


# Iowa Department of Public Health



## Family Planning Manual

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  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Introduction	<b>SUBJECT:</b> Purpose	<b>NUMBER:</b>  <b>101</b>
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## PURPOSE OF THE FAMILY PLANNING MANUAL

This manual contains information necessary for providing family planning and reproductive health services as part of the Iowa Department of Public Health Family Planning (FP) program. It provides the basis for the development of business practices and programming for FP services.

The manual is intended for use by agencies, which contract with the Iowa Department of Public Health, for federal Title X funds to provide family planning services in local communities. The manual outlines federal and state policies and procedures applicable to all contract agencies. *Access to this manual must be available at all clinic sites.*

The FP manual is accessible via the IDPH website at:


<http://idph.iowa.gov/Portals/1/userfiles/38/100s%20through%20400s.pdf>

## IOWA MEDICAID ENTERPRISE MANUAL FOR FAMILY PLANNING

The FP services provider manual is the Iowa Department of Human Service's (IDHS) official interpretation of the federal laws and regulations and the state laws and rules relating to the programs it administers. The purpose of the manual is to present IDHS policies and procedures for program administration in a centralized and usable form. The manual provides the official record of IDHS's interpretation of the policies adopted in its rules and authorizing legislation. IDPH contractors must be in compliance with the manual for the provision and billing of FP services.

Iowa DHS FP services manual can be found at:

<https://dhs.iowa.gov/sites/default/files/5-F.pdf?090120191848>

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Introduction	<b>SUBJECT:</b> Maintenance of the IDPH FP Manual		<b>NUMBER:</b>  <b>102</b>
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## MAINTENANCE OF THE IDPH FAMILY PLANNING MANUAL

The manual contains sections dealing with program administration, clinical policies, quality assurance, and a large appendix. In order for it to fulfill its purpose, the manual must be properly maintained. The clinical portion of the manual is reviewed and revised annually as appropriate by the Family Planning (FP) Medical Advisory Committee. The rest of the manual is reviewed by the program director every three years or when necessary to reflect changes in federal or state requirements. Links to websites that appear in the manual will be checked annually.

The scheduled revision process does not preclude revisions that might be needed at other times. Manual users, state and local, may request consideration of manual revisions at any time through the family planning director.

Policies that are retired will be identified as such in the table of contents and in a blank policy page within the manual.

Every effort is made to distribute manual revisions as soon as they are completed annually. This may be done in hard copy or electronic form. The FP manual is also available online at: <http://idph.iowa.gov/Portals/1/userfiles/38/100s%20through%20400s.pdf>. Sub-recipient agencies will follow the same manual review schedule as IDPH.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Introduction	<b>SUBJECT:</b> FP Organizational Structure		<b>NUMBER:</b>  <b>103</b>
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	<b>Authority:</b> Public Health Service Act 45 CFR Part 59; MCHS Administrative Manual; IAC 641-74			

## FAMILY PLANNING ORGANIZATIONAL STRUCTURE

The Family Planning (Title X) program is administered by the Iowa Department of Public Health (IDPH), Division of Health Promotion and Chronic Disease Prevention, Bureau of Family Health, pursuant to an agreement with the United States Department of Health and Human Services, Office of Population Affairs.

### IOWA DEPARTMENT OF PUBLIC HEALTH

Under the leadership of the director, the IDPH exercises general supervision of the state's public health; promotes public hygiene and sanitation; does health promotion activities; prepares for and responds to bioemergency situations; and unless otherwise provided, enforces laws on public health.

The IDPH programs are conducted through the executive staff and the following divisions:

- Acute Disease Prevention, Emergency Response, and Environmental Health
- Administration and Professional Licensure
- Behavioral Health
- Health Promotion and Chronic Disease Prevention
- Tobacco Use Prevention and Control

The Director's office focuses primarily on the overall development of health related policy, strategic planning and outcome.

The Iowa State Board of Health is the policy-making body for the IDPH. It has the powers and duties to adopt, promulgate, amend and repeal rules and regulations, and advises or makes recommendations to the governor, general assembly, and the IDPH director, on public health, hygiene and sanitation.

### Division of Health Promotion and Chronic Disease Prevention

The Division of Health Promotion and Chronic Disease Prevention promotes and supports healthy behaviors and communities, the prevention and management of chronic diseases, the development of public health infrastructure and access to health care/services at local and state levels.

- Bureau of Nutrition and Physical Activity
- Bureau of Oral & Health Delivery Systems
- Bureau of Family Health
- Bureau of Chronic Disease Prevention & Management

### Bureau of Family Health

The Bureau of Family Health is responsible for administering the portion of the Title X Grant that comes to the IDPH. 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 women and children. The bureau has the primary responsibility for system planning, program development and evaluation; developing and monitoring standards of care; and coordinating health-related services between and among community-based entities serving Iowa women.

The bureau has multiple programs focusing on the health of women, children and families including: Maternal and Child Health Title V programs, Family Planning Title X programs, Healthy Child Care Iowa, Covering Kids and Families, Hawki, Early Periodic Screening Diagnosis and Treatment (EPSDT), Early Hearing Detection and Intervention, Iowa Infant Mortality Prevention Center, the Statewide Perinatal Care Program, and the programs of the Center for Congenital and Inherited Disorders, Personal Responsibility Education Program (PREP), Abstinence Education Program, Pregnancy Risk Assessment Monitoring System (PRAMS), and Maternal, Infant, and Early Childhood Home Visitation Program. The programs within the bureau work closely together and provide in-kind support to one another. Family Planning staff work closely with the staff of the Bureau of HIV, STD and Hepatitis on the Community Based Screening Services (CBSS) project and the Women's Health Team.

In addition to the Core Public Health Functions (published in the 1988 Institute of Medicine Report) and the Ten 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 Family Planning programs. Those goals can be found online at <http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/program-priorities/>.

## **OTHER STATE DEPARTMENTS**

Programs in other departments or entities of state government that serve Iowa women include, but are not limited to, the following:

- The Iowa Department of Human Services Administers services for mental health, developmental disabilities, child welfare, child care, child abuse and neglect, Title XIX (Medicaid) program, Family Planning Program, Title XXI state child health insurance program, and pregnancy prevention grants.

## **NON-STATE FUNDED RELATIONSHIPS**

The IDPH FP 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 family planning services in Iowa.


## **FISCAL**

The IDPH FP program complies with the Iowa Department of Health Fiscal processes which comply with all State and Federal requirements. All funds granted for the Title X service project will be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Per Iowa Administrative Code 641, Chapter 74, funding to local agencies occurs through a competitive bid proposal process.

## **IOWA MEDICAID ENTERPRISE MANUAL FOR FAMILY PLANNING**

The FP services provider manual is the Iowa Department of Human Service's (IDHS) official interpretation of the federal laws and regulations and the state laws and rules relating to the programs it administers. The purpose of the manual is to present IDHS policies and procedures for program administration in a centralized and usable form. The manual provides the official record of IDHS's interpretation of the policies adopted in its rules and authorizing legislation.

IDPH contractors must be in compliance with the manual for the provision and billing of FP services. IDHS FP services manual can be found at:  
<https://dhs.iowa.gov/sites/default/files/5-F.pdf?090120191848>

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Introduction	<b>SUBJECT:</b> FP Director Orientation	<b>NUMBER:</b>  <b>104</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
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	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019, 2014; QFP, 2014		


## ORIENTATION POLICY FOR NEW FAMILY PLANNING DIRECTORS

IDPH will provide an orientation to family planning (FP) services for all newly hired family planning directors in any sub-recipient agency. The orientation will occur within 30 days of hire. The orientation will include but is not limited to:

- Introduction of key personnel at IDPH and contact information
- Review key personnel at regional and federal level
- Title X Overview
- Review of Title X statutes ([Title X of the Public Health Service Act, 42 U.S.C. 300, et seq](#)), the most current Title X Program Requirements (as defined in CFR) Providing Quality Family Planning Services (QFP), 2014 Program Policy Notices, , and key documents. – Review of reporting requirements (state and federal), Family Planning Annual Report (FPAR)
- Review of IDPH FP Policy Manual
- Review of IDPH FP Committees
- Discuss 340B drug program
- Review of agency contract with IDPH to provide FP services to include reporting and meeting requirements, expenditure reports
- Discuss Iowa Family Planning Program (IDHS)
- Orient to IDPH website(s)
- Orient to IDPH FP data collection system

This training will be documented by completion of the Title X Overview slides certificate, which will be maintained in the agency files.



  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Introduction	<b>SUBJECT:</b> Orientation	<b>NUMBER:</b>  <b>105</b>
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## ORIENTATION POLICY FOR NEW MATERNAL CHILD HEALTH ADVISORY COMMITTEE MEMBERS AND MEDICAL ADVISORY COMMITTEE MEMBERS

IDPH will provide an orientation to the family planning program for all new IDPH Maternal Child Health (MCH) Advisory Committee members. The orientation is conducted annually or as requested during the new MCH Advisory Committee member orientation session. The Family planning orientation will include:

- Introduction of key personnel at IDPH and contact information
- An abbreviated form of Title X Overview that includes the funding source, purpose and history of the program, services provided, clients served in Iowa, and program requirements
- Discuss Iowa Family Planning Program
- Orient to IDPH website(s)
- Role of MCH Advisory Committee members (review project plan)


This training will be documented in the MCH Advisory Committee meeting minutes.

New IDPH Medical Advisory Committee members will be oriented by the IDPH FP director using MS Power Point, verbal discussion and written information covering the same topics found in the MCH Advisory Committee orientation and including the most current Title X Program Requirements (as defined in CFR) and Providing Quality Family Planning Services, the most current documents.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Introduction	<b>SUBJECT:</b> New Bureau of Family Health Staff Orientation		<b>NUMBER:</b>  <b>106</b>
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	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74, Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements			

### ORIENTATION POLICY FOR NEW BUREAU OF FAMILY HEALTH STAFF

IDPH will provide an orientation to Title X for all newly hired Bureau of Family Health staff who participate in the Title X project. This training will be documented by completion of the Title X Overview certificate and the checklist found in the appendix as "Orientation/Annual Training".

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Introduction	<b>SUBJECT:</b> Sub-Recipient Staff Orientation		<b>NUMBER:</b>  <b>107</b>
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	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements; QFP, 2014			

## POLICY FOR NEW SUB RECIPIENT STAFF ORIENTATION AND ANNUAL REQUIRED STAFF TRAINING

IDPH will provide an orientation to Title X for all new sub-recipient staff twice yearly or more often as needed, either at the Lucas Building or virtually. Sub-recipient staff will be trained by IDPH within six (6) months of hire. The training includes:

- Family planning (FP) overview that includes the funding source, purpose and history of the program, services provided, clients served in Iowa, and program requirements
- Discussion of Iowa Family Planning Program (DHS FPP)
- Orientation to IDPH website(s)
- Orientation to IDPH FP manual

The trainings will be documented by completion of the Title X overview certificate that will be maintained in the agency staff files.


The Required Annual Trainings and Certifications for Title X are in the Appendices.

Sub-recipient agencies will further orient new staff and assure all competencies are reviewed.

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  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Program Description	<b>NUMBER:</b>  <b>201</b>
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	<b>Authority:</b> USDHHS/Office of Public Health and Science, Office of Population Affairs; <a href="http://www.hhs.gov/opa/title-x-family-planning">http://www.hhs.gov/opa/title-x-family-planning</a> ; IAC 641-74; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## FAMILY PLANNING PROGRAM DESCRIPTION


Family Planning is viewed as a basic health service essential for the promotion of optimal family health throughout the life cycle. Family planning (FP) consists of the educational, comprehensive medical and social services necessary to aid individuals to determine freely the number and spacing of their children. The program strives to improve the health of families through education, health promotion, health screening and the advantageous timing and spacing of pregnancies.

The purpose of FP is to assist individuals and families in identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved. These means include a broad range of acceptable and effective choices, which may range from choosing not to have sex to the use of other FP methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural FP or (other fertility awareness-based methods) and the management of infertility (including adoption). FP services include preconception counseling, education, and general reproductive and fertility health care to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek FP services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children.

The IDPH FP program will provide a broad range of acceptable family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents).


FP services are never coercive and are strictly voluntary.

IDPH will comply with all requirements of Public Health Service Act 42 CFR Part 59. Unless otherwise specified, the requirements imposed by these regulations apply equally to grantees and sub-recipients, and IDPH shall require and ensure that sub-recipients (and the sub-recipients of sub-recipients) comply with the requirements contained in these regulations pursuant to written contracts with each sub-recipients.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Objective	<b>NUMBER:</b>  <b>202</b>
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### OBJECTIVE


To provide comprehensive family planning services to males and females throughout the Iowa Department of Public Health Service Area, who may have difficulty accessing services, due either to economic barriers, confidentiality concerns or a lack of medical resources. Priority for project services is to persons of low-income families.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration		<b>SUBJECT:</b> Eligibility	<b>NUMBER:</b>  <b>203</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014			

### ELIGIBILITY

1. Any client requesting family planning services is eligible. No person shall be denied services due to inability to pay.
2. Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(a)(5)).




  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Non-Discrimination	<b>NUMBER:</b>  <b>204</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> May 2016
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014		

### NON-DISCRIMINATION

Services are provided without regard to religion, race, color, national origin, creed, disability, and gender, number of pregnancies, marital status, age, sexual orientation or contraceptive preference.

Sub-recipients must comply with ACA Section 1557 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, members of the lesbian, gay, bisexual and transgender (LGBT) community, individuals with disabilities and individuals with limited English proficiency (LEP). Specific requirements for posting communications, tag lines, and operations management is available in Appendices of the IDPH FP manual.

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Voluntary Participation	<b>NUMBER:</b>  <b>205</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014		

## VOLUNTARY PARTICIPATION

Services are provided solely on a voluntary basis. Individuals are not subjected to coercion or discrimination in the delivery of services, or to use any particular method of family planning.

Acceptance of family planning services is not a prerequisite to eligibility of any other services, assistance, or participation in any other program. Clients are encouraged to ask questions, and may refuse a service or stop services at any time.

All family planning staff, both state and sub-recipient agencies, must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

Sample voluntary participation acknowledgement of receipt is on the following page. Acknowledgement must be signed annually and maintained in personnel files at the sub-recipient agency.

**Iowa Department of Public Health  
Acknowledgement of Receipt of the Title X  
Voluntary Participation Policy and Conflict of Interest Policy**

I, \_\_\_\_\_, acknowledge that I have received policy 205 (Voluntary Participation) and policy 238 (Abortion services). I have read these policies and been given the opportunity to ask questions regarding their content. I understand the information in these policies and adhere to all provisions.

Furthermore, I also have received policy 207 (Conflict of Interest). I understand that my Title X position is not to be used for purposes of private gain for myself or for others. I have read this policy and been given the opportunity to ask questions regarding its content. I understand the information in this policy and adhere to all provisions.

\_\_\_\_\_  
Employee's Name (print)

\_\_\_\_\_  
Employee's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Supervisor's Signature

\_\_\_\_\_  
Date

*Place the original copy of this form in the employee's personnel file. Give a copy to the employee.*

**Iowa Department of Public Health  
Acknowledgement of Receipt of the Title X  
Voluntary Participation Policy**

I, \_\_\_\_\_, acknowledge that I have received policy 205 (Voluntary Participation) and policy 238 (Abortion services). I have read these policies and been given the opportunity to ask questions regarding their content. I understand the information in these policies and adhere to all provisions.

\_\_\_\_\_  
Employee's Name (print)


\_\_\_\_\_  
Employee's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Supervisor's Signature

\_\_\_\_\_  
Date

*Place the original copy of this form in the employee's personnel file. Give a copy to the employee.*

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Confidentiality	<b>NUMBER:</b>  <b>206</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> July 2019
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	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74 2014; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## CONFIDENTIALITY

Every effort is made to assure client confidentiality and provide safeguards for individuals against the invasion of their personal privacy. This includes records maintained in electronic format. Information about clients that receive services may not be disclosed without individual's written consent, except as required by law, or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification. Information may be disclosed in summary, statistical or other form that does not identify the individual. HIPPA forms must be collected as required.

Each sub-recipient agency shall have a policy for indicating **no-contact** clients in the medical record, including in the financial record.

### ADOLESCENTS AND CONFIDENTIALITY

Adolescents must be assured that the counseling sessions and services are confidential and, if follow-up is necessary, every attempt will be made to assure the privacy of the individual. However, counselors must encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on resisting attempts to coerce minors into engaging in sexual activities. Title X sub-recipient agencies may not require written consent of parents or guardians for the provision of services to minors. Nor can the sub-recipient agency notify parents or guardians before or after a minor has requested and received Title X family planning services.


Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record: (i) That it suspects the minor to be the victim of child abuse or incest; and (ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.

### 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 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. Sub-recipient staff 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 in employee files.

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.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Conflict of Interest	<b>NUMBER:</b> <b>207</b>
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	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74 Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014		

## CONFLICT OF INTEREST

Sub-recipient agencies must have established policies to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others.

A conflict of interest occurs when an employee, consultant, or member of a governing or advisory body is in a position to influence a decision that may result in personal gain for that person or a relative as a result of the business dealings.

No “presumption of guilt” is created by the mere existence of a relationship with outside firms. However, if an employee, consultant, or member of a governing or advisory body has influence on transactions involving purchases, contracts or leases, disclosure of the potential existence of a conflict of interest must be provided immediately.

Sub-recipient agency staff must have signed Conflict of Interest statements kept in their personnel files. Consultants and members of governing/advisory bodies must have signed statements kept in the local family planning director’s office.

Two sample forms appear on the following page. The first is a conflict of interest form. The second is a combined form covering conflict of interest and voluntary participation. Sub-recipient agencies may use these IDPH forms or may modify them to create the specific forms for use within the agency.

Acknowledgement must be signed annually and maintained in personnel files at the sub-recipient agency.

**Iowa Department of Public Health**  
Acknowledgement of Receipt of the Title X  
Conflict of Interest Policy

I, \_\_\_\_\_, have received policy 207 (Conflict of Interest). I understand that my Title X position is not to be used for purposes of private gain for myself or for others. I have read this policy and been given the opportunity to ask questions regarding its content. I understand the information in this policy and adhere to all provisions.

\_\_\_\_\_  
Employee's Name (print)

\_\_\_\_\_  
Employee's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Supervisor's Signature

\_\_\_\_\_  
Date

*Place the original copy of this form in the employee's personnel file. Give a copy to the employee.*

**Iowa Department of Public Health**  
Acknowledgement of Receipt of the Title X  
Voluntary Participation Policy and Conflict of Interest Policy

I, \_\_\_\_\_, acknowledge that I have received policy 205 (Voluntary Participation). I have read this policy and been given the opportunity to ask questions regarding its content. I understand the information in this policy and adhere to all provisions.

Furthermore, I also have received policy 207 (Conflict of Interest). I understand that my Title X position is not to be used for purposes of private gain for myself or for others. I have read this policy and been given the opportunity to ask questions regarding its content. I understand the information in this policy and adhere to all provisions.

\_\_\_\_\_  
Employee's Name (print)


\_\_\_\_\_  
Employee's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Supervisor's Signature

\_\_\_\_\_  
Date


*Place the original copy of this form in the employee's personnel file. Give a copy to the employee.*

 <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Liability Coverage	<b>NUMBER:</b>  <b>208</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74		

### LIABILITY COVERAGE

The CONTRACTOR 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, the following: liability insurance, fidelity bonding of persons entrusted with handling of funds, workers compensation, unemployment insurance and professional liability.




 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Human Subjects Clearance (Research)	<b>NUMBER:</b>  <b>209</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74		

### HUMAN SUBJECTS CLEARANCE (RESEARCH)

Clinical or sociological research on Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. IDPH will advise the Regional Office in writing of research projects involving Title X clients or resources.

Contract agencies shall forward a copy of the Human Research Committee approval to the Department. The Department shall forward it to the Regional Office.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Financial Management	<b>NUMBER:</b>  <b>210</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> Rev. December 2017
	<b>Status:</b>	<b>Cross Reference:</b> IDPH FP Manual policy 211	
	<b>Authority:</b> Public Health Service Act 45; 2CFR Part 200 and Part 75; 2 CFR 200.302(b)(4)) Appendix B 8 m.; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014; QFP 2014, Program Policy Notice 2016-11		

## FINANCIAL MANAGEMENT

Sub-recipients must maintain a financial management system that meets the standards specified in 2CFR Part 200 and Part 75 and 2 CFR 200.302(b)(4)), as applicable, as well as any other requirements which comply with Federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained as required.

Sub-recipient agencies must have a process for reconciliation and verification of all accounting transactions, including time and effort reporting as specified in 2CFR Part 200 and Part 75 and 2 CFR 2300.

## CHARGES, BILLING, AND COLLECTIONS

Contract agencies are responsible for the implementation of written policies and procedures for charging, billing, and collecting funds for the services provided by the project. The governing authority should approve the policies and procedures.

Clients must not be denied project services or be subjected to any variation in quality of services because of the inability to pay. Clients must be made aware that they will not be denied services because of inability to pay. This is accomplished by a sign posted in the waiting room or by another method approved by the Iowa Department of Public Health.

Billing and collection procedures must have the following characteristics:

1. Charges must be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services must be given bills directly. In cases where a third party is responsible, bills must be submitted to that party.
2. A schedule of discounts must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees must be waived for individuals with family incomes above this amount who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.
3. Clients whose documented income is at or below 100% of the Federal poverty level must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services.
4. Individual eligibility for a discount must be documented in the client's financial record.

5. Bills to third parties must show total charges without applying any discount. The remaining balance after insurance payment [or non-payment] is a client responsibility; however, appropriate discounts must be applied to the balance due. IDPH sub-recipients credential providers and obtain contracts with third party payers. After the insurance payment is received, the discount is applied to the services originally rendered. The remaining balance is compared to the discounted fee. The client is charged whichever is the lower of the two.
6. Where reimbursement is available from Title XIX, the Family Planning Program (FPP) or other state funds through Iowa DHS, a written agreement with the Title XIX, FPP or the state agency at the sub-recipient agency level is required.
7. Bills to clients must show total charges less any allowable discounts.
8. Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.
9. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.
10. A method for the “aging” of outstanding accounts must be established.
11. Voluntary donations from clients are permissible. However, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements set out above.
12. Client income should be re-evaluated at least annually.
13. IDPH assures that project sites have current information on the Federal Poverty Guidelines.

Effective financial management will assure the short and long term viability of the project, including the efficient use of grant funds. Technical assistance in achieving this objective is available from the Regional Office. Title X projects offering services that are not required by the statute, regulations or these Guidelines should, whenever possible, seek other sources of funding for such services before applying Title X funds to those activities.

#### **Iowa Department of Public Health Program Requirements to Clarify the above Federal Requirements**

##### **A. Fees For Services**

1. Fees must be determined by cost analysis.
2. Cost analysis shall be completed at least annually and fees adjusted based on the cost analysis findings.
3. Fees for supplies shall be based on the cost of the supplies and may include a reasonable handling and administration fee.

##### **B. Provision Of Contraceptives – Contraceptive supplies cannot be rationed based on client non-payment of bills.**

##### **C. Client Donations – Contract agencies may ask clients for donations. However, the following requirements must be followed:**

1. Donations are always voluntary.
2. Donations cannot be required in order for clients to obtain services.
3. If a sub-recipient agency asks for donations, all clients must be asked to donate.

##### **D. Collection of Fees - Contract agencies may use a collection agency to obtain non-paid client fees under special circumstances, and under the following conditions:**

1. Neither adolescent nor adult confidential clients' bills may be sent to a collection agency.
2. If a contract agency uses a collection agency, clients must be informed of such when they make their appointment or when they enter the clinic.
3. Bills may never be sent to confidential client homes.

4. The agency must have a written policy that indicates under what circumstances client bills are sent to a collection agency. Policies must include:
  - a. Informing clients when they may have to pay for some or all of their services when they make the appointment.
  - b. Handing the clients a statement or bill at the time of service showing full charges, eligible discounts, and amount owed. This policy applies to all clients whether the account balance is paid in full or not.
  - c. Sending at least three monthly statements to the clients with unpaid balances.
  - d. Attempting to discuss the situation and to set up a payment plan when there is no response to the monthly statements.
  - e. Determining the payment plan and reassessing the client's ability to pay. Forgive the balance accordingly.
  - f. Notifying the client twice about the plan and encourage the client to pay if the payment plan is not honored within 30 days.
  - g. Indicating in the second notification that if there is no effort to pay the account balance within 30 days, the account may be sent to a collection agency.
  - h. Sending the account to a collection agency if the client refuses to set up a payment plan.
  - i. Documenting all communications about unpaid account balances.
5. Contract agencies must have a "bad debt" policy for accounts with outstanding balances after a maximum of one year.
6. Sub-recipient agency financial policies must be written and provided to staff.


#### **INTEGRATING TITLE X WITH PRIMARY CARE PROVIDERS**

IDPH and its sub-recipients comply with the Title X Program Policy Notice, *Integrating with Primary Care Providers*, Release Date: November 22, 2016 OPA Program Policy Notice: 2016 – 11. See Appendix 45 for a copy of the Program Policy Notice.

#### **FINANCIAL AUDITS**

Audits of grantees and sub-recipient/contract agencies must be conducted in accordance with the provisions of 45 CFR Part 74, Subpart C, and 45 CFR Part 92, Subpart C, as applicable. The audits must be conducted by auditors meeting established criteria for qualifications and independence.

During administrative audits, time and budget distribution systems will be reviewed to assure time studies are done and expenditures are being reported to the Department correctly.


  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Income Determination	<b>NUMBER:</b>  <b>211</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b> IDPH FP Manual policy 210	
	<b>Authority:</b> Public Health Service Act 45 CFR Part 74; IAC 641-74; QFP 2014.; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## INCOME DETERMINATION

Agencies will have a written policy in place about income determination. Agencies may choose to require income verification for the Title X project. If the agency requires income verification for Title X clients it must require income verification on all clients, including those presenting with payer plans. For the purpose of this policy income determination refers to the process of establishing client income to determine client placement on the schedule of discounts. Income verification means requiring the client to provide proof of income. The policy will reflect the following guidelines:

1. Income information shall be obtained from every client, documented, and updated annually. All clients will have income determination performed. No category or group of clients (for example teens, students, and Medicaid recipients, private insurance) shall be excluded from income determination solely based on the client's membership in that group. Everyone who is a Title X user must be placed on a sliding fee scale regardless of whether or not they have a third party payer.
2. Clients who choose not to provide information regarding income must sign a release stating that they are choosing not to participate and agree that they will be charged full fee for services (if the client is responsible for payment of services).
3. Clients who report annual income but are unwilling to provide income verification may be charged full fee. Clients must be informed that failure to provide proof of income where available may result in full fees being applied (if the client is responsible for payment of services). This only applies in agencies requiring income verification.
4. Clients who report annual income but are unable to provide income verification (teen babysitting money, spouse does not share income information) may be helped to estimate income. Agencies will document why proof of income is not available.
5. Clients who report they have no income are not required to prove absence of income, but may be asked about how they pay for living expenses. Clients can be asked to provide a letter or statement as to how they pay for their expenses.
6. Income determination for minors who request confidential family planning services shall be calculated solely on the minor's income. The provider must, in those cases, document in the minor's medical record the specific action taken by the provider to encourage the minor to involve his/her family (parents or guardians) in his/her decision to seek family planning services. If the provider has documented in the minors medical record a suspicion of child abuse or incest, and has consistent with and permitted by law, appropriately reported the situation, documentation of such encouragement is not required. The resources normally provided by parents/guardians (i.e., food, shelter, etc.) shall not be included in determining the income. Income determination must be completed on all minors.
7. State Family Planning Program (FPP) guidelines will be used for income calculation.

8. If income verification is required to enroll clients into programs such as the FPP, the program guidelines should be followed for that purpose.
9. Depreciation for self-employment: If depreciation keeps the client from eligibility on the FPP, depreciation must be disregarded for Title X placement.
10. Fees may be waived for any client, including individuals with annual incomes above 250 percent of poverty level, who, as determined by the service site project director or their designee, are unable, for good cause, to pay for family planning services.
11. Sub-recipients must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," IDPH means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. This does not include registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage.
12. Sub-recipient project directors, may choose to place the client on the sliding fee scale based on her annual income and ability to pay, for the purpose of payment for contraceptive services or methods only, where a woman has health insurance coverage through an employer that does not provide the contraceptive services or method sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Facilities & Accessibility of Services	<b>NUMBER:</b>  <b>212</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> November, 2016
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 45 CFR Part 84; IAC 641-74 Program Requirements for Title X Funded FP Projects, 2014; ACA Section 1557		


## FACILITIES AND ACCESSIBILITY OF SERVICES

Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e.; they should have evening and/or weekend hours in addition to daytime hours. IDPH defines usual business hours as between 8:00 a.m. and 5:30 p.m. Services will be available outside of usual business hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet 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 room, an adequate reception area and a play area; offer private areas for client interview; include a sufficient number of enclosed single examination 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.

Projects must comply with 45 CFR Part 84, 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 programs so that, when viewed in their entirety, they are readily accessible to people with disabilities. Projects must also comply with any applicable provisions of the Americans with Disabilities Act (Public Law 101-336). The agency's compliance with the ADA and 504 requirements are evaluated during the Agency Administrative On-Site Review. (FP Appendix )

Sub-recipients must comply with ACA Section 1557 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, members of the lesbian, gay, bisexual and transgender (LGBT) community, individuals with disabilities and individuals with limited English proficiency (LEP). Specific requirements for posting communications, tag lines, and operations management is available in Appendices of the IDPH FP manual.


  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Personnel Policies	<b>NUMBER:</b>  <b>213</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b> Policy 232	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Title VI of Civil Rights Act, Sec. 504 or Rehabilitation Act of 1973 and Title 1 of ADA; Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014		

## PERSONNEL POLICIES

Sub-recipient agencies must establish and maintain personnel policies that comply with applicable Federal and state requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title 1 of the Americans with Disabilities Act. These policies should include, but need not be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, trainings, and grievance procedures. Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to and able to deal effectively with the cultural and other characteristics of the client population [59.5 (b)(10)].

1. Personnel records must be kept confidential.
2. An organizational chart and personnel policies must be available to all personnel.
3. Job descriptions must be available for all positions, reviewed annually or as specified by agency policy and updated when necessary to reflect changes in duties.
4. An evaluation and review of the job performance of all project personnel must be conducted annually. Orientation and trainings must be documented in the file.
5. Licenses of applicants for positions requiring licensure are verified **prior** to employment and documentation of licenses is kept current.
6. The project is administered by a qualified project director.
  - a. The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning.
  - b. Protocols exist that provide all project personnel with guidelines for client care.
7. Labor laws required to be posted are posted in staff common areas or are readily available.
8. Cultural competency training must be documented.
9. Sub-recipient staff should be broadly representative of the population it serves when possible.



  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration		<b>SUBJECT:</b> Review and Approval of Medical Policies	<b>NUMBER:</b>  <b>214</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> September 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014			


## REVIEW AND APPROVAL OF MEDICAL POLICIES

### STATE LEVEL COMMITTEE AND APPROVAL

- a. There shall be a Medical Advisory Committee for the Family Planning Program at the state level. This committee shall review current clinical policies annually and modify policies as appropriate. This committee shall also develop new clinical policies. A list of committee members is available from the IDPH Title X director.
- b. All clinical policies and procedures shall be reviewed, approved, and signed by the Iowa Department of Public Health (IDPH) family planning medical director.
- c. The IDPH family planning medical director contact information is available from the IDPH Title X director.

### SUB-RECIPIENT (SR) AGENCY POLICY REVIEW AND APPROVAL

- a. Each sub-recipient agency shall have a Family Planning Program medical director. The medical director will be a physician with education and experience in Family Planning. All clinical policies shall be reviewed, approved, and signed annually by the sub-recipient agency Family Planning Program medical director. A list of SR medical directors is available from the IDPH FP director.
- b. The Iowa Department of Public Health shall review each sub-recipient agency's clinical policies annually. Policies will be submitted electronically to the IDPH yearly by the date established in contract.

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Program Administration		Training and Technical Assistance	<b>215</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		Date: July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019				

## TRAINING AND TECHNICAL ASSISTANCE

### Objectives

1. Describe expectations of IDPH to provide training to sub-recipient agencies in order to assure high quality family planning services are delivered in compliance with Title X requirements.
2. Discuss requirements of sub-recipient agencies regarding participation in all required training activities and Training Advisory Committee. See Contract Conditions for a list required meetings and trainings.

### Purpose


Title X grantees are responsible for the training of all project staff. Title X Requirements state:

- Projects must provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)).
- The project's training plan should provide for routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest.
- IDPH will also provide for routine training of staff on intimate partner violence, as well as on human trafficking.
- The project's training plan should provide for routine training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.
- IDPH, as the grantee, is responsible for assuring sub-recipient agencies receive the necessary training to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

### Key Points

- The IDPH shall provide orientation to the Title X Program for all new department employees assigned to the Family Planning Project.
- The IDPH shall provide orientation and assure all new sub-recipient agency employees are oriented. IDPH staff will provide the Title X Overview training quarterly at a central Iowa location if multiple agencies request training. New sub-recipient staff will attend the training within 6 months of hire. IDPH staff will also provide Title X orientation on site at an individual sub-recipient location if requested.
- IDPH staff will make an archived webinar of the Title X orientation available for training purposes.
- All orientation, other trainings and in-service sessions attended shall be documented in each employee's personnel file unless the agency establishes an alternative system for tracking/ documenting employee training.

- Sub-recipient agencies will assign appropriate staff to participate on the Training Advisory Committee jointly hosted by the IDPH and the Family Planning Council of Iowa.
- Sub-recipient family planning project directors are responsible for assuring staff received training in clinic policies and procedures related to Title X.
- Sub-recipient agencies must provide for the specific agency in-service training of all project personnel, including the staffs of all service sites. All project personnel should participate in continuing education related to their activities. Documentation of continuing education should be maintained and used in evaluating the scope and effectiveness of the staff-training program.
- Sub-recipient agencies will assure that the required annual trainings and reviews occur and maintain records of completion found in the appendix. IDPH recommends review of the annual training and certification checklist at the time of annual employee performance evaluation.
- Training through National Family Planning Training Centers is available to all projects under the Title X program. In addition to training, sub-recipient agencies may receive technical assistance for specific project activities. **All sub-recipient Title X staff must complete the mandatory trainings from the NFPTC which the IDPH program will provide.**
- Technical assistance is provided by contract from the Office of Population Affairs and administered through the Regional Office.
- All sub-recipient agency questions and requests related to training and technical assistance shall be directed to the Title X staff at the department.
- IDPH will collaborate with other state agencies or outside vendors when necessary to facilitate trainings to enable sub-recipients to achieve full compliance and realize full benefits of participation in the Title X project.

 <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Review and Approval of Informational and Educational Materials		<b>NUMBER:</b>  <b>216</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019			

## REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

The Iowa Department of Public Health will use a subset of the Maternal and Child Health Advisory Committee to serve this function when necessary. This committee will review and approve 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 and community for whom they are intended and to assure their consistency with the purposes of Title X when a request for statewide use is received. The Iowa Department of Public Health shall provide orientation to the Title X Program for all committee members before they assume Information and Education review responsibilities.

Each sub-recipient agency shall establish and maintain an I&E Committee. Agency policies must identify committee composition, duties, and relationships to the governing board. The local I&E Committee shall be broadly representative of the community and knowledgeable about family planning services. Each committee shall consist of 5-9 members and be broadly representative of the population of the sub-recipient. Each committee shall provide direction for program planning to the sponsoring sub-recipient and shall approve all educational materials used. Each committee shall meet at least once per year. Each sub-recipient agency shall provide orientation to Title X for all committee members before they assume committee responsibilities. Sub-recipient agencies will re- review and re- approve informational and educational materials made available under the project at least every three years to ensure it is still relevant to the target population and is acceptable to the community. In addition, I&E material should be reviewed internally when there is an update in clinical guidelines to ensure it is accurate and reflects current medical practice.

The I&E Committee(s) must:


- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed
- Consider the standards of the population or community to be served with respect to such materials
- Review the content of the material to assure that the information is factually correct
- Determine whether the material is suitable for the population or community to which it is to be made available
- Establish a written record of its determinations. Minutes from committee meetings must be maintained throughout the project period.

The committee(s) may delegate sub-recipient responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff. However, final approval of the I&E material rests with the committee(s).

Neither IDPH nor any sub-recipient shall develop and/or disseminate materials advocating abortion as a method of family planning, including printed matter, audiovisual materials, web-based materials and classroom materials.

All informational and educational materials developed by the program shall cite Title X as contributing to the development of the materials. Language should include the following:  
*This publication was made possible by grant number (i.e. xxxxxxxxxxxxx) and its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Office of Population Affairs.* When publishing materials, please contact the family planning program for the specific grant number.

Committee rosters, meeting minutes and documentation must be made available to IDPH staff for review when requested.

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Community Participation, Education and Project Promotion	<b>NUMBER:</b>  <b>217</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014		

## **COMMUNITY PARTICIPATION, EDUCATION AND PROJECT PROMOTION**

Boards and advisory committees for family planning services should be broadly representative of the population served. Sample policy and documentation is attached to this policy.

### **COMMUNITY PARTICIPATION**

IDPH Family Planning Program (grantee) and sub-recipient agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services.

The I&E (Information & Education) advisory committee may serve the community participation function if it meets the above requirements, or a separate group may be identified. In either case, the grantee project plan must include a plan for community participation. The community participation committee must meet annually or more often as appropriate.


The Medical Advisory Committee, Family Planning Directors committee and the Maternal Child Health Advisory Committee all serve this purpose for the IDPH. Each sub-recipient agency will document in their request for proposal work plans about how they will elicit community input into their local projects. Implementation will be evaluated through year end reports and review of work plan progress at onsite visits. Sub-recipient agencies will also complete client satisfaction surveys. Summaries of those surveys are submitted to the IDPH at the time of the yearend report.

### **COMMUNITY EDUCATION**

Community education should serve to enhance community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning may be beneficial.


### **PROJECT PROMOTION**

To facilitate community awareness of and access to family planning services, sub-recipients must establish and implement planned activities whereby their services are made known to the community. Sub-recipients should review a range of strategies and assess the availability of existing resources and materials. Promotion activities should be reviewed annually and be responsive to the changing needs of the community.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Publications and Copyright	<b>NUMBER:</b>  <b>218</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 45 CFR Part 74.36; IAC 641-74; Title X Program Requirements, 2014.		

## PUBLICATIONS AND COPYRIGHT


Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. The word “publication” is defined to include computer software. Publications developed under Title X must not contain information, which is contrary to program requirements or to accepted clinical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the *Public Health Service Grants Policy Statement*. Any such copyrighted materials shall be subject to a royalty free, non-exclusive, and irrevocable right of the Government to reproduce, publish, or otherwise use such materials for Federal purposes and to authorize others to do so.

  <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Inventions or Discoveries	<b>NUMBER:</b>  <b>219</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 37 CFR Part 401; IAC 641-74		

## INVENTIONS OR DISCOVERIES

Family planning projects must comply with Government-wide regulations, 37 CFR Part 401, which apply to the rights to inventions made under government grants, contracts and cooperative agreements.



  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Service Plans and Protocols	<b>NUMBER:</b>  <b>220</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b> Policies 221, 314 and 347	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## SERVICE PLANS AND PROTOCOLS

The Department's clinical policies and protocols shall be reviewed and approved by the Program Medical Director. The clinical policies should be consistent with MMWR Providing Quality Family Planning Services, 2014 and supported by evidence based practice guidelines. The clinical policies and protocols in this manual shall also display the signature of the Program Medical Director after annual review and approval of the policies and protocols.

### SERVICE PLAN

The service plan, as outlined in the agency's policies and procedures, is the component of the sub-recipient agency's project plan, which identifies those services to be provided to clients under Title X by the project. As part of the project plan, all sub-recipient agencies must have written clinical protocols and plans for client education which outline procedures for the provision of each service offered and which are in accordance with state laws. Clinical protocols must be consistent with the requirements of the Title X Program Requirements.


### PERSONNEL

- The clinical care component of the project operates under the supervision and responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning.
- Only licensed professionals operating at a level appropriate for their license may provide medical services. Physician assistants and registered nurses perform delegated medical functions under protocols and/or standing orders approved by the medical director. Advanced registered nurse practitioners may provide clinical health services based on their licenses and within the sub-recipient agency's service plan and protocols.

### POLICIES

- Each sub-recipient agency must have clinical policies that are appropriate to the service delivery mechanism in place and that have been signed by the agency's medical director.
- The policies must be reviewed annually. Additionally, all standing orders and protocols/procedures included in the agency's service manual must be reviewed and approved by the agency's medical director annually.
- The policy manual is on-site and accessible to clinic staff.
- Services are provided in a manner that protects the dignity of the individual.
- IDPH staff shall review agency's service plans and protocols annually. Sub-recipient will forward a copy of the administrative and clinical policy manuals in a manner to be determined by IDPH.
- Clinical policies should reflect the current recommendations for practice or standards of care established by nationally recognized health agencies or professional associations.
- IDPH is responsible for ensuring that all sub-recipient agencies maintain and use written clinical policies that are consistent with nationally recognized practice standards.

- h. If a sub-recipient further subcontracts, a written agreement that is consistent with the IDPH contract and Title X Program Guidelines, which consist of both the current Title X Requirements as published in CFR and Providing Quality FP Services: Recommendations for the U.S Centers for Disease Control and the Office of Population Affairs (QFP). IDPH requires applicants to submit signed program assurances that the agency will provide services as required in these documents. (Refer to the Application Forms section in the most recent RFP).

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Minimum Standards of Service	<b>NUMBER:</b>  <b>221</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b> Policies 301 302, 312, 313, MCH Administrative Manual	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## MINIMUM STANDARDS OF SERVICE

Title X Sub-recipient agencies (SRs) are expected to provide high quality care to clients seeking family planning services. Health care quality has the following attributes: safety, effectiveness, client centered, efficient, timely, accessible, and equitable and is cost-effective (value). Family Planning (FP) services include, at a minimum, contraceptive service, pregnancy testing and education, achieving pregnancy, basic infertility services, preconception health and sexually transmitted disease services. A broad range of contraceptive methods will be provided. Related preventive services include those things that may impact reproductive health such as breast and cervical cancer screening. This document outlines the minimum standards of services expected from Title X SRs. SR will provide for medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices.

Preliminary questions for all clients attending the clinic: 1) purpose of visit, 2) do they have a medical home or Primary Care Provider, 3) what is the client's reproductive life plan?

### DETERMINING THE CLINICAL PATHWAY:

- Does the client need preconception services?
- Does the client need STD (STI) services?
- What other related preventive services does the client need?

### FOR INITIAL HEALTH SCREENING VISITS:

#### History

- a. Demographic data requested by the Title X project as required.
- b. Data required by the National Center for Health Statistics
- c. Complete medical and surgical history, including items necessary for safe provision of contraceptive methods:
  - Thromboembolic disease
  - Hepatic or renal disease
  - Breast and genital neoplasm
  - Cephalgia and migraine
  - Diabetes and pre-diabetes
  - Hematologic disorder
  - Smoking habits
  - Allergies

- Blood transfusion or blood products
- Psychiatric or mental health history
- d. Complete menstrual, obstetric and gynecologic history, including complications and unexpected pregnancy outcomes for females
- e. Complete reproductive health history for males, including unexpected pregnancy outcomes
- f. Sexual health assessment and contraceptive history
- g. Partner medical/risk history, if available
- h. Family history
- i. Social history
- j. Immunizations including rubella and HPV

**Assessing reasonable certainty that a client is not pregnant:**

- Absence of pregnancy signs and symptoms
- ≤7 days after the start of normal menses,
- has not had sexual intercourse since the start of last normal menses,
- using a reliable method of contraception correctly and consistently,
- ≤7 days after spontaneous or induced abortion,
- within 4 weeks postpartum,
- fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrhea, and <6 months postpartum

**Physical Exam – as required by contraceptive method chosen, national standards of practice and clinical protocol**

Must include but is not limited to:

- Height
- Weight
- BMI
- Blood pressure
- Pelvic and/or genital exam as indicated for method and as required by clinic protocol according to national standards of practice.

**Patient Consent**

- The project must obtain a written, informed consent from the patient to indicate voluntary acceptance of FP services. The consent must be obtained prior to providing services. All consents must appear in the client's record. If clients choose to delay or defer a service, counseling must be provided about the risks associated with such a delay and documented in the record.
- The project must document that the client received education about contraceptive alternatives, safety, effectiveness, advantages, disadvantages, potential side effects and complications of the method. Documentation of teach back or a check box in the health record is acceptable as long as a policy indicates what teaching is done for each method.

**Confidentiality**

- There must be a confidentiality statement signed by the client in the record that they were informed about confidentiality and any limitations.

**Laboratory Services:**

- There is no need to repeat laboratory results performed at another facility or provider's office and available in the record unless medically indicated or appropriate by client status.

- All laboratory services required in the provision of a contraceptive method must be provided onsite or paid for by the SR referring for the testing, as appropriate.
- STI testing is performed according to guidelines and risk profile.
- Pregnancy tests must be available on site.

### **Reproductive Life Plan/One Key Question**

- All clients will be asked about making a reproductive life plan through One Key Question (OKQ). Clients will be asked the question “do you want to become pregnant in the next year?” and given the following options for a response: “Yes”, “No”, “Unsure”, or “Ok either way”. Based on the client’s response, the provider will use the Clinical Algorithm tool to provide preconception/interconception or contraception counseling and care or a combination of both. Refer to the appendix for clinical algorithm tool.

### **FOR PERIODIC HEALTH SCREENING VISITS**

- An updated history or interim history is obtained, including:
  - Demographic data requested by the Title X project as required by the Office of Management and Budget
  - Data required by the National Center for Health Statistics
  - Significant illnesses, surgeries or hospitalizations and medical care incurred since most recent visit at which a medical history was obtained or updated.
  - Update RLP as appropriate
  - Immunization history
  - Review of method use, problems, barriers, satisfaction with method
  - Updated sexual assessment and social histories
  - Review of systems as indicated
  - Physical exam as indicated
  - Plan for continued use and follow up
  - If client requests an alternative method, follow initiation guidelines

### **Education should include:**

- Information about all methods of contraception using a client centered approach.
- Basic reproductive anatomy and physiology
- Importance of FP to client’s health
- Emergency contraception
- Clinic procedures
- Referrals as medically necessary or requested by client
- For adolescents: clients must receive counseling on parental involvement (or involvement of trusted adult if parental involvement is not an option), confidentiality, resisting attempts of sexual coercion, STI and HIV risk reduction. Adolescent counseling will include information that normalizes abstinence for adolescents and not sexual activity, and clearly communicates the benefits of delaying sex or returning to a sexually risk-free status and support strong resistance skills as a way to opt out of unwanted sexual activity.”
- All counseling and education must be documented in the client record
- Contraceptive counseling is neutral, factual and nondirective on each option. Counseling is non-coercive and informative, while prioritizing the holistic health needs and optimal wellbeing of the client, regardless of parenting intent, including participation of trusted adult.
- Client centered counseling is provided that is culturally sensitive, includes client priorities about pregnancy prevention, acceptability of methods, considers the relationship, partner

comfort and function, and CDC Medical Eligibility Criteria and US Selected Practice Recommendations.

#### **Client Education:**

- Universal education about relationship safety
- Abstinence and natural family planning For methods, client should receive information about mechanism of action, effectiveness and failure rates, advantages and disadvantages, noncontraceptive benefits, STD protection, including HIV, side effects and potential complications, managing side effects, correct method use and discontinuation, resumption of menses when method discontinued for any method(s) for which interest is expressed. Discuss potential barriers to correct and consistent use with the client.
- Male clients should also be given information about female controlled methods as well as emergency contraception when interest is expressed.
- Emergency procedures and contacts
- Reduction of risk of STI and HIV

#### **Referral and Follow up**

- Agency must have a planned mechanism for client follow-up;
- Referral for services beyond the scope of the agency is expected. Each SR is expected to have, by prior arrangement, providers or agencies to which the client may be referred. These include local health and welfare departments, hospitals, voluntary organizations, and health service providers provided by other federal programs.
- If a SR does not offer comprehensive primary health services onsite, SRs must have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.
- Provision of medications and/or supplies as needed. If a Sub-recipient Agency (SR) does not provide a contraceptive method on site that SR will have a written policy for referring clients for that method.
- Grantee must arrange and pay for referral of required services

#### **REPORTING REQUIREMENTS**

- SRs are expected to follow all state and local reporting requirements for STD/HIV cases, child abuse, and dependent adult abuse.

#### **INFERTILITY**

- The SR is expected to provide Level I infertility services as per the IDPH Manual.

#### **STERILIZATION**

- SRs using Title X funding to arrange for sterilization must follow the requirements of 42CFR Chapter 1 Subpart B- Sterilization of Persons in Federally Funded Family Planning Programs and per the IDPH Family Planning Manual.

#### **DOCUMENTATION**

For client record retention and storage information, refer to the current contract under Additional Conditions.

#### **SERVICES TO YOUTH**

According to the WHO, to be considered adolescent friendly, health services should be accessible, acceptable, equitable, appropriate and effective, as outlined below:


**Accessible:** Adolescents *are able to* obtain the health services that are available.

**Acceptable:** Adolescents *are willing to* obtain the health services that are available.

**Equitable:** *All adolescents*, not just selected groups, are able to obtain the health services that are available.

**Appropriate:** The *right health services* (i.e. the ones they need) are provided to them

**Effective:** The *right health services are provided in the right way*, and make a positive contribution to their health.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Medical Records	<b>NUMBER:</b>  <b>222</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b> MCH Administrative Manual	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; Title X Program Requirements, 2014; QFP, 2014		

## MEDICAL RECORDS

Projects must establish a medical record for every client who obtains clinical services. These records must be maintained in accordance with accepted medical standards and State laws with regard to record retention. Records must be:

1. Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;
2. Signed by the clinician and other appropriately trained health professionals making entries, including name, title, and date;
3. Readily accessible;
4. Systematically organized to facilitate prompt retrieval and compilation of information;
5. Confidential;
6. Safeguarded against loss or use by unauthorized persons;
7. Secured by lock or password protected when not in use; and
8. Available upon request to the client.

## 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. Personal data;
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. Projects 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.



## **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. HIV information should be handled according to law. 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 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. **Sub-recipients shall comply with Iowa Code 622.10 (5) (a) regarding release for records and charges for release of records.** Charges for records released directly to the client must be placed on the appropriate sliding fee scale.

### **Electronic Health Records**

Sub-recipients transitioning to electronic health records will be held to the requirements of this policy. Every effort must be made to maintain confidentiality in the electronic health record system. Clients should be informed if the agency uses an electronic health record system that can be accessed by other providers and acknowledge that they received that information. Sub-recipients may choose to keep "confidential client" records in hard copy. However, one of the purposes of electronic health records is to protect client safety. The client should be informed of this as well and encouraged to report a complete medical history to any other providers they see.

### **IDPH HIPAA Statement**

The effect of HIPAA privacy provisions on the release of protected health information to the Iowa Department of Public Health

The Iowa Department of Public Health (IDPH), 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). However, both the EPSDT Program and Enhanced Services for Maternal Health Program are actually a part of the Medicaid Program of the Iowa Department of Human Services and, as such these programs, will be business associates of the Iowa Department of Human Services and, therefore, subject to many HIPAA provisions. Because IDPH 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 the IDPH 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 to the IDPH, the covered entity should follow that requirement. Many disclosures of PHI to IDPH 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 protected health information 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). The IDPH has such a mandate and, therefore, is a public health authority under HIPAA.

The IDPH, in conjunction with the Iowa Attorney General's Office, has reviewed its programs and determined that protected health information being received by the Department from covered entities in Iowa is disclosed for public health activities. The disclosure of such information to IDPH is, therefore, unaffected by HIPAA and should continue in accordance with past practices. Because IDPH 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 IDPH in order for the exchange of protected health information to take place.

Third, in some instances, the IDPH 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:

1. 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 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 Dept. 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 health care plans, oversight of health benefit plans; oversight of health care providers; oversight of health care and health care delivery; oversight activities that involve resolution of consumer complaints; oversight of pharmaceutical, medical products and devices, and dietary supplements; and 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 IDPH 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 IDPH 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 IDPH. Further, as a health oversight agency a local health department is permitted, and in most cases required, to disclose protected health information to IDPH. Disclosures of PHI by local public health departments and local contractors to IDPH do not require business associate agreements and are not prohibited or otherwise affected by HIPAA.

Please call Assistant Attorney General, should you have additional questions regarding these issues.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Emergencies (Medical and Non-medical)	<b>NUMBER:</b>  <b>223</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## **EMERGENCIES (MEDICAL AND NON-MEDICAL)**

Emergency situations involving clients and/or staff may occur at any time. All projects must therefore have written plans for the management of on-site medical and non-medical emergencies. All project staff must be familiar with these plans. Sub-recipient agencies shall develop emergency guidelines, with input from their medical director, that reflect local resources.

### **MEDICAL EMERGENCIES**

At a minimum, written protocols must address:

- vaso-vagal reactions
- anaphylaxis
- syncope
- cardiac arrest
- shock
- hemorrhage
- respiratory difficulties

Protocols must also be in place for emergencies requiring:

- transport
- after-hours management of contraceptive emergencies
- clinic emergencies


### **NON-MEDICAL EMERGENCIES**

At a minimum, written protocols must address:

- Severe Weather (tornado, flood)
- Fire
- Intruder in the building
- Intoxicated patient or client
- Lost or abducted child
- Bomb threat guidance
- Chemical spill
- Power failure

### **RESOURCES**

1. kinner
2. *medical/emergency-critical-care-pocket-guide-7<sup>th</sup> edition*

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Referrals and Follow-Up	<b>NUMBER:</b>  <b>224</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## REFERRALS AND FOLLOW-UP

Sub-recipient agencies must provide all family planning services identified as core family planning services in the QFP either on-site or by referral. When required services are to be provided by referral, the SR agency must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.


Sub-recipients will have processes for effective referrals to relevant social and medical services agencies, for example: child care agencies, transportation providers, Women, Infant and Children (WIC) programs. (Optimally signed written collaborative agreements). The relevant agencies may also include emergency care, HIV/AIDS care and treatment, infertility, other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs. If SR does not offer comprehensive primary health services onsite it must have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.

SRs must have written policies/procedures for documentation of and follow-up on referrals that are made as a result of client history, abnormal physical examination or laboratory test findings. These policies must be sensitive to clients' concerns for confidentiality and privacy.

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

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

Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care. Agencies must maintain a current list of health care providers, local health and human services departments, hospitals, voluntary agencies, and health services projects supported by other public programs to be used by referral purposes. Whenever possible, clients should be given a choice of providers from which to select.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Client Education	<b>NUMBER:</b>  <b>225</b>
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR 50; IAC 641-74; OPA Instruction Series 98-1 Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014 (MMWR, Vol 63, No. 4)		

## CLIENT EDUCATION

Sub-recipient agencies must have written plans for client education that include goals and content outlines to ensure consistency and accuracy of information provided. Client education must be documented in the client record. The education provided should be appropriate to the client's age, level of knowledge, language, and socio-cultural background and be presented in an unbiased manner. A mechanism to determine that the information provided has been understood should be established. Documentation that the client appears to understand the information must be made.

When possible, client centered counseling about contraceptive methods should be employed. Information must be medically accurate, balanced and provided in a non-judgmental manner. Providers should work with a client interactively to establish a plan; identify barriers to correct and consistent use and work on a follow up plan.

1. Contraceptive counseling is neutral, factual and nondirective on each option. Counseling is non-coercive and informative, while prioritizing the holistic health needs and optimal wellbeing of the client, regardless of parenting intent, including participation of trusted adult.
2. Client centered counseling is provided that is culturally sensitive, includes client priorities about pregnancy prevention, acceptability of methods, considers the relationship, partner comfort and function, and CDC Medical Eligibility Criteria and US Selected Practice Recommendations.
3. Adolescent counseling will include information that normalizes abstinence for adolescents and not sexual activity, and clearly communicate the benefits of delaying sex or returning to a sexually risk-free status and support strong resistance skills as a way to opt out of unwanted sexual activity."

### EDUCATION SERVICES MUST PROVIDE CLIENTS WITH THE INFORMATION NEEDED TO:

1. Make informed decisions about family planning;
2. Use specific methods of contraception and identify adverse effects;
3. Perform breast/testicular self examination with appropriate disclaimers about efficacy;
4. Reduce risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV);
5. Understand the range of available services and the purpose and sequence of clinic procedures; and
6. Understand the importance of recommended screening tests and other procedures involved in the family planning visits.

Additional education should include information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse.

### **INFORMED CONSENT**

Written informed consent must be signed before services are provided. The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen. Clients must be informed that services are voluntary and can be stopped at any time.

The signed informed consent form must be a part of the client's record.


Federal sterilization regulations [42 CFR Part 50, Subpart B], which address informed consent requirements, must be complied with when a sterilization procedure is performed by the project.

### **RESOURCE**

<http://www.arhp.org/methodmatch>

Appendix C – QFP

Appendix E – QFP

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Pharmaceuticals	<b>NUMBER:</b>  <b>226</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b> 239	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014 (MMWR, Vol 63, No. 4)		

## PHARMACEUTICALS


Sub-recipient agencies must be operated in accordance with Federal and Iowa laws relating to security and record keeping for drugs and devices. IDPH requires agency policy to identify the person/persons responsible for pharmaceutical services, formulary procurement, storage, monitoring, and drug and device recalls management. The inventory, supply, logs and packaging and distribution of pharmaceuticals (including mailing) must be conducted in accordance with Iowa pharmacy laws and professional practice regulations.

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

IDPH Sub-recipients 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.


IDPH requires sub-recipient agencies to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.



  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Program Planning and Development	<b>NUMBER:</b>  <b>227</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014		

## PROGRAM PLANNING AND DEVELOPMENT

The Iowa Department of Public Health Family Planning Directors group, the Medical Advisory Committee, and the IDPH Maternal and Child Health Advisory committee will provide input for program planning, implementation, evaluation, and policy development.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Exception to Policy	<b>NUMBER:</b>  <b>228</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> June 2018
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74		

## EXCEPTION TO POLICY


Program requirements and performance standards are in place to maintain the quality of services, protect the public, and to assure the proper use of public funds.

### EXCEPTION

Any sub-recipient agency that is not in compliance with all Title X requirements and additional state requirements as part of the contract may file a written request for exception to policy. The request shall be sent through IowaGrants via correspondence to the family planning director. The request shall contain the following:

1. Executive Director and Board Chair signatures;
2. Statement of the requirement for which the request for exception is being made;
3. The rationale for failure to meet the requirement;
4. The time period for which the exception is requested; and
5. A remediation plan to meet the requirement.

It will be the decision of the Department whether the exception will be granted. A written decision will be made within 30 days of the request.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Child Abuse Reporting	<b>NUMBER:</b>  <b>229</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b> Manual Appendix	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## CHILD ABUSE REPORTING

The fiscal year 1999 Omnibus Appropriations bill (P.L. 105-277), section 219, states  
*“Notwithstanding any other provisions of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification, or reporting of child abuse, child molestation, sexual abuse, rape, or incest”.*

*Title X also requires that all SRs ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities. Providers will conduct a preliminary screening of any teen who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor.*

*Such screening is required with respect to any individual who is under the age of consent in the Iowa. Compliance with screening is maintained in records to demonstrate compliance with each of the requirements including: (i) indicate the age of minor clients, and (document each notification or report made pursuant to such State notification laws. (d) The Secretary may review records maintained by a grantee or Sub-recipient for the sole purpose of ensuring compliance with the requirements of this section.*

*Iowa law does not require documentation of the age of the minor client’s sexual partners but providers shall ask if suspicion arises.*

All IDPH FP Sub-recipient agencies shall have policies in place that specify agency compliance with Iowa Code that address child abuse, reporting of child abuse, child molestation, sexual abuse, rape, or incest. The parts of the Iowa Code that apply to this requirement are sections:

- 232.68 – Definition of child and child abuse, including child sex trafficking
- 232.69 – Mandatory and Permissive reports---Training required
- 232.70 – Reporting Procedure
- 709.1 – Sexual abuse defined
- 709.2 – Sexual abuse in the first degree
- 709.3 – Sexual abuse in the second degree
- 709.4 – Sexual abuse in the third degree
- 726.2 – Incest
- 728.12 – Sexual exploitation of a minor

There are no reporting requirements for adult IPV or adult human trafficking in Iowa at this time.

HF731, signed into law on May 8, 2019 delegates responsibility for mandatory reporter training to the Iowa Department of Human Services (DHS). Mandatory reporters are required to complete the training every three years. This will be the only approved training allowed in Iowa. DHS access for the course: <https://dhs.iowa.gov/child-welfare/mandatoryreporter>

**Clarification:** In the event that a person older than 17 states they were abused as a child, a report is **NOT** required. In other words, the law is only set up to protect children (under 18) and dependent adults. However, if a mandatory reporter discovers that a youth 17 or under was sexually abused in the past by a caretaker – even several years prior – that must be reported.

Sub-recipient agencies shall have written policies outlining the following:

1. The provision of initial required training opportunities on child abuse identification and reporting of child abuse for appropriate program personnel
2. The provision of additional required training on child abuse identification and reporting every five years for appropriate program personnel
3. Documentation of completed training in each staff file
4. Job classifications considered mandatory assessors and reporters of child abuse
5. Job classifications required to file the reports to the Department of Human Services, both oral and written
6. The procedure for filing the reports, both oral and written
7. Referral of questionable calls to the appropriate staff


Sub-recipient agencies are responsible for contacting local Department of Human Services for guidance and interpretation of the law.

## **RESOURCES:**

DHS Publication: *A Guide for Mandatory Reporters*, most current version located at <https://dhs.iowa.gov/sites/default/files/Comm164.pdf?072020190023>

Iowa Code Chapters – most current versions of the following chapters:

- 709.2 Sexual Abuse
- 728.12 Sexual exploitation of a minor
- 232.69 Mandatory and permissive reporters — training required
- 726.2 Incest

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Immunizations	<b>NUMBER:</b>  <b>230</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 45 CFR Part 59, IAC 641-74, QFP 2014		


## IMMUNIZATIONS

Family Planning agencies should provide immunization for Human Papilloma Virus (HPV). Family Planning agencies should use patient assistance programs to assist with HPV vaccines when they are available from the manufacturer. Agencies providing HPV vaccine to minors will be able to provide the required written information to parents and guardians.

Agencies also may provide other immunizations as appropriate.

As providers of immunizations they shall participate in the Iowa Department of Public Health Vaccine for Children Program (VFC) and comply with all VFC rules and requirements.

As VFC providers they shall enroll and participate in Iowa's Immunization Registry Information System (IRIS) and comply with all IRIS rules and requirements.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Limited English Proficiency – Use of Interpreters	<b>NUMBER:</b>  <b>231</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b> 213	
	<b>Authority:</b> PHSA 42 CFR 59; IAC 641-74; Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,; Title IV of Civil Rights Act; Section 504 o Rehabilitation Act of 1973; Title I or ADA; Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014.		

## LIMITED ENGLISH PROFICIENCY – USE OF INTERPRETERS

Meeting the reproductive health and contraceptive needs of diverse populations will enhance efforts to eliminate racial and ethnic disparities by increasing access to family planning services. A client with limited English proficiency (LEP) cannot speak, read, write, or understand the English language at a level that permits him/her to interact effectively with health care and social service providers.

To ensure meaningful access, Sub-recipient agencies must take steps to provide language assistance resulting in accurate and effective communication for LEP clients at no cost to the client. Sub-recipient agencies shall implement strategies to provide services to those with LEP. Recipients of U.S. Department of Human Services funds, including Title X funds, must have policies in place for providing effective services to those with LEP in accordance with Title III at 28 C.F.R. Part 36 and Title IV of the Civil Rights Act of 1964 and 65 Federal Regulation 52761.

### ASSESSING LANGUAGE ASSISTANCE NEEDS

Family planning agencies must regularly assess the language needs of clients and the population in general in their service area and determine appropriate measures to meet the language needs of LEP clients. The language assistance provided should be based on the following factors:

- The types and number of client languages
- The size of the LEP population
- The staffing and resources available

Interpretation services include sign language or oral interpretive services and telephonic oral interpretive services.

The following are strategies that can be used for meeting the language needs of LEP clients:

- Hiring bilingual staff, who are trained and competent in interpreting- these services may be billed to Medicaid in some circumstances.
- Contracting with trained and competent interpreters
- Using trained community volunteers, who are competent in interpreting
- Enrolling family planning staff in language classes
- Using a telephone interpreter
- Providing forms and educational materials in languages other than English

It is the responsibility of the sub-recipient agency to determine the interpreter's competency. Sign language interpreters should be licensed pursuant to Iowa Administrative Code 645 Chapter 361. Oral interpreters should be guided by the standards developed by the National Council on Interpreting in Health Care ([www.ncihc.org](http://www.ncihc.org)).

Some LEP persons may feel more comfortable when a trusted family member or friend acts as an interpreter. However, when a recipient of federal financial assistance (in this case the sub-recipient agency, SR) encounters an LEP person attempting to access its services, the SR should make the LEP person aware that he/ she has the option of having the SR provide an interpreter for him/her without charge, or of using his/her own interpreter. As with the use of other non-professional interpreters, the SR may need to consider issues of competence, appropriateness, conflicts of interest, and confidentiality in determining whether to respect the desire of the LEP person to use an interpreter of his or her own choosing.

Although SRs should not plan to rely on an LEP person's family members, friends, or other informal interpreters to provide meaningful access to important programs and activities, the SR should respect an LEP person's desire to use an interpreter of his or her own choosing (whether a professional interpreter, family member, or friend) in place of the free language services expressly offered by the SR. However, a SR may not require an LEP person to use a family member or friend as an interpreter.


Extra caution should be exercised when the LEP person chooses to use a minor as the interpreter. While the LEP person's decision should be respected, there may be additional issues of competency, confidentiality, or conflict of interest when the choice involves using minor children as interpreters. The SR should take reasonable steps to ascertain whether the LEP person's choice is voluntary, whether the LEP person is aware of the possible problems if the preferred interpreter is a minor child, and whether the LEP person knows that a competent interpreter could be provided by the SR at no cost.

If the LEP person voluntarily chooses to provide his or her own interpreter, a SR should consider making a record of the person's choice, and of the SR's offer of assistance.

## **USING TRANSLATED MATERIALS**

Local family planning agencies must provide culturally competent materials in languages other than English when a significant percentage of clients served require information in a language other than English to communicate effectively. Options for providing written materials to non-English speaking clients include:

- Using non-English materials available from the healthy Families Line
- Developing original Materials in cooperation with a translator
- Translating English language materials in cooperation with a translator

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Excluded Providers	<b>NUMBER:</b>  <b>232</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Social Security Act Sections 1128, 1156.		

## EXCLUDED PROVIDERS

### EXCLUSION OF CERTAIN INDIVIDUALS FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS

IDPH supports efforts to prevent Medicare fraud by requiring sub-recipient agencies (SRs) to assure that newly hired employees are not listed as excluded providers under Medicare. Bases for exclusion include convictions for program-related fraud and patient abuse, licensing board actions and default on Health Education Assistance Loans (<http://oig.hhs.gov/fraud/exclusions.asp>). For exclusions implemented after August 4, 1997, this program includes Medicare, Medicaid, and all other plans and programs that provide health benefits funded directly or indirectly by the United States.


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 health care 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)

The Office of the Inspector General (OIG) urges health care providers and entities to check the OIG List of Excluded Individuals/Entities on the OIG web site (<https://exclusions.oig.hhs.gov>) prior to hiring or contracting with individuals or entities.

Monitoring of this activity will be performed during the course of the Title X Program Review and during Administrative Reviews (found in the Appendix). For IDPH this activity must be documented for all employees at the beginning of each project period and on all new hires.



 <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Human Trafficking	<b>NUMBER:</b>  <b>233</b>
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59: IAC 641-74; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## HUMAN TRAFFICKING

All Iowa Department of Public Health Family Planning Sub-recipient agencies shall have policies in place that specify agency compliance with Human Trafficking requirements of Title X.

Sub-recipient agencies shall have written policies outlining the following:

1. The provision of initial training opportunities on Human Trafficking. Training must be provided upon hire with updates yearly for all program personnel
2. Documentation of completed training in each staff file
3. Job classifications of those required to file the reports according to applicable law.
4. The procedure for filing the reports, both oral and written, if a minor.
5. Referral of questionable situations to the appropriate staff.
6. Agencies and their employees must comply with all state and federal reporting laws.
7. Employees must be informed and assure compliance with the provisions outlined below.

### APPLICABLE PROVISIONS

1. IDPH, Sub-recipient agency or any sub-recipients' employees may not—
  - a. Engage in severe forms of trafficking in persons during the period of time that the award is in effect;
  - b. Procure a commercial sex act during the period of time that the award is in effect; or
  - c. Use forced labor in the performance of the award or sub awards under the award.
2. IDPH must be informed immediately of any information received from any source alleging a violation of a prohibition in section 1.
3. IDPH may unilaterally terminate the agency award, without penalty, if an agency or sub-recipient—
  - a. Is determined to have violated a prohibition in section 1 of these provisions; or
  - b. Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in section 1 of these provisions through conduct that is either—
    - i. Associated with performance under this award; or
    - ii. Imputed to the sub-recipient agency or the sub-recipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, "OMB Guidelines to Agencies on Government wide Debarment and Suspension (Nonprocurement)," as implemented by OPA at 2 CFR part 376.
    - iii. Government wide Debarment and Suspension (Nonprocurement)," as implemented by OPA at 2 CFR part 376.
  - c. The IDPH right to terminate the agency award described in above:
    - i. Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 U.S.C. 7104 )g) , and
    - ii. Is in addition to all other remedies for noncompliance.

4. Sub-recipients must include the requirements of Section 1 of this policy in any sub award they make to a private (non-governmental, Indian tribe or foreign public entity) entity.

## **DEFINITIONS: FOR PURPOSES OF THIS AWARD TERM**

1. "Employee" means either:
  - a. An individual employed by sub-recipient agency or a sub recipient who is engaged in the performance of the project or program under this award; or
  - b. Another person engaged in the performance of the project or program under this award and not compensated, including but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing or matching requirements.
2. "Forced Labor" means labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.
3. "Severe forms of trafficking in persons", "Commercial sex act", and "coercion" have the meanings given at Section 103 of the TVPA, as amended (22 U.S.C. 7102).
4. "Force" involves the use of rape, beatings, and/or confinement to control victims. Forceful violence is used to especially in the early stages of victimization, known as the 'seasoning process', which is used to break victim's resistance to make them easier to control.
5. "Fraud" often involves false offers that induce people into trafficking situations. For example, women and children will reply to advertisements promising jobs as waitresses, maids, and dancers in other countries and are then trafficked for purposes of prostitution once they arrive at their destinations.
6. "Coercion" involves threats of serious harm to, or physical restraint of, any person; any scheme, plan, or pattern intended to cause a person to believe that failure to perform an act would result in serious harm to or physical restraint against any person; or the abuse or threatened abuse of the legal process.

## **EDUCATION**

### **Human trafficking occurs in two forms**

**Sex Trafficking:** the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act, in which a commercial sex act is induced by force, fraud, or coercion, or in which the person forced to perform such an act is under the age of 18 years; or

**Labor Trafficking:** the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage or slavery.

### **Who are the victims?**

- Anyone
- Strangers, friends, family members or neighbors
- US Citizens and Foreign Nationals
- Males and Females
- Adults and Minors
- Any race
- Of diverse socioeconomic backgrounds

**Examples of sex trafficking**

- Street prostitution
- Massage parlors
- Residential brothels
- Escort services
- Online exploitation
- Hotels and motels
- Truck stops
- Hostess clubs/Cantina bars
- Exotic dancing/Stripping
- Pornography

**Examples of labor trafficking**

- Domestic servitude
- Agriculture, forestry, fishing
- Construction
- Peddling and begging rings
- Factories
- Service industry (hotels and restaurants)
- Small business
- Hostess clubs/Cantina bars
- Exotic dancing/Stripping
- Pornography

**When do victims seek medical services?**

- In an emergency
- After an assault
- For a gynecological exam
- For neonatal care
- For routine checkups
- For unrelated health issues

**Health indicators for commercial sex**

- Under age 18 and in commercial sex
- Language from “the life”
- Persistent or untreated STD/STI’s or UTI’s
- Abnormally high number of sex partners
- Trauma to vagina or rectum
- Presence of cotton or debris in the vagina
- Repeated abortions or miscarriages
- Unintended pregnancies or fertility problems

**Health indicators for labor trafficking**

- Dehydration, heat stress/stroke
- Sleep deprivation
- Musculoskeletal and ergonomic injuries
- Pesticide or chemical exposure
- Water and sanitation related illness
- Air quality or respiratory problems
- Untreated skin infections/irritations
- Evidence of sexual abuse

**RED FLAGS: Force and abuse**

- Hematoma or contusion
- Laceration or scarring
- Missing or broken teeth
- Dislocated limbs or fractures
- Bald spots
- Burns

**RED FLAGS: Coercion and control**

- Inability to keep appointments
- Inability to follow care instructions
- Accompanied by a person that does not let the patient speak
- No identification documents
- Addictive behaviors
- Hyper-vigilance, fear, paranoia, anxiety, and/or depression

**Sample Rapid Assessment Questions:**

- Did you ever feel pressured to do something that you didn’t want to do or felt uncomfortable doing?
- Were you promised something, but it didn’t happen?
- Has anyone ever approached you asking you to get involved in prostitution?
- Have you ever had to trade sex for money or something else you needed?
- Can you tell me about the person who came with you today?

- What is your job like? If you want to leave your job and find another one, can you?
- Does anyone supervise or monitor your conversations with your family and friends?
- Did anyone ever take and/or keep your legal papers for you, such as your ID, passport, or visa?

**Be aware that a trafficking victim may:**

- Exhibit trauma bonding with the perpetrator
- Not self-identify as a victim
- Report conflicting stories or misinformation
- Refuse services
- Distrust authority
- Be accompanied by the controller

**Suggestions for the patient/provider interactions:**

- The story may emerge in pieces and/or after 3-5 encounters
- Ask open-ended questions
- Use a non-judgmental tone
- Take language and vocabulary cues from the victim
- Avoid victimizing them again by referring to them as prostitutes, slaves...
- Do not make promises that cannot be kept
- Make sure an interpreter is known to the victim

**RECOMMENDED PROCEDURE**

If human trafficking is suspected, the provider should:

- Discuss the suspicion with provider's supervisor
- Call the Human Trafficking Hotline at 1-888-373-7888
- Follow existing mandatory reporting protocols for victims of child abuse
- Follow existing protocols for victims of domestic violence or crime
- Provide options for the victim
- Explain reporting obligations. If the victim is an adult, authorities may only be notified with permission from the victim. To ensure permission is given, the call will be made in the presence of the victim.

**RESOURCES**

Polaris Project for a World Without Slavery: <https://polarisproject.org>

Human Trafficking hot line 1-888-373-7888

<https://humantraffickinghotline.org/state/iowa>

[http://www.dps.state.ia.us/intell/ht/ht\\_overview.pdf](http://www.dps.state.ia.us/intell/ht/ht_overview.pdf)

<http://www.acf.hhs.gov/trafficking/index.html>.

Rescue and Restore Coalition [http://www.acf.hhs.gov/trafficking/rescue\\_restore/index.html](http://www.acf.hhs.gov/trafficking/rescue_restore/index.html).


For a list of Rescue and Restore Coalition members:

[http://www.acf.hhs.gov/trafficking/about/coalition\\_list.html](http://www.acf.hhs.gov/trafficking/about/coalition_list.html).

Iowa Code 728.12 - Sexual exploitation of a minor.

Iowa Code 701A - Human Trafficking **Network Against Human Trafficking** [www.iowanaht.org](http://www.iowanaht.org)

Iowa Code 232.68 - Child Sex Trafficking

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Review and Approval of External Websites	<b>NUMBER:</b>  <b>234</b>
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; Title X Program Requirements, 2014; QFP, 2014		

## REVIEW AND APPROVAL OF EXTERNAL WEBSITES

IDPH realizes that it is impossible to fully evaluate every website where the client might seek information. However, each agency shall provide for a review of any external websites clients are specifically referred to by the provider or agency for information. The agency must review and approve all such websites prior to their distribution to assure that the materials are suitable for the population and community for whom they are intended and to assure their consistency with the purposes of Title X.

The website review includes:


- Consideration of the educational and cultural backgrounds of the individuals to whom the materials on the website are addressed. Reading levels should be considered. If a question arises, members of the agency's I & E committee are contacted for input.
- Consideration of the standards of the population or community to be served with respect to such materials
- Review the content of the material to assure that the information is factually correct
- Determine whether the material is suitable for the population or community to which it is to be made available. If a question arises, members of the agency's I & E committee are contacted for input.
- Establish a written record of the review.

The following format is used as an example. Agencies may develop their own review tool. Refer to the appendix for a detailed example.

### EVALUATION:

Please record the number value that you assess of this educational resource considering that this resource will be distributed to clients.

<b>Scale:</b>	<b>1 = strongly agree</b>	<b>2 = agree</b>	<b>3 = disagree</b>
	<b>Comments</b>		<b>Rating</b>
Vocabulary appropriate/readability			
Culturally appropriate			
Attractiveness/appeal			
Suitable for audience			
Factually correct			
<b>Additional Comments</b>			

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Contraceptive Access in Disasters	<b>NUMBER:</b>  <b>235</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> September 2014
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR 59; IAC 641-74; Title X Program Requirements, 2014.		

## CONTRACEPTIVE ACCESS IN DISASTERS

### EMERGENCY REPLACEMENT OF CONTRACEPTION DUE TO NATURAL DISASTER


The World Health Organization (WHO) defines a disaster as “any occurrence that causes damage, ecological disruption, loss of human life or deterioration of health and health services on a scale sufficient to warrant an extraordinary response from outside the affected community area.”<sup>2</sup>

Natural and manmade disasters may occur that result in displacement of persons and loss of access to contraceptive methods. Sub-recipients will develop an emergency plan to assure the availability of prescription and nonprescription contraceptive methods for their clients in the event of a natural disaster (tornado, flooding, earthquake, ice storms for example) or manmade disaster (hazardous waste spills and terrorism for example). Sub-recipients must replace (per the client’s last refill history) supplies equivalent to the number that the client had on hand when the disaster occurred. If the client has FPP, Medicaid or another third party payer, the agency must provide supplies equivalent to the number needed until the agency is able to bill for another refill of contraceptives.

Sub-recipients are encouraged to participate in community-based disaster preparedness and response model that takes women's reproductive needs into account.

### REFERENCES:

1. Natural and Social Disasters: Racial Inequality in Access to Contraceptives After Hurricane Ike Ophra Leyser-Whalen, Mahbubur Rahman, Abbey B Berenson *Journal of Women’s Health* (2002).
2. Maternal Health Considerations During Disaster Relief Nawal N Nour, MD, MPH *Obstet Gynecol.* 2011; 4(1): 22–27.

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Closing, Moving Or Opening Clinic Locations	<b>NUMBER:</b>  <b>236</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> December, 2017
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014		

## CLOSING, MOVING OR OPENING CLINIC LOCATIONS

OPA processes require approval and notification of changes in the scope of the IDPH Title X project. The change in scope should be approved by OPA prior to implementation. This policy addresses the procedures for requesting clinic closure, moves or additions.

If a sub-recipient agency is considering closing down a clinic site, the agency must notify IDPH. The agency must also provide the following information and plan at least **60 days prior to the projected closing date**.

1. Notify IDPH of scheduled closing date.
2. Provide explanation on why the clinic site is being closed and what arrangements are being made to ensure the continuation of services.
3. Develop a listing of other family planning services providers and clinic resources for distribution to the clients, especially a referral list to the nearest Title X or other free/sliding fee scale clinics. This list must include clinics that are not another satellite of the agency if those sites are within the same travel distance as the agency's other satellite sites. The list must include phone number(s) to call for an appointment and must be provided to clients. A copy must be provided to IDPH.
4. Contact other family planning providers in the service area and the closest Title X provider as a courtesy to ascertain their capacity to take on additional clients. Determine as much information from the providers as possible that might be useful to clients (e.g. wait times for appointments, anticipated amount of time for clinic visit, etc.).
5. If possible, discuss in person with every client receiving services that family planning services will be discontinued at that location, and the anticipated date of discontinuation. This notification should be done as soon as possible. The agency should consider creating a brief handout that contains this information.
6. Inform clients of information about other family planning providers and any information known about their services (# 1 above). Offer to send medical record information to the provider of choice. Have the client sign a consent form releasing his/her records.
7. If referral agreements are developed between providers, include this information when notifying clients.
8. Post signs in the clinic (and possibly elsewhere in the agency) of the agency's plans to discontinue providing family planning services. Public notice should be posted at the clinic at least 30 days in advance of closure.
9. Make provisions to accommodate as many client visits for contraceptive supplies as needed to ensure that clients have sufficient supplies to cover the transition period.
10. Ensure that a mechanism is in place to follow-up on clients with abnormal lab results and positive STD tests.

11. Identify a process for handling the request/transfer of client records of any client that seeks services elsewhere, to eliminate any barriers and ensure continuity of care for the client. This process must be provided to IDPH.
12. Follow record retention policies to maintain medical records (make sure records are handled in accordance with applicable Iowa laws and generally accepted medical practice standards).
13. Consider posting closing information on social media sites.
14. Ensure that all data from the clinic to be closed will be submitted to the IDPH FP database for the appropriate FPAR and other data reports.
15. Ensure that any financial reports are available for review.
16. Work with IDPH for the disposition of any property or equipment that may have been purchased with federal grant dollars
17. Notify IDPH of the plans for disposition of 340B medications and supplies.

If the entire agency is closing down or withdrawing from the Title X program, there is a more detailed closeout list. Contact IDPH FP director for additional information.

#### **CHANGE OF LOCATION FOR EXISTING TITLE X CLINIC SITE:**

If a sub-recipient agency plans to move the location of any of its existing Title X clinic sites it must notify IDPH in writing at least 60 days prior to the proposed moving date. The sub-recipient must provide the following information.

- 1) Location of existing clinic site and proposed new location
- 2) Reason for changing the location.
- 3) If the change is to different community, provide the rationale for selecting that community

If the location must be moved due to an emergency (water damage, fire, utility issues, structure damage for example), the agency will notify IDPH as soon as possible.


#### **ADDITION OF A TITLE X CLINIC SITE:**

As a Title X grantee, IDPH has responsibility for assuring access to family planning services within its project area. IDPH must identify all clinic sites funded through the project.

IDPH supports the development of additional clinic sites. The addition of a clinic site to a sub-recipient's Title X project must receive prior approval from the IDPH before Title X funds can be used at that site. The following procedure must be followed:

1. Written email requesting approval, with justification for the addition of another clinic in that area, for example need or access.
2. Assure required Title X documentation can be achieved
3. Assure data collection plans are in place
4. Plan for complete and accurate billing; is credentialing required for new location?
5. Plan for securing 340B inventory if used
6. Assure all staff are oriented to Title X
7. Assess ability to provide confidential services in the location
8. Assess LEP assistance availability



 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Abortion Services	<b>NUMBER:</b>  <b>237</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 45 CFR Part 74; IAC 641-74; 2011-1 Title X Statute, Section 1008; 42 CFR 59.5 (a) (5); Grant Policy Statement, II-22; Section 3.3; 65 Fed. Reg. 41281; ; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019		

## ABORTION SERVICES

No Title X funds will be used in programs where abortion is a method of family planning.

No Title X funds will be used in the provision of abortion or abortion related services.

All contracts initiated by IDPH for family planning services will contain language stating that no Title X funds will be used in the provision of abortions or abortion related services.

All contracted Sub-recipients will have a written policy stating that no Title X funds will be used in the provision of abortions or abortion related services.

All subcontracts for family planning services (subcontractors and/or contracted employees) initiated by a Sub-recipient of IDPH will contain language stating that no Title X funds will be used in the provision of abortions or abortion related services.

A Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion. For example, sub-recipient staff may not take assistive action (such as negotiating a fee reduction, making an appointment, or providing transportation) for clients seeking abortion.


Sub-recipient staff will be notified they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure. This will be documented in employee files annually.

Neither IDPH nor any SR will participate in activities that encourage, promote or advocate for abortion or develop or disseminate in any way materials (including printed matter, audiovisual materials and web-based materials) advocating abortion as a method of family planning. activities, advocates abortion as a method of family planning. Refer to Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019 for examples.

Definitions of Abortion:

- "Abortion will not be used as a method of family planning" includes all abortion services that do not fall into the "abortion as a medically necessary procedure" category below
- Abortion as a medically necessary procedure:
  - A situation where it is necessary to save the life of the woman or to preserve her health (ACOG).

- The treatment of a woman for a spontaneous abortion, commonly known as a miscarriage, when not all of the products of human conception are expelled.
  - Situations when rape or incest has occurred.
- Abortion referral - When there is a medical necessity (e.g. suspected ectopic pregnancy) a referral to a specific medical provider is permitted. Providing a list of licensed, qualified comprehensive providers is not considered an abortion referral.

  <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Use of 340B Medications	<b>NUMBER:</b>  <b>238</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b> 226	
	<b>Authority:</b> IAC 641-74; IME Information Letter 699		

## USE OF 340B MEDICATIONS

### OBJECTIVE

**To establish a policy related to the use of 340B medications by IDPH Title X sub-recipients.**

- 1 Each agency is responsible for annual recertification of any clinic sites where 340B purchased medications are used. Failure to recertify will result in the agency being unable to use 340B medications in any clinic sites that are not certified.
- 2 IDPH will confirm that the Entity or Entities as updated and certified via the Office of Pharmacy Affairs' electronic forms system are recipients of grant funds related to the treatment of Family Planning clients through the Iowa Department of Public Health as a Title X grantee.
- 3 Each agency must certify that reasonable safeguards are in place to assure compliance with the provisions of Section 340B of the PHS Act that prohibit Drug Diversion and Double Discounts/Rebates.
- 4 Each sub recipient will have a policy clearly describing their safeguards for Drug Diversion and Double Discounts/Rebates in their FP manual. Sub recipients will describe how they will maintain control over their inventory of 340B medications.
- 5 Each sub recipient will comply with Iowa Medicaid Enterprise policies regarding claims filed for 340B medications (See IME Information letter 699).
- 6 Sub recipients may use 340B medications for individuals meeting the definition of patient as outlined below:

### DEFINITION OF A PATIENT

The Office of Pharmacy Affairs has published final notice of guidelines on definition of a patient to allow a clearer understanding of which individuals may receive prescribed medications purchased at the legislatively mandated discount of [Section 602](#) of the [Veterans Healthcare Act of 1992](#).

In summary, an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

- the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other


arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

- the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

**An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting.**

**If a family planning agency chooses to provide emergency contraceptives for non-patients, that individual may not receive medications from stock purchased as 340B medications. The individual may not be counted as a client for FPAR purposes.**

An individual registered in a State operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.


 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Sub-Recipient Closure	<b>NUMBER:</b>  <b>239</b>
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> February 2016
	<b>Status:</b>		<b>Cross Reference:</b>
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014		

## SUB-RECIPIENT CLOSURE

When a sub-recipient agency withdraws from the project, the following procedures must be conducted:

- Notify IDPH in writing of the intent to discontinue services. The letter must include the reason for discontinuing, the location of all clinic sites affected, and the anticipated date of termination of both clinic services and the Title X contract. This notification must be submitted at least 60 days prior to scheduled closeout date.
- Provide a written plan that identifies how the following items will be completed and who is responsible for each item. This must be provided within two (2) weeks of the written notification.
  - a. Contact other family planning providers in the service area to ascertain their capacity and willingness to take on the agency's clients. Determine as much information from the providers as possible that might be useful to clients (e.g. number to call for appointment, anticipated amount of time for clinic visit, costs, etc.). Develop a referral mechanism with those providers;
  - b. Notify clients that family planning services will be discontinued and the anticipated date of discontinuation. This notification should be done at least one month in advance of anticipated closing date (sooner, if possible);
  - c. Inform clients about other family planning providers and any information known about their services. Offer to send client's medical record information to their provider of choice (must have a signed release from client to do this);
  - d. Make provisions within the agency to accommodate as many client visits for contraceptive supplies as needed to ensure that clients have sufficient supplies to cover the transition period;
  - e. Ensure that a mechanism is in place for tracking and obtaining any outstanding lab test results;
  - f. Ensure that a mechanism is in place to follow-up on clients with abnormal lab results and positive STD tests;
  - g. Develop a system to ensure that medical record information is transferred according to client request and Title X guidelines, generally accepted medical practice standards and HIPAA regulations (if applicable);
  - h. Determine what is to be done with medical records of inactive clients, clients with IUD's and minors (make sure that those records are handled in accordance with Title X guidelines, generally accepted medical practice standards and HIPAA regulations (if applicable). This included electronic health records;
  - i. Identify how client medical records will be stored and available for access according to Title X guidelines, generally accepted medical practice, and HIPAA regulations (if applicable). This included electronic health records;
  - j. Notify community partners of the clinic closing;
- Financial Management:

- a. Return to IDPH any unobligated Title X funds;
- b. Disperse any Title X grant-related income in accordance with federal regulations as noted in either OMB Circular A-102 (government entities) or A-110 (non-profit agencies);
- c. Submit to IDPH a list of equipment purchased with Title X funds and a request for disposition in accordance with federal regulations as noted in either OMB Circular A-102 (government entities) or A-110 (non-profit agencies);
- d. Submit to IDPH copies of the annual agency financial audit that covers the period during which close-out occurred;
- e. Submit to IDPH all applicable monthly revenue and expenditure reports;
- f. Submit a final revenue and expenditure report to IDPH within 90 days of the closing of the clinic;
- g. Submit to IDPH all necessary information for the Family Planning Annual Report (FPAR) for the year during which close-out occurred within 90 days after closing (unless closing occurs at calendar year end, then FPAR is due on regular schedule);
- h. Complete the data entry according to the deadlines established by the family planning data system;
- i. Submit to IDPH a close out report (based on the work plan submitted with the Contractor Application Packet) for the year during which close-out occurred. This must be submitted within 90 days of the closing of the clinic; and
- j. Identify what will be done with sub-recipient Title X financial records and how they will be available if needed.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Program Administration	<b>SUBJECT:</b> Data Use and Sharing	<b>NUMBER:</b>  <b>240</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019
	<b>Status:</b>	<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59 (42 CFR 59.11); IAC 641-74; Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014; IDPH Data Sharing Agreement (DSA) Policy #CO 01-16-001; IDPH Data Standards		

## DATA USE AND SHARING

### OBJECTIVES

Describe expectations of IDPH and sub-recipient agencies for compliance with release and sharing of Title X data.

### Purpose

- To assure that client personal identifiable information remains strictly confidential.
- To assure that when releasing data from the Title X family planning database (TAV) all sub-recipient agencies comply with the IDPH data sharing agreement (DSA) Policy #CO 01-16-001, IDPH Research Agreement and Research and Ethics Review Committee Policy # AD 07-12-004, IDPH 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 IDPH General Conditions, and any future revisions to any of these.

### Key Points

1. Contractors shall use Title X data only for the purposes outlined within the contract and shall ensure that the minimum number of individuals have 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; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals."
3. Therefore, Contractors may only release their own agency family planning 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 6 or if the denominator is fewer than 100. See IDPH 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, Business Associate agreement or an attestation document. Copies of the appropriate documentation will be available for review by IDPH staff.
5. All other requests received for family planning database will be referred to the Iowa Department of Public Health.



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 <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Initial Visit (Female Client)	<b>NUMBER:</b> <b>301</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b> Policies 221, 314, 317 and 347	
	<b>Authority:</b> PHSA 42 CFR Part 59; IAC 641-74; ASCCP Consensus Guidelines 2006; ACOG Practice Bulletin 109; USPSTF Recommendations 2012; QFP, 2014; Recommendations for Well Woman Care, A Well Woman Chart, HRSA, 2019			

### INITIAL VISIT - FEMALE CLIENT

Family Planning agencies must implement policies that reflect current national standards of care in the provision of cervical cancer screening the national standards may include American Congress of Obstetricians and Gynecologists (ACOG) or American Society for Colposcopy and Cervical Pathology (ASCCP) and the US Preventive Services Task Force (USPSTF). This can also be considered a preconception visit.

#### REASON FOR VISIT

Obtain and record the purpose of the visit, chief complaint, and/or additional health concerns prompting the desire for health care.

#### HISTORY (SEE POLICY 221 FOR MINIMUM STANDARDS)

Assess the client's knowledge and level of understanding, and obtain pertinent information concerning the following:

**Past Medical History (illnesses, hospitalizations, exposure to blood products, chronic or acute medical conditions, injectable drug use):**

1. Anemia
2. Blood Dyscrasia
3. Breast Neoplasm
4. Cancer
5. Diabetes Mellitus
6. Epilepsy/seizures
7. Gall Bladder Disease
8. Hemoglobinopathy
9. Hyperlipidemia
10. Hypertension/Heart Disease
11. Surgery
12. Liver disease/Jaundice/Mononucleosis
13. Lung Disease
14. Migraine
15. Renal/UTI
16. Thromboembolism
17. Transfusions
18. Visual Disturbances
19. Immunization history, especially Rubella, HPV and varicella
20. Thyroid Disease

21. DES or intrauterine estrogen exposure (if born in USA before 1971), if positive, counsel and screen
22. Psychosocial history
  - a. Depression, counseling
  - b. Family Dynamics
  - c. Trauma/violence
  - d. Educational level
23. Substance use, including tobacco, alcohol, injectable drugs, prescription drugs, illegal substances. Screen and counsel.

**History of Allergies:**

- Medicine
- Other

**Current use of prescription and over-the-counter medication:**

1. Current medications (prescription and over-the-counter, herbs, and supplements)
2. Medication taken in past 60 days
3. Other concerns not specifically mentioned by interviewer

**Extent of use of tobacco, alcohol, and other drugs**

- Assess current smoking/alcohol/drug usage (how much/day, for how long/months, years)

**Immunization status: required to check Rubella, HPV and HBV**

- Discuss Tdap vaccine, especially if around newborns

**Review of systems**

- Include nutrition and weight changes, include folic acid discussion

**Family History (first degree relatives: mother, father, brother, sister):**

1. Cancer
2. 2019 USPSTF recommends using an assessment tool (like the Ontario Family History Assessment Tool) for women with a personal or family history of breast, ovarian, peritoneal, or tubal cancer or those with ancestry associated with BRAC 1/2 (like Ashkenazi Jewish descent). Routine genetic assessment and testing is not indicated in women who don't meet the above criteria.
3. Diabetes
4. Hypertension/Heart Disease
5. Stroke
6. Other (i.e. Sickle Cell Anemia, Phenylketonuria (P.K.U.))
7. Blood clots or bleeding disorders

**Partner History**

1. injectable drug use
2. multiple partners
3. risk history for STD and HIV
4. bisexuality

**Contraceptive History:**

1. What methods of birth control has the client used by name?
2. What was the method last used regularly? When was it discontinued and why?
3. Name the current method.
4. If not presently on a method, how long did the client use the last method?
5. History of a significant contraceptive complication.(Specific type, symptomatology and outcome)

**Menstrual History:**

1. Onset
2. Interval
3. Duration
4. Dysmenorrhea
5. Premenstrual symptoms
6. Last Menstrual Period (LMP)
  - a. Normal
  - b. Abnormal
  - c. Withdrawal bleeding

**Sexual History/IPV (Sexual history combined with contraceptive history and partner history completes the sexual health assessment):**

1. Is the client sexually active and at what age became sexually active?
2. Monogamous relationship or multiple partners
  - a. Do you have a steady partner (or more than one)?
  - b. Have you changed partners in the last six (6) months?
3. Engage in anal sex or oral sex?
4. Are you experiencing any pain, discomfort or bleeding related to sexual activity?
5. Do you have any questions about human sexuality? (i.e. orgasm, sexual response, lubrication)
6. Have you ever experienced sexual trauma or been forced into having sexual activity against your will?
7. Have you ever had a partner of the same sex?
8. Does a partner or anyone at home hit, punch, slap, push, kick, hurt, or threaten you or your children?
9. Does a partner or anyone at the home put you down or humiliate you?
10. Has anyone ever approached you asking you to get involved with prostitution?

**Obstetrical History:**

1. Gravidity, and parity, dates
2. Number of living children
3. Number of abortions (spontaneous or induced)
4. Neonatal deaths, still births
5. Past obstetrical complications

**Gynecologic History:**

1. Abnormal bleeding
2. Dyspareunia
3. Genital Neoplasm
4. Endometriosis
5. Sexually Transmitted Disease (STD)
6. Vaginitis
7. Gynecological surgery

**Sexually transmitted diseases: (includes HBV)****HIV****Cervical cancer screening History****CURRENT INTIMATE VIOLENCE SCREENING. FAMILY PLANNING NEEDS****Anatomy and Physiology of reproduction**

1. An overview of all contraceptive methods must be offered, especially for new or undecided clients.

2. Offer guidance to facilitate choice of method.
3. Assess ability to comply with chosen method.
4. Provide instructions concerning effectiveness, proper use, indications/precautions, risks, benefits, possible minor side effects and potential life threatening complications of their chosen method must be provided.
5. Initiate method of choice.
6. Discuss future plans for pregnancy, desired family size, spacing of children.
7. Provide interim contraception for sexually active clients if a visit with the provider cannot be accommodated on the day of the visit. Clinic policies must address same day starts. Encourage consistent and correct use of condoms for all at-risk for STD/HIV.
8. Discuss the value of family planning.
9. Instruct the client on clinic routines and exam procedures.
10. Document elements of informed consent.

## PHYSICAL ASSESSMENT

During the process of evaluation, the following systems are assessed and the findings documented on the chart by the examining practitioner and/or physician.

1. Height, Weight
2. Blood pressure
3. Hgb. and/or Hct. if indicated
4. Serology for syphilis, rubella, HIV and hepatitis B, hepatitis C, if indicated
5. UA (dipstick assessment for glucose, protein, ph) if indicated
6. Cervical cancer screening screening– Though many clients will not need to have a cervical cancer screening every year, they may need to have STI testing. See **Policy 315** - Cervical cancer screening and Pelvic Exam.
  - a. *Women under 21 years old* - cervical cancer screening, pelvic exam and breast exam are not a routine part of physical assessment in this population if no previous abnormal Pap. See **Policy 317**.
  - b. *Women aged 21 to 29 years* cervical cytology screening is recommended every 3 years if no previous abnormal Pap. Annual bimanual pelvic exams may still be indicated.
  - c. *Women aged 30 years to 65 years* receive cytology testing every three years; every five (5) years with hrHPV testing alone or every five years with cervical cytology plus hrHPV testing.
  - d. *Women older than age 65* who have had recommended screenings and follow-up without recent evidence of abnormal cytology and are not at high risk do not receive cervical cytology testing.
7. Thyroid
8. Heart
9. Lungs
10. Breast and axillary nodes (Instruct breast self-examination), as age appropriate.
11. Abdomen/extremities
12. Rectovaginal as indicated
13. Inspection of rectum and rectal exam for clients 50 years and over as indicated.
14. Other lab tests as indicated and available (sickle cell, pregnancy, blood glucose, cholesterol, lipid screen, diabetes testing)
15. cholesterl, lipid screen, diabetes testing)
16. GC, Chlamydia screening and testing and wet mount as indicated

## **COUNSELING/EDUCATION**

### **Counseling and education efforts includes an exploration of the following:**

1. Safety; firearm safety, domestic violence, relationship safety and bullying (in appropriate age groups) – explore all affirmative responses
2. Education
3. Employment
4. Health Promotion
5. Affiliations
6. Tobacco
7. Substance and alcohol use
8. Living situation
9. Mental health, suicide, depression, anger management, rage
10. Reproductive Life Plan
11. Condom use
12. STI/HIV risk reduction and HPV Vaccine
13. Emergency contraception
14. Mammography as indicated

### **Counseling for Adolescents must also include:**


1. Abstinence
2. Safer Sex Practice Options
3. Resisting sexual coercion
4. Confidentiality of services
5. Family Involvement/Participation

### **If Problems Are Discovered**

During the course of the assessments, which are beyond the scope of the clinic, the nurse practitioner or physician will order appropriate testing and/or make appropriate referrals.

## **REFERENCES**

- ACOG Practice Bulletin #122 "Breast Cancer Screening", 2011.
- ACOG Practice Bulletin #131 "Screening for Cervical Cancer", 2012
- U.S. Preventive Services Task Force Recommendation Statement, August 2018, JAMA 2018;320(7):674-686.
- Risk Assessment, Genetic Counseling, and Genetic Testing for *BRCA*-Related Cancer, accessed 8/26/19 at <https://jamanetwork.com/journals/jama/fullarticle/2748515>

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Periodic Health Assessment (Female Client)	<b>NUMBER:</b>  <b>302</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b> Policies 221, 317, 347	
	<b>Authority:</b> IAC 641-74; Public Health Service Act 42 CFR Part 59; IAC 641-74; National Cancer Institute: <a href="http://www.cancer.org">http://www.cancer.org</a> ; QFP, 2014			

## PERIODIC HEALTH ASSESSMENT - FEMALE CLIENT

### HISTORY

Update the initial history

1. Obstetrical history
2. LMP
3. Medical history
4. Gynecologic history
5. Family history
6. Allergy history
7. Contraceptive history
8. Sexual history, including IPV and sexual violence
9. Psycho-social history
10. Miscellaneous Information:
  - a. Review current medication intake
  - b. Review smoking/alcohol/drug abuse
  - c. Domestic violence, sexual violence, human trafficking

### ASSESS CONTRACEPTIVE NEEDS

1. Review knowledge, correct use, and compliance of current method of birth control
2. Review client's acceptance of method. If a method change is indicated a review of any contraceptive methods the client expresses interest in, and any appropriate alternatives must be done.
3. Review side effects and warning signs related to current method of choice
4. Discuss Emergency Contraception

### PERFORM THOROUGH CHART REVIEW

Include assessment of past/current lab (including routine and exam procedures).

Review Clinic Routine and Exam Procedures Initiation of Mammography Examinations, if indicated 2019 USPSTF recommends using an assessment tool (like the Ontario Family History Assessment Tool) for women with a personal or family history of breast, ovarian, peritoneal, or tubal cancer or those with ancestry associated with BRAC 1/2 (like Ashkenazi Jewish descent). Routine genetic assessment and testing is not indicated in women who don't meet the above criteria.

Initiate mammography examinations as indicated \*using national standard of practice: recommended mammography schedule for women with no family history of breast cancer.

Baseline Mammogram..... 40 years  
 Mammogram yearly..... between 40 and 50 years  
 Mammogram every one to two years.....50 years +



*\* National Institute of Cancer, annually after 40*

*\*The U.S. Preventative Task Force (USPTF) updated its guidelines January 2016, advising women of average cancer risk to get screened every other year between ages 50-74 while high-risk women should begin at 40.*

*\*ACOG updated guidelines in June, 2017*

- Women at average risk of breast cancer should be offered screening mammography starting at age 40 years. If they have not initiated screening in their 40s, they should begin screening mammography by no later than age 50 years. The decision about the age to begin mammography screening should be made through a shared decision-making process. This discussion should include information about the potential benefits and harms.  
Women at average risk of breast cancer should have screening mammography every one or two years based on an informed, shared decision-making process that includes a discussion of the benefits and harms of annual and biennial screening and incorporates patient values and preferences.*
- Women at average risk of breast cancer should continue screening mammography until at least 75 years. Beyond age 75 years, the decision to discontinue screening mammography should be based on a shared decision making process informed by the woman's health status and longevity.*

Women with a family history of breast cancer diagnosed in a first degree relative before the age of 50 should be managed according to ACS Guidelines or referred to their primary care provider for appropriate screening.

#### **PHYSICAL ASSESSMENT (AS ON INITIAL VISIT) - REFERENCE POLICIES 301 & 317**

Hgb/Hct only as indicated.


#### **REVIEW STD/HIV RISKS AND PREVENTION OF STDS/HIV**

#### **INITIATE APPROPRIATE REFERRALS**

If abnormalities are noted, order appropriate testing and/or refer to appropriate provider.

#### **REFERENCE:**

*Obstetrics & Gynecology*, 2017 Practice Bulletin #170 "Breast Cancer Risk Assessment in Average Risk Women." Risk Assessment, Genetic Counseling, and Genetic Testing for *BRCA*-Related Cancer, accessed 8/26/19 at <https://jamanetwork.com/journals/jama/fullarticle/2748515>

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Adolescent Services	<b>NUMBER:</b>  <b>303</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	Date: July 2019
	<b>Status:</b>		<b>Cross Reference:</b> Policies 221, 230, and 234	
	<b>Authority:</b> IAC 641-74; <a href="http://brightfutures.aap.org">http://brightfutures.aap.org</a> ; Iowa MCH Administrative Manual, 307 (Appendix 36; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019			

## ADOLESCENT SERVICES

Services for adolescents should follow the standard of care as outlined for initial and periodic visits. They also must include:

1. Appointments  
Adolescent appointments for counseling and clinical services should be made as soon as possible.
2. Counseling
  - a. Regarding their decision to be sexually active;
  - b. All clients under the age of 18 will be encouraged to talk with their parents/guardian or a trusted adult about their decision to seek family planning (FP) services. Resources should be provided to parents and guardians to assist them in these discussions.
  - c. Regarding resisting coercive sexual activity, sexual violence and human trafficking. All SRs will ensure that every minor who presents for services (or care) is provided counseling on how to resist attempts to coerce them into engaging in sexual activities. Providers will conduct a preliminary screening of any teen who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Such screening is required with respect to any individual who is under the age of consent in the Iowa. Compliance with screening is maintained in records to demonstrate compliance with each of the requirements including the age of minor clients, and documentation of each notification or report made pursuant to State notification laws. Iowa law does not require documentation of the age of the minor client's sexual partners but providers shall ask if suspicion arises.
  - d. Abstinence as an acceptable birth control method, including alternative methods of sexual expression.
  - e. Comprehensive information about how to prevent pregnancy and STDs.

## DISCUSSION OF CONTRACEPTIVE METHODS

If client is new or undecided he/she must receive information about any and all methods of birth control. Discuss safer sexual practices to reduce the risk of STDs, including abstinence as the most effective method.

## REFERRALS:

All IDPH FP SRs will have policies and provide appropriate referrals to youth, including but not limited to, referrals of pregnant and parenting youth to social service programs in their area.

## **CONSENT FOR SERVICES AND CONFIDENTIALITY STATEMENT**

Adolescents must be assured that counseling and services are confidential and if follow-up is necessary every attempt will be made to assure privacy.

Parents or guardians cannot be notified before or after a minor has requested or received Title X services without written consent. Parental consent for services (or care) will not be required for adolescent services.

A provision for the notification of a parent in the event that a life threatening condition is identified must be included in the consent for services. This provision is exercised only if the minor is unwilling or unable to follow up on referrals.

Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record: (i) That it suspects the minor to be the victim of child abuse or incest; and (ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.

### **CHILD ABUSE REPORTING:**

All IDPH FP SRs shall have policies in place that specify agency compliance with Iowa Code that address child abuse, reporting of child abuse, child sex trafficking, child molestation, sexual abuse, rape, or incest.

Title X also requires that all SRs ensure that every minor who presents for services (or care) is provided counseling on how to resist attempts to coerce them into engaging in sexual activities. Providers will conduct a preliminary screening of any teen who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor.

Such screening is required with respect to any individual who is under the age of consent in the Iowa. Compliance with screening is maintained in records to demonstrate compliance with each of the requirements including: (i) indicate the age of minor clients, and (document each notification or report made pursuant to such State notification laws. (d) The Secretary may review records maintained by a grantee or Sub-recipient for the sole purpose of ensuring compliance with the requirements of this section.

Iowa law does not require documentation of the age of the minor client's sexual partners but providers shall ask if suspicion arises.

### **HUMAN TRAFFICKING:**


All IDPH FP SRs shall have policies in place that address screening for human trafficking as required in Policy 233.

## **SERVICES TO YOUTH**

According to the WHO, to be considered adolescent friendly, health services should be accessible, acceptable, equitable, appropriate and effective, as outlined below:

- **Accessible:** Adolescents *are able to* obtain the health services that are available.
- **Acceptable:** Adolescents *are willing to* obtain the health services that are available.

- **Equitable:** *All adolescents*, not just selected groups, are able to obtain the health services that are available.
- **Appropriate:** The *right health services* (i.e. the ones they need) are provided to them
- **Effective:** The *right health services are provided in the right way*, and make a positive contribution to their health.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Pregnancy Test Visit	<b>NUMBER:</b>  <b>304</b>		
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> July 2019			
	<b>Status:</b>				<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019					

## PREGNANCY TEST VISIT

A pregnancy test may be performed at the client's request or if the practitioner deems it necessary.

### EDUCATING A CLIENT

Regarding the results of a pregnancy test is provided in a structured interview session.

### DETERMINE CLIENT'S REASON

Determine client's reason for suspecting pregnancy.

#### Regardless Of the Results

Obtain the following information and/or update:

1. Obstetrical history
2. Medical History
3. Menstrual history (with emphasis on LMP)
4. Contraceptive history and current status
5. Date of last unprotected intercourse
6. Sexual history, sexual violence, and reproductive coercion
7. Current medication, prescription, over-the-counter drug use
8. Alcohol, tobacco, and illicit or prescription drug use as indicated.

#### Determine

The presence and time of onset of signs and symptoms of pregnancy:

1. Amenorrhea or irregular menses
2. Breast tenderness
3. Nausea and/or vomiting
4. Urinary frequency
5. Fatigue

### EDUCATION AND REFERRAL

Depends upon the results of the pregnancy test:

1. Interpret the test results and exam findings.
2. Consider possible reasons for false negative results.
3. If a possibility exists that it is too early to confirm or rule out a pregnancy:
  - a. The client should be advised to return to clinic in two (2) weeks for a repeat pregnancy test.
  - b. Discontinue hormone contraceptive methods if early gestation is probable as indicated. Provide an alternative contraceptive, such as foam, condoms, sponge or diaphragm if the client does not desire pregnancy at this time. A provider may choose to use reasonable certainty that the client is not pregnant and allow the client to continue hormone contraception if the client meets any of the following

criteria and has been educated about the risks: less than 7 days from start of normal menses; consistently and correctly using a reliable method of contraception; less than 7 days after spontaneous or induced abortion; within 4 weeks postpartum; is fully or nearly fully exclusively breastfeeding and amenorrhea and less than 6 months postpartum; or has not had intercourse since the last normal menses.


4. Those clients who have a positive pregnancy test may have a pelvic exam to corroborate the test results. If the pregnancy test and/or the exam findings are positive for pregnancy, the following counseling should be rendered and documented:
  - a. All clients with a positive pregnancy test will be offered the following education:
    - i. Assess any risk factors which might adversely influence the pregnancy and provide appropriate education.
    - ii. If the client is using contraceptives, advise to discontinue hormone contraceptives immediately.
    - iii. All clients will be provided a referral for prenatal care and for any medically necessary care. The referral will be documented in the client's chart.
    - iv. Clients requesting information on options for the management of unintended pregnancy may be given health education on prenatal care, delivery, infant care, foster care, adoption, and pregnancy termination. Health Education provided by a nurse or social worker is defined as the provision of factual non-directive education on all legal options following a positive test. The agency may provide this information with the exception of any options about which the pregnant woman indicates she does not wish to receive information.
    - v. Provide information regarding early and continuous prenatal care and pregnancy problem symptoms, including when to seek medical attention.
    - vi. Clients should be provided initial prenatal education about medication use in pregnancy, prenatal vitamins, folic acid, lifestyle, diet and nutrition. All education is documented in the client's chart.
    - vii. See Appendix 10, Location of Maternal Health Services, for the list of maternal health centers or [http://www.idph.state.ia.us/hpcdp/common/pdf/mh\\_map.pdf](http://www.idph.state.ia.us/hpcdp/common/pdf/mh_map.pdf).
  - b. Women with positive pregnancy test who desires delivery with adoption or interim care should be assessed for any needed services #1-7 above. Clients may also be referred for adoption services; prenatal care continues to remain an essential care component.
  - c. While all pregnancy counseling must be nondirective, the physician or Advance Practice Provider (APP) may exercise discretion on whether to offer options counseling (nondirective) to assist the patient in making a free and informed decision. In nondirective counseling, abortion must not be the only option presented by physicians or APP. This involves presenting the options in a factual, objective, and unbiased manner and (consistent with other Title X requirements and restrictions) offering factual resources that are objective, rather than presenting the options in a subjective or coercive manner. A list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care).
5. Clients with negative pregnancy test results who wish to become pregnant:
  - a. Instruct regarding timing of intercourse. Intercourse prior to ovulation is important to conception. While sperm can survive over 72 hours in the female genital tract, the ovum has a life expectancy of only 12 hours if it is not fertilized.

The availability of sperm in the genital tract at or shortly after ovulation is essential. Clients should receive instruction to determine their most fertile time of the month. Natural family planning techniques may be useful.

- b. Women who have been trying to achieve pregnancy for more than 12 months or if the client is 35 or older with unprotected intercourse with the same partner, referral for infertility work-up should be made. Clinics should maintain a resource list where services are available.
6. Clients with negative pregnancy test results who do not wish to become pregnant should be assessed for continued appropriateness of current contraceptive method and offered family planning services. A contraceptive method should be provided with detailed instructions on use. Reproductive life plan counseling should be done during this session.
7. If ectopic pregnancy is suspected, immediately refer client for follow-up.
8. All clients, regardless of pregnancy test results, should be offered STI screening at the time of the pregnancy test visit.

#### **DEFINITIONS:**

- "Abortion will not be used as a method of family planning" includes all abortion services that do not fall into the "abortion as a medically necessary procedure" category below
  - Abortion as a medically necessary procedure:
    - A situation where it is necessary to save the life of the woman or to preserve her health (ACOG). The treatment of a woman for a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would base on the best medical evidence, place the woman in danger of death.
    - The treatment of a woman for a spontaneous abortion, commonly known as a miscarriage, when not all of the products of human conception are expelled.
    - Situations when rape or incest has occurred.
  - Abortion referral - When there is a medical necessity (e.g. suspected ectopic pregnancy) a referral to a specific medical provider is permitted. Providing a list of licensed, qualified comprehensive providers is not considered an abortion referral.
- Health Education (following a positive pregnancy test): the provision of factual non-directive education on all legal options following a positive test. If the woman chooses to continue the pregnancy, the education should include the importance of early access to prenatal care, and a referral to prenatal care provider and to other providers that are or other medically necessary care.
- Pregnancy options counseling: a non-directive counseling between an advanced practice provider (APP) and a client about potential options following a positive pregnancy test. It can include discussion about risks, benefits, alternatives, and future implications of any medical procedures.

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Postpartum Visit	<b>NUMBER:</b>  <b>305</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b> Policy 221		
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Contraceptive Technology, 19 <sup>th</sup> edition: <a href="http://www.who.int/reproductive-health/publications/msm_98_3/msm_98_3_14.html">www.who.int/reproductive-health/publications/msm_98_3/msm_98_3_14.html</a> ; QFP, 2014; Women's Preventive Services Initiative "Recommendations for Well-Woman Care, A Well Woman Chart" HRSA, 2019.			

## POSTPARTUM VISIT

Ideally, clients will have their postpartum exam done by the physician who provided prenatal care and delivery. Attempts to obtain records of prenatal care and delivery should be made.

- New-- postpartum client, initiate initial visit protocol, counseling.
- Revisit-- postpartum client, initiate annual visit protocol, and counseling.

### REVIEW OF DISCHARGE SUMMARY (IF AVAILABLE)

1. Date and Method of delivery (vaginal or cesarean)
2. Infant's sex, weight, health status
3. Complication of pregnancy and/or Labor and Delivery
  - a. Hemorrhage
  - b. Infection
  - c. Pregnancy-induced hypertension
  - d. Gestational diabetes
  - e. Premature rupture of membranes
  - f. Premature delivery
  - g. Other
4. Length of hospital stay

### OTHER CONCERNS


1. History of coitus since delivery and birth control method used.
2. Review when client may resume coitus and discuss associated fears
3. Knowledge of breast care/presence of breast engorgement
4. Infant feeding choice/concerns/immunizations/referral
5. Postpartum depression signs or symptoms
6. Bladder and bowel function
7. Support and help at home
8. Sleep patterns and rest
9. Resolution of lochia, onset of menses
10. Current medication
11. Status of episiotomy, or abdominal incision
12. Contraceptive plans and reproductive life planning
13. Intimate violence screening and education
14. Tobacco screening and counseling
15. Folic Acid supplementation
16. Infant care (with a focus on safety and shaken baby prevention)



## **INITIATE CONTRACEPTIVE METHOD ACCORDING TO PROTOCOLS**

### **INITIATE APPROPRIATE REFERRALS**

If abnormalities are noted, order appropriate testing and/or refer to appropriate provider.  
Refer to home visitation program in your community when available.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Post-Termination Visit	<b>NUMBER:</b>  <b>306</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014			

## POST-TERMINATION VISIT

### (UP TO SIX (6) WEEKS)

Abortion services are not a part of Title X Services. Ideally, the post abortion examination will be provided by the facility that performed the procedure, and should include a negative pregnancy test.

1. **NEW** post-abortion client, initiate initial visit protocol counseling.
2. **REVISIT** post-abortion client, initiate annual visit protocol, counseling
3. If current with annual exam need only a pelvic exam

### ADDITIONAL HISTORY COMPONENTS TO BE OBTAINED


1. Type of abortion: elective (surgical or medical), therapeutic or spontaneous
2. Gestational age at time of abortion
3. Presence of pregnancy symptoms
4. Results of pregnancy test performed this visit (pregnancy test may be positive if less than 4 weeks post abortion)
5. History of post-abortion complications:
  - a. Excessive vaginal bleeding
  - b. Nausea
  - c. Abdominal tenderness
  - d. Fever > 38 degrees C (100.4 degrees F)
6. Current medication status
7. Sexual history: history of intercourse since abortion (protected or unprotected)
8. Feelings about abortion

### REASSESS CURRENT CONTRACEPTIVE NEEDS

Past method/user satisfaction/ method failure  
 Reproductive life plan counseling  
 Education about all method options

### INITIATE APPROPRIATE REFERRALS

If abnormalities are discovered, order appropriate testing and/or refer to appropriate provider.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Problem Visit	<b>NUMBER:</b>  <b>307</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Women's Preventive Services Initiative "Recommendations for Well-Woman Care, A Well Woman Chart" HRSA, 2019.			

## PROBLEM VISIT

### REASON FOR VISIT

Obtain the purpose of the visit, chief complaint, and/or additional health concerns prompting the desire for health care.

### UPDATE THE FOLLOWING HISTORIES

1. Obstetrical
2. LMP
3. Medical
4. Gynecological
5. Allergy history
6. Family history
7. Contraceptive history
8. Sexual history
9. Psychosocial history

### ANALYZE SYMPTOM(S):

#### Onset:

1. Date of onset
2. Manner of onset
3. Precipitation and predisposing factors related to onset

#### Characteristics of pain:

1. Character (quality, quantity, consistency)
2. Location and radiation
3. Intensity or severity
4. Timing
5. Aggravation and/or relief factors
6. Associated symptoms

#### Course since onset:

1. Incidence
2. Progress
3. Effect of therapy

#### Unusual discharge/bleeding

1. Amount
2. Timing
3. Character (quality, quantity, consistency)
4. Aggravation and/or relief factors
5. Associated symptoms

**REVIEW**

Clinic routine and exam procedures and stress importance of follow-up care, if indicated.

**ELICIT CLIENT'S OPINION**

Elicit client's opinion about the cause and continuation of problem.


**REASSESS CONTRACEPTIVE STATUS AND REPRODUCTIVE LIFE PLAN (AS APPROPRIATE)****PHYSICAL ASSESSMENT AS INDICATED**

Order appropriate testing or refer to appropriate provider

**TREATMENT**

Treat as indicated using clinic protocols.

**INITIATE APPROPRIATE REFERRALS AND/OR FOLLOW UP**

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Initial Visit (Male Client)	<b>NUMBER:</b>  <b>308</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; United States National Institutes of Health; National Cancer Institute <a href="http://www.cancer.org">http://www.cancer.org</a> ; The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP); QFP, 2014; <a href="https://www.fpnctc.org">https://www.fpnctc.org</a>			

### INITIAL VISIT - MALE CLIENT

Men may accompany their partners who are clients to the clinic, or they may come to the clinic as clients. Sexually experienced males are twice as likely as non-experienced males to have received information about birth control, but only one-third of those males have actually received counseling on this topic.

Research shows that young men recognize unintended pregnancy, STDs and HIV/AIDS as serious problems and acknowledge that prevention is a joint responsibility. Experience has also shown that drawing males into family planning and reproductive health information and services programs requires approaches that focus on their unique needs. Males, as well as females, need to be offered services in culturally competent ways and in ways that serve the total individual.

Remember that accidents, suicides and homicides are the leading cause of mortality in males aged 10 to 24.

Counseling and referral for sterilization, infertility studies, and provision of birth control methods, HPV and other immunizations are provided if appropriate.

#### HISTORY – (REFER TO APPENDIX FOR SAMPLE OF MALE HISTORY FORM)

1. Reason for visit
2. Medical history, including allergies and anything that may impair his reproductive health
3. Surgeries
4. Family History, including genetic history
5. Social History, including smoking, alcohol and substance use, nutrition and weight history
6. Immunizations (HBV, HPV, Meningococcal vaccine. Discuss Tdap vaccine, especially if around newborns)
7. Current medications
8. Sexual history and sexual health assessment (including gender of partner, pregnancy prevention, number of partners, IV drug use, STI exposure, sexual difficulties)
9. Pregnancy and fatherhood status, previous unexpected pregnancy outcomes
10. Psychosocial/mental health history
11. STDs/HIV/Hepatitis/Genital lesions
12. Assess for safety (see Counseling and Education)

#### CURRENT COMPLAINTS/REVIEW OF SYSTEMS (EXAMPLE)

1. Urinary symptoms such dysuria, frequency, nocturia, hematuria,

2. Painful ejaculation or problems with sexual function
3. Urethral discharge
4. Rash, pruritus, lesions

## **PHYSICAL EXAM**

While a BP, height, weight and BMI are always indicated, the remainder of the PE should be performed only as indicated by purpose of visit and age of the client. For adolescent males, examination of the genitals should be conducted. This includes documentation of normal growth and development and other common genital findings, including hydrocele, varicocele and signs of STDs. Components of this exam include inspecting skin and hair, palpating inguinal nodes, scrotal contents and penis and inspecting the perianal region (as indicated).

1. BP
2. Height and Weight (BMI)
3. Extremities
4. Skin
5. HEENT
6. Thyroid
7. Lungs
8. Heart
9. Breast
10. Abdomen
11. Back
12. Genital Exam- for adolescent males
13. Inspection
14. Tanner stages as indicated
15. Circumcised or uncircumcised
16. Testes location (left testicle is usually lower than right in the scrotum)
17. Rashes, vesicles, lesions
18. Inspection of the urethral meatus
19. Palpation
20. Inguinal nodes
21. Hernia
22. Testicles for masses
23. Epididymis for tenderness
24. Rectal exam:
25. Inspection for lesions or vesicles
26. Hemorrhoids
27. Fissures
28. Digital exam; tenderness of the prostate gland
29. No standard age to begin –start at age 50 in men of average risk.

## **COUNSELING/EDUCATION:**

Counseling and education efforts for males includes an exploration of the following:

1. Safety; firearm safety, bullying (in appropriate age groups), intimate partner violence
2. Education
3. Employment
4. Health Promotion, immunizations
5. Affiliations
6. Tobacco
7. Substance and alcohol use
8. Living situation
9. Mental health, suicide, depression, anger management, rage

10. Reproductive Life Plan and preconception counseling, infertility, sexual health and function
11. Condom use
12. STI/HIV risk reduction and HPV Vaccine
13. Pregnancy prevention, including male and female methods and emergency contraception
14. Sexual health and relationships

### **INSTRUCTION ON SELF-EXAM FOR TESTICULAR CANCER**

Some doctors recommend that men ages 15 to 40 perform monthly testicular self-examination. But this is controversial. Many doctors do not believe monthly TSE is necessary for men at average risk of developing testicular cancer. Monthly TSE may be recommended for men at high risk of developing testicular cancer. This includes men with a history of an undescended testicle or a family or personal history of testicular cancer.

### **COUNSELING FOR ADOLESCENT MALES MUST ALSO INCLUDE:**

1. Abstinence
2. Safer Sex Practice Options
3. Resisting sexual coercion
4. Confidentiality of services
5. Family Involvement/Participation

### **LABORATORY TESTS AS INDICATED BY PURPOSE OF VISIT, CDC GUIDELINES AND RISK STATUS**

1. Chlamydia
2. Gonorrhea
3. HIV
4. Syphilis
5. Hepatitis C
6. Diabetes

### **INITIATE APPROPRIATE REFERRALS**


If abnormalities are noted, order appropriate testing and/or refer to appropriate provider

### **RESOURCES**

Engender Health. 2008. Introduction to men's reproductive health services—

Revised edition: Trainer's resource book. New York.

Preventive Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice, Arik V. Marcell, MD, MPH et al, 2014 at [www.maletrainingcenter.org](http://www.maletrainingcenter.org) September 11, 2014.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Periodic Health Assessment - Male Client	<b>NUMBER:</b>  <b>309</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b> Policies 301, 302, 308, and 320	
	<b>Authority:</b> IAC 641-74; United States National Institutes of Health; National Cancer Institute <a href="http://www.cancer.org">http://www.cancer.org</a> ; The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP); ; QFP, 2014; <a href="https://www.fpnctc.org">https://www.fpnctc.org</a>			

## PERIODIC HEALTH ASSESSMENT -MALE CLIENT

### HISTORY

Update the initial history

1. Medical history, including immunizations
2. Nutrition and weight changes
3. Family history
4. Allergy history
5. Contraceptive history
6. Sexual history, including STIs
7. Psycho-social history
8. Social History, including safety
9. Review current medication intake
10. Review smoking/alcohol/drug abuse
11. Pregnancy – has he fathered any children since his last visit to the clinic?

### ASSESS CONTRACEPTIVE NEEDS

1. Review knowledge, correct use, and compliance of current method of birth control
2. Review client's acceptance of method
3. Review side effects and warning signs related to current method of choice as indicated

### PERFORM THOROUGH CHART REVIEW

Include assessment of past/current lab (including routine and exam procedures).

### REVIEW CLINIC ROUTINE AND EXAM PROCEDURES

### PHYSICAL ASSESSMENT

Reference Policy 308

### LABORATORY EXAMINATIONS AS INDICATED

### REVIEW STD/HIV RISKS AND PREVENTION OF STDS/HIV; PROVIDE HPV VACCINE AND OTHER VACCINATIONS AS INDICATED

### COUNSELING AND EDUCATION

Counseling and education efforts for males includes an exploration of the following:

1. Safety; firearm safety, bullying (in appropriate age groups), Intimate partner violence
2. Education
3. Employment



4. Health Promotion, immunizations
5. Affiliations
6. Tobacco
7. Substance and alcohol use
8. Living situation
9. Mental health, suicide, depression, anger management, rage
10. Reproductive Life Plan and preconception counseling, infertility, sexual health and function
11. Condom use
12. STI/HIV risk reduction and HPV Vaccine
13. Pregnancy prevention, including male and female methods and emergency contraception
14. Sexual health and relationships

**Instruction on self-exam for testicular cancer**

Some doctors recommend that men ages 15 to 40 perform monthly testicular self-examination. But this is controversial. Many doctors do not believe monthly TSE is necessary for men at average risk of developing testicular cancer. Monthly TSE may be recommended for men at high risk of developing testicular cancer. This includes men with a history of an undescended testicle or a family or personal history of testicular cancer.

**Counseling for Adolescent Males must also include:**


1. Abstinence
2. Resisting sexual coercion
3. Family Participation

**INITIATE APPROPRIATE REFERRALS**

If abnormalities are noted, order appropriate testing and/or refer to appropriate provider

**RESOURCES**

Preventive Male Sexual and Reproductive Health Care: Recommendations for Clinical Practice, Arik V. Marcell, MD, MPH et al, 2014 at [www.maletrainingcenter.org](http://www.maletrainingcenter.org) September 11, 2014.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Oral Contraceptive Refill Visit	<b>NUMBER:</b>  <b>310</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b> Policies 301, 302, 308, and 320		
	<b>Authority:</b> IAC 641-74;Contraceptive Technology, 19 <sup>th</sup> edition; ; QFP, 2014			

## ORAL CONTRACEPTIVE REFILL VISIT

### NEW CLIENTS

Clients on new methods should be monitored after 3 months. A new client who chooses to continue a method already in use may choose not to return for this early revisit unless a need for re-evaluation is determined on the basis of the findings of the initial visit. Oral contraceptive (OCP) refill counseling is provided in a structured interview session. It incorporates the following areas routinely but is not necessarily limited to:

1. A brief update of LMP, obstetrical, contraceptive, gynecological and medical histories, and current use of medications, or changes in smoking habits.
2. An assessment of the client's correct utilization of the method, satisfaction with the method, and knowledge of how to make up missed OCP's.
3. A review of minor side effects and provisions of counseling appropriate to resolution/relief if a problem is identified.
4. Screening for symptoms of serious, possibly life threatening complications and appropriate referral of the identified problem, including:
  - a. Shortness of breath
  - b. Severe chest pain
  - c. Severe, persistent headaches
  - d. Visual disturbances (double vision-blurring)
  - e. Severe pain, redness or numbness in extremity
  - f. Hypertension
  - g. Acute abdominal pain


### REFILL COUNSELING

Sessions vary with the individual client, usually numbering one to four visits per year. Established clients may receive a one-year supply of OCP's (from the date of the annual visit) in the absence of contraindication or a provider identified need for increased surveillance.

### BLOOD PRESSURE AND WEIGHT (BMI)

Are checked. Other laboratory tests as indicated. Review results of last laboratory tests.

### UPDATE INFORMATION ON PREVIOUS REFERRALS

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Intrauterine Device Check Visit	<b>NUMBER:</b>  <b>311</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-74, Contraceptive Technology, 19 <sup>th</sup> edition; QFP, 2014			

## INTRAUTERINE DEVICE (IUD) CHECK VISIT

### AN “IUD CHECK”

Is routinely performed 4-8 weeks following insertion, but clients are encouraged to call for a follow-up appointment at any time if they suspect the Intrauterine Device (IUD) has been expelled, partially expelled, or if the client identifies any other IUD related problem.

### IDENTIFY THE TYPE OF IUD

Identify the expected replacement date, if appropriate. Remind the client of the replacement date.

### REVIEW THE FOLLOWING

1. LMP (amount and length of flow)
2. Sexual concerns and satisfaction with IUD.
3. History of STDs

### ASSESS THE CLIENT’S UTILIZATION OF THE IUD

1. Review the technique for checking IUD strings following menses and reinforce the importance of periodic self-checks.
2. Assess the client and partner’s acceptance of the IUD as her contraceptive method.
3. Reinforce instructions regarding the need for follow-up care in the following circumstances:
  - a. Strings not felt
  - b. IUD expelled/partially expelled
  - c. Partner complaining of feeling strings during coitus

### REVIEW POSSIBLE SIDE EFFECTS:

1. Dysmenorrhea
2. Menorrhagia
3. Dyspareunia
4. Vaginal discharge
5. Intermenstrual bleeding (after 1st 3 months of use)
6. Amenorrhea, metorrhagia

### REVIEW THE WARNING SIGNALS

For the IUD and reinforce the need to call clinic or report to physician if any of the following should occur:

1. Fever/chills
2. Severe cramps/abdominal pain
3. Foul smelling vaginal discharge
4. Amenorrhea (if not progesterone containing)
5. Intermenstrual bleeding/spotting


6. Unusually heavy bleeding or cramping with menses
7. Absence of strings
8. Positive pregnancy test
9. Subjective signs or concerns about pregnancy

**REMINDERS**

Reinforce the need for continued screening and pelvic exams, as indicated, even though she may have an effective birth control method for many years.

**VITAL SIGNS**

Blood Pressure and weight are checked as indicated. Other lab procedures may be done according to need, i.e., pregnancy test for amenorrhea, Hgb and/or Hct for menorrhagia, STD screen.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Intrauterine Device Removal Visit	<b>NUMBER:</b>  <b>312</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; QFP, 2014			

## INTRAUTERINE DEVICE (IUD) REMOVAL VISIT

An IUD Is removed at the client's request or when there is a medical indication to do so. If the removal is elective, it is recommended that it be performed during menses, although this is not mandatory.


### IF CLIENT DESIRES REMOVAL OF THE IUD DEVICE

1. Obtain and document the reason for the request (seeking pregnancy, partner's request, pain/discomfort, increased menses or dysmenorrhea, etc.)
2. If client requests removal for reason other than seeking pregnancy, offer counseling regarding:
  - a. Available methods of contraception
  - b. How to initiate chosen method
3. Counsel client regarding exam technique utilized to remove IUD
4. Notify client before removing the device
5. Counsel client regarding possibility of dysmenorrhea and increased bleeding for the first 1-3 cycles after removal of device, depending on the type of the IUD. Discuss resumption of normal menses.
6. Suggest measure to alleviate and discomfort
7. Assess the need for other methods of contraception

### REFER TO PHYSICIAN AS INDICATED

### VITALS SIGNS

Blood Pressure is obtained routinely on all clients in for IUD removal. Height, weight and BMI are also recommended. Other lab may be performed as indicated, i.e. pregnancy test, Hgb and/or Hct, or urinalysis.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Health Promotion		<b>SUBJECT:</b> Reproductive Life Plan, Preconception Assessment and Counseling	<b>NUMBER:</b>  <b>313</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b> Policies 350, 301, and 302	
	<b>Authority:</b> IAC 641-74; ACOG Committee Opinion No. 313, 2005; CDC MMWR 4/21/06; QFP, 2014;			

## REPRODUCTIVE LIFE PLAN, PRECONCEPTION ASSESSMENT AND COUNSELING

Preconception assessment and counseling are useful tools not only for clients planning to become pregnant, but also for men and women in promoting their own health. Preconception assessment and counseling should be part of every person of reproductive age's health care at least annually.

At initial, annual, pregnancy testing, STI, and postpartum visits the client, even though not planning to become pregnant, will be counseled about developing a reproductive life plan. A reproductive life plan is a set of goals about having or not having children. Because the reproductive capacity of individuals spans almost four decades, optimizing health before and between pregnancies requires the full participation of all segments of health care. Part of the reproductive life plan includes goals to improve personal health. Individuals should be reminded of the fact whenever one is sexually active, the possibility of pregnancy must be considered.

If a woman/couple has had an unexpected pregnancy outcome, like preterm birth, a discussion of potential lifestyle changes, pregnancy spacing issues and helping them to access any health care services needed between pregnancies will be important to helping avoid another unexpected/adverse outcome.

### PRECONCEPTION ASSESSMENT ADDRESSES THE FOLLOWING AREAS:

1. Family History
2. Genetic History, including indications for referral: family history of a genetic condition, birth defect or chromosomal disorder, a woman who plans to become pregnant at 35 years or older, an increased risk of passing on a genetic disorder because of one's ethnic background, or people related by blood who want to have children together
3. Medical History, including prescription and non-prescription medications
4. Immunization History
5. Reproductive History including pregnancy losses, stillbirth, or a baby who died, a child with a known inherited disorder, birth defect, or intellectual disability,
6. Social History, Intimate Partner Violence
7. Mental Health History and screening
8. Nutrition and folic acid supplementation
9. Substance Use History (including drugs, alcohol and tobacco)
10. Occupational/Environmental Exposure
11. Exercise/Activity
12. Sexual health assessment including STI and HIV screening as appropriate
13. Height, weight and BMI

14. Blood pressure assessment
15. Education for risk factor for Type II Diabetes, screening can be provided on site or by referral
16. Reproductive Life Plan


### **THE REPRODUCTIVE LIFE PLAN**

A reproductive life plan (RPL) should include a discussion of whether a client is planning to parent, what actions can be taken to prevent that from happening before they are ready, and what steps can be taken to protect their fertility. Clients might be encouraged to think about things like:

1. Do you plan to have a child in the next year or two?
2. Where do you see yourself in five years?
3. Do you want to be a parent one day?
4. If no, what will you do to prevent pregnancy?
5. If yes, how old do you want to be when you have your first child? How many children do you want? How far apart would you like them to be?
6. Have you discussed this with your partner?
7. Have you discussed this with your parents?
8. How do you plan ahead financially to be a parent? What kinds of things do you need to think about?
9. What are your plans after finishing school?
10. If you experience a pregnancy before you are ready, what will you do?
11. What can you do to keep from getting pregnant before you are ready? What will you do to keep from getting pregnant before you are ready?
12. What rewards and sacrifices do you think you might have as a result of being a parent?
13. Do you think there are things you can do now to help you achieve your parenting goals some day? I.e. avoid STI's, diet, exercise, substance use and smoking, update vaccinations, learn family history. These are opportunities for improving health
14. Are there things you can do to get ready to have a healthy pregnancy when you are ready? i.e. deal with emotional and physical well-being, manage depression, abuse, stress, avoid or quit smoking, diet, exercise, avoid alcohol and substance use
15. Provide information about the impact social, environmental, medical, behavioral, genetic and occupational factors may have on pregnancy outcome

### **RESOURCES:**

- <http://www.cdc.gov/ncbddd/preconception/QandA.htm>
- <http://www.marchofdimes.com/> click "Before pregnancy"
- [http://www.health.state.ut.us/rhp/pdf/RPL\\_Adult.pdf](http://www.health.state.ut.us/rhp/pdf/RPL_Adult.pdf)
- <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5506a1.htm>
- <http://beforeandbeyond.org/toolkit/>

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Health Promotion		<b>SUBJECT:</b> One Key Question	<b>NUMBER:</b>  <b>314</b>		
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019			
	<b>Status:</b>				<b>Cross Reference:</b>	
	<b>Authority:</b> PHSA 42; CFR Part 59; IAC 641-74; ACOG Committee Opinion No. 313, 2005; CDC MMWR 4/21/06; OPA FP Program Priorities; QFP, 2014; Program Requirements for Title X Funded FP Projects, 2014;					

## ONE KEY QUESTION

Preconception assessment and counseling are useful tools not only for clients planning to become pregnant, but also for men and women in promoting their own health. Preconception assessment and counseling should be part of every person of reproductive age's health care.

Power to Decide One Key Question® (OKQ) provides a framework to start a conversation with clients about if, when, and under what circumstances women or partners want to get pregnant and have a child. Providers utilizing the OKQ framework receive training to ensure they provide person-centered counseling, are responsive to clients' cultural, religious, and personal values and preferences, are aware of and have addressed personal biases that may impact client care, are respectful of a range of pregnancy intentions, ensure clients are aware of all reproductive health services, and ensure all client choices are free of coercion.

## PROCESSES

Clients will be asked the question "do you want to become pregnant in the next year?" and given the following options for a response: "Yes", "No", "Unsure", or "Ok either way". Based on the client's response, the provider will use the Clinical Algorithm tool to provide preconception/interconception or contraception counseling and care or a combination of both.

All clients will be asked OKQ at all client visits, with the following exceptions outlined below:

<b>Situation</b>	<b>When to ask OKQ</b>
Clients who have had a hysterectomy, bilateral oophorectomy, are naturally or prematurely menopausal, or sterilization	Never
Clients who are abstinent and accessing services for reasons other than preventing pregnancy	Revisit annually or if the client reports a change
Frequent access clients – those accessing STD screenings or other services weekly or bi-weekly	Every 3 months at a minimum

## COUNSELING, EDUCATION, AND CARE

Based on the client's response, provide the following counseling, education, and care. This is based on the One Key Question Clinical Algorithm©.

### Client responds "yes"

1. Counseling/education:



- a. When would you like to become pregnant? (if client is not trying to get pregnant immediately, assess for birth control use and consider contraceptive counseling)
  - b. Can we talk about some simple ways to prepare for a healthy pregnancy?
- 2. Preconception/interconception care:
  - a. Prescribe or dispense a multivitamin with folic acid
    - i. Note that it is important to begin taking folic acid 1-3 months before getting pregnant
  - b. Recommend at least 18 months between a birth and the next pregnancy
  - c. Review medications
  - d. Screen for and manage chronic conditions
  - e. Evaluate drug/alcohol/smoking risks
  - f. Identify support system
  - g. Assess for safety/violence
  - h. Recommend healthy diet, daily exercise, plenty of sleep, stress reduction
  - i. Screen for STIs, toxins and other exposures in the home or at work, and dental status

**Client responds “no”**

- 1. Counseling/education:
  - a. Are you currently using a birth control method?
  - b. How is this method working for you?
  - c. How important is it to you to prevent a pregnancy?
  - d. What is most important to you in a birth control method?
- 2. Contraceptive care:
  - a. If the patient is satisfied with their method, no other care is needed
  - b. Recommend birth control methods based on patient’s response to questions
  - c. Evaluate for correct and consistent use
  - d. Provide full range of contraceptive methods onsite or through referral
  - e. Offer emergency contraception

**Client response “unsure” or “ok either way”**

Note it is not the provider’s responsibility to resolve the client’s ambivalence or change their belief.

- 1. Counseling/education:
  - a. Do you want to have (more) children in the future? If yes, when might that be?
  - b. How would you feel if you found out you were pregnant today?
  - c. How important is it to you to prevent a pregnancy now?
  - d. Are you currently using a birth control method? How is this method working for you?
  - e. Can we talk about some simple ways to prepare for a healthy pregnancy?
- 2. Preconception/interconception/contraceptive care – based on client responses
  - a. Preconception/interconception care:
- 3. Prescribe or dispense a multivitamin with folic acid
  - a. Note that it is important to begin taking folic acid 1-3 months before getting pregnant
- 4. Recommend at least 18 months between a birth and the next pregnancy
- 5. Review medications
- 6. Screen for and manage chronic conditions
- 7. Evaluate drug/alcohol/smoking risks
- 8. Identify support system
- 9. Assess for safety/violence
- 10. Recommend healthy diet, daily exercise, plenty of sleep, stress reduction
- 11. Screen for STIs, toxins and other exposures in the home or at work, and dental status


12. Contraceptive care:
13. If the patient is satisfied with their method, no other care is needed
14. Recommend birth control methods based on patient's response to questions
15. Evaluate for correct and consistent use
16. Provide full range of contraceptive methods onsite or through referral
17. Offer emergency contraception

**Documentation**

Document specific client responses and details on counseling provided in the EHR. Document client response in the IDPH Title X database under "Plan Type" and indicate which counseling type was provided (preconception, contraceptive, or both).

**RESOURCES:**

- <http://www.cdc.gov/ncbddd/preconception/QandA.htm>
- <http://www.marchofdimes.com/> click "Before pregnancy"
- [http://www.health.state.ut.us/rhp/pdf/RLP\\_Adult.pdf](http://www.health.state.ut.us/rhp/pdf/RLP_Adult.pdf)
- <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5506a1.htm>
- <http://beforeandbeyond.org/toolkit/>

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Abnormal Conditions		<b>SUBJECT:</b> Pap Smear and Pelvic Exam	<b>NUMBER:</b>  <b>315</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b> Policies 316, and 320	
	<b>Authority:</b> IAC 641-74, ASCCP Consensus Guidelines 2012; QFP, 2014 ACOG Committee Opinion on the Utility and Indications for Routine Pelvic Exam, 754, 2018  US Preventive Services Task Force   EVIDENCE REPORT August 2018.			

## PAP SMEAR AND PELVIC EXAM

### INITIATION AND TIMING OF CERVICAL CANCER SCREENING

Title X providers must use a nationally recognized standard of practice for cervical cancer screening. Acceptable standards include the American Congress of Obstetrics and Gynecology, US Preventive Services Task Force, ASCCP or the American Cancer Society. Agency healthcare providers who choose to implement guidelines that vary from national standards must have a policy in place referencing evidence based literature supporting their decision.

Women at any age should NOT be screened annually by any screening method; rather, recommended screening intervals for women are based on age and clinical history. Cytology screening should begin at age 21 years, regardless of the age of initiation of sexual activity with the exception of women who are HIV positive or who are otherwise immunocompromised.

Cervical cytology screening should be avoided before the age of 21 regardless of their sexual history or HPV vaccination, because it may lead to unnecessary and harmful evaluation and treatment procedures in women at very low risk of cancer. HPV testing should not be used for screening or management of ASC-US in this group. Human papillomavirus vaccination status does not change these cervical cytology screening recommendations.

The USPSTF recommends cervical cytology screening alone every 3 years for women between the ages of 21 and 29 years, regardless of their sexual history or HPV vaccination. Annual pelvic exams may still be indicated. HPV testing should not be used for screening in this age group.

For women aged 30 to 65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (HPV) testing alone, or every 5 years with HPV testing in combination with cytology (cotesting), regardless of their sexual history or HPV vaccination.

Patients at average risk (without immune-compromise or history of CIN grade 2 or higher) should start screening at age 21 with repeat cytology every 3 years between ages 21-65. End screening at age 65 for women with three consecutive negative cytology results or two negative results with negative high risk HPV tests within 10 years of screening cessation. The most recent test should have been performed within the last 5 years.

High-risk women (immune-compromised, prior CIN 2 results or higher) should start screening when sexually active or by 21 years if HIV positive. Otherwise, start at age 21. Thereafter, screen annually and extend to every three years if three tests are negative. From age 30

onward, perform cytology every year until three normal tests, then every three years or cytology plus high risk HPV testing every three years. Continue lifelong screening.

For women with DES exposure in utero, screen annually.

Women who have had removal of the cervix but have a history of CIN 2 or higher (or for whom no record is available) should be screened every three years until they have a 10-year history of no abnormal Pap smear results.

Do not screen women over 65 years of age with evidence of adequate negative prior screening and no history of CIN2 results or higher within the last 20 years should not be screened for cervical cancer with any modality. The USPSTF recommends against screening for cervical cancer in women older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.

Once screening is discontinued, it should not resumed for any reason, even if a woman reports having a new sexual partner. Following spontaneous regression or appropriate management of CIN2, CIN3, or adenocarcinoma in situ (AIS), routine screening should continue for at least 20 years (even if this extends screening past age 65).

### **SAMPLING TECHNIQUE**

1. Cells should be collected before the bimanual examination.
2. If testing for sexually transmitted diseases is indicated, cell collection for cervical cytology should be undertaken first.
3. Ideally, the entire os of the cervix should be visible when the sample is obtained

Conventional and liquid-based techniques are both acceptable, although the liquid-based method allows for reflex HPV DNA testing, thus eliminating the need for a return visit to evaluate some cytological abnormalities. Any advantages in terms of sensitivity and specificity are unclear.

### **POSSIBLE FINDINGS**

1. Negative for intraepithelial lesion or malignancy
2. Atypical squamous cells of undetermined significance (ASCUS)
3. Low-grade squamous intraepithelial lesions (LSIL)
4. High-grade squamous intraepithelial lesions (HSIL)
5. Atypical Squamous cells, cannot exclude HSIL (ASCH)
6. Atypical glandular cells
7. Adenocarcinoma in situ

The absence of endocervical cells or a transformation zone component on the cervical cytology sample may reflect that the transformation zone was not well sampled. This finding is common in pregnant women and in postmenopausal women in whom the transformation zone has receded onto the canal. Data conflict as to whether the lack of these cells is associated with an increase in squamous intraepithelial lesions. Women with this finding whose recent cervical cytology test results have been normal without intervening findings of ASC-US or worse may be monitored by repeat cervical cytology screening in 1 year. Others, including those with incompletely evaluated abnormal test results, incompletely visualized cervix, immunocompromised status, and poor prior screening, should have repeat cervical cytology screening within 6 months. Pregnant women lacking endocervical cells or transformation zone component should have repeat cervical cytology screening postpartum.

*Please see ASCCP Consensus Guidelines, ACOG recommendations or USPDTF guidelines on management of abnormal pap smears.*

## WHAT ABOUT HPV TESTING?

The American Society for Colposcopy and Cervical Pathology has issued these recommendations:

1. As HPV DNA testing becomes more widespread we need to remember that there are situations where high-risk HPV DNA testing and genotyping are NOT recommended. These include:
  - a. adolescents, defined as women 20 years and younger (regardless of their cytology results, if performed)
  - b. women 21 years and older with ASC-H, LSIL, or HSIL cytology (note: “reflex” HPV testing is acceptable in postmenopausal women with LSIL)
  - c. routine screening in women before the age of 30 years
  - d. in women considering vaccination against HPV
  - e. for routine STD screening
  - f. as part of a sexual assault workup
  - g. HPV genotyping is not recommended for women with AGUS
  - h. HPV genotyping is not recommended as the initial screening test for women 30 years and older.
2. It should also be recognized that there are situations where the 2006 Consensus Guidelines recommend limits on the frequency of HPV DNA testing to avoid over-testing and unnecessary treatment. When managing women with ASC-US it is recommended that HPV DNA testing not be performed at intervals of less than 12 months. In addition, women 30 years of age and older who are negative by both cytology and high-risk HPV DNA testing should not be rescreened (using either cervical cytology or HPV DNA testing) before 3 years.

## THE PELVIC EXAM

The pelvic examination serves multiple purposes, including the assessment of the vulva, vagina, cervix, uterus, and adnexa. Pelvic exams should be performed when indicated by medical history or symptoms.

Pelvic examination is not a routine part of the annual assessment in females aged 13–21 years, unless medically indicated.

Based on the current limited data on potential benefits and harms and expert opinion, the decision to perform a pelvic examination should be a shared decision between the patient and her obstetrician–gynecologist or other gynecologic care provider.

A limited number of studies have evaluated the benefits and harms of a screening pelvic examination for detection of ovarian cancer, bacterial vaginosis, trichomoniasis, and genital herpes. Data from these studies are inadequate to support a recommendation for or against performing a routine screening pelvic examination among asymptomatic, non-pregnant women who are not at increased risk of any specific gynecologic condition. Data on its effectiveness for screening for other gynecologic conditions are lacking.


Women with current or a history of cervical dysplasia, gynecologic malignancy, or in utero diethylstilbestrol exposure should be screened and managed according to guidelines specific to those gynecologic conditions.

After reviewing risks and benefits, the pelvic examination also may be performed if a woman expresses a preference for the examination.

Regardless of whether a pelvic examination is performed, a woman should see her obstetrician–gynecologist at least once a year for well-woman care.

A pelvic examination is not necessary before initiating or prescribing contraception, other than an intrauterine device, or to screen for sexually transmitted infections.

The QFP Guidelines, 2014 discuss the physical and laboratory assessment recommendations prior to initiating a birth control method (page 11-12).

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Protocols: Abnormal Conditions		<b>SUBJECT:</b> Abnormal Cervical Cancer Screening Test Results (excluding adolescents)	<b>NUMBER:</b>  <b>316</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date: July 2019</b>	
	<b>Status:</b>		<b>Cross Reference:</b> Policy 317	
	<b>Authority:</b> IAC 641-74; American Society for Colposcopy and Cervical Pathology Guidelines, 2012; QFP, 2014; ACOG Practice Bulletin No. 168, October 2016, Interim Update			

## ABNORMAL CERVICAL CANCER SCREENING TESTS

### (Excluding Adolescents)

Family planning agencies must implement policies that reflect current national standards of care for the management of abnormal cervical cancer screening tests. The national standards may include United States Preventive Services Task Force (USPSTF), American Congress of Obstetricians and Gynecologists (ACOG) or American Society for Colposcopy and Cervical Pathology (ASCCP).

The cervical cancer screening measure for cervical cancer, and as such is not diagnostic. **Abnormal results must be further evaluated.** The cervical cancer screening test is less than 50% effective in the identification of endometrial cancer. An endometrial tissue biopsy or some other diagnostic procedure would be necessary to identify endometrial cancer.

### RISK FACTORS

**Human Papilloma Virus infection (HPV):** HPV is a group of viruses that can infect the cervix. An HPV infection that doesn't go away can cause cervical cancer in some women. HPV is the cause of nearly all cervical cancers.

**Lack of regular Cervical Cancer Screening tests:** Cervical cancer is more common among women who don't have regular cervical cancer screening tests.

**Other factors may increase the risk of cervical cancer in women with HPV.** These include: smoking, immunocompromised, multiple sexual partners or having a male sexual partner with who has had multiple sexual partners., personal or family history of cervical dysplasia or cancer, early sexual debut, certain sexually transmitted infections (such as Chlamydia).

**DES (diethylstilbestrol):** DES may increase the risk of a rare form of cervical cancer in daughters exposed to this drug before birth. DES was given to some pregnant women in the United States between about 1940 and 1971. It is no longer given to pregnant women but is currently used in the treatment of prostate cancer and occasionally, breast cancer.

### TERMINOLOGY

There are multiple categories of epithelial cell abnormalities identified on cervical cancer screening test, including Unsatisfactory, atypical squamous cells (ASC), low- grade or high-grade squamous intraepithelial lesions (LSIL or HSIL), atypical glandular cell abnormalities (AGC), and adenocarcinoma in situ (AIS). The histological diagnosis of cervical cell abnormalities are reported as cervical intraepithelial neoplasia (CIN) categories from 1-3.

## DISCUSSION OF FOLLOW UP FOR ABNORMAL FINDINGS

A small risk of missing high grade CIN or cancer exists. Attempts to achieve zero risk may result in greater harm than good in the form of overtreatment.

New 2012 Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors were released in March of 2013. Essential changes include:

- It is now recommended that women with unsatisfactory cytology result have repeat cytology testing in 2-4 months, regardless of negative, unknown or no HPV results. Treatment to resolve atrophy or obscuring inflammation is acceptable.
- Women with negative cytology but lacking endocervical cells can be managed without early repeat cytology. In women over 30 years, HPV is preferred. If HPV is not performed, repeat cytology in 3 years is acceptable. If HPV is done and negative, return to routine screening.
- For women with negative cytology and positive HPV, repeat co-testing in 1 year or HPV genotyping are both acceptable.
- For women with ASC-US, immediate colposcopy is not an option. The serial cytology option for ASC-US incorporates cytology at 12 months, and if negative, a return to cytology every 3 years. More frequent cytology is not required at 6 and 12 months.
- HPV negative and ASC-US results are followed with co-testing at 3 years instead of 5 years.
- ASC-US and positive HPV triages the woman to colposcopy, regardless of genotype.
- Women ages 21-24 years are managed conservatively. In women ages 21-24, one may repeat the cervical cancer screening test at 12 months rather than go to immediate colposcopy for mild abnormalities (ASCUS and LGSIL).
- Genotyping for HPV 16 or 18 triages women to early colposcopy even with negative cytology.
- HPV-negative and ASC-US results are insufficient to allow exit from screening at age 65 years. HPV ASC-US results should be considered abnormal and continued surveillance is recommended. Repeat co-testing at 1 year is preferred, but cytology alone is acceptable.
- Immunosuppressed women with abnormal results should be managed in the same manner as immunocompetent women.
- AGUS findings on cancer screening are indication for referral and may require colposcopy and endometrial sampling to evaluate.
- CIN1 on endocervical curettage should be managed as CIN1, not as a positive ECC.
- Genotyping triages HPV positive women with HPV types 16 or 18 to colposcopy only if cytology is negative; colposcopy is indicated for all women with HPV positive results and ASC-US, regardless of genotyping result.



\*Please see the algorithm from the American Society of Colposcopy and Cervical Pathology presented as a resource to guide clinicians in appropriate follow up of abnormal test results. Other acceptable recommendations may include United States Preventive Services Task Force (USPSTF) and the American Congress of Obstetricians and Gynecologists (ACOG). Nurse practitioners and Physicians Assistants must consult with their medical director regarding policies for abnormal test result test management.

### **WHEN IS HPV TESTING APPROPRIATE?**


**HPV testing is not indicated in women less than 30 years of age.**

Although it is estimated that up to 100% of women with histological CIN 2 or CIN 3 will test positive for a high-risk type of HPV, many women harbor the virus in their lower genital tracts without showing cytological or histological changes.

The utility of HPV testing has been well demonstrated for the primary triage of cervical cytology tests read as ASC-US. In this setting, high-risk HPV DNA testing has been shown to have a sensitivity ranging from 78% to 96% for the detection of CIN 2 or CIN 3, with rates of referral for colposcopy ranging from 31% to 56%. The use of "reflex" HPV testing has been recommended as a convenient and cost-effective approach to evaluating ASC-US. The clinician may collect a sample for high-risk HPV DNA testing at the same time as cervical cytology screening and evaluate it only if the cytology is read as ASC-US. Reflex HPV testing may be done by testing from residual preservative if liquid-based cytology is used or by performing a separate HPV DNA test at the same time as cervical cytology and storing it for use if ASC-US is the result.

High-risk HPV DNA test results would be expected to be positive when cervical cytology results indicate HSIL, so the test has little utility in this setting. Likewise, up to 83% of women with LSIL diagnosed by cervical cytology have been shown to be positive for high-risk HPV types, thus limiting the usefulness of the test in this setting as well.

Another clinical setting in which HPV DNA testing may be useful is in the secondary triage of women with a cytological diagnosis of ASC-US, ASC-H, or LSIL in whom colposcopy is negative or biopsy fails to reveal CIN. A protocol of follow-up in 1 year with HPV DNA testing has been suggested as an alternative to repeat cytology in this group, with repeat colposcopy for those with positive test result.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Protocols: Abnormal Conditions		<b>SUBJECT:</b> Management of Abnormal Cervical Cytology - Adolescents	<b>NUMBER:</b>  <b>317</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b> Policy 314	
	<b>Authority:</b> IAC 641-74; ACOG Committee Opinion 436, 6/09; ACOG Committee Opinion 463, 8/10; OPA Program Instruction Series 4-09; QFP, 2014; Update of the 2003 U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for cervical cancer, ACOG Practice Bulletin 168, October 2016, Interim Update.			

## MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY RESULTS - ADOLESCENTS

### BACKGROUND INFORMATION

*Routine cervical cytology screening is not recommended in women under 21 years of age.* (Reference Policy 317). *If cervical cytology testing was completed for clinical indications, the following policy should apply.*

ACOG and the USPSTF recommend that cervical cancer screening should only begin at age 21, unless sexually active and: 1) HIV positive 2) Organ transplant recipient, or 3) Immuno-compromised. In these instances, begin testing yearly after diagnosis and extend to every three years after three tests are negative.

The management of abnormal cervical cytology in adolescents differs from that of the adult population. Cervical cancer is almost nonexistent in adolescents; yet human papilloma virus (HPV) infection is very common in this population. Natural history studies of adolescents with newly acquired HPV infection show that HPV usually becomes undetectable after an average of 8 months. In most adolescent patients with an intact immune system, 90% of HPV infections will resolve within 24 months.

The American Society of Colposcopy and Cervical Pathology guidelines now advise against HPV testing and recommend against treatment of low-grade squamous intraepithelial lesions or cervical intraepithelial neoplasia in adolescents. These new guidelines were established to minimize the potential negative impact that treatment can have on future pregnancy outcomes, while taking advantage of the natural history of HPV in young women.

Each agency must have a policy in place for management and follow up of abnormal cervical cytology results in adolescents. Women under 21 with normal cytological screening in the past should not be rescreened until 21 years of age.

### ABNORMAL CERVICAL CYTOLOGY RESULTS

ASC-US: Atypical squamous cells of undetermined significance

ASC-H: Atypical squamous cells, cannot exclude High grade squamous intraepithelial lesion

LGSIL: Low grade squamous intraepithelial lesion

HGSIL: High grade squamous intraepithelial lesion

AGC: Atypical glandular cells

## MANAGEMENT OF ABNORMAL FINDINGS

If cervical cytology screening is performed during adolescence for the three reasons indicated above, or screening occurred prior to the issuance of the recommendation not to perform screening on women under 21 (2010), follow-up is dictated by the Pap smear result:

- If no abnormality -No further testing is required till age 21
- If ASCUS or LSIL
  - Perform cervical cytology screening yearly for 2 years
  - If followed by two normal cervical cytology screens, can halt further testing until age 21
  - If ASC-US/LSIL persists for 2 years, colposcopy
  - If any single cervical cytology screening shows HSIL, colposcopy is indicated
- If ASC-H: Follow with a six month repeat screening
  - If negative x 2, no further testing until age 21
- If HSIL: refer for colposcopy with ECC

## SPECIAL CONSIDERATIONS


Pregnancy in adolescents does not alter screening and management of abnormal cytology. Endocervical curettage and excisional procedures should never be performed during pregnancy unless invasive cancer is highly suspected. Screening for pregnancy, therefore, should be performed before evaluation and management of abnormal cervical cytology in adolescents.

## CONSENT

Minors undergoing a colposcopic examination may find it helpful to have parental involvement for the procedure. However, colposcopic examinations are considered evaluation for sexually transmitted diseases (STDs), and minors generally are allowed to consent for diagnosis and treatment of STDs. For that reason, parental consent, although preferred, should not be required. If parental consent is not obtained, consent for the examination should be obtained from the minor and indicated in the medical record. Any health care provider who delivers such care should be fully informed of their state laws and established local standards of care. Even if the minor legally can consent, the law may not ensure confidentiality. Some states allow minors to consent for STD care, but give the health care provider discretion to disclose information to parents, particularly if it is necessary to protect the minor's health. Colposcopy, biopsy, and therapy for cervical dysplasia are likely to generate a bill, which can compromise confidentiality. These issues need to be considered when determining whether parental consent should be obtained, even if it is not legally required.

## SCREENING FOR SEXUALLY TRANSMITTED DISEASES

Having a non-HIV STI diagnosis is not an indicator for earlier cervical cytology screening. Because of high rates of STDs in adolescents, screening and treatment for Chlamydia trachomatis and Neisseria gonorrhea before treatment for abnormal cervical cytology is strongly recommended.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Protocols: Abnormal Conditions		<b>SUBJECT:</b> Abnormal Breast Findings	<b>NUMBER:</b>  <b>318</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; ACOG Practice Bulletin #122 "Breast Cancer Screening", 2011'; "Well-woman visit. Committee Opinion No. 534. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2012;120:421–424"; QFP, 2014; Risk Assessment, Genetic Counseling, and Genetic Testing for <i>BRCA</i> -Related Cancer, accessed 8/26/19 at <a href="https://jamanetwork.com/journals/jama/fullarticle/2748515">https://jamanetwork.com/journals/jama/fullarticle/2748515</a>			

## ABNORMAL BREAST FINDINGS

Despite a lack of definitive data for or against clinical breast exams, they do have the potential to detect previously undetected breast masses. Patients should be informed there is not enough evidence to balance the benefits and risks of screening. However, if a client presents with concerns, the following should be considered. If a client requests a clinical breast exam it should be performed. An August, 2019 USPSTF report recommends using an assessment tool (like the Ontario Family History Assessment Tool) for women with a personal or family history of breast, ovarian, peritoneal, or tubal cancer or those with ancestry associated with BRAC 1/2 (like Ashkenazi Jewish descent). Routine genetic assessment and testing is not indicated in women who don't meet the above criteria.

### ABNORMAL BREAST MASS

#### Subjective may include:

1. "Lump" felt on self-exam
2. Enlarging breast mass with no cyclic changes
3. Maternal history of breast cancer
4. History of nipple change, discharge or bleeding
5. Breast Pain
6. History of previous mastitis, papillomas or fibroadenomas
7. Recent postpartum breast-feeding

#### Objective: may include:

1. Uneven nipple line on breast exam
2. Palpable, fixed, unilateral, hard mass
3. Orange peel appearance
4. Unilaterally enlarged or tender axillary and/or supraclavicular lymph nodes
5. Galactorrhea
6. Nipple discharge
7. Reddened and/or warm heat area on breast
8. Pain on palpation
9. Fever > 38°C (100°F)

#### Assessment

Suspicious breast mass or mastitis

#### Plan

1. Order appropriate testing or refer to appropriate provider. If lesion is not suspicious and client is on oral contraceptives, may continue for 1-2 cycles pending evaluation.

2. Order appropriate testing or refer to appropriate provider. If lesion is suspicious discontinue combined oral contraceptive and offer alternate birth control method pending evaluation

**Patient education**

1. Stress importance of immediate follow-up evaluation
2. If mastitis is suspected, instructions include:
  - a. Use heat to area
  - b. Continue nursing or use breast pump if breastfeeding
  - c. Rest and hydration
  - d. Complete course of antibiotics if ordered
  - e. Good hygiene and attentive breast care

**FIBROCYSTIC BREAST DISEASE****Subjective: may include:**

1. Increased "lumpiness" of breasts
2. Multiple masses (may or may not be cyclic)
3. Breast tenderness

**Objective**

Multiple, non-fixed masses, usually bilateral

**Plan**

Order appropriate testing or refer to appropriate provider.

**Alternative treatment**

Recheck after menses if patient is premenstrual and exam is suspicious

**Patient education**

1. Reinforce self-breast exam as desired
2. Stress importance of follow up
3. Advise patient of the following:
  - a. Consider limiting or eliminating caffeine if symptoms are associated, although medical studies of caffeine's effect on breast pain and other premenstrual symptoms have been inconclusive.
  - b. Heat or cold compresses may decrease pain
  - c. Breasts should be well supported
  - d. Mild analgesics may be helpful
  - e. Wear a firm support bra, fitted by a professional if possible.
  - f. Wear a sports bra during exercise and while sleeping, especially when your breasts are extra sensitive.
  - g. Decrease the fat in your diet to less than 20 percent of total calories, which may decrease breast pain or discomfort associated with fibrocystic breasts

**GALACTORRHEA****Subjective: may include:**

1. Nipple discharge, bilateral or unilateral
2. History of recent pregnancy
3. History of recent use of:
  - a. Marijuana
  - b. Tranquilizers and antipsychotics (e.g.: Phenothiazines such as Chlorpromazine, Thioridazine, Trifluoperazine, Thiothixene Hcl; and Haloperidol)
  - c. Tricyclic antidepressants (e.g.: Amitriptylines, Tofranil)
  - d. Narcotics (e.g.: Morphine, Codeine, Methadone)
  - e. Antihypertensives (e.g.: Methyldopa, Reserpine. Verapamil)

- f. Oral contraceptives/Depo Provera
  - g. Cimetidine, metoclopramide
- 4. History of breast stimulation
- 5. Recent change in headache patterns
- 6. Recent change in peripheral vision
- 7. Symptoms of hyperthyroidism, acromegaly, Cushing's Syndrome

## **OTHER BREAST DISCHARGE**

### **Subjective: may include:**

- 1. Bloody, purulent or greenish discharge, bilateral or unilateral
- 2. History of breast stimulation
- 3. History of pain or redness
- 4. History of fever
- 5. History of previous ductal papillomas or other

### **Objective: may include:**


- 1. Bilateral or unilateral bloody or purulent discharge
- 2. Reddened and/or warm area on breast
- 3. Pain on palpation

### **Assessment**

Other breast discharge

### **Plan**

Order appropriate testing or refer to appropriate provider.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Protocols: Health Promotion		<b>SUBJECT:</b> Colorectal cancer screening (CRC)	<b>NUMBER:</b>  <b>319</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> Public Health Service Act 45 CFR Part 59; IAC 641-74: QFP, 2014; <a href="https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/colorectal-cancer-screening2">https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/colorectal-cancer-screening2</a> , accessed July 2019			

## COLORECTAL CANCER SCREENING (CRC)

### BACKGROUND INFORMATION

Colon cancer is the second most common cancer killer overall and the third most common type of cancer in the US, in both males and females. Screening means looking for cancer or polyps when no symptoms are present. Sub-recipient agencies will either offer annual fecal testing to appropriate clients with a sensitive screening method or refer for testing, according to national standards of care. Most colon and rectal cancers arise from benign polyps. Not all polyps have the potential to become cancerous. Early identification of polyps reduces CRC mortality in persons aged 50-75.


### SCREENING RECOMMENDATIONS

Beginning at age 50, both men and women at *average risk* for developing colorectal cancer should use one of the screening tests below. Screening for African American persons should begin at age 45 because of the high incidence of CRC and a greater prevalence of proximal or right-sided polyps and cancerous lesions in this population. Screening should continue until 75 years of age.

### EARLIER SCREENING IS INDICATED IF THE CLIENT HAS:

- A close relative with colorectal polyps or colorectal cancer;
- Client has an [inflammatory bowel disease](#) such as Crohn's disease or ulcerative colitis;
- Client has a genetic syndrome such as [familial adenomatous polyposis \(FAP\)](#), [external](#) or [hereditary non-polyposis colorectal cancer \(Lynch syndrome\)](#).

Young adults are being diagnosed and dying more from colon cancer. Potential risk factors include genetic diseases, obesity, diet, smoking and ulcerative colitis. Studies show that younger people are more likely to be diagnosed with late-stage colorectal cancer because they assume their symptoms are due to something less serious. While the symptoms are vague any changes in bowel function or pain should be assessed. The symptoms include abdominal pain, blood in the stool, constipation, diarrhea, decreased appetite or weight loss.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Problems		<b>SUBJECT:</b> Amenorrhea	<b>NUMBER:</b>  <b>320</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-74; Guidelines 8.5, 8.6; Speroff, L. Clinical Gynecologic Endocrinology and Infertility, 2005; QFP, 2014			

## AMENORRHEA

### BACKGROUND INFORMATION


Amenorrhea is the absence of menstruation. Primary amenorrhea refers to the absence of menstrual periods by age 16. Clients with primary amenorrhea should be referred to a physician for evaluation. Secondary amenorrhea occurs when a woman was previously menstruating, but then stopped having periods for an equivalent of three previous cycle intervals or for six months. In sexually active women, pregnancy is the most likely reason for missed periods.

### SCREENING RECOMMENDATIONS

If amenorrhea is accompanied by a negative pregnancy test, clinicians should consider other causes for the absence of menses. Clinicians may choose either to refer clients with secondary amenorrhea to another provider or clinic for evaluation or initiate evaluation. The evaluation of amenorrhea is not a Title X service except for pregnancy diagnosis. Clients who are referred must be made aware of the importance of follow up care to their long term health.

If initial evaluation is undertaken in the family planning clinic, a policy agreed upon by the ARNP/PA and medical director must be in place, including indications for referral.



  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Health Promotion		<b>SUBJECT:</b> Reproductive Health Screening	<b>NUMBER:</b>  <b>321</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>	<b>Cross Reference:</b> Policies 301,302, 308, 309, 314, 316, and 317		
	<b>Authority:</b> IAC 641-74; ACOG Committee Opinion #179; July 2017; QFP, 2014; US Preventative Task Force, 2018;			

## REPRODUCTIVE HEALTH SCREENING

At the initial and annual visit the health professional needs to review with the client the importance of routine health screening. These screens are not only for reproductive health but also for health in general. The purposes of periodic health screening include:

1. Screen for diseases or infections, including sexually transmitted infections
2. Assess risk of future medical problems
3. Encourage a healthy lifestyle including a discussion of: exercise, nutrition, smoking cessation and substance use avoidance, avoiding risky behaviors and disease prevention
4. Update vaccinations
5. Initiate discussion of a healthy lifestyle relative to reproductive outcomes, including pregnancy intention and reproductive life planning

The health screens to be addressed include the following:

1. Breast Cancer Screening Procedure for women including:
  - a. Self-Breast Exam – Providers may counsel women that desire SBE how to perform it. The appropriate procedure may be demonstrated and a brochure may be given to all female clients to take home. Beginning in their early 20s, women should be told about the benefits and limitations of BSE. Regardless of whether a woman ever performs BSE, the importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination.
  - b. Annual breast examination by a health care professional for cancer screening in women over 40 and at least every 3 years in women between the ages of 21 and 40.
  - c. The decision to begin mammography screening is an individual one. Women should be given a choice about when to begin screening after a discussion of risks and benefits with their provider\*. Routine mammography screening should be discussed with each client even when the client is not yet of the age for the screening. Mammography using the USPSTF<sup>†</sup> criteria for “average risk” women should be encouraged:

Baseline Mammogram.....women who wish to begin screening earlier may choose to begin biennial screening between the ages of 40 and 49 years.


\* ACOG updated guidelines in 2017 stating that women at average risk of breast cancer should be offered screening mammography starting at age 40 years. If they have not initiated screening in their 40s, they should begin screening mammography by no later than age 50 years. Between 50 and 74 years, women at average risk of breast cancer should have screening mammography every one or two years based on an informed, shared decision-making process

<sup>†</sup> The U.S. Preventative Task Force (USPTF) updated its guidelines in 2018, advising women of average cancer risk to get screened every other year between ages 50-74 while high-risk women should begin at 40.

Women with a parent, sibling or child with breast cancer may benefit from beginning screening in their 40s.

Mammogram every one to two years.....For women who are at average risk for breast cancer, most of the benefit of mammography results from biennial screening during ages 50 to 74 years

2. Self-Testicular Exam - A brochure should be given to all interested male clients to take home. Some doctors recommend that men ages 15 to 40 perform monthly testicular self-examination. But this is controversial. Many doctors do not believe monthly TSE is necessary for men at average risk of developing testicular cancer. Monthly TSE may be recommended for men at high risk of developing testicular cancer. This includes men with a history of an undescended testicle or a family or personal history of testicular cancer.
3. Annual pelvic exam for all women 21 years and older. In the context of this policy, the "pelvic exam" serves multiple purposes. It may include inspection of the external genitalia, urethra, vaginal introitus and anus. The pelvic exam typically includes the bimanual portion of the exam, assessing the vagina, cervix, uterus, bladder and adnexa. The pelvic exam may also include a speculum exam of the vagina and cervix and a rectovaginal exam, as appropriate.
4. Annual pelvic examination is not a routine part of the annual assessment in women aged 13-21 unless medically indicated.
5. Cervical Cytology (*Reference Policy 317*)
  - a. Cytology screening should begin at age 21 years, regardless of the age of initiation of sexual activity.
  - b. Cervical cytology screening is recommended every 3 years for women between the ages of 21 and 29 years. Annual pelvic exams may still be indicated. HPV testing should not be used for screening in this age group.
  - c. Women 30 years and older should receive screening every three years with cervical cytology alone. Every five years with high risk HPV testing along or HPV and cervical cytology "co-testing" every five years.
  - d. Women with a history of cervical cancer, CIN2 or CIN3, or DES exposure should follow the same guidelines as average risk women before age 30 and should continue with that protocol after age 30 years.
  - e. Women who have been treated in the past for CIN2, CIN3 or cancer remain at risk for persistent or recurrent disease for at least 20 years post treatment and should continue routine screening for at least 20 years.
  - f. Women who are on immunosuppressant therapy or HIV positive should have cervical cytology testing every 6 months during the first year after diagnosis, and annually thereafter.
  - g. Women who have had a hysterectomy with removal of the cervix for benign disease and no history of CIN 2 or worse may discontinue cervical cytology testing.
  - h. Women who have had removal of the cervix but have a history of CIN 2 or CIN 3 (or for whom no record is available) should be screened until they have a 10 year history of no abnormal Pap smear results.
6. Men should have yearly prostate exams after the age of 50.
7. Clinicians should provide information about recommendations for periodic screening tests such as diabetes, thyroid, and cholesterol
8. Emphasize importance of folic acid supplementation in all women who may/can get pregnant.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Abstinence	<b>NUMBER:</b>  <b>322</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-74; QFP, 2014; <a href="https://weascend.org/">https://weascend.org/</a> , accessed July 2019			

## ABSTINENCE

### DEFINITION

Abstinence is another form of sexual expression. The term “abstinence” has several meanings:

- Refraining from all sexually expressive behavior (Sexual Risk Avoidance)
- Refraining from sexual behavior involving genital contact (Sexual Risk Reduction)
- Refraining from penetrative sexual practices (Sexual Risk Reduction)

### MODE OF ACTION

For the purpose of contraception, abstinence is the refraining from penile-vaginal intercourse. For the purpose of preventing sexually transmitted infections, abstinence is defined as refraining from those acts that permit exposure to infectious lesions or secretions.

### EFFECTIVENESS

When used correctly and consistently, abstinence is 100% effective against pregnancy and STIs

### CONTRAINDICATIONS

There are no known contraindications to abstinence.

### ADVANTAGES

1. Only form of birth control that is 100% effective when used consistently and correctly
2. May promote intimacy by discussing sexual choices with partner
3. Prevents STIs
4. Reversible

### DISADVANTAGES

There are no known disadvantages to abstinence

### SIDE EFFECTS

There are no known side effects from abstinence

### SUBJECTIVE

1. Ask the client how they define abstinence and work with their definition.
2. Primary abstainers have never had sexual intercourse with another person.
3. Secondary abstainers are sexually experienced but for various reasons no longer engage in behaviors they consider as “having sex.” Individuals may voluntarily abstain; not be in a current relationship; unhappy with a relationship or have an estranged relationship; be fearful of a sexually transmitted infection; have the presence of others in the home; have a geographical separation from their partner; have poor health, an illness or injury; or be pregnant or had a recent childbirth.
4. Abstinence may be involuntary in instances of loss of a partner, incarceration, medical reasons, or other causes.

## **OBJECTIVE**

Clinical examination is not necessary

## **PLAN**

1. Support the individual's choice
2. Provide information about abstinence
3. Authorize Emergency Contraception
4. Recommend age appropriate periodic assessment

## **CLIENT EDUCATION**

1. Clients must receive:
  - a. Information about all types of contraceptive options
  - b. Information about emergency contraceptives including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, side effects, warning signs, etc.
2. Discuss with client:
  - a. They should make decisions about abstinence when they are clearheaded and sober, not in the heat of the moment. Decide with their partner about the right time to have sex
  - b. Discuss and decide with their partner, in advance what sexual activities they will and will not do
  - c. Avoid high-pressure sexual situations (drunk or high)
  - d. Always have condoms on hand if they change their minds
  - e. Learn more about their bodies and how to keep it healthy
  - f. Learn about contraception and safe sex
  - g. 100% abstinence, 100% of the time is 100% effective, against pregnancy and STDs
  - h. Abstinence is free and always available to everyone
  - i. Abstinence requires a high level of motivation
3. Recommend the use of condoms, barrier method or initiation of contraceptive method to prevent pregnancy if/when they are no longer abstinent
4. Instruct client about health promotion and disease prevention (especially STI/HIV)
5. Correct and consistent use of condoms is recommended for STI/HIV protection
6. In instances of involuntary abstinence, counseling about relationships or other forms of sexual expression can be offered.


## **REFERRAL**

(Referred services are not Title X funded)

As indicated by history, physical examination or lab findings

## **REFERENCES**

Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart F, Kowal D. *Contraceptive Technology*. 20<sup>th</sup> Rev. ed. New York, NY: Ardent Media, Inc., 2011. 81-86.

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Withdrawal	<b>NUMBER:</b> 323
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-74; Contraceptive Technology, 20 <sup>th</sup> edition: Contraception, 2011;			

## WITHDRAWAL

### DESCRIPTION

Withdrawal refers to the removal of the penis from the vagina before ejaculation.

### MODE OF ACTION

Ejaculation occurs outside the vagina and away from the vulva, decreasing the possibility of conception.

### EFFECTIVENESS

Withdrawal is only slightly less effective than male condom. With typical use, 18% of couples relying on withdrawal will conceive within one year, compared to 17% of couples relying on condoms. More than eight in ten avoid pregnancy.

### ADVANTAGES

1. Withdrawal requires no devices, involves no chemicals, and is available in any situation at no cost.
2. It is far more effective than the use of no method at all.

### DISADVANTAGES

1. Interrupts the excitement or plateau phase of sexual response and can diminish the pleasure for a couple. It can be difficult to do correctly all of the time.
2. The ejaculate, which may contain sperm, may be emitted from the penis prior to climax or ejaculation, exposing the woman to pregnancy.
3. Offers no protection against sexually transmitted infections.

### CONTRAINDICATIONS


There are no absolute or strong relative contraindications

### SIDE EFFECTS

Interruption in the excitement or plateau of sexual response, diminishing the sensation of pleasure.

### INSTRUCTIONS TO CLIENT

1. Low effectiveness rate makes a second method in addition to withdrawal advisable.
2. Care should be taken to see that ejaculation does not take place until the penis is clear of the vulva.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Natural Family Planning (NFP)	<b>NUMBER:</b>  <b>324</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74, Contraceptive Technology, 20 <sup>th</sup> edition; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019			

## NATURAL FAMILY PLANNING (NFP)

### AVAILABILITY OF NATURAL FAMILY PLANNING SERVICES IN IDPH SERVICE AREA

All Title X agencies must provide at least two options for Natural Family Planning as approved methods of contraception. Other options can be provided either on site or by referral.

Natural Family Planning (NFP) is a means of either achieving or avoiding a pregnancy based on a couple's knowledge of their cycle of fertility and infertility. It is an educational means of family planning, as opposed to a technological means, such as the pill, IUD, etc.

There are several methods of NFP currently being taught and promoted. The first of these is called the Sympto-thermal Method (ST). This combines the observation of three different ovulation-related events: the production of mucus by the cervix (the mucus symptom), a change in the consistency of the cervix itself (which can be noted by placing the fingers inside the vagina to feel the cervix directly), and a change in basal body temperature. Couples who use the ST Method often feel greater security with its triple-check technique.

The second of these NFP methods is the Ovulation Method (OM). This method depends only upon the woman's observation and interpretation of the mucus symptom to determine that ovulation is approaching, and that it has passed. Couples who choose this method like its simplicity. Another variation is the use of cycle beads. Cycle beads are color coded beads that represent the days of a woman's cycle. A rubber ring is placed on the red bead on the first day of a menses. The rubber ring is then moved daily in the direction of the arrow. When the ring is on a red bead or a dark bead, there is little chance of conception occurring if intercourse occurs. When the ring is on a white bead, there is a high chance of conception occurring if unprotected intercourse occurs. Cycle Beads work best in women with 26-32 day cycles.

### MECHANISM OF ACTION

NFP uses one or more methods to identify the beginning and end of the fertile time in a menstrual cycle. In most cycles, ovulation occurs near the middle of the cycle and lasts about 6 days. Ovulation is expected to fall between cycle day 8-19 in cycles ranging from 26 and 32 days long (about 78% of cycles).

### ADVANTAGES OF NFP

1. It is safe. There are no medical side effects associated with its use.
2. It is reliable. As a means of preventing childbirth, it is said to be 94.8% theoretically effective.
3. It is natural. The use of NFP does not interfere with the body's natural reproductive processes, nor does it interfere with any of its other normal metabolic processes.

4. It can be used in all stages of a woman's reproductive life: regular cycles, irregular cycles, long cycles, following childbirth (breast-feeding or not breast-feeding), during the menopause, coming off birth control pills. It is now also gaining popularity as an initial approach to infertility.
5. Natural methods of family planning are basically easy to use and easy to learn.
6. NFP is morally acceptable to all major world religions.
7. NFP is the responsibility of both partners; NFP is a shared method of family planning.

### **DISADVANTAGES OF NFP**

There are two disadvantages frequently mentioned in regards to NFP. The first of these is the fact that, if these methods are to be used to avoid pregnancy, they require the avoidance of all genital contact (abstinence, continence) for a variable number of days each cycle. The second disadvantage often discussed is that NFP methods take a lot of time and energy in order to be learned and used properly.

### **EFFECTIVENESS**

Of either method is measured in three different categories:

1. To avoid pregnancy: if used properly, according to instructions to avoid pregnancy, the method-effectiveness is about 94.8%.
2. To achieve pregnancy (normal fertility): If a couple of normal fertility utilizes days of fertility (as determined by NFP) their chances of achieving pregnancy in the very first cycle are quite high: 75-80%.
3. To achieve pregnancy (previously infertile): Some couples, who have previously been considered infertile, are able to achieve a pregnancy by learning and using NFP. (Many couples trying to achieve pregnancy without success, can be referred to a NFP center, and thus may avoid expensive infertility testing).

### **FACTORS WHICH INFLUENCE THE EFFECTIVENESS OF NFP**

Mutual motivation by both partners has long been recognized as a very important factor in the success of NFP. However, it is now also recognized that the teacher of NFP is nearly as important, and in some cases even more important, than the initial motivation of the couple being taught. There is no doubt that the teachers who themselves use NFP, produce the best success statistics in their clients.

A couple of words of caution are in order. Self-taught NFP (e.g. from a book, from a well-meaning friend) has a notably higher unplanned pregnancy rate than that learned from qualified teachers.

### **OLDER METHODS OF NFP**

1. **RHYTHM**: This was the earliest of the natural methods of family planning. Its use is based on anticipating when ovulation is likely to occur in the present menstrual cycle, calculated from the longest and shortest lengths in the previous 6-12 cycles. It is no longer recommended.
2. **BASAL BODY TEMPERATURE**: There is usually .4 to .5 degree body temperature rise following ovulation, which is then maintained until the onset of the next menstrual period. This is a very effective method of determining post-ovulatory infertility. Although satisfactory to some couples, many would feel BBT used alone to avoid pregnancy is too restrictive. In general, BBT used alone is no longer recommended.

### **PLAN**

1. Provide back-up method of contraception as indicated
2. Authorize Emergency Contraception
3. Return for age appropriate periodic assessment

## **CLIENT EDUCATION**


Clients must receive:

1. Information about all types of contraceptive options if they are new or undecided
2. Information about natural family planning methods including mechanism of action, efficacy, benefits/risks, advantages/disadvantages, etc
  - a. Natural Family Planning or Fertility Awareness may incorporate 1 or more of these methods to help predict when ovulation might occur.
  - b. To prevent pregnancy: Use a barrier method or avoid sexual intercourse when ovulation or fertile times are identified
  - c. Clients should be counseled about the advantages, disadvantages of NFP (as described above).
  - d. Instruct client about health promotion and disease prevention (especially STI/HIV)
  - e. Advise client that natural family planning methods do NOT provide STI/HIV protection
  - f. Correct and consistent use of condoms is recommended for STI/HIV protection
  - g. Refer client for additional information if requested. A list of "training" or education resources should be provided.

## **RESOURCE**

Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart F, Kowal D. *Contraceptive Technology*. 20<sup>th</sup> Rev. ed. New York, NY: Ardent Media, Inc., 2011.



 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Sterilization	<b>NUMBER:</b>  <b>325</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-74; QFP, 2014; Requirements for Sterilization of persons in Federally Assisted Family Planning Program 42 CFR part 50, subpart B			

## STERILIZATION

Federal regulations must be met if sterilization procedure is performed or arranged by the project. Sterilization of clients as part of the Title X program must be consistent with 42 CFR part 50 subpart B, ("Sterilization of Persons in Federally Assisted Family Planning Projects").

### DESCRIPTION

1. Sterilization is a permanent method of birth control and must be considered irreversible. There are generally two accepted types of permanent sterilization available in the US.
2. Vasectomy (male)
3. Bilateral tubal ligation (female)

### MODE OF ACTION

1. Interruption of the tubes in the male prevents sperm from being ejaculated in the semen.
2. Interruption of the tubes in the female prevents the ovum from descending the tube and from coming in contact with the sperm.

### EFFECTIVENESS

1. Sterilization is almost 100% effective.
2. There is a failure rate of 1 in 600 for vasectomies and 1 in 400 for tubal ligation.
3. For vasectomies another method of contraception must be used until a negative sperm count is obtained.

### ADVANTAGES

1. Tubal sterilization - most effective method of birth control for women (except hysterectomy); usually done as an outpatient procedure requiring no hospitalization; provides permanent protection, removing the worry of temporary contraception and permitting no interference with sexual relations.
2. Vasectomies - most effective birth control for men; no hospitalization required; recuperation time from the procedure is very short (approximately 48 hours); with no interference with sexual relations in most instances. Most cost effective method of birth control.

### DISADVANTAGES

1. All surgical operations have some risks, but serious complications are uncommon.
2. For several days after the procedure, males, and females may experience some discomfort and/or bruising.
3. Time off from work may be required.
4. In rare instances, the wrong structure is tied off or the tubes grow back together, and as a result, a pregnancy may occur.


### CONTRAINDICATIONS

The only absolute contraindication is if more children are desired.

## **REQUIREMENTS FOR STERILIZATION OF PERSONS IN FEDERALLY ASSISTED FAMILY PLANNING PROGRAM 42 CFR PART 50, SUBPART B**

Programs will perform or arrange for sterilization of an individual only if the following requirements have been met:

1. The individual is at least 21 years old at the time the consent is signed
2. The individual is not a mentally incompetent individual
3. The individual has voluntarily given his/her informed consent (consent is not obtained by the Title X clinic unless a clinic provider is performing the procedure).
  - a. All questions must be answered for the individual
  - b. Individual is advised that they can withdraw consent any time before the sterilization without affecting his or her future care and without withdrawal of federal funded program benefits.
  - c. A description of alternative birth control methods must be discussed
  - d. Individual is advised that sterilization is not reversible
  - e. Risks and benefits must be discussed
  - f. An interpreter must be provided when indicated (limited English proficiency, hearing impaired or blindness)
  - g. Sterilization regulations must be explained to the individual
  - h. The consent must be witnessed
4. At least 30 days but not more than 180 days have passed between the date of informed consent and the date of sterilization, except in the cases of premature delivery or emergency abdominal surgery. See PHS Act for complete exceptions.
5. Required signatures on the consent include:
  - a. The individual to be sterilized
  - b. The interpreter, if one is provided
  - c. The person who obtained the consent
  - d. The physician who will perform the procedure. This person must also certify on the consent form that all of the provisions of the consent have been performed

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Contraceptive Sponge	<b>NUMBER:</b>  <b>326</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-7; QFP, 2014, Contraceptive Technology, 20th Edition.			

## CONTRACEPTIVE SPONGE

### DESCRIPTION

The contraceptive vaginal sponge is a soft, disposable polyurethane foam sponge containing nonoxynol 9, which kills sperm on contact. Insertion is similar to diaphragm.

### MODE OF ACTION

The sponge prevents pregnancy in three ways:

1. The spermicide contained in the sponge kills sperm before they reach the egg (spermicidal).
2. The sponge blocks the cervix (barrier).
3. The sponge traps and absorbs sperm (absorption).

### EFFECTIVENESS

1. Theoretical effectiveness: 89-91%
2. Typical use effectiveness: 84-87%--Effectiveness rate is higher in nulliparous women (91%).

### CONTRAINDICATIONS

You should NOT use the Today® Sponge if you:

1. Are menstruating
2. You and/or your partner has a sensitivity to:
  - a. sulfa drugs
  - b. the [spermicidal, nonoxynol 9](#)
  - c. [polyurethane](#) [medical grade]
3. Have a vaginal abnormality
4. Currently have a vaginal infection
5. Have ever had toxic shock syndrome
6. Have recently had a vaginal delivery (within 6 weeks), miscarriage, or other termination of pregnancy and have not been examined by your physician

### ADVANTAGES

1. No prescription or special fitting is required.
2. Conveniently packaged (portable)
3. Disposable
4. May be inserted up to immediately before intercourse or up to 16 hours prior to intercourse and therefore doesn't interfere with lovemaking. Protection lasts for up to 24 hours. Leave sponge in place an additional 6 hours after intercourse before removing it.
5. The sponge may be retained in place for up to 24 hours allowing for multiple acts of intercourse. If you have intercourse when sponge has been in place for 24 hours, leave

it in place an additional 6 hours after intercourse before removing it. Today® Sponge must not be left in place for more than 30 hours.

6. The sponge will be effective even if you swim or bathe after intercourse.

### **DISADVANTAGES**

1. May decrease sexual spontaneity if not inserted in advance.
2. Some reports of difficulty removing device.
3. With frequent intercourse, may be more costly than other methods.
4. Associated with possible increase of Toxic Shock Syndrome (TSS).
5. Does not provide protection against STDs or HIV

### **SIDE EFFECTS**

1. Possible vaginal burning or itching.
2. Allergic reactions

### **WARNING SIGNS OF TOXIC SHOCK SYNDROME**

Report to the ER or clinic immediately if one or more warning signs of TSS should occur including:

1. fever
2. vomiting
3. diarrhea
4. muscular pain
5. dizziness
6. rash similar to sunburn

### **HOW TO USE THE CONTRACEPTIVE SPONGE**


1. Sponge must be inserted before penis enters vagina.
2. Wet the sponge with water and squeeze it gently. This activates the spermicide. (You will notice suds.)
3. Fold the sponge in half (the loop must be on the outside) and insert it into the vagina.
4. Push it deep into the vagina to cover the cervix.
5. You can have sex immediately after you put the sponge in, or you can wait up to 24 hours to have sex. If you have intercourse when sponge has been in place for 24 hours, leave it in place an additional 6 hours after intercourse before removing it. Today® Sponge must not be left in place for more than 30 hours.
6. Sexual intercourse may be repeated without adding cream or jelly.
7. After intercourse, you must leave the sponge in place for at least six (6) hours after the last act of intercourse.
8. To remove the sponge, grab the loop and pull down gently and slowly
9. Check to make sure the entire sponge has been removed.
10. Throw the sponge away. It can be used only once.

### **OTHER**

1. A higher degree of protection against pregnancy will be afforded by using another method of contraception in addition to a spermicidal contraceptive. This is especially true during the first few months, until the client becomes familiar with the method. Clinical studies have demonstrated that approximately one-half of all accidental pregnancies occurred during the first three months of use.
2. After childbirth or spontaneous or induced abortion, the effectiveness of the sponge may be decreased. Do not use until bleeding has stopped.

### **RESOURCE**

<http://todaysponge.com>.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Spermicidal Foam, Suppositories, Tablets	<b>NUMBER:</b>  <b>327</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; Contraceptive Technology, 20 <sup>th</sup> edition; QFP, 2014;			

## SPERMICIDAL FOAM, SUPPOSITORIES, TABLETS

### DESCRIPTION

Spermicidal foam, suppositories and tablets are chemical substances, which are toxic to sperm.

### MODE OF ACTION

The foam or suppositories are placed in the vagina, as close as possible to the cervical opening, allowing the chemical action to kill sperm on contact. Some suppositories and tablets must dissolve over a period of 10-30 minutes after placement in the vagina, prior to intercourse.

Should be used in combination with other methods (i.e. condoms) to increase protection.

### EFFECTIVENESS

1. Theoretical effectiveness rate is 97%.
2. Use effectiveness rate is 85.1%

### ADVANTAGES

1. An effective, safe method of contraception if used correctly.
2. May act as an effective lubricant.
3. May be purchased at a drugstore without a prescription and is readily accessible.

### DISADVANTAGES

1. Some women consider the use of foam as “messy”.
2. Must be used consistently with each act of intercourse.
3. May cause irritation.
4. May increase exposure to HIV and does not protect from STD

### CONTRAINDICATIONS

There are no absolute or relative contraindications except allergy to foam or suppositories.


### SIDE EFFECTS

1. Possible irritation or burning. If this occurs, change to a different brand.
2. Couples having oral-genital sex have noted that foam has an unpleasant taste, although odorless and tasteless preparations are available.

### INSTRUCTIONS TO CLIENT

1. Foam
  - a. Several brands of foam come in pre-loaded applicators, ready for use. If the foam comes in a separate container from the applicator, the applicator is filled to a designated mark by pressure applied directly on the top of the container or by tilting the applicator (Instructions differ with brands)
  - b. Shake the can at least 20 times before using to insure adequate mixing of the spermicide and foam.

- c. The filled applicator should be inserted as far as possible into the vagina, and withdrawn about 1/2 inch. Then push the plunger to deposit the foam.
  - d. Foam protection lasts about 30 minutes. The foam should not be inserted more than 30 minutes prior to intercourse. If more than 30 minutes has elapsed, another applicator full of spermicide should be used. Insert a new applicator full of foam before every act of intercourse.
  - e. Douching is discouraged; however, if a woman thinks she must douche, she should be instructed to wait 6- 8 hours after the last act of intercourse.
  - f. Wash the applicator with soap and lukewarm water.
  - g. The effectiveness of foam in preventing pregnancy can be greatly increased if it is used in conjunction with condoms.
2. Suppositories
- a. Foil or plastic wrapper must be removed.
  - b. Slide the suppository into the vagina as far as it will go, and as close to the cervix as possible to obtain maximal protection as it melts and foams.
  - c. After insertion, wait for the correct amount of time to elapse before having intercourse. (Times may vary with brands).
  - d. Use one suppository for each act of intercourse. If more than 1/2 hour has elapsed since insertion, insert another suppository to insure protection.
  - e. Douching is discouraged. If a woman thinks she must douche, she should be instructed to wait 6- 8 hours after the last act of intercourse.
3. Does not protect from exposure to STD and may increase exposure to HIV.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Vaginal Contraceptive Film (VCF)	<b>NUMBER:</b> <b>328</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; Contraceptive Technology, 20 <sup>th</sup> edition; QFP, 2014;			

## VAGINAL CONTRACEPTIVE FILM (VCF)

### DESCRIPTION

Vaginal Contraceptive film (VCF) is a 2.5 by 2.5-inch water-soluble square containing the spermicide nonoxynol-9, a chemical substance that is toxic to sperm.

### MODE OF ACTION

1. VCF is folded over the finger and placed as close to the cervix as possible. It dissolves quickly, but unlike foam, does not liquefy, but becomes a tenacious gel. VCF must be inserted at least five (5) minutes, and not more than one hour, prior to intercourse.
2. VCF should be used in combination with condoms for increased protection.

### EFFECTIVENESS

Theoretic effectiveness equal to foam (97%). Effectiveness increased when used in conjunction with condoms.

### ADVANTAGES

1. Readily available over-the-counter without a prescription.
2. An effective, safe contraceptive if used correctly.
3. Very portable.
4. No hormonal side effects.
5. Does not have to be removed

### DISADVANTAGES

1. Must be used with each act of intercourse.
2. May cause vaginal irritation and/or increased vaginal discharge.
3. May increase exposure to HIV and does not protect from STD's

### CONTRAINDICATIONS

1. No absolute or relative contraindications.
2. Allergy to known ingredients.

### SIDE EFFECTS

1. Possible irritation/burning/vaginal discharge.
2. May be unpleasant to the taste for clients having oral-genital sex.

### INSTRUCTIONS TO CLIENT


1. Fold film in half over the index finger and insert into the vagina as close to the cervix as possible.
2. VCF should be inserted at least five minutes prior to intercourse to allow it to liquefy. If more than one hour elapses between insertion and intercourse, another film should be inserted.

3. Additional film should be used with each subsequent act of intercourse.
4. VCF does not need to be removed. Its residual gel is flushed from the vagina by vaginal and cervical fluids.
5. Douching is discouraged. If a woman thinks she must douche, she should be instructed to wait six hours or more to douche.
6. Does not protect from exposure to STD and may increase exposure to HIV

**POTENTIAL COMPLICATIONS**

None



 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Contraceptive Patch	<b>NUMBER:</b>  <b>329</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; CDC U.S. Medical Eligibility Criteria, 2010, Contraceptive Technology, 20 <sup>th</sup> ed; QFP, 2014; Program Requirements for Title X Funded FP Projects, 2014			

## CONTRACEPTIVE PATCH

### DESCRIPTION

The patch is a thin, beige piece of plastic that looks like a square bandage. It's easy to use and works like the pill, but only needs to be changed once a week.

### MODE OF ACTION:

Inhibition of ovulation and forming thickened cervical mucus that inhibits sperm mobility.

The patch contains the same hormones as combined birth control pills but the hormones are delivered through the skin. But, hormones from the patch get into the blood stream and are processed by the body differently than hormones from birth control pills. Women are exposed to about 60% more estrogen using the patch than a typical birth control pill containing 35 micrograms of estrogen. In general, increased estrogen may increase the risk of side effects, including blood clots.

See full prescribing information. The FDA has issued this black box warning for the contraceptive patch:

***WARNING: CARDIOVASCULAR RISK ASSOCIATED WITH SMOKING, RISK OF VENOUS THROMBOEMBOLISM, AND PHARMACOKINETIC PROFILE OF ETHINYL ESTRADIOL***

### CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR RISKS

Cigarette smoking increases the risk of serious cardiovascular events from hormonal contraceptive use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, hormonal contraceptives, including the patch, should not be used by women who are over 35 years of age and smoke.

### RISK OF VENOUS THROMBOEMBOLISM

The risk of venous thromboembolism (VTE) among women aged 15 to 44 who used the norelgestromin and ethinyl estradiol transdermal system compared to women who used several different oral contraceptives was assessed in five U.S. epidemiologic studies using electronic healthcare claims data. The relative risk estimates ranged from 1.2 to 2.2; one of the studies found a statistically significant increased relative risk of VTE for current users of norelgestromin and ethinyl estradiol transdermal system.

### PHARMACOKINETIC (PK) PROFILE OF ETHINYL ESTRADIOL (EE)

The PK profile for the norelgestromin and ethinyl estradiol transdermal system is different from the PK profile for oral contraceptives in that it has a higher steady state concentrations and a lower peak concentration. It is not known whether there are changes in the risk of serious

adverse events based on the differences in PK profiles of EE in women using norelgestromin and ethinyl estradiol transdermal system compared with women using oral contraceptives containing 30 mcg to 35 mcg of EE. Increased estrogen exposure may increase the risk of adverse events, including VTE.

### **EFFECTIVENESS**

The patch is 99 percent effective, similar to birth control pills, if used correctly and consistently. The patch may not be as effective in women weighing more than 198 lbs. (90 kg).

### **INDICATIONS FOR USE**

Any woman who is a candidate for combination oral contraceptives may use the patch with the limitations identified in the black box warning. See contraindications below.

### **CONTRAINDICATIONS FOR USE**

The patch should not be prescribe to women at high risk of arterial or venous thrombotic diseases. Examples include women who:

- Smoke, if over age 35
- Have deep vein thrombosis or pulmonary embolism, now or in the past
- Have inherited or acquired hypercoagulopathies
- Have cerebrovascular disease
- Have coronary artery disease
- Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
- Have uncontrolled hypertension
- Have diabetes mellitus with vascular disease
- Have headaches with focal neurological symptoms or have migraine headaches with aura
- Women over age 35 with any migraine headaches

Other contraindications include:

- Liver tumors, benign or malignant, or liver disease
- Undiagnosed abnormal uterine bleeding
- Pregnancy, because there is no reason to use hormonal contraceptives during pregnancy
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past•
- Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for alanine aminotransferase (ALT) elevations

### **ADVANTAGES**

1. The same as for oral contraceptives (See policy 320).
2. The patch only needs to be placed once per month.
3. The patch does not interfere with intercourse.
4. Application of the patch is done by the client.
5. The patch does not require a daily regimen
6. Easily reversible

### **SIDE EFFECTS**

1. The same side effects as oral contraceptives (See policy 320).
2. See black box warning above.

### **RISKS**

Risks are the same as for combined oral contraceptive pills. Women are exposed to about 60% more estrogen using the patch than a typical birth control pill containing 35 micrograms of

estrogen. In general, increased estrogen may increase the risk of side effects, including blood clots.

## **PRECAUTIONS**

- Precautions are the same as for combined oral contraceptive pills.
- Hormonal birth control methods help to lower the chances of becoming pregnant. They do not protect against HIV infection (AIDS) and other sexually transmitted infections.

## **DRUG INTERACTIONS**

1. See complete prescribing information. Examples include: Hepatitis C drug combinations; itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase plasma hormone concentrations; Human Immunodeficiency Virus (HIV)/Hepatitis C Virus (HCV) Protease Inhibitors and Non-Nucleoside Reverse Transcriptase Inhibitors; Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because serum concentration of thyroid-binding globulin increases with use of CHCs.
2. Certain drugs to treat cystic fibrosis may reduce effectiveness of hormonal contraceptives including oral, injectable, transdermal and implantable contraceptives.

## **INITIATION:**

1. No hormonal contraceptive used in the last month
  - a. Begin on or before day 5 of the cycle. Apply even if not done bleeding.
  - b. Use backup-method until Patch has been in place for 7 consecutive days
2. Switching from combination oral contraceptives
  - a. Apply on or before start of the new pill cycle and back-up method need not be used.
  - b. Use back-up method for 7 consecutive days if applied after oral contraceptive restart day.
3. Switching from Progestin only method. Use a back-up method until patch has been in place for 7 days.
  - a. Progestin only pills – may apply on any day. Do not skip any days between pills and patch application.
  - b. Apply on the same day as removal of the progestin implant.
  - c. Apply on the same day as removal of progestin containing IUD or IUS
  - d. Apply prior to the 14th week or 98 days from last Depo Provera injection. If applied after the 14th week or 98th day use a back-up method until patch has been in place for 7 consecutive days


## **Use:**

1. Use: apply one patch weekly for 3 weeks to the upper outer arm, upper torso, lower abdomen, or buttocks. The patient is patch free for 1 week. The patch is never to be worn on the breasts.
2. Initiate the patch:
  - a. Begin the patch within the first 24 hours of menses and no back-up is needed.
  - b. If the patch is started after the first 24 hours of the menses a back-up is required for 7 days.
  - c. The patient will change her patch on the day she initiated the patch for three consecutive weeks. The fourth week is a patch-free week.
  - d. Reinforce importance of not going longer than 7 days without a patch which would increase the risk for pregnancy.
3. If the patch becomes partially detached for 24 hours or less have reattach it or reapply a new patch. The patch change day will remain the same.
4. If the patch has been detached for more than 24 hours, apply a new patch and that day is now the patch change day. A back-up method should be used for 7 days.

5. If it has been more than 48 hours since a patch detached and unprotected intercourse occurred in the last 72 hours, consider offering emergency contraception.
6. Advise patient to observe for skin irritation at the patch removal site. Encourage rotation of site application.
7. Contact health provider if:
  - a. Sharp chest pain or shortness of breath
  - b. Crushing chest pain or chest heaviness
  - c. Sudden severe headache or vomiting, dizziness or fainting, problems with vision or speech, weakness or numbness of arms or legs
  - d. Sudden loss of vision
  - e. Yellowing of skin or whites of the eyes
  - f. Severe pain in the abdomen
  - g. Breast lumps
  - h. Irregular vaginal bleeding for 2 or more cycles
  - i. Signs of severe depression
  - j. Severe leg pain or swelling.
8. Discuss return of normal menses and fertility after discontinuation of method

### **HORMONE CONTRACEPTION AND HIV**

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive. Women with HIV should be strongly advised to always use condoms if using a progestin-only injectable contraceptive because of the inconclusive body of evidence on the possible increased risk for HIV acquisition.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Diaphragm	<b>NUMBER:</b> 330
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; Contraceptive Technology, 20 <sup>th</sup> edition,; QFP, 2014; ACOG, FAQ Barrier Methods of Birth Control: <b>Spermicide, Condom, Sponge, Diaphragm, and Cervical Cap</b>			

## DIAPHRAGM

### DESCRIPTION

The diaphragm is a dome-shaped cup made of silicone that fits inside the vagina and covers the cervix. It must be used with a spermicidal jelly or cream to achieve maximum effectiveness. All diaphragms require a prescription. There is one type of diaphragm available in the United States.

- One-size diaphragm, which fits most, but not all women. The one-size diaphragm does not require fitting.

### MODE OF ACTION

The diaphragm fits inside the vagina over the cervix. The dome forms a barrier between the cervix and the semen, preventing sperm entry into the uterus. The spermicidal cream or jelly is used with the diaphragm for additional protection, killing any sperm that accidentally go past the rim of the diaphragm.

### EFFECTIVENESS

1. Theoretical effectiveness rate of 97%
2. Use effectiveness rate of 87%

### ADVANTAGES

1. There are no serious side effects with this device
2. Insertion may be incorporated into foreplay.

### DISADVANTAGES

1. Some women may consider the diaphragm “messy”.
2. Insertion may be embarrassing for these women who dislike touching their genitals.
3. It must be used every time intercourse occurs.
4. Warn client of the risks of Nonoxonol-9
5. Using a diaphragm and spermicide is associated with increased urinary tract infections and vaginal infection
6. Rare instances of toxic shock syndrome have been reported

### CONTRAINDICATIONS

#### Strong Relative Contraindications

1. Allergy to spermicide is a strong relative contraindication.

#### Relative Contraindications

1. Complete uterine prolapse
2. Vesico-vaginal fistula
3. Recto-vaginal fistula

4. Severe cystocele or rectocele
5. Small “button” cervix
6. Severe retroversion of the uterus (this varies from client to client)
7. Inability of client to learn correct insertion technique
8. History of Toxic Shock Syndrome or vaginal colonization of Staph aureus

There are no absolute contraindications to diaphragm use

### **SIDE EFFECTS**

1. Possible slight discomfort (bladder pressure, uterine cramps) especially if not fitted or inserted improperly.
2. Foul smelling, profuse vaginal discharge if the diaphragm is forgotten or left in place too long.
3. Toxic Shock Syndrome is rare but possible.

### **TIMING OF DIAPHRAGM FIT**


1. Postpartum -Total uterine involution, usually 4-6 weeks after delivery with complete uterine involution.
2. Post-Abortion:
  - a. 1st trimester abortion- client may be fitted at 1 week
  - b. 2nd trimester abortion- client may be fitted at 1-2 weeks with complete uterine involution.
3. Anytime client desires a fit and has no contraindication to use of the device.

### **INSTRUCTIONS TO CLIENT**

1. To apply contraceptive jelly or cream: Hold the diaphragm with dome down (like a cup). Squeeze the jelly or cream from the tube into the dome (be sure to use plenty - about 1 tablespoon); then spread a little around the rim of the diaphragm with your finger. The contraceptive jelly or cream remains active for about 6 hours. The diaphragm may be inserted with cream or jelly prior to intercourse. Use an additional application of spermicide if the diaphragm has been in place for more than 2 hours prior to intercourse to ensure spermicidal effectiveness.
2. To insert diaphragm: With one hand, hold the diaphragm dome down (spermicide in the dome) and press opposite sides of the rim together so that the diaphragm folds. Spread the labia with the other hand, and insert the folded diaphragm into the vaginal canal. This can be done standing with one foot propped up (on the edge of a bathtub), squatting, or lying on your back. Push the diaphragm downward and back along the floor of the vagina as far as it will go. Then tuck the front rim up behind the pubic bone. If it is uncomfortable, it may be incorrectly placed and should be removed and reinserted.
3. To check the placement of the diaphragm: When the diaphragm is correctly placed, the back rim of the device is below and behind the cervix, and the front edge of the rim is tucked up behind the pubic bone. Often it is not possible to feel the back rim. The client should check to be sure that she can feel her cervix through the soft rubber dome of the diaphragm and that the front rim is snugly in place behind the pubic bone. The spermicidal cream (in the dome of the diaphragm) should be on the inside, next to the cervix.
4. To remove the diaphragm: Place the index finger behind the front rim of the diaphragm and pull down and out. Be careful not to puncture the diaphragm with a fingernail. If it is hard to hook a finger behind the rim, try a squatting position and push downward with the abdominal muscles.
5. For the next week, the client should practice inserting and removing the diaphragm until she can do so easily and is confident about checking its position. If she has intercourse during this time, instruct her to use an additional method (such as condoms). The client

should wear the diaphragm for a trial 8 hours before her return visit. Instruct client to return in 2-4 weeks with her diaphragm in place so that its size and position can be checked. Inform client that if intercourse occurs within 8 hours of this exam, she should plan to use an alternate method.

6. Instruct client to use the diaphragm each time she has intercourse. Each episode of intercourse requires a new application of jelly or cream. DO NOT remove or dislodge the diaphragm within a 6-hour timeframe. Use the spermicidal applicator to insert additional jelly or cream in front of the diaphragm if intercourse occurs more than once during the 6-hour timeframe. If additional spermicide is too messy, condoms may be used for subsequent intercourse. DO NOT remove the diaphragm, however.
7. Instruct the client that after intercourse, she should leave the diaphragm in place for 6-8 hours. She should not douche during that time. After intercourse-- and after the 6-hour minimum time--the diaphragm may be removed whenever it is convenient. If subsequent intercourse is anticipated, she may wash the diaphragm, apply new spermicide, and re-insert it. It should be removed and washed at least once every 24 hours to avoid developing an unpleasant odor. But, remember--stick to the 6-hour minimum after intercourse for leaving the diaphragm in place.
8. Instruct client that diaphragm should not be used during menses due to risk of Toxic Shock Syndrome.
9. Care of the diaphragm: Always follow care instructions that come with the diaphragm. After use, the diaphragm should be washed with mild soap and water, thoroughly rinsed, dried with a towel, and then stored in its plastic container. It may be dusted with cornstarch if desired. Talcum or perfumed powder should not be used since they can cause vaginal irritation or the diaphragm to disintegrate.
10. Inspect the diaphragm each time it is used for defects or holes. Vaseline should not be used with the diaphragm since it may cause deterioration. If a lubricant is needed, K-Y jelly may be used without harming the diaphragm. The diaphragm should be stored away from heat. The diaphragm will normally discolor (darker brown) over time, but the diaphragm should last several years if cared for properly.
11. Warn client of the risks of Nonoxonol-9: Possible increased risk of acquiring HIV.
12. Douching is discouraged. If a woman thinks she must douche, she should be instructed to wait six hours or more to douche.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Contraceptive Vaginal Ring	<b>NUMBER:</b>  <b>331</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; CDC U.S. Medical Eligibility Criteria, 2010, Contraceptive Technology. 20 <sup>th</sup> ed: QFP, 2014			

## CONTRACEPTIVE VAGINAL RING

### DESCRIPTION

The vaginal ring is a flexible, transparent ring containing progesterone and estrogen. The ring releases a continuous low dose of hormone into the body once inserted into the vagina.

### MODE OF ACTION

The vaginal ring works by inhibiting ovulation and forming thickened cervical mucus that inhibits sperm mobility.

### EFFECTIVENESS

The effectiveness of the vaginal ring is approximately 98%-99%.

### INDICATIONS FOR USE

Any woman who is a candidate for combination oral contraceptives may use the vaginal ring.

### CONTRAINDICATIONS FOR USE

Contraindications for use of the contraceptive vaginal ring are the same as those for oral contraceptives (See policy 320).

### ADVANTAGES

1. The same as for oral contraceptives (See policy 320)
2. The vaginal ring only needs to be placed once per month, although hormone levels remain therapeutic for 35 days after insertion
3. The vaginal ring does not interfere with intercourse
4. Insertion and removal of the vaginal ring is done by the client
5. The vaginal ring does not require a daily regimen
6. Easily reversible

### SIDE EFFECTS

1. The same side effects as oral contraceptives (See policy 320).
2. Vaginal infection and irritation

### CONTRAINDICATIONS

Contraindications are the same as for combined oral contraceptive pills.

### RISKS

Risks are the same as for combined oral contraceptive pills except for vaginal infection and irritation.

### PRECAUTIONS

Precautions are the same as for combined oral contraceptive pills.



## **DRUG INTERACTIONS**

Drug interactions are the same as for combined oral contraceptives.

## **USE**

Insert one ring per cycle and leave for three weeks. Position in the vagina is not important. Quick start method may be used.

## **INITIATE IF**

1. No hormonal contraceptive used in the last month
  - a. Begin on or before day 5 of the cycle. Insert even if not done bleeding.
  - b. Use backup-method until ring has been in place for 7 consecutive days
2. Switching from combination oral contraceptives
  - a. Insert ring on or before start of the new pill cycle and back-up method need not be used.
  - b. Use back-up method for 7 consecutive days if inserted after oral contraceptive restart day.
3. Switching from Progestin only method. Use a back-up method until ring has been in place for 7 days.
  - a. Progestin only pills – may insert the ring on any day. Do not skip any days between pills and insertion of the ring.
  - b. Insert on the same day as removal of the progestin implant.
  - c. Insert on the same day as removal of progestin containing IUD or IUS
  - d. Insert prior to the 14<sup>th</sup> week or 98 days from last Depo Provera injection. If inserted after the 14<sup>th</sup> week or 98<sup>th</sup> day use a back-up method until ring has been in place for 7 consecutive days

## **DEVIATIONS FROM RECOMMENDED REGIMEN**

1. Inadvertent removal, expulsion – The ring may be rinsed with lukewarm (never hot) water and replaced in the vagina. A back-up method should be used until the ring has been in place for 7 consecutive days. NOTE: The ring may be removed for periods of 3 hours or less without losing effectiveness.
2. If the ring is in place for more than 3 weeks up to 4 weeks, remove and observe the ring-free week. If ring is in place for more than 4 weeks pregnancy must be ruled out and another method used until the ring can be reinserted. A back-up method must be used until the ring has been in place for 7 consecutive days.

## **IN THE EVENT IF MISSED MENSES**

1. If the regimen has been adhered to the ring may be inserted at the prescribed time.
2. If regimen has not been adhered to (ring out more than 3 hours or ring free period was extended) pregnancy should be considered.
3. If the regimen has not been adhered to and two consecutive menses have been missed pregnancy must be ruled out.
4. If ring has been retained longer than 4 weeks pregnancy should be ruled out.


## **CLIENT INSTRUCTIONS**

1. This method does not protect against STD/HIV.
2. Dispose of the ring in the foil pouch away from pets or children.
3. Contact health provider if:
  - a. Sharp chest pain or shortness of breath
  - b. Crushing chest pain or chest heaviness
  - c. Sudden severe headache or vomiting, dizziness or fainting, problems with vision or speech, weakness or numbness of arms or legs
  - d. Sudden loss of vision

- e. Yellowing of skin or whites of the eyes
  - f. Severe pain in the abdomen
  - g. Breast lumps
  - h. Irregular vaginal bleeding for 2 or more cycles
  - i. Signs of severe depression
  - j. Severe leg pain or swelling.
4. Discuss return of normal menses and fertility after discontinuation of method, especially with continuous cycle use.
  5. Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.

### **HORMONE CONTRACEPTION AND HIV**

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive. Women with HIV should be strongly advised to always use condoms if using a progestin-only injectable contraceptive because of the inconclusive body of evidence on the possible increased risk for HIV acquisition.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Female Condom (FC1 & FC2)	<b>NUMBER:</b>  <b>332</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; The Female Health Company <a href="http://www.femalehealth.com">http://www.femalehealth.com</a> ; QFP, 2014; <a href="https://www.hhs.gov/opa/pregnancy-prevention/index.html">https://www.hhs.gov/opa/pregnancy-prevention/index.html</a>			

## FEMALE CONDOM - INTERNAL CONDOM

### DESCRIPTION

The intravaginal pouch is a thin condom designed to provide women with protection against pregnancy and to reduce the risk of AIDS and other STD's. It consists of a soft, loose fitting sheath and two flexible rings. One of the rings is used to insert the device and to hold it in place. The other ring remains outside the vagina after insertion. The condom covers the labia and the base of the man's penis during intercourse. Upon insertion, it lines the vagina. It is disposable and can be used only once.

### MODE OF ACTION (BARRIER METHOD)

Ejaculation can occur while the penis is in the vagina, since the ejaculate is contained within the vaginal pouch.

### EFFECTIVENESS

79% at one year of usage.

### ADVANTAGES

1. Does not require a prescription.
2. May be used as a back-up method of birth control.
3. Reduces the risk of sexually transmitted infections.
4. Enables woman to use protection when her partner will not.
5. May be inserted several minutes or hours before intercourse.
6. May enhance pleasure for women.

### DISADVANTAGES

1. More expensive than male condom. Can be used only once and then must be discarded.
2. Easily torn by sharp object like a ring or fingernail.
3. Must be used with each act of intercourse.

### CONTRAINDICATIONS


None

### SIDE EFFECTS

No allergic reactions have been reported.

### INSTRUCTIONS TO CLIENT

1. Should not be used in conjunction with a male condom.
2. Follow insertion instructions on the package.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Male Condoms	<b>NUMBER:</b>  <b>333</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; Contraceptive Technology, 20 <sup>th</sup> edition; QFP, 2014			

## MALE CONDOMS

### DESCRIPTION

A condom (or rubber) is a thin rubber latex or polyurethane or lamb caecum sheath (closed tube) which is put on an erect penis to prevent ejaculated sperm from being deposited inside the vagina.

### MODE OF ACTION (BARRIER METHOD)

Ejaculation can occur while the covered penis is in the vagina, the ejaculate being contained within the condom.

### EFFECTIVENESS

1. Theoretical effectiveness rate is 97%.
2. Typical Use effectiveness rate is 90%.
3. Must be used for each act of anal, vaginal, or oral intercourse when any risk of infection exists.

### CONTRAINDICATIONS

Allergic reaction to rubber condoms and/or pre-lubricated condoms. If this occurs, synthetic condoms are an alternative.

### ADVANTAGES

1. Condoms do not require a prescription and are easily accessible.
2. Condoms are relatively inexpensive.
3. May be kept as “reserve” or “back-up” method if not prepared for other methods or if supplies run out.
4. Encourages male participation in contraception.
5. Can be used as dual method to increase effectiveness.
6. Protects from some STI's that other birth control options do not.

### DISADVANTAGES


1. Use of condoms may decrease sensual pleasure for the male/female.
2. Putting on the condom may interrupt foreplay unless efforts are made to incorporate it into a part of foreplay.
3. In rare instances, condoms may break.
4. Use of Nonoxynol – 9 lubricated condoms does not reduce the risk of STD and may increase exposure to HIV and herpes virus. Unlubricated condoms are recommended.
5. Must be used with each act of intercourse

### SIDE EFFECTS

Use of the condom may reduce glans sensitivity for the male.

## INSTRUCTIONS TO CLIENT

1. Since sperm are present in pre-ejaculatory semen, the condom should be placed on an erect penis before the penis comes into contact with the vulvar area. Unroll the condom all the way to the base of the penis, leaving about one-half inch of empty space, not filled with air, at the tip (or buy condoms with nipple tips to hold the semen). Lubrication may be used on the outside of the condom (some are lubricated to aid the penis in entering the vagina). Petroleum jelly (Vaseline) or any oil-based product should not be used because it may cause the rubber to deteriorate. K-Y jelly, contraceptive foam, and saliva are excellent lubricants.
2. After intercourse, hold onto the condom, as the penis is withdrawn, taking care not to spill semen anywhere near the opening of the vagina. The penis should be withdrawn shortly after ejaculation occurs. As the erection subsides, the condom could slip off, spilling semen into the vagina and pregnancy could result.
3. If the condom tears or comes off in the vagina, insert contraceptive foam or jelly immediately.
4. Condoms should be used only once and then thrown away.
5. Heat may cause deterioration of the rubber. Do not keep condoms in wallet, glove compartment or any area where they are exposed to heat.
6. Use of condoms lubricated with Nonxynol -9 does not reduce the risk of STD and may increase the risk of HIV and herpes virus. Unlubricated condoms are recommended.
7. Clients should be instructed not to use a condom that has been worn during anal intercourse for vaginal intercourse. A new condom should be used every time a change occurs from vaginal to anal or from anal to vaginal intercourse.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Progestin Hormone Injection (Depo-Provera)	<b>NUMBER:</b>  <b>334</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; CDC Contraceptive Technology, 20th Edition QFP, 2014; ACOG Committee Opinion, June 2014; Current CDC US Medical Eligibility Criteria for Contraceptive Use. Current US Selected Medical Practice Recommendations for contraceptive use.			

## PROGESTIN HORMONE INJECTION - DEPO-PROVERA

Family planning providers should use the most current CDC US Medical Eligibility Criteria for Contraceptive Use and US Selected Medical Practice Recommendations for Contraceptive Use to initiate and manage contraceptive methods,

### DESCRIPTION

Depo-Provera (DMPA) may be administered by either deep intramuscular injection (150mg/1 ml) or subcutaneously (104mg/0.65 ml) based on the manufacturer's recommendation. The only difference between these formulas is the route of administration.

To increase assurance that the client is not pregnant at the time of the first administration, it is recommended that Depo-Provera be administered only during the first five days after onset of a normal menstrual period; within two weeks of the date a repeat injection is due; within five days postpartum if not breast feeding; or if breast feeding, at four weeks postpartum. Clinician may utilize Same Day start protocol.

### HORMONE CONTRACEPTION AND HIV

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive. Women should be strongly advised to always use condoms if using a progestin-only injectable contraceptive because of the inconclusive body of evidence on the possible increased risk for HIV acquisition.

### MODE OF ACTION

When administered at the recommended dose to women every three months, inhibits the secretion of gonadotropin, which in turn prevents follicular maturation and ovulation and results in endometrial thinning. These actions produce its contraceptive effect.

### EFFECTIVENESS

99% effective, but effectiveness depends upon the punctuality of injection every three months.

### INDICATIONS FOR USE

1. Women who have developed estrogen related complications while taking combined OC's.
2. Clients who are non-compliant with other methods of contraception
3. Lactating women
4. Contraception before tubal ligation
5. Sickle cell disease

### CONTRAINDICATIONS

1. Absolute Contraindications

- a. Known or suspected pregnancy
- b. Undiagnosed vaginal bleeding
- c. Known or suspected malignancy of the breast
- d. Active thrombophlebitis
- e. Liver dysfunction or disease
- f. Known sensitivity to DMPA
- g. Current Breast Cancer
- 2. Relative Contraindications
  - a. Diabetes longer than 20 years or if accompanied by vascular disease, neuropathy or retinopathy
  - b. Hypertension (systolic  $\geq$  160 or diastolic  $\geq$  100) or heart disease
  - c. Kidney disease
  - d. Epilepsy
  - e. Asthma
  - f. Migraine headaches with aura
  - g. History of depression requiring treatment
  - h. Plans pregnancy within 1 year
  - i. Inability to tolerate irregular, frequent bleeding which may occur with DMPA
  - j. Inability to tolerate amenorrhea which is common with DMPA
  - k. History of breast cancer with no evidence of current disease for 5 years
  - l. Liver tumor or Hepatocellular adenoma
  - m. History of CVA
  - n. Systemic lupus erythematosus with positive antiphospholipid antibodies or severe thrombocytopenia
  - o. Unexplained vaginal bleeding
  - p. Multiple risk factors for cardiovascular disease

### **ADVANTAGES**

- 1. May be used for clients who cannot take estrogen
- 2. Convenient; not related to sexual intercourse
- 3. Provides relatively long-term protection
- 4. Because of decreased menstrual flow, may decrease menstrual cramps, PMS, ovulatory pain
- 5. Does not suppress lactation.

### **DISADVANTAGES**

- 1. Bleeding irregularity, principally amenorrhea. Possible delay in resumption of menses after discontinuing method.
- 2. Bone mineral density changes. A 3-year study of 18–39-year-old users noted women experienced steady gains in BMD after discontinuation of DMPA, regardless of duration of use. Lumbar spine BMD of DMPA users was similar to that of nonusers by 30 months after discontinuation. Increases in BMD at the hip among those discontinuing use of DMPA also were noted, but the gain in BMD at this location was lower than DMPA nonusers 30 months after discontinuation.
- 3. Fluid retention
- 4. Weight changes (average 8.1 lb. in 2 years)
- 5. Delayed return of fertility (median time is 10 months following the last injection)
- 6. Decrease in glucose tolerance
- 7. Must be repeated every three months for optimal effectiveness

## **SIDE EFFECTS**

1. Irregular bleeding patterns/amenorrhea- delayed return of menses after discontinuing method.
2. Weight gain
3. Delayed fertility – discuss return of fertility after discontinuation with client
4. Mood swings
5. Decreased libido
6. Hair loss
7. Bloating
8. Breast tenderness
9. Possible loss of bone density

## **INSTRUCTIONS TO THE CLIENT**

1. No back-up method is needed if administered at the proper time, If DMPA is started greater than 7 days after a menstrual period, and the woman needs to abstain from intercourse for 7 days after the injection or use additional contraceptive protection for the next 7 days.
2. Does not provide protection against STI's
3. Encourage adequate calcium intake
4. Efficacy is diminished if more than three months elapses between shots.
5. May be given early when necessary.
6. If a woman is more than 15 weeks from the date of the last injection, she can have the injection if it is reasonably certain that she is not pregnant (See US SPR for guidelines below for determining with reasonable certainty that a woman is not pregnant).
7. Document counseling about maintaining bone density:
  - a. adequate calcium intake
  - b. adequate vitamin D intake
  - c. adequate weight bearing exercise
  - d. not smoking
  - e. Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.

## **RETURN INJECTIONS**

1. At each injection visit:
  - a. check blood pressure (optional)
  - b. check weight (optional)
  - c. if the pt. reports heavy bleeding check Hgb. or Hct.
  - d. update LMP or bleeding patterns
  - e. review side effects:
    - i. changes in bleeding pattern
    - ii. may delay return to fertility
    - iii. weight changes
    - iv. headache
    - v. possible bone mineral changes
    - vi. decreased libido
  - f. review next injection date and provide calendar outlining next due date according to schedule
2. If return visit is 15th weeks since the last injection, the repeat injection can be given without requiring additional contraceptive protection. If a woman is more than 2 weeks late for her DMPA injection, she can have the injection if it is reasonably certain that she



is not pregnant. She needs to abstain from intercourse or use a backup method for 7 days after the injection. She may consider using EC if appropriate.

- a. Reasonably rule out pregnancy
  - i. Assure client is informed of the increased risk of pregnancy with very late injection (after 15 weeks)
  - ii. Reinforce the importance of timely injections.
- b. If unable to reasonably rule out pregnancy at 15 week visit:
  - i. Have client return when an accurate pregnancy test can be done
  - ii. Give a barrier to use until next Depo shot
3. Counsel about return of menses after discontinuing method.

#### **IF WANTING TO CHANGE TO ORAL CONTRACEPTIVES WHILE ON DEPO-PROVERA**


1. Start oral contraceptive pills no later than the beginning of the 13th Depo week. This will allow coverage for the first cycle
2. If starting oral contraceptive pills after the 14th week or 98 days,
  - a. Rule out pregnancy
  - b. Start pills with instructions to use a barrier method also for the first week.

#### **SAME DAY START**

1. Clinicians need to obtain a thorough history of unprotected intercourse since the last menstrual period to determine the need for pregnancy testing.
2. Women who have had unprotected intercourse in that time frame should have a sensitive urine pregnancy test to determine their status.
3. If patients have had unprotected intercourse in the last five days, they should be provided emergency contraception.
4. If Depo is given in the Same Day start manner, condoms must be used for the next seven days.
5. Patients will need to repeat the pregnancy test two to three weeks after the injection if they have had any recent unprotected intercourse.

#### **RESOURCES:**

*Contraceptive Technology* 20<sup>th</sup> Edition. Ch. 9. Injectable Contraceptives.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Protocols: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Progestin only oral contraceptives	<b>NUMBER:</b>  <b>335</b>
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	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> IAC 641-74; Contraceptive Technology, 20 <sup>th</sup> edition; QFP, 2014; Current CDC US Medical Eligibility Criteria for Contraceptive Use. Current US Selected Medical Practice Recommendations for contraceptive use.			

## PROGESTIN ONLY ORAL CONTRACEPTIVES

### DESCRIPTION

Oral Contraceptive Pills (POP) containing progestin or drospirenone only

### MODE OF ACTION

1. Ovulation is inhibited
2. Mid-cycle peaks of LH and FSH are suppressed
3. Cervical mucus thickened and decreased inhibiting sperm penetration
4. Endometrial changes including the development of an atrophic endometrium

### ABSOLUTE CONTRAINDICATIONS

1. Breast cancer- Current

### STRONG RELATIVE CONTRAINDICATIONS

1. History of breast cancer with no evidence of current disease for 5 years
2. Severe cirrhosis of the liver
3. History of a malabsorptive procedure type of bariatric surgery
4. Ischemic heart disease
5. Liver malignancy or Hepatocellular adenoma
6. Stroke
7. Systemic lupus erythematosus if positive antiphospholipid antibodies
8. See specific drug interaction information for antiretroviral and antimicrobial medication

### RELATIVE CONTRAINDICATIONS

1. Undiagnosed breast mass
2. DVT/ with high risk for recurrence
3. Major surgery with prolonged immobilization
4. Diabetes
5. Gallbladder disease
6. Headache without aura
7. History of cholestasis with prior combined oral contraceptive use
8. Hyperlipidemia
9. Hypertension with systolic  $\geq 160$  or diastolic  $\geq 100$  or vascular disease
10. Benign liver tumors
11. Multiple risk factors for cardiovascular disease
12. Past ectopic pregnancy
13. Systemic lupus erythematosus
14. Peripartum cardiomyopathy with moderately or severely impaired cardiac function

15. Solid organ transplant
16. Unexplained vaginal bleeding or unusual bleeding patterns
17. Postpartum state between 21 and 42 days without other risk of VTE.

### **ADVANTAGES**

1. Can be taken by women who cannot take estrogen.
2. Does not have the serious but rare complications of estrogen.
3. Can be started at any time if it is reasonably certain a woman is not pregnant.
4. Scanty or no menses, less anemia
5. Decreased cyclic menstrual cramps, pain, mood changes, headaches, breast tenderness, nausea
6. Suppresses pain during ovulation
7. Decreases risk of endometrial cancer, ovarian cancer, and pelvic inflammatory disease
8. Reestablish fertility quickly after discontinuing.
9. Users take the same pill every day (same color and hormone content and no pill free week)
10. Decrease in pelvic inflammatory disease because of less penetrable cervical mucus
11. Can be used by breast feeding women after breast feeding is well established without adverse effects on breast milk volume

### **DISADVANTAGES & PRECAUTIONS**

1. Lack of protection against STDs
2. Menstrual Cycle disturbances, irregular menstruation and amenorrhea
3. Weight gain
4. Breast tenderness
5. Increase in depression
6. Pills are very low-dose and must be taken daily at the same time each day.
7. Some medications decrease effectiveness.

### **EFFECTIVENESS**

When taken at approximately the same time every day 9 out of 100 women will become pregnant over a year's time. Clients should be told to take POPs within several hours of the same time daily. This recommendation is based on serum progestin levels which peak shortly after ingestion and decline to nearly undetectable levels 24 hours later. No clinical data are available that correlate pregnancy rates with timeliness in taking POPs. Drospirenone package labeling reported a first year failure rate of 4%, comparable to the failure rate in combined oral contraceptives.

### **WARNING SIGNS**

1. Abdominal Pain
2. Delayed period after several months of regular cycles
3. Repeated, very severe headaches

### **DIRECTIONS FOR USE**

1. Start the first pill on the day of the visit to the clinic or on the first day of the next period.
2. Take one pill per day until all pills from pack are finished. Try to take pills at the same time every day. Choose a time and take the pill at that time or within three hours after that time. If you take the pill more than three hours late, use condoms or a backup method or abstain from intercourse for the next 48 hours. Never miss a day.
3. When each pill pack is finished start a new pill pack the next day.
4. Use a back-up method for the first 2 days on POPs unless you have started your pills within the first five days of menstrual bleeding.
5. Use a latex condom if at risk on STDs /HIV

6. Ask for a package of or prescription for Plan B.

### **LATE OR MISSED PILLS**

1. Late or 1 Missed Pill
  - a. If you miss 1 pill take the missed pill as soon as you remember you did not take it. This may require taking two pills in a day.
  - b. Use a back-up method for 48 hours (2 days).
2. Two or more missed pills (increased chance of pregnancy)
  - a. Immediately start back-up method.
  - b. Restart pills right away
  - c. Take two (2) pills a day for two (2) days
  - d. If menstrual period does not begin within 4-6 weeks get a pregnancy test.
3. If pill taken even 3 hours late use a back-up method for two days.

### **PROGESTIN ONLY PILLS AND MENSTRUAL PERIODS**

1. Progestin only pills tend to make periods less regular and spotting is common. Some women stop having periods completely.
2. If bleeding pattern is a concern, return to the clinic for anemia test and to rule out pregnancy or STD.
3. There may be a delay of return to normal menses after method discontinuation.

### **DISCONTINUING PILLS**

1. If pills are discontinued start another method of contraception immediately.
2. If the client desires pregnancy, discuss return of normal menses and provide preconception information.
3. Fertility returns very quickly after discontinuation.

### **WARNING SIGN**


1. Severe lower abdominal pain, contact a physician immediately.
2. Delayed period after several months of regular cycles may be a sign of pregnancy.
3. Repeated very severe headaches

### **HORMONE CONTRACEPTION AND HIV**

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

### **INTERACTIONS WITH MEDICATIONS**

Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.

 <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Combined Oral Contraceptive Pills	<b>NUMBER:</b>  <b>336</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b>	
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## COMBINED ORAL CONTRACEPTIVE PILLS

### DESCRIPTION

Combined Oral contraceptive pills containing estrogen and progestin.

### COMBINED ORAL CONTRACEPTIVES FOR WOMEN IN LATER YEARS

Women aged 35 and older may continue to use oral contraceptives in the absence of risk factors. Women who have current or past history of thrombophlebitis or thromboembolic disorder, or cardiovascular disease, diabetes with vascular involvement, smoke more than 15 cigarettes daily, or are hypertensive, should not use combined oral contraceptives. The risks to women with hyperlipidemia who use combined oral contraceptives usually outweigh the advantages.

### HORMONE CONTRACEPTION AND HIV

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

### INITIAL PILL SELECTION

Family planning providers should use the most current CDC US Medical Eligibility Criteria for Contraceptive Use and US Selected Medical Practice Recommendations for Contraceptive Use to initiate and manage contraceptive methods,

Clinics currently begin all new pill candidates on OCP's containing <35 mcg. estrogen.

Note: Based on an epidemiologic review, the FDA concluded in September, 2011, that drospirenone-containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing pills. FDA is adding information about the studies to the labels of drospirenone-containing birth control pills. The revised drug labels will report that some epidemiologic studies reported as high as a three-fold increase in the risk of blood clots for drospirenone-containing products when compared to products containing levonorgestrel or some other progestins, whereas other epidemiological studies found no additional risk of blood clots with drospirenone-containing products.

The studies reviewed did not provide consistent estimates of the comparative risk of blood clots between birth control pills that contain drospirenone and those that do not. It is unclear whether the increased risk seen for blood clots in some of the epidemiologic studies is actually due to drospirenone-containing birth control pills.

To put the risk of developing a blood clot from a birth control pill into perspective: The risk of blood clots is higher when using any birth control pills than not using them, but still remains lower than the risk of developing blood clots in pregnancy and in the postpartum period.

Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.

**Healthcare providers should consider the risks and benefits of drospirenone-containing birth control pills and a woman's risk for developing a blood clot when prescribing these drugs.**

### REVISIT SCHEDULE

After initiation of oral contraceptives, the client may be given a year's supply of pills unless there is a clinical indication for follow-up earlier. If the client has initiated oral contraceptives at least 2 months previously, all parameters are assessed within normal limits, and there are not pill related complications, the client may be given a year's supply of oral contraceptives.

### EFFECTIVENESS

1. Theoretical effectiveness rate of 99.7%
2. Typical Use effectiveness rate of 98%

### MODE OF ACTION

Hormonal inhibition of ovulation

### CONTRAINDICATIONS

1. Absolute
  - a. Thrombophlebitis, thromboembolic disorders, cerebral vascular disease, coronary occlusion, or a past history of these conditions, or conditions predisposing to these problems, including severe hypertension
  - b. Markedly impaired liver function. Steroid hormones are contraindicated in patients with acute viral hepatitis until liver function tests return to normal
  - c. Known or suspected breast cancer
  - d. Undiagnosed abnormal vaginal bleeding
  - e. Known or suspected pregnancy
  - f. Smokers over the age of 35 who smoke more than 15 cigarettes daily. (see CDC US Medical Eligibility Criteria)
  - g. Headaches with focal neurological symptoms
  - h. Current major surgery with prolonged immobilization
  - i. Diabetes with vascular, renal or retinal involvement
  - j. Known or suspected carcinoma of the endometrium or other estrogen-dependent cancer
  - k. Liver cancer or Hepatocellular adenoma
  - l. Peripartum cardiomyopathy with moderately or severely impaired cardiac function
  - m. Within 6 months of peripartum cardiomyopathy with normal or impaired cardiac function
  - n. Less than 21 days postpartum in both breast feeding and non-breastfeeding women
2. Strong Relative
  - a. Migraine history without focal neurologic symptoms
  - b. Diabetes, prediabetes, or strong family history
  - c. Gallbladder disease/previous cholestasis on combined oral contraceptives
  - d. Hypertension with resting BP  $\geq$  140/90 on three different occasions
  - e. Elective major surgery planned in 4 weeks or less unless low dose heparin therapy is to be employed in conjunction with surgery
  - f. Chronic renal disease with hypertension
  - g. Full leg cast

- h. Woman over 35 who smoke less than 15 cigarettes/day (see CDC US MEC Criteria)
  - i. History of a malabsorptive procedure type of bariatric surgery
  - j. See specific drug interaction information for antiretroviral and antimicrobial medication
  - k. More than six months after peripartum cardiomyopathy with normal or impaired cardiac function
  - l. Women 21-30 days postpartum with other risk factors for VTE (age >35, history of VTE, BMI >30, smoking and others)
  - m. Breastfeeding women up to 30 days postpartum with or without other risk factors for VTE
  - n. Breastfeeding women 30-42 days postpartum with other risk factors for VTE
3. Relative
- a. History of heavy smoking and currently smokes (consider age factor)
  - b. Breastfeeding more than one month postpartum
  - c. Unreliable client
  - d. May initiate pills and observe for any worsening of the following conditions:
    - epilepsy
    - asthma
    - history of liver disease (with normal liver function test)
  - e. woman over the age of 35, non-smoker, and no predisposition to coronary artery disease
  - f. Varicose veins
  - g. Sickle Cell disease, advantages generally outweigh theoretical or proven risks
  - h. Women 21-42 days postpartum without other risk factors for VTE
  - i. Breastfeeding women >42 days postpartum without other risk factors for VTE

### **ADVANTAGES OF ORAL CONTRACEPTIVES**

1. Reliable method of contraception when used properly.
2. There is no interference with the normal sequence of sexual relations.
3. There are no requirements for preparation or disposal.
4. Definitely beneficial:
  - a. Dysfunctional uterine bleeding
  - b. Dysmenorrhea
  - c. Mittelschmerz
  - d. Endometriosis prophylaxis
  - e. Acne and Hirsutism
  - f. Hormone replacement for hypothalamic amenorrhea
  - g. Prevention of menstrual porphyria
5. Probably beneficial:
  - a. Functional ovarian cysts
  - b. Premenstrual syndrome
  - c. Control of bleeding (dyscrasia, anovulation)
6. Noncontraceptive benefits:
  - a. Decreased endometrial cancer
  - b. Decreased ovarian cancer
  - c. Decreased benign breast disease
  - d. Fewer ovarian cysts
  - e. Fewer uterine fibroids
  - f. Fewer ectopic pregnancies
  - g. More regular menses, decreased menstrual flow, decreased dysmenorrhea, decreased anemia

- h. Decreased Salpingitis
- i. Increased bone density
- j. Probable decreased endometriosis
- k. Decreased incidence of sickle cell crises

### **DISADVANTAGES OF ORAL CONTRACEPTIVES**

- 1. Potentially harmful side effects
- 2. Must remember to take pill every day
- 3. Does not protect against STI's
- 4. Possible decreased libido.

### **EMPHASIZE INSTRUCTIONS**

To call the clinic or report to the ER if any of the following warning signs should occur:

- A**.....Abdominal Pain (severe)
- C**.....Chest Pain (shortness of breath)
- H**.....Headaches (severe)
- E**.....Eye Problems (blurred or loss of vision)
- S**.....Severe Leg Pain (calf or thigh)

### **COUNSEL REGARDING THE POTENTIAL COMPLICATIONS ASSOCIATED WITH THE PILL:**

- 1. Possible life-threatening
  - a. Blood clots in the legs, pelvis, lungs or brain (see Initial Pill Selection)
  - b. Liver tumors (hepatocellular adenomas)
- 2. Serious
  - a. Gallbladder disease
  - b. Hypertension

### **COUNSEL REGARDING THE POTENTIAL SIDE EFFECTS ASSOCIATED WITH THE PILL:**

- 1. Nausea
- 2. Weight gain while commonly reported is usually associated with non-contraceptive causes
- 3. Fluid retention, breast fullness, or tenderness
- 4. Breakthrough bleeding (common in first three months of use)
- 5. Decreased menstrual flow (not always a nuisance)
- 6. Missed periods
- 7. Chloasma
- 8. Libido alterations
- 9. Depression, mood changes, and fatigue
- 10. Worsened acne – most often OCPs improve symptoms
- 11. Mild headaches
- 12. Alopecia (loss of hair)
- 13. Interaction with other drugs.
- 14. If history of depression, epilepsy, diabetes, hyperlipidemia, liver impairment client should inform primary provider of hormonal contraception.
- 15. Resumption of menses after discontinuation of the method.

### **LACTATION CONCERNS AND THE COMBINATION PILL**

- 1. Mini-pill (progestin only) is preferred for lactating women to avoid the decrease in lactation from combined pills and potential infant effects.
- 2. A combination oral contraceptive pill may be prescribed after 1 month postpartum (U.S. Medical Eligibility Criteria), under the following conditions:



- a. Client should understand that lactation may decrease in amount once combined oral contraceptives are started.
- b. Client understands that small amounts of hormone may be present in breast milk.
- c. Client understands that the amount of hormone present in breast milk at these dosages should not have any adverse effects on the infant.

**Instructions for Beginning Combination Oral Contraceptives: Instruct client that oral contraceptive pills do not protect against acquiring STDs/HIV. A barrier contraceptive should be used in combination with pills to help reduce the risk of STDs.**

1. When to initiate pills for a new or restart family planning client (not postpartum, not post-abortion, and not currently on pills):
  - a. Day 1 Start (28 day regimen): One tablet is taken daily from the first day of the menstrual cycle through day 28, counting the first day of the menstrual flow as "Day 1".
  - b. Sunday Start (28-day regimen): The first pill is taken on the Sunday after the start of menses. If menses starts on Sunday, the first pill should be taken on that day, and continued throughout the 28 days. (With either the same day or Sunday start, the client should be encouraged to use a backup method of condoms for seven (7) consecutive days.
  - c. Quick Start: If there is no suspicion of pregnancy, take the first pill in the clinic. Count the day the first pill is taken as day 1. Counsel the client that she is not fully protected until she has taken pills seven (7) days. Offer condoms as a back-up method. (Document that condoms were offered).
2. Postpartum in a non-breastfeeding woman
  - a. Women 21-42 days postpartum without other risk factors for VTE. Rule out pregnancy and begin pills per normal initiation protocol. Counsel that client is not fully protected until she has taken pills for 7 days
3. Post-abortion
  - a. Up to 2 weeks if no risk of pregnancy, initiate pills per normal pill initiation protocols. Client is not fully protected until pills are taken for seven (7) days. Offer condoms for a backup method, (document).
  - b. Initiate pills per normal protocol after menses. Client is not fully protected until she has taken pills for 7 days. Offer condoms, and document.

## **MAKING UP MISSED PILLS**

**Instructions to client:**

1. If you MISS one "active" pill:
  - a. Take as soon as you remember. Take next pill at your regular time. This means you may take two pills in one day.
2. You do not need to use a back-up birth control method. If you missed pills early in the cycle or during the last week of the previous cycle, you may want to use EC, If you MISS two or more "active" pills in a row:
  - a. Take the most recent missed pill as soon as possible. This means you will take two pills on the day you remember them. Discard any other missed pills.
  - b. Then take 1 pill a day until you finish the pack.
  - c. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as male condoms, female condoms, foam, contraceptive sponge, or abstinence) until you have taken the pills correctly for 7 days in a row.
  - d. Offer emergency contraception.
  - e. If you miss pills in the last week of the hormonal pill, do not take the hormone free pills, simply finish the rest of any hormone pills and then immediately start a new

pack. If you are unable to start anew pack right away, use a backup method of birth control or abstain from intercourse until you can start the new pack and have taken 7 consecutive pills from the new pack.


3. If you forget any of the seven “reminder” pills in Week 4:
  - a. THROW AWAY the pills you missed.
  - b. Keep taking 1 pill each day until the pack is empty.
  - c. You do not need a back-up method.
4. Client should call the clinic if one of the following situations should occur:
  - a. If one or more pills is missed and no menses occur.
  - b. If two (2) consecutive menses are missed (regardless of whether any pills were missed)
  - c. If intermenstrual spotting occurs for 3 or more cycles.

#### **EXTENDED CYCLE OCP USE**

1. Up to 91-day cycle or 13 week cycle, 84 days of active pills/7 days of inactive pills with up to four withdrawal bleeds per year
2. Same mechanism of action as regular combined contraceptive pills and same effectiveness
3. Same contraindications as regular combined contraceptive pills
4. Same advantages and disadvantages as regular combined contraceptive pills with an additional advantage of only four withdrawal bleeds per year instead of 13
5. Same side effects as combined contraceptive pills with the additional side effect of increased likelihood of break through bleeding during the first few cycles
6. Same instructions as regular combined contraceptive pills except that it is up to a 91 day/ 13 week regimen not 28 day/4 week regimen

#### **FERTILITY RETURN**

Clients should be aware of the variable lengths of time for fertility return after discontinuing any contraceptive.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Subdermal Progestin Implant	<b>NUMBER:</b>  <b>337</b>
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## SUBDERMAL PROGESTIN IMPLANT

### DESCRIPTION

Nexplanon is an implantable form of birth control. It is a single flexible, radioopaque, soft, thin plastic rod that is placed under the skin of the client's upper arm (ideally, non-dominant arm). All healthcare providers performing insertions and/or removals of NEXPLANON should receive instructions and training prior to inserting or removing the implant. A single NEXPLANON implant is inserted subdermally just under the skin at the inner side of the non-dominant upper arm. The insertion site is overlying the triceps muscle about 8-10 cm (3-4 inches) from the medial epicondyle of the humerus and 3-5 cm (1.25-2 inches) posterior to the sulcus (groove) between the biceps and triceps muscles. This location is intended to avoid the large blood vessels and nerves lying within and surrounding the sulcus. An implant inserted more deeply than subdermally (deep insertion) may not be palpable and the localization and/or removal can be difficult or impossible. Providers should see Warnings and Precautions on current Prescribing Information. Follow manufacturer information for removing the implant. It contains the progestin etonogesterol that is steadily released over a 3-year period to prevent pregnancy. Counsel clients about back up contraception as appropriate.

Clients should be given information about the risks of implant insertion as part of the informed consent process.

### EFFECTIVENESS

The pregnancy rate is less than 1 per 200 women. There is theoretical decreased effectiveness for women with a BMI over 130%.

### MODE OF ACTION

Nexplanon has two main mechanisms of action

1. Primarily, it effectively inhibits ovulation
2. It increases the viscosity of cervical mucus

### CONTRAINDICATIONS

1. **Absolute Contraindications--**
  - a. Pregnancy
  - b. Current breast cancer
  - c. Known hypersensitivity to any components of Nexplanon-plastic rod, core of ethylene vinyl acetate and etonogesterol
2. **Strong Relative Contraindications--** exercise caution when providing/monitor for side effects
  - a. Undiagnosed vaginal bleeding
  - b. Malignant liver tumors or Hepatocellular adenoma

- c. Current and/or history of ischemic heart disease
- d. Past history of breast cancer with no evidence of disease for 5 years
- e. Active liver disease including active viral hepatitis, cirrhosis, and liver tumors (benign and malignant)
- f. Use of certain anticonvulsants: phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine
- g. Cirrhosis - severe
- h. Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies
- i. History of stroke
- 3. **Relative Contraindications-** The advantages of using the Nexplanon generally outweigh the risk
  - a. Multiple risk factors for arterial cardiovascular disease
  - b. Valvular heart disease such as aortic stenosis without complications
  - c. Hypertension with systolic > 160 or diastolic > 100 or with vascular disease
  - d. History of DVT/PE
  - e. Major surgery with prolonged immobilization
  - f. Known thrombogenic mutations
  - g. Known hyperlipidemia
  - h. Migraine
  - i. Vaginal bleeding patterns, irregular, heavy or prolonged
  - j. Abnormal Pap smear or cervical neoplasia awaiting treatment
  - k. Undiagnosed breast mass with pending evaluation
  - l. Diabetes
  - m. Gallbladder disease
  - n. Breastfeeding less than 4 weeks
  - o. Benign liver tumors
  - p. Peripartum cardiomyopathy with moderately or severely impaired cardiac function
  - q. Undiagnosed breast mass
  - r. History of cholestasis on COCs
  - s. Stroke
  - t. Systemic lupus erythematosus with severe thrombocytopenia or immunosuppressive therapy

#### **WARNING SIGNS ASSOCIATED WITH NEXPLANON**

1. Any subjective symptoms of pregnancy
2. Any sign of a blood clot; including sharp chest pain, sudden shortness of breath, persistent calf pain, crushing chest pain, heaviness in the chest, sudden severe headache, vomiting, dizziness or fainting with visual problems
3. Sudden partial or complete blindness
4. Yellowing of skin and whites of the eyes
5. Severe pain, swelling or tenderness in the abdomen
6. Breast lumps
7. Signs of severe depression
8. Heavy vaginal bleeding

#### **COUNSELING REGARDING THE POTENTIAL COMPLICATIONS ASSOCIATED WITH NEXPLANON**

1. Complications with insertion or removal of device
  - a. Pain, irritation, swelling, hematoma or bruising at insertion site

- b. Scarring, including a thick scar called a keloid
- c. Infection
- d. Implant breaks make removal difficult
- e. Thick scar tissue forms around Nexplanon making removal difficult
- f. Rarely expulsion of implant
- g. Rarely need for surgery to remove implant
- 3. Ectopic pregnancy
- 4. Interactions with other medicines (see website)
- 5. Headache
- 6. Weight gain
- 7. Acne

### **COUNSEL REGARDING POTENTIAL SIDE EFFECTS (ASSOCIATED WITH NEXPLANON)**

- 1. Irregular and unpredictable bleeding ranging from infrequent to prolonged
- 2. Headache
- 3. Acne
- 4. Weight gain average gain is 2.8 pounds at 1 year and 3.7 pounds at 2 years
- 5. Depression

### **ADVANTAGES**

- 1. No action is required for contraception
- 2. It is always there when needed
- 3. Progestin is considered to be estrogen friendly therefore no impact on bone density
- 4. Can be inserted at any time if it is reasonably certain that the woman is not pregnant

### **DISADVANTAGES**

- 1. Must be changed every 3 years
- 2. Unpredictable bleeding patterns, perhaps a delay in return of normal menses after method discontinuation.
- 3. Requires clinical provider to insert and remove

### **MAINTENANCE**

- 1. The only maintenance of Nexplanon involves:
  - a. Client aware of danger signs
  - b. Annual exam to assess problems and check position of Nexplanon
  - c. Client should be aware of when it should be replaced
  - d. Call the clinic with any problems related to method

### **FERTILITY RETURN**

Clients should be aware of the variable lengths of time for fertility return after discontinuing any contraceptive.

### **HORMONE CONTRACEPTION AND HIV**


The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

### **INTERACTIONS WITH OTHER MEDICATIONS**

Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.

### **RESOURCE:**

*Contraceptive Technology* 20<sup>th</sup> Edition. Ch. 8. Contraceptive Implants.

 <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Intrauterine Device (IUD): Paragard	<b>NUMBER:</b>  <b>338</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b> FP Policy 339, IUS: Mirena	
	<b>Authority:</b> IAC 641-74; Current CDC U.S. Medical Eligibility Criteria; Contraceptive Technology, 20 <sup>th</sup> Edition; QFP, 2014			

## INTRAUTERINE DEVICE (IUD): PARAGARD

### DESCRIPTION

The Copper T Intrauterine Device is a small T-shaped device made of polyethylene with added barium sulfate for x-ray visibility. The T shaped device has fine copper wire wound around the vertical stem. The horizontal arms of the T have a sleeve of copper around them. The bottom of the T has a white knotted loop of polyethylene string. Misoprostol is not recommended for routine use before IUD insertion. Misoprostol at the time of insertion might be helpful in select circumstances (e.g., in women with a recent failed insertion). Paracervical block with lidocaine might reduce patient pain during IUD insertion. Clients should be given information about the risks of insertion as part of the informed consent process.

### EFFECTIVENESS

1. Theoretical effectiveness rate of 99.2%
2. Use effectiveness rate of 99.4%

### MECHANISMS OF ACTION

It is not known exactly how the IUD works; the following are hypotheses:

1. Increased mobility of ovum in fallopian tubes.
2. Local foreign body inflammatory response causing lysis of the blastocyst and/or prevention of implantation.
3. Mechanical dislodging of the implanted blastocyst from the endometrium.
4. Copper interferes with estrogen uptake and its intracellular effects on the endometrium.
5. Immobilization of sperm as they pass through the uterine cavity.
6. Prevents fertilization

### CONTRAINDICATIONS

1. Absolute contraindications
  - a. Acute, active pelvic infections/STD, including immediate postpartum uterine infection
  - b. Pregnancy or suspected Gestational trophoblastic disease
  - c. Uterine abnormalities: a distorted uterine cavity such as bicornuate uterus
  - d. Cervical cancer
  - e. Endometrial cancer
  - f. Immediately post septic abortion
  - g. Pelvic tuberculosis
  - h. Unexplained vaginal bleeding
2. Strong Relative Contraindications
  - a. AIDS
  - b. Complicated solid organ transplant
  - c. Risk factors for STD's

- d. Impaired response to infection
- e. Previous problems with an IUD or IUS
- f. Previous severe vaso-vagal reaction
- g. Known or suspected allergy to copper
- h. Severe thrombocytopenia related to Systemic lupus erythematosus
- i. Unresolved abnormal pap smear
- 3. Relative Contraindications - The advantages of using the IUD generally outweigh the risk
  - a. Severe dysmenorrhea
  - b. Prolonged or heavy menstrual bleeding
  - c. Endometriosis-Copper IUD may intensify dysmenorrhea
  - d. Anemia-Copper IUD may increase blood loss
  - e. Solid organ transplant – uncomplicated
  - f. Single episode of pelvic infection if client desires future pregnancy
  - g. Rheumatoid arthritis on immunosuppressive therapy

### **WARNING SIGNS ASSOCIATED WITH IUD**

- 1. A late or missed period and/or feelings of pregnancy
- 2. Abdominal pain or pelvic pain or pain with intercourse (suggests perforation or infection)
- 3. Fever/chills (suggests infection)
- 4. Foul vaginal discharge (suggests infection)
- 5. Missing or change in length of IUD strings (suggests expulsion or displacement)
- 6. Severe or prolonged vaginal bleeding (suggests dislocation or perforation).

### **COUNSEL REGARDING THE POTENTIAL COMPLICATIONS (ASSOCIATED WITH THE IUD)**

- 1. Uterine perforation
- 2. Vaso-vagal response with insertion/removal (hypotension, pallor, brachycardia)
- 3. Pelvic inflammatory disease
- 4. Rejection/expulsion of device; rate of expulsion may be increased with nulliparous women
- 5. Pregnancy
- 6. Risk of possible spontaneous abortion if conception occurs (chances are 25% risk if IUD removed, and 50% if IUD left in place)
- 7. Advise clients that copper devices may not be effective after ten years.
- 8. Advise client the importance of remaining in a long term mutually monogamous relationship.

### **COUNSEL REGARDING POTENTIAL SIDE EFFECTS (ASSOCIATED WITH IUD)**

- 1. Increased dysmenorrhea
- 2. Heavier menstrual flow
- 3. Mid cycle bleeding (may be symptom of infection)
- 4. Spotting (not unusual in first 3 months)

### **ADVANTAGES**

- 1. No action is required for contraception except for monthly string checks up to 10 years.
- 2. The IUD should not be noticeable during intercourse.
- 3. It is always there when needed.

### **DISADVANTAGES**

- 1. Must be changed periodically as indicated by manufacturer (10 years).
- 2. May cause painful or very heavy menses.

3. May be expelled without the woman's knowledge.
4. Does not protect against STDs.

### **MAINTENANCE**

1. The only maintenance of the IUD involves:
  - a. Client checking IUD strings at end of each menses.
  - b. Client aware of danger signs.
  - c. Annual exam to assess problems and check position of the IUD.
  - d. Client should be aware of type of IUD to insure timely replacement.
  - e. Call the clinic with any problems related to method.

### **STD TESTING**

If a woman has not been screened for STDs according to STD screening guidelines, screening must be performed at the time of insertion.


### **FERTILITY RETURN**

Clients should be aware of the variable lengths of time for fertility return after discontinuing any contraceptive.

### **RESOURCES**

*Contraceptive Technology* 20<sup>th</sup> Edition. Ch. 7. Intrauterine Devices (IUDs)



  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods	<b>SUBJECT:</b> Intrauterine System (IUS): Hormone containing IUDs	<b>NUMBER:</b>  <b>339</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> July 2019
	<b>Status:</b>	<b>Cross Reference:</b> FP Policy 338, IUD: Copper T	
	<b>Authority:</b> IAC 641-74; Current CDC U.S. Medical Eligibility Criteria; QFP, 2014; Current CDC US Medical Eligibility Criteria for Contraceptive Use		

## INTRAUTERINE SYSTEM

### DESCRIPTION

There are multiple Intrauterine System (IUS): Hormone containing IUDs available in the US. The prescribing information is similar for each but providers are expected to know the specific indications and prescribing information for each method. The policy below is generalized.

Misoprostol is not recommended for routine use before IUD insertion. Misoprostol at the time of insertion might be helpful in select circumstances (e.g., in women with a recent failed insertion). Paracervical block with lidocaine might reduce patient pain during IUD insertion. Clients should be given information about insertion risks as part of the informed consent process.

### EFFECTIVENESS

1. Theoretical effectiveness rate of 99.9%
2. Use effectiveness rate of 99.9%

### MECHANISMS OF ACTION

It is not known exactly how the IUS works; the following are hypotheses:

1. The progestin thickens cervical mucus, which interferes with sperm motility and function
2. A weak local foreign body inflammatory response is noted with the IUS but is less pronounced than with copper IUD's
3. Prevents endometrial proliferation-full suppression noted after about 3 months with substantial decrease in menstrual flow.

### CONTRAINDICATIONS

1. Absolute Contraindications-
  - a. Acute, active pelvic infections/STD, including immediate post-partum uterine infection
  - b. Pregnancy
  - c. Uterine abnormalities:
    - i. Bicornuate uterus
    - ii. Uterine leiomyoma that distorts uterine cavity
  - a. Breast cancer - current
  - b. Cervical cancer awaiting treatment
  - c. Endometrial cancer
  - d. Gestational trophoblastic disease with persistent levels of  $\beta$  -hCG levels
  - e. Immediately post septic abortion
  - f. Unexplained vaginal bleeding
  - g. Pelvic tuberculosis
2. Strong Relative Contraindications-
  - a. Undiagnosed abnormal bleeding,

- b. Unresolved abnormal pap smear
- c. Previous problems with an IUD or IUS
- d. Previous severe vaso-vagal reaction
- e. AIDS (see drug interactions)
- f. History of breast cancer and no evidence of current disease for 5 years
- g. Severe cirrhosis of the liver
- h. Migraine with aura
- i. Current history of ischemic heart disease
- j. Liver tumors or Hepatocellular adenoma
- k. Complicated solid organ transplant
- l. Systemic lupus erythematosus with antiphospholipid antibodies
- m. Gestational trophoblastic disease with decreasing or undetectable  $\beta$  – hCG levels
- 3. Relative Contraindications-The advantages of using the IUS generally outweigh the risk
  - a. Solid organ transplant - uncomplicated
  - b. Current DVT/PE
  - c. Diabetes
  - d. Undiagnosed breast mass
  - e. Uterine fibroids, cervical stenosis or any other anatomical abnormality that does not cause uterine distortion
  - f. Multiple risk factors for cardiovascular disease: older age, smoking, diabetes, hyperlipidemia, and hypertension-with multiple risk factors. Some progestins may increase the risk of thrombosis
  - g. Elevated blood pressure measurements over 160/100 or HTN with vascular disease
  - h. History of DVT/PE-some progestins may increase risk of thrombosis
  - i. Major surgery with prolonged immobilization
  - j. Current and history of ischaemic heart disease including stroke-some progestins may reduce HDL levels
  - k. Headaches without focal neurologic s/s- some progestins may increase headaches
  - l. Cervical intraepithelial neoplasia
  - m. Gallbladder disease
  - n. HIV
  - o. Immediate postpartum (<4 weeks)
  - p. Rheumatoid arthritis on immunosuppressive therapy
  - q. Systemic lupus erythematosus with severe thrombocytopenia or on immunosuppressive treatment
  - r. Thrombotic mutations

### **WARNING SIGNS ASSOCIATED WITH IUS**

1. A late or missed period is seldom related to pregnancy unless accompanied by other signs and symptoms of pregnancy but should be evaluated if new onset.
2. Abdominal pain or pelvic pain or pain with intercourse (suggests perforation or infection)
3. Fever/chills (suggests infection)
4. Foul vaginal discharge (suggests infection)
5. Missing or change in length of IUS strings (suggests expulsion or displacement)
6. Severe or prolonged vaginal bleeding or spotting
7. Yellowing of skin or eyes

### **COUNSEL REGARDING THE POTENTIAL COMPLICATIONS (ASSOCIATED WITH THE IUS)**

1. Uterine perforation
2. Vaso-vagal response with insertion/removal (hypotension, pallor, brachycardia)

3. Pelvic inflammatory disease
4. Rejection/Expulsion of device; rate of expulsion may be increased with nulliparous women
5. Pregnancy, specifically ectopic pregnancy
6. Risk of possible spontaneous abortion if conception occurs (chances are 25% risk if IUS removed, and 50% if IUS left in place)
7. Sepsis
8. The FDA approved lifespan for each IUS is variable. See prescribing information. Use of any IUS beyond the approved lifespan is considered off-label use and clinics should have a policy in place for off-label medication use approved by their medical director. Advise clients the importance of remaining in a long term mutually monogamous relationship
9. IUS are very effective in preventing pregnancy so there is an overall decreased risk of pregnancy. Because there is an increased risk of ectopic pregnancy in the unlikely event a pregnancy occurs, women should be encouraged to seek immediate care with known or suspected pregnancy.

### **COUNSEL REGARDING POTENTIAL SIDE EFFECTS (ASSOCIATED WITH IUS)**

1. Irregular periods for 3 to 6 months post insertion, delay in return to normal menses after discontinuation of the method. Discuss return of fertility following discontinuation.
2. Amenorrhea in 1/5 of women
3. Possible hormonal side effects (mood changes, acne, headache, breast tenderness, nausea, hirsutism)

### **ADVANTAGES**

1. No action is required for contraception except for monthly string checks for up to 5 years.
2. The IUS should not be noticeable during intercourse.
3. It is always there when needed.
4. Reduction in bleeding and related anemias
5. Reduction in dysmenorrhea
6. Reduction in ectopic pregnancies through an overall reduction in pregnancies.
7. Can be inserted at any time if it is reasonably certain the woman is not pregnant as described in the US SPR.

### **DISADVANTAGES**

1. Must be changed periodically as indicated by manufacturer (5 years).
2. May be expelled without the woman's knowledge.
3. Does not protect against STDs
4. Require cervical inspection and bimanual exam before insertion.

### **MAINTENANCE**

1. The only maintenance of the IUS involves:
  - a. Client checking IUS string monthly.
  - b. Client aware of danger signs.
  - c. Annual exam to assess problems and check position of the IUS.
  - d. Client should be aware of type of IUS to insure timely replacement.
  - e. Counsel about need for back up contraception as appropriate
  - f. Call the clinic with any problems related to method.

### **STD TESTING**


If a woman has not been screened for STDs according to STD screening guidelines, screening must be performed at the time of insertion.

**INTERACTIONS WITH OTHER MEDICATIONS**

Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives

**RESOURCE**

*Contraceptive Technology 20th Edition*. Ch. 7. Intrauterine Contraceptives (IUCs)

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Emergency Contraceptive Pills	<b>NUMBER:</b>  <b>340</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b> Policies 335 and 336		
	<b>Authority:</b> IAC 641-74; Contraceptive Technology, 19th edition; QFP, 2014			

## EMERGENCY CONTRACEPTIVE PILLS

### DESCRIPTION

There are three types of emergency contraceptive pills

1. Progestin, (levonogestrel) only pills, (preferred method based on tolerance and side effects)
2. Estrogen (ethinyl estradiol) and progestin, (norgestrel or levonogestrel) combined pills
3. Ulipristal acetate (ella™), progesterone agonist/antagonist whose likely main effect is to inhibit or delay ovulation. ella™ is available by prescription only.

### MODE OF ACTION

1. Delay or inhibit ovulation
2. Interferes with sperm migration and function
3. May interfere with fertilization
4. Interferes with the development of a receptive uterine lining and may inhibit implantation
5. Affects necessary hormone levels, by the corpus luteum
6. May interfere with tubal transport.

### CONTRAINDICATIONS

Pregnancy – if a woman is already pregnant treatment with emergency contraceptive pills is ineffective (Emergency contraceptive pills will not disrupt an established pregnancy.) There is no evidence of post-fertilization effect. Breastfeeding - women who are breastfeeding should not use ella™.

### PRECAUTIONS, RISK DURING PREGNANCY USUALLY OUTWEIGHS RISKS FOR ECPS

There are no medical contraindications to the use of emergency contraceptive pills except pregnancy. The advantages of ECP usually outweigh the theoretical risk even for women with contraindications to the ongoing use of combined oral contraceptive pills (such as vascular disease). In the United States, labeling for Plan B includes three contraindications: 1) pregnancy 2) undiagnosed abnormal genital bleeding, 3) sensitivity to any component of the product.

Ella™ is contraindicated for use in the case of known or suspected pregnancy. The risks to a fetus when ella™ is administered to a pregnant woman are unknown. If this drug is inadvertently used during pregnancy, the woman should be apprised of the potential hazard to the fetus.

### CLIENT EDUCATION AND COUNSELING

All family planning clients need to be provided information about emergency contraceptive pills and when to use them. Clients must be provided with any one of the following:

1. Emergency contraceptive pills to have on hand
2. A prescription for emergency contraceptive pills
3. A phone number to call in case of need

## INDICATIONS FOR USE

1. No contraceptive used during intercourse
2. Male condom slipped, broke or leaked
3. Female condom, diaphragm or cervical cap inserted incorrectly
4. Missed contraceptive pills
5. More than 14 days late for Depo Provera injection
6. More than 2 days late starting vaginal ring or patch
7. Error in coitus interruptus
8. Error in periodic abstinence
9. IUD partially or totally expelled
10. Exposure to a teratogen when not protected by effective contraception

## PROGESTIN ONLY CONTRACEPTIVE PILLS

### Effectiveness

Up to 89% effective

### Possible Side Effects

1. Nausea and vomiting
2. Fatigue
3. Breast tenderness
4. Headache
5. Abdominal pain
6. Dizziness

Directions for use progestin only pills - multiple brands are available and clients should follow the directions for the pill they use

Brand Name	First Dose	Second Dose
Plan B One Step	1 pill	(no second dose)
Next Choice	1 pill	1 pill 12 hours after first dose
Or		
Progestin only pills	20 within 72 hours	20 pills 12 hours after first dose

### Instructions to the client

1. Take the first dose as soon as possible after unprotected sex.
2. When directed by pill label, take second dose of Progestin Only Pill 12 hours after the first dose.
3. Common side effects:
  - a. Nausea
  - b. Breast tenderness
  - c. Headache
  - d. Abdominal pain
  - e. Dizziness
4. Menstrual changes:
  - a. Spotting
  - b. Change in amount, duration or timing of next period

## COMBINED ESTROGEN AND PROGESTIN EMERGENCY CONTRACEPTIVE PILLS

### Effectiveness

75% effective

### Directions for Use

### Number of Pills to Use

Brand Name	First dose within 120 hours	Second dose 12 hours after first dose	Anti-nausea RX recommended
CRYSSELLE	4 white	4 white	yes
OVRAL	2 white	2 white	yes
LO-OVRAL	4 white	4 white	yes
LEVORA	4 white	4 white	yes
LEVLEN	4 yellow-orange	4 yellow-orange	yes
NORDETTE	4 light orange	4 light orange	yes
TRIPHASIL	4 yellow	4 yellow	yes
TRILEVLEN	4 yellow	4 yellow	yes
TRIVORA	4 pink	4 pink	yes
ALESSE	5 pink	5 pink	yes
LEVLITE	5 pink	5 pink	yes
AVIANE	5 orange	5 orange	yes
LOW-OGESTREL	4 white	4 white	yes
OGESTREL	2 white	2 white	yes
PORTIA	4 pink	4 pink	yes
SEASONALE	4 pink	4 pink	yes
ENPRESS	4 orange	4 orange	yes
LESSINA	5 pink	5 pink	yes

### Patient Instructions

1. Take the first 1, 2, 4, or 5 pills as soon as you can after you have unprotected intercourse
2. Take the next 1, 2, 4, or 5 pills 12 hours after you took the first
3. Common side effects
  - a. Nausea and/or vomiting
  - b. Breast tenderness
  - c. Irregular bleeding
  - d. Headaches
4. Counsel patient to eat a snack or drink milk before she takes the pills
5. If you feel sick to your stomach this will only last for one day. Options for treating nausea:
6. Nonprescription drugs:
  - a. Dramamine 50mg tablets, 1 or 2 tablets by mouth every 4-6 hrs.
  - b. Marezine 50mg tablets, 1 tablet by mouth every 4-6 hrs.
7. Prescription drugs: (warn patients not to drive or use dangerous equipment)
  - a. Tigan 250mg tablets, 1 tablet every 8 hrs. Or 200mg suppository, 1 suppository rectally every 8 hrs.
  - b. Phenergan 25mg tablets, 1 tablet every 12 hrs. Or 25mg rectal suppository, 1 rectally every 12 hrs.
8. If you throw up less than one hour after you take the pills, call the clinic. (Current research suggests that enough medication has been absorbed if vomiting occurs after one hour.)

## **ULIPRISTAL ACETATE (ELLA™)**

### **Effectiveness**

ella™ statistically significantly reduced the pregnancy rate, from an expected 5.6% to an observed 1.9%, when taken within 72 hours after unprotected intercourse. There were no pregnancies observed in the women who took ella™ more than 72 hours after unprotected intercourse (10% of women who received ella™). BMI may impact effectiveness.

### **Directions for use**

1. ella™ is not indicated for termination of an existing pregnancy. Exclude pregnancy before administering.
2. Ectopic pregnancy: Women who become pregnant or complain of lower abdominal pain after taking ella™ should be evaluated for ectopic pregnancy
3. Effect on menstrual cycle: ella™ may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be ruled out.
4. The profile of side effects for ella™ is similar to that of FDA-approved levonorgestrel emergency contraceptives.

### **Patient instructions**

1. Instruct patients to take ella™ as soon as possible and not more than 120 hours after unprotected intercourse or a known or suspected contraceptive failure.
2. Advise patients that they should not take ella™ if they know or suspect they are pregnant and that ella™ is not indicated for termination of an existing pregnancy.
3. Advise patients to contact their healthcare provider immediately in case of vomiting within three hours of taking the tablet, to discuss whether to take another tablet.
4. Advise patients to seek medical attention if they experience severe lower abdominal pain 3 to 5 weeks after taking ella™, in order to be evaluated for an ectopic pregnancy.
5. Advise patients to contact their healthcare provider and consider the possibility of pregnancy if their period is delayed after taking ella™ by more than 1 week beyond the date it was expected.
6. Advise patients not to use ella™ as routine contraception, or to use it repeatedly in the same menstrual cycle.
7. Advise patients that ella™ may reduce the contraceptive action of regular hormonal contraceptive methods and to use a reliable barrier method of contraception after using ella™, for any subsequent acts of intercourse that occur in that same menstrual cycle.
8. Inform patients that ella™ does not protect against HIV-infection (AIDS) and other sexually transmitted diseases/infections.
9. Advise patients that they should not use ella™ if they are breastfeeding.
10. Abstain from intercourse or use barrier contraception for the next 7 days starting or resuming regular contraception or the next menses, whichever comes next.
11. Resume hormonal contraception no sooner than 5 days after use of UPA. Starting them sooner may decrease effectiveness of UPA>


### **FOLLOW-UP INSTRUCTIONS FOR ALL EMERGENCY CONTRACEPTIVE PILL USERS**

1. Your next period may start a few days earlier or later. If your period does not start within 4 weeks, or you have symptoms of pregnancy, call the clinic.
2. Make an appointment to come back to the clinic in 4 weeks for a follow-up visit as indicated.
3. Remember, ECPs do not protect against AIDS or other sexually transmitted disease.
4. Avoid intercourse or use a barrier method until onset of next menses.
5. If using OCPs continue taking remaining pills for that cycle, but use a barrier method until your next menses.



6. As soon as possible, start using a method of birth control. Emergency Contraceptive pills are meant for emergency use only
7. Serious complications are rare. If any of the following occur, report to the clinic immediately:
  - a. Chest or arm pain
  - b. Shortness of breath
  - c. Unusual pain or swelling in the legs
  - d. Severe headaches, dizziness, numbness, weakness
  - e. Abdominal pain
  - f. Blurred vision, loss of vision, trouble speaking
  - g. Jaundice

<b>If</b>	<b>Then</b>
Client takes ECPs during the first week of her cycle when on oral contraceptives,	Restart pills with the pill for the first day after ECPs and abstain or use a barrier method until menses
Client takes ECPs during the first week of her cycle with the patch or vaginal ring,	Replace the patch or ring immediately after taking ECPs and abstain or use a barrier method until menses
Client is past the first week of oral contraceptives, patch, or vaginal ring,	Abstain or use a barrier method until next menses
Client is past the 13 <sup>th</sup> week of Depo Provera,	Wait until menses or a negative pregnancy test after 2 weeks to give more Depo Provera, abstain or use a barrier method until next Depo Provera shot is given
Client misses menses after ECPs,	Restart previous or new method only after a negative pregnancy test
Client restarts a method after menses,	Abstain or use a barrier method as with any new restart
Client is not using any method,	Abstain or use a barrier method until next menses

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Contraceptive Methods		<b>SUBJECT:</b> Paragard intrauterine Contraceptive System as Emergency Contraception	<b>NUMBER:</b> <b>341</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b> FPM 338 INTRAUTERINE DEVICE (IUD): Paragard		
	<b>Authority:</b> IAC 641-74; Current CDC U.S. Medical Eligibility Criteria; ACOG Practice Bulletin No. 112, Emergency Contraception, May 2010; QFP, 2014; Current US Selected Medical Practice Recommendations for contraceptive use.			

## PARAGARD INTRAUTERINE CONTRACEPTION SYSTEM AS EMERGENCY CONTRACEPTION

### WHO ARE CANDIDATES FOR EMERGENCY CONTRACEPTION?

The World Health Organization's "Medical Eligibility Criteria for Contraceptive Use" include no conditions in which the risks of emergency contraception use outweigh the benefits. These criteria note specifically that women with previous ectopic pregnancy, cardiovascular disease, migraines, or liver disease and women who are breastfeeding may use emergency contraception. Reproductive-aged women who are victims of sexual assault should always be offered emergency contraception.

### WHAT SCREENING PROCEDURES ARE NEEDED BEFORE PROVISION OF EMERGENCY CONTRACEPTION?

No clinical examination or pregnancy testing is necessary before provision or prescription of emergency contraception is provided. One should exclude the possibility that a woman may already be pregnant by assessing the date of the last menstrual period and the first episode of unprotected intercourse and the last episode of unprotected intercourse. A pregnancy test may be helpful if there is some doubt about whether she is already pregnant from intercourse in the past. Emergency contraception should not be withheld because the unprotected coital act may not have occurred on a fertile day of the menstrual cycle.

### WHEN SHOULD EMERGENCY CONTRACEPTION BE INITIATED?

Treatment should be initiated as soon as possible after unprotected or inadequately protected intercourse to maximize efficacy, which decreases with time. The copper IUD can be inserted within 5 days of the first act of unprotected intercourse as an EC. If the day of ovulation can be estimated, the copper IUD can be inserted beyond 5 days of sexual intercourse as long as insertion does not occur >5 days after ovulation.

### STD TESTING

If a woman has not been screened for STDs according to STD screening guidelines, screening must be performed at the time of insertion.

### WHEN IS AN INTRAUTERINE DEVICE APPROPRIATE FOR EMERGENCY CONTRACEPTION?

Use of a copper IUD for emergency contraception, first reported in 1976 has been studied in prospective cohort trials with pregnancy rates of 0–0.1%. In these trials, the IUD was inserted

up to 5 days after unprotected intercourse. A more recent report of 1,013 women who underwent insertion of a copper IUD for emergency contraception, including 170 nulliparous women, found a pregnancy rate of 0.2%. One advantage of using the copper IUD for emergency contraception is that it can be retained for continued long-term contraception. The same study found 86% of parous women and 80% of nulliparous women maintained the IUD for contraception. Insertion of an IUD is not cost saving when used solely for emergency contraception. However, it becomes cost-effective when used for as little as 4 months as an ongoing contraceptive method following insertion as an emergency contraceptive.


No randomized controlled trials have compared IUD insertion with medical regimens for emergency contraception. A recent meta-analysis concluded that the IUD is very effective for emergency contraception but that further comparative studies are needed.

The copper IUD is appropriate for emergency contraception in women who meet standard criteria for IUD insertion and is most effective if inserted within 5 days after unprotected intercourse. This method is particularly useful for women who desire long-term contraception and who are otherwise appropriate candidates for IUD use. The levonorgestrel-releasing intrauterine system is not effective as an emergency contraceptive.

#### **WHAT CLINICAL FOLLOW-UP IS NEEDED AFTER USE OF EMERGENCY CONTRACEPTION?**

Side effects after emergency insertion of an IUD are similar to those experienced after routine IUD insertion and include abdominal discomfort, cramping and vaginal bleeding or spotting.

Follow up should be scheduled according to IUD insertion guidelines. The woman should be advised that if her menstrual period is delayed by a week or more, she should consider the possibility that she may be pregnant and seek clinical evaluation. A woman also should seek follow-up care for persistent irregular bleeding or lower abdominal pain because these symptoms could indicate a spontaneous abortion or an ectopic pregnancy. Women also should be advised about available resources if they need ongoing contraceptive or other services at the time emergency contraception is provided.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Dispensing		<b>SUBJECT:</b> Pharmacy Labeling of Medications and Supplies	<b>NUMBER:</b>  <b>342</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-74; IAC 234.22; IAC 147.107; QFP, 2014			


## PHARMACY LABELING OF MEDICATIONS AND SUPPLIES

The IDPH Family Planning Program adheres to the Iowa Board of Pharmacy Examiners guidelines for labeling prescriptions. Title X family planning agency staff is allowed by code to dispense contraceptive methods (Iowa Code, Section 234.22).

Clinics should not fill prescriptions for contraceptive supplies not written/provided by clinic staff. Family planning clinics are not licensed pharmacies, and therefore provide prescriptive supplies to only their own patients. This policy is not intended to prohibit supplying of non-prescription contraceptive methods.

Patient safety is best insured by providing clear, written information about any prescription provided. Therefore, each prescription medication must be labeled with the following:

- a. Client name
- b. Provider name and Agency name
- c. Name of prescribed medication
- d. Directions for use
- e. Lot number
- f. Quantity dispensed

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>  Clinical Policies: Health Promotion		<b>SUBJECT:</b>  Sexually Transmitted Infections (STIs) and HIV	<b>NUMBER:</b>  <b>343</b>
	<input type="checkbox"/> <b>Implementation</b>	<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b> Community Based Screening Services Manual; 348, 301,302, 313		
	<b>Authority:</b> IAC 641-74; Current CDC STD Treatment Guidelines; CDC revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings; CDC's Testing Recommendations for Hepatitis C Virus Infection; QFP, 2014, Update 2016;			

## SEXUALLY TRANSMITTED INFECTIONS AND HIV

### PREVENTION

At the initial visit and annually thereafter each client must be counseled about Sexually Transmitted Infections (STIs) and be given information needed to reduce their risk of acquiring or transmitting of STIs and HIV. Clients should be made aware that whenever they have unprotected sexual intercourse (no barrier method is used), they are exposed to any STIs their partner either has had or has and also to any diseases that the partner's former or current partners have had.

Clients need to be made aware of common STIs, their symptoms and complications, and the importance of diagnosis and treatment. Clients will be informed about where to go for testing, treatment and follow-up if services are not provided on site.

Counseling and education requires addressing the following areas:

1. Individual dialogue about personal risks and risk reduction
2. At-risk behavior – risk reduction and further evaluation
3. HIV education, risks, and referral

Counseling should also include the following information:

1. Abstinence is the most effective method to avoid STIs and HIV
2. Barrier methods can significantly reduce, but not eliminate STIs
3. Oral sex can also result in STIs.

STIs that must be discussed include:

1. HIV
2. Chlamydia
3. Gonorrhea
4. Human Papilloma Virus

STIs that should be discussed include:

1. Genital Herpes
2. Cytomegalovirus
3. Trichomoniasis
4. Pediculosis Pubis
5. Scabies
6. Hepatitis B
7. Syphilis

## **SCREENING AND TESTING**

The IDPH Family Planning program participates in the state Community Based Screening Services project (CBSS). This program provides for Chlamydia and gonorrhea testing. Contract agencies that participate in the CBSS must comply with the following:

1. CBSS screening criteria
2. Iowa STI reporting requirements
3. Centers for Disease Control and Prevention Treatment Guidelines.

Screening and testing for other STDs should be conducted based on the CDC recommendations.

Hepatitis C testing should be recommended based on CDC's Testing Recommendations for Hepatitis C Virus Infection. Persons with HIV infection should be tested at least annually for Hepatitis C.


## **TREATMENT**

The Iowa CBSS gives the IDPH FP access to sexually transmitted infection treatment drugs purchased by the Iowa Department of Public Health, STD Prevention Program. Treatment must follow the current Centers for Disease Control and Prevention STD Treatment Guidelines. Follow up must also follow CDC STD Treatment guidelines.

Expedited partner therapy (EPT) is legal in Iowa and should be utilized when appropriate.

## **REPORTING**

Sub-recipient agencies are required to comply with all reporting laws. In the State of Iowa, Chlamydia, gonorrhea, syphilis, HIV, and AIDS are reportable to the Iowa Department of Public Health. By Iowa Code, both the clinician who ordered the test and the laboratory that processed the specimen are to report names and other patient demographics to IDPH. This information is protected by law and cannot be released to anyone other than individuals (disease prevention specialists and county public health communicable disease investigators) who perform partner notification and partner referral. In Iowa, by law, a minor can be tested and treated for a sexually transmitted disease without parental consent.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Clinical Policies: Health Promotion		Nutrition Promotion	<b>344</b>
	<input type="checkbox"/> Implementation	<input checked="" type="checkbox"/> Revision	Date: July 2019	
	Status:	Cross Reference: Policies 301,302, 313		
<b>Authority:</b> IAC 641-74; QFP, 2014				

## NUTRITION PROMOTION

All clients seen for an initial family planning appointment shall be assessed for nutrition risk. Assessment for nutritional risk includes height, weight, and ideally, body mass index. Nutritional risk factors include being overweight, underweight, elderly, eating fewer than 2 meals per day, few fruits and vegetables, dental problems, poverty and unintentional weight gain or loss. Tools for completing a self nutritional assessment can be found at the following links:


- <http://www.womensheart.org/PDFs/DetermineYourNutritionalHealth.pdf>
- <https://www.sampleforms.com/nutrition-assessment.html>

Warning signs of disordered eating behaviors include:

- Binge eating or eating large amounts of food, more than what most people would eat under similar circumstances
- Loss of control during these eating episodes
- Self-induced vomiting
- Misuse of laxatives, diuretics, enemas, or other medications
- Fasting
- Excessive exercise
- Severe self-scrutiny of one's weight or shape

Clients identified as being at nutritional risk and requiring a level of expertise which the family planning provider does not have, should be scheduled to return when a nutritionist is available, or referred for nutrition services. Written procedures and defined criteria for referrals are recommended along with list of outside professional nutrition services, which will accept referrals.

All clients should be instructed on adequate calcium intake and folic acid supplementation.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Clinical Policies: Health Promotion		Smoking Cessation	345
	<input type="checkbox"/> Implementation	<input checked="" type="checkbox"/> Revision	Date: July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
<b>Authority:</b> IAC 641-74; QFP, 2014				

## SMOKING CESSATION

All clients who smoke should be urged to discontinue smoking at each visit.

All clients who smoke should be given written materials about smoking cessation programs available in their area. Free resources include:

- <http://www.smokefree.gov/>
- [http://www.cdc.gov/tobacco/quit\\_smoking/how\\_to\\_quit/index.htm](http://www.cdc.gov/tobacco/quit_smoking/how_to_quit/index.htm)
- <http://www.quitlineiowa.org/>

Any time a client has a condition which is caused by, exacerbated by, or adversely affected by smoking, smoking cessation should be discussed.


Any client who smokes and is known to have children living with them should be told of the dangers of environmental smoke to the children.

All clients who smoke and are using estrogen contraceptives should be informed of their increased risk for vascular diseases and the requirement to discontinue smoking or the estrogen contraceptive at age 35.

All clients who smoke and may become pregnant should be informed about the hazards of smoking on the unborn.

The AAR protocol is recommended: Ask Advise and Refer.



 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Clinical Policies: Health Promotion		Alcohol & Substance Abuse Prevention	<b>346</b>
	<input type="checkbox"/> Implementation	<input checked="" type="checkbox"/> Revision	Date July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
<b>Authority:</b> IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019				


## ALCOHOL AND SUBSTANCE ABUSE PREVENTION

All clients who give a history of substance use (including alcohol) should be counseled about the impact that substance use may have on their ability to use some methods of contraception effectively. Based on the clinician's judgment, they may be given a referral phone number or an appointment for the local substance abuse treatment facility.

All clients who give a history of substance use should be advised about the potential for birth defects and poor pregnancy outcome caused by various substances. If the client is planning a pregnancy in the future counseling should be offered about the need to discontinue substance use before pregnancy begins. Based on the clinician's judgment, clients should be given a referral phone number or an appointment for the local substance abuse treatment facility. Clients requesting help with a substance abuse problem should be referred immediately to a local substance abuse treatment facility.

When the client seems to be impaired at the time of clinic visit, the clinician should:

1. tell the client of concern about their ability to give informed consent for a method and about their ability to understand and remember instructions for use of the method;
2. arrange for the client to return to clinic as soon as possible at a time when they are more likely to be sober (perhaps first appointment in the AM)
3. provide a non-prescription method to last until next appointment
4. arrange alternate means of transportation if the client drove to the clinic
5. contact the police if the client insists on driving while impaired
6. Screening tools for clinicians to incorporate into their practice can be found at the following links:
  - [http://www.who.int/substance\\_abuse/activities/assist\\_v3\\_english.pdf](http://www.who.int/substance_abuse/activities/assist_v3_english.pdf) (WHO program)
  - <http://idph.iowa.gov/substance-abuse>
  - <http://idph.iowa.gov/sbirt/tools>

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Clinical Policies: Health Promotion		Domestic Abuse	<b>347</b>
	<input type="checkbox"/> Implementation	<input checked="" type="checkbox"/> Revision	Date: July 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
<b>Authority:</b> QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019				

## DOMESTIC ABUSE


All clients should have universal education and access to information about domestic abuse, including information about community resources for battered women.

All clients should be questioned regarding violence in their recent intimate relationships and should be assessed for evidence of physical injury yearly and as indicated.

If domestic abuse is suspected refer to appropriate community resources. The client should be given information regarding domestic abuse and encouraged to develop a plan for protection and assistance in case of emergency.

### RESOURCES:

- Iowa Coalition Against Domestic Violence  
1-800-942-0333  
24 hour statewide hotline
- <https://idph.iowa.gov/disability-injury-violence-prevention/violence-against-women>
- If in immediate danger, clients can call 911 or the 24-hour Iowa Victim Service Call Center at 1-800-770-1650 or text "iowahelp" to 201211-800-770-1650

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Clinical Policies: Health Promotion		Immunization	348
	<input type="checkbox"/> Implementation	<input checked="" type="checkbox"/> Revision	Date: July 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
<b>Authority:</b> IAC 641-74; QFP, 2014; The Advisory Committee on Immunization Practices (ACIP), June 2019				

## IMMUNIZATION

Clinic staff should review immunization status of all clients. This review may include MMR, HPV, Tdap, Hepatitis B, Varicella, Influenza, Meningococcal Conjugate, and Pneumonia as appropriate.

Both male and female clients should be offered information about the HPV vaccine (females and males age 9-26). Vaccination of persons 27 through 45 years of age based on "shared clinical decision-making" between the patient and the clinician. This means that the decision to vaccinate persons 27 through 45 years of age should be based on a discussion of benefits and risks between the patient and the clinician


All youth under 19 and all unvaccinated adults should be informed about the importance of Hepatitis B vaccines.

Follow the policies and procedures of the Iowa Department of Public Health when administering immunizations to family planning clients.

Immunizations administered in the family planning clinic must be documented in the client's record and in IRIS. Consents for vaccines should be placed in the client's record. If the client declines immunization, note in the record.

Clients should be provided with referral information about vaccines if they are not available in the family planning agency.

Sub-recipient agencies will participate in the Vaccines for Children (VFC) program and comply with all VFC audits and policies.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Clinical Policies: Health Promotion		Level I Infertility Services	<b>349</b>
	<input type="checkbox"/> Implementation	<input checked="" type="checkbox"/> Revision	Date: July 2019	
	Status:	Cross Reference: 313		
<b>Authority:</b> IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019				

## LEVEL I INFERTILITY SERVICES

Grantees must make basic infertility services available to women and men desiring such services. Infertility services are categorized as follows:

**Level I:** Includes initial infertility interview, education, physical examination, counseling, and appropriate referral.

**Level II:** Includes such testing as semen analysis, assessment of ovulatory function and postcoital testing.

**Level III:** More sophisticated and complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Level II services may be offered in projects with clinicians who have special training in infertility. Level III services are considered beyond the scope of Title X program.


## BASIC INFERTILITY CARE

Infertility is commonly defined as the failure to achieve pregnancy after 12 months or longer or regular unprotected intercourse. Earlier assessment is appropriate for women over age 35, women with a history of infrequent menstruation, with a known or suspected uterine or tubal disease or abnormality. Earlier assessment may also be appropriate in the presence of male risk factors for infertility, or questions about the male partner's fertility potential. The family planning provider's role is to determine potential causes of infertility and provider referrals for further evaluation and management.

Basic Infertility Care for Women should include a thorough medical history, obstetric history, sexual health assessment and complete physical examination. Their Reproductive Life Plan and a reproductive history about the client's efforts to conceive should be taken. Clients should be referred for further diagnosis and treatment as appropriate.

Basic Infertility Care for Males should include a thorough medical history, obstetric history, sexual health assessment and physical examination focusing on examination of the genitals for abnormalities. Their Reproductive Life Plan and a reproductive history about the client's efforts to conceive should be taken. Semen analysis may be offered but referral for further diagnosis and management is also appropriate.

Couples may also be counseled about ways to maximize fertility and offered resources to deal with the emotional and psychological issues of dealing with infertility.

 <b>Title X</b> <b>Family Planning</b> <b>Services</b> <b>Manual</b>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Related Preventive Health Services	<b>NUMBER:</b>  <b>350</b>
	<input type="checkbox"/> <b>Implementation</b>		<input checked="" type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>		<b>Cross Reference:</b> Policies 301, 302, 314, 315, 316, 317	
	<b>Authority:</b> IAC 641-74; QFP, 2014			

## RELATED PREVENTIVE HEALTH SERVICES

For many individuals the family planning (FP) clinic is their only source of health care. Therefore, visits should include the provision of or referral for other preventive health services.

For agencies without an infrastructure to provide comprehensive primary care services, a strong link to other community providers should be developed to ensure clients have access to services.

For clients without a primary care provider, the following services should be provided while the client is linked to a primary care services.

### MEDICAL HISTORY

USPSTF recommends that women be asked about family history that would be suggestive of an *increased risk for deleterious mutations in BRCA1 or BRCA2 genes* (e.g. receiving a breast cancer diagnosis at an early age, bilateral breast cancer, history of both breast and ovarian cancer, presence of breast cancer in one or more female family members, multiple cases of breast cancer in the family, both breast and ovarian cancer in the family, one or more family members with two primary cases of cancer, and Ashkenazi background). Women with identified risk(s) should be referred for genetic counseling and evaluation for BRCA testing (Grade B). The USPSTF also recommends that women at increased risk for breast cancer *should be counseled about risk-reducing medications* (Grade B).

### CERVICAL CYTOLOGY

Because clients seeking services at FP clinics may expect/prefer to obtain cervical cancer screening services at that location, providers should provide cervical cancer screening to clients receiving related preventive health services. Providers should follow USPSTF recommendations to screen women with cervical cytology screening alone every 3 years for women between the ages of 21 and 29 years, regardless of their sexual history or HPV vaccination. HPV testing should not be used for screening in this age group.

For women aged 30 to 65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting), regardless of their sexual history or HPV vaccination.

Sub-recipients may choose to follow ACOG standards as well. Cervical cytology no longer is recommended on an annual basis. Further, it is not recommended (Grade D) for women aged <21 years. Women with abnormal test results should be treated in accordance with professional standards of care, which may include colposcopy. The need for cervical cytology should not delay initiation or hinder continuation of a contraceptive method. Providers should also follow

ACOG and AAP recommendations that a genital exam should accompany a cervical cancer screening to inspect for any suspicious lesions or other signs that might indicate an undiagnosed STD.


### **CLINICAL BREAST EXAMINATION**

Despite a lack of definitive data for or against, clinical breast examination has the potential to detect palpable breast cancer and can be recommended. Patients should be informed there is not enough evidence to balance the benefits and risks of screening. If a client requests a clinical breast exam it should be performed.

ACOG recommends annual examination for all women aged >19 years. ACS recommends screening every 3 years for women aged 20–39 years, and annually for women aged ≥40 years. However, the USPSTF recommendation for clinical breast exam is an (I) and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of the service.

### **MAMMOGRAPHY**


Providers should follow USPSTF recommendations to screen women aged 50–74 years on a biennial basis; they should screen women aged <50 years if other conditions support providing the service to an individual patient.

 <p><b>Title X Family Planning Services Manual</b></p>	<b>SECTION:</b> Clinical Policies: Counseling and Management for Common Family Planning Visits		<b>SUBJECT:</b> Voluntary Participation	<b>NUMBER:</b> <b>351</b>
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> July 2019	
	<b>Status:</b>	<b>Cross Reference:</b> Policy 205		
	<b>Authority:</b> IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019; Title X Statute <a href="https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf">https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf</a>			

### VOLUNTARY PARTICIPATION

Services are provided solely on a voluntary basis. Individuals are not subjected to coercion or discrimination in the delivery of services, coerced to use a family planning method, or coerced to use any particular method of family planning. Clients are encouraged to ask questions, and may refuse a service or stop services at any time.

Acceptance of family planning services is not a prerequisite to eligibility of any other services, assistance, or participation in any other program.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: LGBTQ Care		<b>SUBJECT:</b> LGBTQIA	<b>NUMBER:</b> 352
	<input checked="" type="checkbox"/> <b>Implementation</b>		<input type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> IAC 641-74; Current CDC U.S. Medical Eligibility Criteria QFP, 2014; Current US Medical Eligibility Criteria for Contraceptive Use			

## CARE OF INDIVIDUALS IDENTIFYING THEMSELVES AS LGBTQIA

### DESCRIPTION

People who are lesbian, gay, bisexual, transgender, questioning, intersex or asexual (LGBTQIA) are members of every community. They are diverse, come from all walks of life, and include people of all races and ethnicities, all ages, all socioeconomic statuses, and from all parts of the country. Sexual identity, gender identity, gender expression and gender transition should all be considered during the course of a family planning visit.

The perspectives and needs of LGBTQIA people should be routinely considered in efforts to improve the overall health of every person and eliminate health disparities. There is also a need for culturally competent medical care and prevention services that are specific to this population. Social inequality is often associated with poorer health status, and sexual orientation has been associated with multiple health threats.


Members of the LGBTQIA community are at increased risk for a number of health threats when compared to their heterosexual peers. Differences in sexual behavior account for some of these disparities, but others are associated with social and structural inequities, such as the stigma and discrimination that LGBTQIA populations experience.

The following websites provide information about sexual and reproductive health care, vaccines, specific health concerns and preventive health recommendations for LGBTQIA individuals. Transgender clients should be assessed for STDs and HIV related risks on the basis of current anatomy and sexual behaviors.

### RESOURCES

- <http://www.cdc.gov/lgbthealth>
- <http://www.cdc.gov/msmhealth/for-your-health.htm>
- <http://www.cdc.gov/lgbthealth/women.htm>
- <http://www.cdc.gov/lgbthealth/transgender.htm>
- <http://www.cdc.gov/lgbthealth/youth.htm>
- <http://glma.org>
- More information can be found here: <http://www.lgbthealtheducation.org>



 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Health Promotion		<b>SUBJECT:</b> LARC Removal	<b>NUMBER:</b> 353
	<input checked="" type="checkbox"/> <b>Implementation</b>		<input type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>	<b>Cross Reference:</b> FP Policy 337, 338,339, Implant, IUS: Mirena, Policy 205		
	<b>Authority:</b> IAC 641-74; Current CDC U.S. Medical Eligibility Criteria; Contraceptive Technology, 20 <sup>th</sup> Edition; QFP, 2014; Title X Statute <a href="https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf">https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf</a>			

## LARC REMOVAL

Each Sub-recipient agency will have a policy in place regarding LARC removal.


Clients willing to attempt management of side effects in order to resolve problems and continue using the LARC will be provided appropriate treatment.

A client may not be required to attempt to “manage side effects” if she does not want to continue the method. The clinic will assure that clients are provided LARC removal without any required mitigation efforts that the client does not agree to.

If a client requests LARC removal, even if the agency did not provide the LARC initially, the client’s request will be honored. If the clinic schedule does not allow same day removal, the client will be given the next available appointment for removal.

Except as restricted by third party payers, no time restrictions may be placed on the client’s choice of receiving another LARC if no medical contraindications exist.

Removal of the LARCs should only be performed under aseptic conditions by a healthcare provider who is familiar with the removal technique. Providers should receive training in insertion AND removal techniques prior to attempting removal and follow current manufacturer's instructions.

 <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Clinical Policies: Health Promotion		<b>SUBJECT:</b> Expedited Partner Therapy	<b>NUMBER:</b> <b>354</b>
	<input checked="" type="checkbox"/> <b>Implementation</b>		<input type="checkbox"/> <b>Revision</b>	<b>Date:</b> July 2019
	<b>Status:</b>	<b>Cross Reference:</b>		
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; CDC U.S. Medical Eligibility Criteria, 2010, Contraceptive Technology, 20 <sup>th</sup> ed; QFP, 2014; Program Requirements for Title X Funded FP Projects, 2014; CDC STD Treatment Guidelines; <a href="https://www.cdc.gov/std/treatment/default.htm">https://www.cdc.gov/std/treatment/default.htm</a>			

## EXPEDITED PARTNER THERAPY

### PURPOSE


To promote health of individuals by treating the sex partners of patients diagnosed with a sexually transmitted infection (STI). Providers may provide prescriptions or medications to the patient's partner(s) without the health care provider first examining the partner(s). This practice is recommended by the CDC and allowed under Iowa Code section 139A.41.

### PROCEDURES

1. When a client requires treatment for sexually transmitted disease; providers should recommendation that any sexual partners in the past 60 days be treated.
2. Ideally the partner(s) should attend the clinic to be evaluated, examined, tested, counseled, and treated by a medical provider.
3. If the partner is unable or unwilling to seek medical care, Expedited Partner Therapy (EPT) will be offered.
4. When treating Chlamydia or gonorrhea, the client and partner may present to the clinic together and both be treated at the same time. Treatment should be provided for all partners with possible contacts in the past 60 days.
5. If a client reports no partners in the past 60 days, medication or a prescription is provided for the most recent partner.
6. The client and partner will be instructed to avoid intercourse until 7 days after both have been treated.
7. The patient's chart will include information about the number of partners being provided with EPT and the medication and dosage provided to the partner. Each agency will determine how documentation is completed for EPT.
8. When treating for trichomonas, a client will be offered a prescription for his/her partner.
9. Patient's insurance or Medicaid will NOT be billed for EPT for his/her partner.
10. Written medication information will be provided for each partner, either in person or given to the client to give to the partner using medication sheets provided by the Iowa Department of Public Health. Partners are encouraged to be clinically evaluated after receiving their EPT, informed of symptoms that need immediate evaluation, warned not to take medication if he/she is allergic, and common side effects are reviewed. Telephone numbers are provided if partner has questions.

## **400 -- CONTENTS OF SECTION**


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  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Quality Assurance/Oversight		<b>SUBJECT:</b> Quality Assurance and Audit	<b>NUMBER:</b> <b>401</b>
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> September, 2019	
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	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019			

## QUALITY ASSURANCE AND AUDIT

Quality assessment (performance management) activities assist an agency to do a self-assessment to identify if goals are met and plan how to meet them. A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality system should include:

1. An established set of clinical, administrative and programmatic standards by which consistency would be maintained;
2. A tracking system to identify clients in need of follow-up and/or continuing care including: cervical cytology screening test results and follow-up, the need for colposcopy, mammography results and necessary follow up if done, laboratory tests and radiologic studies, pathology reports and any afterhours emergencies;
3. Ongoing medical audits to determine compliance with agency protocols;
4. Procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;
5. Annual review of medical protocols to insure maintenance of current standards of care;
6. A process to elicit consumer feedback as a way to capture community input into program planning and evaluation;
7. Progress on performance measures; and
8. Annual quality improvement projects.


  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Quality Assurance/Oversight		Monitoring Standards	<b>402</b>
	<input type="checkbox"/> Implementation	<input checked="" type="checkbox"/> Revision	<b>Date:</b> September 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019				

## MONITORING STANDARDS

### THE IOWA FAMILY PLANNING PROGRAM IS REQUIRED TO:

Maintain compliance with Title X monitoring standards as established Program Review Tools. Refer to the Appendix for a copy of the program monitoring tools. Following are the monitoring standards for the clinical program component:

1. The sub-recipient must provide clinical services that are in compliance with Title X laws, regulations, and guidelines.
2. The sub-recipient must provide clinical services according to written policies, procedures, and protocols that adhere to currently accepted medical practices.
3. The sub-recipient must have a quality assurance system that provides for the continued development and evaluation of services.
4. The sub-recipient must have a mechanism in place for annual review of medical policies internally and by the agency medical director.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Quality Assurance/Oversight		Grantee Monitoring Processes	<b>403</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		Date: September 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019				

## GRANTEE MONITORING PROCESSES

### OBJECTIVES

1. To identify the authority IDPH has to monitor sub-recipient compliance with Title X and state requirements.
2. To outline the processes involved in on-site monitoring

### IDPH MONITORING AUTHORITY

The General Conditions of the Contract with IDPH, states:

- a. The Department reserves the sole right to monitor Contractor performance through site visits, reports, or other means deemed necessary by the Department. The Contractor agrees that the Department may conduct site visits to review contract compliance, assess management controls, assess relevant services and activities, and provide technical assistance. The Contractor agrees to ensure the cooperation of the Contractor's employees, agents, and board members in such efforts and provide all requested information to the Department in the manner determined by the Department.
- b. Following each site visit or review of requested information, the Department may submit a written report to the Contractor, which identifies the findings. A Corrective Action Plan with a timetable to address any deficiencies or problems noted in the report may be requested. The Corrective Action Plan shall be submitted to the Department for approval within the timelines outlined in the written report. The Contractor agrees to implement the plan after the Department approves it.
- c. Failure to do so may result in suspension or termination of the contract. The Assistant Attorney General assigned to IDPH is involved in all determinations of suspension or termination of contracts.

### ON SITE MONITORING PROCESSES:

On-site monitoring of the program and clinical components of each contract agency occurs on an annual basis. The different components are monitored on alternate years (i.e., Clinic/Provider Review, Administrative Review, and Non-Administrative Review). One aspect of on-site monitoring will occur for each contract agency annually. On-site visits may be conducted more frequently when a need is identified by IDPH FP staff. The following steps will occur:

1. The sub-recipient agency director will be notified in writing at least three weeks prior to the on-site review of the dates and times the review is to occur. Additional information provided to the director will include a copy of the review instrument to be used and a request for any materials or records to be reviewed at the agency. If the reviewer wishes to meet specifically with other staff of the agency in addition to the director, these staff positions will also be identified. The sub-recipient agency director may designate agency staff to attend

part or all of the review as desired. If agency clients are to be observed, the notification will include the types of clients to be observed and the clinic location and times of the observation. If there are additional instructions pertaining to the area of review, these will be attached to the review instrument.

2. The sub-recipient agency director or other designated agency staff is to be available throughout the review period to answer questions and discuss issues pertaining to the program.
3. The review will include an initial meeting to provide an overview of the review activities to occur, as well as a meeting following the review to summarize any problems identified or follow-up to occur or corrective actions necessary by the sub-recipient or the state agency.
4. At the time of the visit, the program manager will be given feedback about the performance measures identified during the funding process. Before the visit, staff pulls the data on the performance measures from the FP Database. A spreadsheet is prepared and provided to each contractor at the time of an annual site visit. The spreadsheet may compare data on the same PM to the same time frame the previous year for their individual agency and for the state averages. Challenges to advancing the measures are discussed and strategies for improvement are brainstormed.

### **Unannounced visits (FP Coordinator, CNC, and CHC)**

Unannounced visits may be indicated from time to time. The Bureau Chief, Division Director and AAG (at the discretion of the Bureau Chief and Division Director) will authorize all unannounced visits. General Contract conditions state the Department reserves the sole right to monitor Contractor performance through site visits, reports, or other means deemed necessary by the Department. The Contractor agrees that the Department may conduct site visits to review contract compliance, assess management controls, assess relevant services and activities, and provide technical assistance. The Contractor agrees to ensure the cooperation of the Contractor's employees, agents, and board members in such efforts and provide all requested information to the Department in the manner determined by the Department.

### **FINDINGS/RECOMMENDATIONS**

A letter containing the findings and recommendations from the review is sent to the sub-recipient agency director following completion of the review. The summary report will also include any corrective action required or suggested. Where indicated, dates for follow-up monitoring by the state as well as any follow-up activity will be included.

#### **Agency Response**


Sub-recipient agencies will respond to the letter within by a specific date. The response must be in writing and include a plan for completing the requirements. IDPH staff will review the response and may modify requirements for follow-up action. The sub-recipient agency will be notified in writing within two weeks of receiving the agency response of the status of needed follow-up, including any modifications to the required follow-up action or completion dates.

### **FOLLOW-UP**

IDPH Staff will monitor and document remediation and follow-up completed by the sub-recipient agency and dates follow-up is completed in writing. IDPH staff will notify sub-recipient agency staff in writing following the receipt of evidence action. This notification will include an acknowledgment that follow-up has been satisfactorily completed, or a request for additional actions needed to satisfy the requirements. Additional site reviews may be scheduled as needed to review compliance or to provide technical assistance.

Documentation of the required corrections and dates of submission will be kept by IDPH staff to monitor completion of this activity.



  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Quality Assurance/Oversight		Chart Audits	<b>404</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019	
	<b>Status:</b>	<b>Cross Reference:</b> FP Manual Appendix 6		
<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74				

## CHART AUDITS


The Iowa Department of Public Health family planning chart audit is part of the Title X family planning program quality assurance policy.

Family planning program chart audits are required for all IDPH sub-recipient agencies for Title X services as follows:

1. Selected contract agency shall submit a summary of the results and follow-up from an internal chart audit each year as outlined in the annual contract and as part of a quality assurance strategy.
2. Audits of hard copy and/or electronic medical records for each sub-recipient agency will be completed by IDPH staff, with or without the assistance of agency staff, every project period as part of the program monitoring schedule.

The chart audits must evaluate the care provided to a variety of types of family planning clients. The following chart audit requirements are provided:

1. A minimum of fifteen (15) charts shall be audited.
2. Charts are to be randomly selected from all clinic sites for clients served within the past 12 months and should include a minimum of 5 charts of adolescents and confidential clients.
3. Of the charts audited a minimum of the following charts are required:
  - a. Four (4) initial charts
  - b. Two (2) annual charts
  - c. Two (2) pregnancy test charts
  - d. Two (2) chart that required follow-up
  - e. Five (5) charts of adolescents and confidential clients
4. The chart audit tool provided by the department will be used for all chart audits.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Quality Assurance/Oversight		<b>SUBJECT:</b> Grantee Oversight	<b>NUMBER:</b>  <b>405</b>
	<input type="checkbox"/> <b>Implementation</b> <input checked="" type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019			

## GRANTEE OVERSIGHT

The Appendices in the family planning manual provides references to the Title X statutes and requirements that establish the standards with which the sub-recipients and IDPH operations must comply including both state and federal laws, and regulations. Refer to Appendices section of this manual for details.

### OBJECTIVES


1. To determine that family planning clinic services have been planned, organized, and delivered to conform to accepted principles of health practices as set by federal and state regulations and guidelines, Title X requirements and IDPH contract.
2. To ensure that technical and program performance is meeting acceptable standards of quality care.
3. To document that corrective action is taken to improve quality and compliance based on review findings.
4. Identify and disseminate best practices at sub-recipient (SR) sites
5. Encourage peer support in the provider network to enhance quality of care and support problem solving (Title X Provider Review).
6. To promote strong partnerships with Title X SR staff and providers.

### Monitoring Activities

IDPH uses the following methods to monitor performance of sub-recipients:

- Desk audits of documents submitted by the sub-recipient documents
- Review of required sub-recipient self-audits
- On-site reviews of sub-recipient operations
- Assistance to the sub-recipients in meeting deadlines and adequately completing information and data submissions required by funder
  - Meetings and trainings where the grantee presents new information to the sub-recipients and the convening of work groups to establish and share best practices and to work toward performance improvement.

These activities are conducted at regular intervals throughout the grant period. Refer to the Appendix for the contract monitoring schedule.

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b>		<b>SUBJECT:</b>	<b>NUMBER:</b>
	Quality Assurance/Oversight		Cost Analysis	406
	<input checked="" type="checkbox"/> <b>Implementation</b> <input type="checkbox"/> <b>Revision</b>		<b>Date:</b> September 2019	
	<b>Status:</b>	<b>Cross Reference:</b>		
<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014; Public Health Service Act 42 CFR Part 59 Compliance with Statutory Program Integrity Requirements, 2019				

## COST ANALYSIS POLICY

### OBJECTIVES


1. Describe IDPH expectations and processes related to annual cost analysis and compliance with Title X requirements.

### PURPOSE

1. The goals for implementing the cost analysis methodology are two-fold: first, to assist programs in determining their agency's actual cost for providing family planning services; and second, to establish a fee schedule for the unbundled services provided by the agency. This allows programs to set appropriate fees to recover the "reasonable cost" of the services they provide. This information is also useful in negotiations with third party payers regarding appropriate reimbursement for services.
2. Federal regulations require each family planning project to have a schedule of fees for the services they provide. Charges must be based on an analysis of the reasonable costs for all services offered by the project. Each program is expected to develop realistic fees that reflect the cost of operation, yet are competitive to the local market. These fees are to be "designed to recover the reasonable cost of providing services".

### Key Points

1. Annually, all IDPH sub-recipient agencies will participate in a cost analysis of IDPH's choosing. The collection and analysis of financial information will provide insight to the real and complete costs of doing business. This information should help programs to analyze the efficiency of program operations and to develop and implement measures to assist in controlling costs.
2. IDPH will then provide the manual and workbooks to sub-recipient agencies for completion and submission.
3. IDPH staff will review cost analysis submissions within 6 weeks of submission. IDPH may request edits, re-submission, clarification or accept the original submission.
4. Requests for resubmission will be sent to the FP Director in [lowagrants.gov](http://lowagrants.gov) with a deadline for resubmission.
5. Requests for clarification may be handled in communications ([IowaGrants.gov](http://IowaGrants.gov) or email).

  <b>Title X Family Planning Services Manual</b>	<b>SECTION:</b> Quality Assurance/Oversight		<b>SUBJECT:</b> Adherence to OSHA and CLIA Regulations	<b>NUMBER:</b> <b>407</b>
	<input type="checkbox"/> Implementation <input checked="" type="checkbox"/> Revision		<b>Date:</b> September. 2019	
	<b>Status:</b>		<b>Cross Reference:</b>	
	<b>Authority:</b> Public Health Service Act 42 CFR Part 59; IAC 641-74			

## ADHERENCE TO OSHA AND CLIA REGULATIONS

All agencies must comply with the following regulations:

1. Occupational exposure to blood borne pathogens (OSHA regulations), 29 CFR Part 1910.1030
2. Clinic Lab Improvement Act Programs, (HCFA regulations), 42 CFR Part 493