therefore, if there is another federal or state statute or administrative rule which requires a covered entity to disclose protected health information (PHI) to Iowa HHS, the covered entity should follow that requirement. Many disclosures of PHI to Iowa HHS are required by state laws, including Iowa Code chapters 135, 136A, 136B, 136C, 139A, 141A, 144, 147A and 272C, and the administrative rules that implement these chapters. These disclosures are legally required and must continue to be made as mandated by state law.



Second, HIPAA allows a covered entity to disclose PHI to public health authorities for public health activities. (Section 164.512). HIPAA defines a public health authority as "an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate." (Section 164.501). Iowa HHS has such a mandate and, therefore, is a public health authority under HIPAA.

lowa HHS, in conjunction with the lowa Attorney General's Office, has reviewed its programs and determined that PHI being received by the department from covered entities in Iowa is disclosed for public health activities. The disclosure of such information to Iowa HHS is, therefore, unaffected by HIPAA and should continue in accordance with past practices. Because Iowa HHS is a public health authority that is authorized to receive PHI under this provision, covered entities are not required to enter into a Business Associate Agreement with Iowa HHS in order for the exchange of PHI to take place.

Third, in some instances, Iowa HHS is a health oversight agency as defined by HIPAA. Under HIPAA, a "health oversight agency" is "an agency or authority of the United States, a state, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant."

HIPAA permits a covered entity to disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits (civil, administrative or criminal investigations); inspections (licensure or disciplinary actions); civil, administrative or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

- The health care system (e.g., State insurance commissions, state health professional licensure agencies, Offices of Inspectors General of federal agencies, the Department of Justice, state Medicaid fraud control units, Defense Criminal Investigative Services, the Pension and Welfare Benefit Administration, the Iowa HHS Office for Civil Rights, the FDA, data analysis to detect health care fraud);
- 2. Government benefit programs for which health information is relevant to beneficiary eligibility (e.g., SSA and Department of Education);
- 3. Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards (e.g., Occupational Health and Safety Administration and the EPA; the FDS's oversight of food, drugs, biologics, devices, and other products pursuant to the Food, Drug, and Cosmetic Act and the Public Health Service Act); or
- 4. Entities subject to civil rights laws for which health information is necessary for determining compliance (the U.S. Department of Justice's civil rights enforcement activities, enforcement of the Civil Rights of Institutionalized Persons Act, the Americans with Disabilities Act, the EEOC's civil rights enforcement activities under titles I and V of the ADA). (Section 164.512(d)).

"Overseeing the health care system," encompasses activities such as:

- Oversight of healthcare plans.
- Oversight of health benefit plans.



- Oversight of healthcare providers.
- Oversight of healthcare and healthcare delivery.
- Oversight activities that involve resolution of consumer complaints.
- Oversight of pharmaceutical, medical products and devices, and dietary supplements.
- A health oversight agency's analysis of trends in health care costs, quality, health care delivery, access to care and health insurance coverage for health oversight purposes.

Health oversight agencies may provide more than one type of health oversight. Such entities are considered health oversight agencies under the rule for any and all of the health oversight functions that they perform. The disclosure of protected health information to Iowa HHS for these purposes is unaffected by HIPAA and should continue in accordance with past practices.

Finally, local public health departments and local contractors which are covered entities may release protected health information to lowa HHS under the above-cited legal authority applicable to all covered entities. For example, certain statutes and rules require local public health departments and local contractors to disclose protected health information to lowa HHS. Further, as a health oversight agency, a local health department is permitted, and in most cases required, to disclose protected health information to lowa HHS. Disclosures of PHI by local public health departments and local contractors to lowa HHS do not require Business Associate Agreements and are not prohibited or otherwise affected by HIPAA.

Please contact the Assistant Attorney General, should you have additional questions.

Date Revised	September 2023
References	
Additional Resources	



A5.4 - REVIEW AND APPROVAL OF CLINICAL POLICIES

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs and service sites) with development and maintenance of policies and procedures to provide high-quality, voluntary family planning and related preventive health services.

Policy

The CSP includes physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health and basic infertility care will be familiarized with the policies of family planning services.

Procedure

Iowa HHS will ensure:

- Title X clinical protocols are consistent with the MMWR Providing Quality Family Planning Services (most up to date version) and supported by evidence-based practice guidelines.
- All clinical policies reviewed, approved and signed each project period by the Iowa HHS contracted Medical Director or as needed, whatever is first..
- The Iowa HHS Title X Nurse Clinician will send out policy revisions as needed to ensure SRs policies are up to date using current screening guidelines.

Iowa HHS will ensure that each SR is in compliance with the following:

- Written clinical protocols that outline procedures for the provision of each service offered. Clinical protocols must be consistent with the requirements of Title X.
- Clinical protocols reviewed, approved, and signed each project period by the CSP (must be a prescribing provider), as the Title X representative.
- Submittal of clinical policies will be part of the annual site visit and/or as outlined in the contract required due date. Every project period, Title X clinical policies will be compared with the Title X federal program review tool unless otherwise noted.

Date Revised	September 2023
References	
Additional Resources	



A5.5 – EXCEPTION TO POLICY

Purpose

The purpose of this policy is for Iowa HHS (including SRs and services sites as appropriate) to ensure that program requirements and performance standards are in place to maintain the quality of services, protect the public, and to assure the proper use of federal funds.

Policy

SRs not in compliance with all Title X Family Planning Program, federal rules, and regulations along with state law requirements as part of the contract, may file a written request for a temporary exception to policy. An exception to policy shall not constitute a waiver of any terms and conditions of the contract. It is within the scope of the Program Director along with the Maternal and Reproductive Health Unit Lead to determine whether an exception to policy can be granted. A determination to grant an exception to policy does not affect the rights of the (SR and service sites, as applicable) to pursue any remedies under the contract or otherwise available under law.

Procedure

If a SR is requesting an exception to the policy, the SR will comply with the following:

- 1. Submit a request through the lowaGrants.gov Correspondence component.
- 2. Identify the timeframe needed for the exception to policy. An exception to policy may be written for up to one year, unless a different time limitation is stated in the requirement and granted by lowa HHS.
- 3. An extension to an approved exception to policy may be granted only under limited circumstances upon a showing of substantial progress towards compliance. The extension request shall include the rationale for extension and the progress made to date on the remediation plan.
- 4. Failure to request an exception to policy to a contract requirement prior to the anticipated noncompliance may result in the reduction or elimination of funding or the enforcement of other remedies authorized by the contract.
- 5. Failure to demonstrate satisfactory progress on the remediation plan may result in the reduction or elimination of funding or the enforcement of other remedies authorized by the contract.

Iowa HHS will:

- 1. Reserve the right to specify the format for reporting. In the absence of a prescribed format, the SR shall include the following components in the request:
 - a. Executive director shall submit the request;
 - b. Statement of the requirement for which the request for exception is being made;
 - c. The rationale for failure to meet the requirement;
 - d. The time period for which the exception is requested; and
 - e. A remediation plan to meet the requirement.
- It will be the decision of the Program Director and the Maternal and Reproductive Health Unit Lead whether 2. the exception will be granted. The decision will be entered into lowaGrants.gov within 30 days of the request.



Date Revised	September 2023
References	
Additional Resources	Iowa Administrative Code [641] Chapter 76



A5.6 – PHARMACEUTICALS

Purpose

The purpose of this policy is to ensure that SRs are in compliance with federal and lowa laws relating to security and record keeping for drugs and devices.

Procedure

lowa HHS requires SRs to identify the person/persons responsible for pharmaceutical services, formulary procurement, storage, monitoring, and drug and device recalls management as well as create policies and procedures. The inventory, supply, logs and packaging, and distribution of pharmaceuticals (including mailing) must be conducted in accordance with lowa pharmacy laws and professional practice regulations.

It is essential that each SR/service site maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Title X should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of Title X.

Title X SRs are qualified as 340B users and must recertify annually with the Office of Pharmacy Affairs (HRSA) to continue to have access to 340B drug purchases. *Refer to the Use of 340B Medications policy for further guidance.*

Title X requires SRs to assure compliance with the provisions of Section 340B of the PHS Act which prohibit drug diversion and double discounts/rebates. *Refer to the Use of 340B Medications policy for further guidance.*

Date Revised	September 2023
References	Providing Quality Family Planning Services
	Recommendations of CDC and the U.S. Office of
	Population Affairs (QFP) [2014]
	(https://www.hhs.gov/opa/guidelines/clinical-guideli
	nes/quality-family-planning/index.html)
	Title X Program Handbook,
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
Additional Resources	340B Requirements and Program Participation
	(https://www.hrsa.gov/opa/program-requirements)



A5.7 TELEHEALTH VISITS FOR TITLE X SERVICES

Purpose

The purpose of this policy is to describe the Iowa HHS Title X process for ensuring SRs and service sites compliance with the Title X FP requirements if a SR /service site chooses to provide services virtually through telehealth.

Policy

The provision of health care via telehealth is a mechanism to increase access to healthcare services by allowing healthcare providers to assess, diagnose, and treat patients without requiring both the individuals to be physically co-located.

"Telehealth" is not a service or a service delivery method; rather, telehealth is a mechanism or means for delivering a health service(s) to health center patients using telecommunications technology or equipment.

Procedure

Iowa HHS will ensure each SR has the following if telehealth services are provided:

- A policy developed and maintained that outlines which visits can be done remotely.
- Staff workflows developed and maintained.
 - Best practices from University of California San Francisco: https://beyondthepill.ucsf.edu/contraceptive-care-during-covid-19#telehealth-clinic.
- Equipment/Training Utilization of appropriate equipment, internet security, connectivity, HIPAA compliant telehealth platform, with staff appropriately trained to operate such equipment.
- Privacy/Confidentiality Maintaining the confidentiality of patient information and records, including all
 information as to personal facts and circumstances obtained by the health center staff about recipients of
 services delivered via telehealth.
- Medical Records/Documentation Documenting services provided via telehealth and reflected in the FP data system.
- Billing Has the ability to follow appropriate billing guidelines for authorized telehealth services.

Guidance for SRs Rendering Services via Telehealth*

- Identify clients via three unique identifiers, such as name, date of birth and address.
- Verify the client is in a private space or identify other individuals who are with the client.
- Confirm how patients will be fully informed about and consent to the delivery of health services via telehealth.
- Ensure appropriate client documentation.

Date Revised	September 2023



References	Title X Program Handbook (<u>https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2</u> <u>022-508-updated.pdf</u>)
Additional Resources	Health Resources & Services Administration (HRSA) - Program Assistance Letter, January 27, 2020 (https://bphc.hrsa.gov/sites/default/files/bphc/programrequirements/pdf/telehealth -pal.pdf) Best practices from University of California San Francisco (https://beyondthepill.ucsf.edu/contraceptive-care-during-covid-19#telehealth-cli
	nic) Telehealth Visit Etiquette Checklist by the American Medical Association (://www.ama-assn.org/system/files/2020-04/telehealth-appendix-g4-telehealth-visi t-etiquette-checklist.pdf)



A5.8 – OSHA AND CLIA REGULATIONS

Purpose

The purpose of this policy is to ensure that each SR along with each service site meets applicable fire, building, and licensing codes and standards established by federal, state, and local governments and maintain Exit Routes, Emergency Action Plans, and Fire Prevention Plans in accordance with OSHA.

Policy

All SRs must comply with the following regulations:

- 1. Occupational Exposure to Blood Borne Pathogens (OSHA regulations), 29 CFR Part 1910.130
- 2. Clinic Lab Improvement Act (CLIA) Laws and Regulations https://www.cdc.gov/clia/law-regulations.html

Procedure

lowa HHS will review this as part of the annual site visit with each SR and documented compliance will be noted on the federal review tool.

Date Revised	September 2023
References	Title X Program Handbook, page 31,
	(https://hhs.iowa.gov/sites/default/files/portals/1/userfiles/88/title%20x%20
	program%20handbook_final.pdf)
Additional Resources	CLIA Laws and Regulations
	(https://www.cdc.gov/clia/law-regulations.html)
	US Department of Labor - Occupational Safety and Health Standards
	(https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1
	<u>030</u>)



A5.9 – HUMAN SUBJECTS CLEARANCE (RESEARCH)

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs, and service sites) with the legal requirements governing human subjects research.

Policy

Clinical or sociological research on Title X clients must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. Iowa HHS will contact their assigned OASH Title X Project Officer in writing for approval of research projects that involve Title X clients.

Procedure

If a SR would like to engage in human subjects research, the SR shall submit their request to Iowa HHS Title X Program Director. The Iowa HHS Title X Program Director will forward a copy of the request to the Human Research Committee for approval. When a request for human subject clearance is received, the following will take place:

 Institutional Review Board (IRB): Iowa HHS will submit Institutional Review Board (IRB) approvals, when required, via Grant Solutions Grant Notes within 5 business days of receipt from the IRB. No activities that require IRB approval may take place prior to receipt of the IRB approval. For more information on 45 CFR Part 46 Protection of Human Subjects, recipients should refer to the HHS Office of Human Research Protections.

Iowa HHS will monitor this as part of the site visits with each SR as well as part of the manual review process.

Date Revised	September 2023
References	Title X Program Handbook
	(https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-
	2022-508-updated.pdf#)
Additional Resources	



F6.I – FINANCIAL ACCOUNTABILITY: LOW-INCOME CLIENTS

Purpose

The purpose of this policy is to describe the Iowa HHS (including SRs and service sites) process for ensuring that no charge is made for services provided to any clients from a low-income family except to the extent that payment is made by a third party (including a government agency), which is authorized to or is under legal obligation to pay this charge.

Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reason, to pay for family planning services. (Section 1006(c)(1), PHS Act; 42 CFR § 59.5(a)(7) and 42 CFR § 59.2)

Policy

- Clients are not denied project services or subjected to any variation in quality of services because of inability to pay.
- Clients whose documented income is at or below 100% of the federal poverty level (FPL) are not charged for family planning services.
- Third-party payers are billed when authorized or legally obligated to pay for services.
- Clients with incomes that exceed 100% of the FPL but who are unable to pay for family planning services, may, at the discretion of the project director, have their fees waived.

Procedure

Iowa HHS will ensure that each SR complies with the following:

- Process to ensure staff are using the most recent FPL guidelines and schedule of discounts.
 - o lowa HHS will be responsible for distributing annual income limits and any updated worksheets (if applicable)
- Process for annually updating poverty guidelines and schedule of discounts that are used at recipient and/or subrecipient sites.
- Process for referring clients with incomes over 100% of the FPL to the project director for possible fee waiver, when appropriate.
- Process for notifying staff about this policy along with any updates to changes on this policy.

The items listed above will be monitored on an annual basis as part of the site visit using the federal review tool.

Date Revised	September 2023
References	Title X Program Handbook, Section 3 Financial
	Accountability #I
	(https://opa.hhs.gov/sites/default/files/2022-08/title





F6.2 – INCOME VERIFICATION

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs, and service sites) that projects take reasonable measures to verify client income, without burdening clients from low-income families. 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. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income. (42 CFR § 59.5(a)(9)).

Policy

- Client income is verified, without burdening low-income families.
- If clients' income cannot be verified after reasonable attempts to do so, charges are based on the client's self-reported income.

Procedure

Iowa HHS will ensure that each SR complies with the following:

- Process by which the agency verifies client income. •
- Process through which other program income data (such as WIC) are accessed when applicable.
- Definition of what is included (or excluded) in the client income. •
- Process by which clients are able to self-declare their income. •
- Frequency with which income is assessed (at least annually and/or as the client identifies). •

The items listed above will be monitored on an annual basis as part of the site visit using the federal review tool.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Financial
	Accountability #6
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=22</u>)
	2021 Title X Final Rule 42 CFR § 59.5(a)(9)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	<u>bchapter-D/part-59#5</u>)
Additional Resources	



F6.3 – DISCOUNT ELIGIBILITY FOR MINORS

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs, and service sites) that unemancipated minors who wish to receive services on a confidential basis in regards to billing must be considered on the basis of their own resources. (42 CFR § 59.2).

Policy

- Eligibility for discounts for unemancipated minors seeking or receiving confidential services in the Title X Project are based solely on the income of the minor.
- Unemancipated minors that are not seeking confidential services have their family income assessed.

Procedure

Iowa HHS will ensure that each SR complies with the following:

- Process for determining and documenting whether a minor is seeking confidential billing (e.g., question on intake form).
- Process for assessing and documenting a minor's income.
- Process for alerting all clinic and billing staff about minor clients who are seeking and receiving confidential billing.
 - Each SR will be required to show lowa HHS how this is documented and monitored in the electronic health records system as part of the annual site visit.
- Process for how staff are notified about this policy and updated on changes to the policy (if applicable).

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Financial
	Accountability #2
	(https://opa.hhs.gov/sites/default/files/2022-08/title-x-pr
	ogram-handbook-july-2022-508-updated.pdf#page=22)
	2021 Title X Final Rule 42 CFR § 59.2
	(https://www.ecfr.gov/current/title-42/chapter-l/subchap
	ter-D/part-59/subpart-A/section-59.2)
Additional Resources	

Health and Human Services

F6.4 – FEE SCHEDULE AND SCHEDULE OF DISCOUNTS

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs, and service sites) that charges are made for services to clients other than those from Iow-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) are made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR § 59.5(a)(8)).

The schedule of discounts should be updated annually in accordance with the federal poverty level (FPL).

The HRSA Health Center Program and the OPA Title X Program have unique sliding fee discount schedule (SFDS) program expectations, which include having differing upper limits. Title X agencies (or providers) that are integrated with or receive funding from the HRSA Health Center Program may have dual fee discount schedules: one schedule that ranges from 101% to 200% of the FPL for all health center services, and one schedule that ranges from 101% to 250% FPL for clients receiving only Title X family planning services directly related to preventing or achieving pregnancy, and as defined in their approved Title X project. (OPA PPN 2016-11).

Policy

- Services provided to individuals with family incomes between 101% and 250% of the FPL are based on individuals' ability to pay.
- Services provided to those above 250% FPL are charged fees designed to recover the reasonable cost of providing services.

Procedure

Iowa HHS will ensure that each SR complies with the following:

- Process for assessing and documenting client income and discounts, including the frequency with which clients are reassessed and what is counted toward family income.
- Process by which the schedule of discounts was established (i.e., the reasoning behind the increments between 100% and 250% of poverty).
- Process for informing clients about the availability of the SFDS.
- Process by which fees are determined to recover the reasonable cost of providing services.
- Process for how staff are notified about this policy and updated on changes to this policy.

Each SR will be required to show Iowa HHS how this process is completed and documented as part of the annual site visit.

Date Revised	September 2023



References	Title X Program Handbook, Section 3, Financial
Relefences	G
	Accountability #3
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=22</u>)
	2021 Title X Final Rule 42 CFR § 59.5(a)(8)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	<u>bchapter-D/part-59 - 59.5</u>)
	OPA Program Policy Notice 2016-11
	(https://opa.hhs.gov/grant-programs/title-x-service
	-grants/about-title-x-service-grants/program-polic
	<u>y-notices/opa-program-policy-notice-2016-11-inte</u>
	grating-with-primary-care-providers)
Additional Resources	



F6.5 – THIRD-PARTY PAYMENTS, COPAYMENTS & ADDITIONAL FEES

Purpose

The purpose of this policy is to describe the lowa HHS process for ensuring compliance (including SRs and service sites) that family income is assessed before determining whether copayments or additional fees are charged. (42 CFR § 59.5(a)(8)).

Title X funded agencies must also ensure that, with regard to insured clients, clients whose family income is at or below 250 percent of the federal poverty level (FPL) should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied. (42 CFR § 59.5(a)(8)).

Title X-funded agencies should take all reasonable efforts to obtain the third-party payment without application of any discounts, if a third party (including a government agency) is authorized or legally obligated to pay for services. Where the cost of services is to be reimbursed under Title XIX, XX, or XXI of the Social Security Act, a written agreement with the Title XIX, XX, or XXI agency is required. (42 CFR § 59.5(a)(10)).

Policy

- All reasonable efforts are made to bill and obtain third-party payment, without the application of discounts, from all public and private third-party reimbursement sources authorized or legally obligated to pay for services.
- Family income is assessed before determining whether copayments or additional fees are charged.
- Insured clients whose family income is at or below 250% of the FPL do not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

Procedure

Iowa HHS will ensure that each SR complies with the following:

- Process for obtaining and/or updating contracts with private and public insurers.
- Process for assessing and documenting family income before determining whether copayments or additional fees are charged.
- Process for ensuring that financial records indicate that clients with family incomes between 101%–250% of the FPL do not pay more in copayments or additional fees than they would otherwise pay when the schedule of discounts is applied.
- Process for identifying third-party payers that the recipient and/or SRs should bill to collect reimbursements for the cost of providing services.
- Process for how Title X SRs along with service sites bill Iowa Medicaid Enterprise, the Managed Care
 Organizations, and private insurance for family planning services provided through the Iowa Family Planning
 Program (FPP), the Medicaid Program (refer to each MCO's Provider Manuals for additional information on
 billing for FP services), and private insurance (individual agency contracts). Maximum reimbursement rates per
 service are established by each third party payer. Services reimbursed under family planning are considered part
 of the services supported by this RFP/RFA and must be reinvested back into the program.
- Process for how staff are notified about this policy and updated on changes to the policy.



The items listed above will be monitored on an annual basis as part of the site visit using the federal review tool.

Date Revised	September 2023
References	Title X Program Handbook, Section 3, Financial
	Accountability #4, #5, #7
	(https://opa.hhs.gov/sites/default/files/2022-08/title
	-x-program-handbook-july-2022-508-updated.pdf
	<u>#page=22</u>)
	2021 Title X Final Rule 42 CFR § 59.5(a)(8, 10)
	(https://www.ecfr.gov/current/title-42/chapter-l/su
	<u>bchapter-D/part-59#59.5)</u>
Additional Resources	



F6.6 – PROGRAM INCOME AND NON-FEDERAL SHARE

Purpose

The purpose of this policy is to describe the Iowa HHS process for ensuring compliance (including SRs, and service sites) with the expectations that:

- Recipients include financial support from sources other than Title X as no grant may be made for an amount equal to 100 percent of the project's estimated costs. Although projects are expected to identify additional sources of funding and not solely rely on Title X funds, there is no specific amount of level of financial match requirement for this program. (42 CFR § 59.7(c)).
- Recipients must ensure that program income (fees, premiums, third-party reimbursements which the project may reasonably expect to receive), as well as state, local and other operational funding, is used to finance the non-federal share of the scope of project as defined in the approved grant application and reflected in the approved budget.
- Program income and the level projected in the approved budget are used to further program objectives. Program income may be used to meet the cost sharing or matching requirement of the federal award. The amount of the federal award stays the same.
- Program income in excess of any amounts specified must be added to the federal funds awarded. They must be used for the purposes and conditions of this award for the duration of the project period. (45 CFR § 75.307(e); FY 22 Notice of Award Special Terms and Requirements)
- Recipients must ensure that Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office. (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022).

Policy

- The budget shows support from other income sources outside of the Title X grant.
- All program income is used to support the non-federal share of the project and used to further program objectives.
- Title X funds, including program income are not used to promote public support or opposition to any legislative proposal or candidate for public office

Procedure

Iowa HHS will ensure that each SR complies with the following:

- Process for ensuring that there is a contribution of non-federal funds used to support the project.
 - o This will be reviewed on an annual basis as part of the RFP/RFA process as well as monthly with claim submission. Sources that may be used for program income and cost sharing include:
 - Medicaid (Title XIX) reimbursements
 - State Family Planning Program (FPP) reimbursement



- Title V or Title XX
- Reimbursement from third parties such as insurance
- Local funds from non-federal sources
- In-kind contributions
- Private foundations
- Cash
- Other Interest, donations
- Process for identifying if program income is used to meet the cost sharing or matching requirement of the federal award.
 - o Program income collected from public or private sources, or third-party sources for service provision related to this project must be reported monthly to the state and must be expended on program-related activities. Subcontractors are required to report program income to the contract agency.
 - o Direct care services for other third-party liability are billed in a manner prescribed by that third-party payer.
 - o This will be reviewed on an annual basis as part of the RFP/RFA process.
- Process to ensure that all program income (as defined above), including the level projected in the approved budget and any amounts which exceed the original estimate, is used to further program objectives.
- Process for ensuring that Title X funds (including any form of income derived from approved program activities) are not expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office (Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022)).

Date Revised	September 2023	
References	Title X Program Handbook, Section 3, Financial Accountability #12, #13, #14	
	(https://opa.hhs.gov/sites/default/files/2022-08/title-x-program-handbook-july-2022-508-updated.	
	pdf#page=23)	
	FY 22 Notice of Award Special Terms and Requirements	
	PA-FPH-22-001 NOFO	
	(https://www.grantsolutions.gov/gs/preaward/previewPublicAnnouncement.do?id=95156)	
	2021 Title X Final Rule 45 CFR § 75.307(e)	
	(https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75#75.307)	
	Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022)	
	(https://www.congress.gov/117/plaws/publ103/PLAW-117publ103.pdf)	
Additional		
Resources		