

**WASHINGTON STATE DEPARTMENT OF HEALTH
FAMILY PLANNING AND REPRODUCTIVE HEALTH
ON-SITE MONITOR TOOL FOR TITLE X AGENCIES**



CLINICAL SERVICES: The sub-recipient provides family planning services to clients that are consistent with Title X regulations and with nationally recognized standards of care.

The Clinical Section of the Program Review is based on the following Title X and other Federal grant requirements:

- Title X Legislation and Title X Implementing Regulations, 42 CFR Part 59
- Sterilization of Persons in Federally Assisted Family Planning Projects, 42 CFR Part 50 Subpart B

Appropriate clinical services include compliance with the criteria listed in this section of the Program Review tool. Program Review consultants may review the documents listed below to aid in assessing compliance:

- Sub-recipient Family Planning clinical/medical policies, protocols, standards and procedures
- Medical record charting forms (such as consent forms, medical history forms, etc.) and written policies for accepted medical record documentation
- Information related to the medical oversight of the program
- Written emergency procedures
- Referral agreements and lists of referral agencies/organizations and physicians
- Written policies for the use of interpreters
- Educational material routinely given to clients
- State laws regarding requirements for Advanced Practice Nurses
- Quality assurance and monitoring processes, procedures, schedules and reports
- Sub-recipient’s service plan

The family planning service sites to be visited should make available the following types of medical records for the clinical consultant to review. Medical records reviewed should be for recent visits (i.e., clients seen within the last year, with all lab results in the chart):

- Contraceptive clients
- Adolescent patients (can be initial or returning visits)
- Male family planning patients
- “Problem visit” patients (i.e., abnormal Pap follow-up, method problems, vaginal discharge, etc.)
- Pregnancy testing patients
- Sterilization patients, if applicable

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Criteria for Compliance	C	NC	Comments/Documentation/Explanation
A. Client Services			
1. Sub-recipient meets the following criteria for Title X services:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Sub-recipient provides clinical, informational, educational, social and referral services related to family planning <i>(42 CFR 59.5(b) (2))</i> • Clinical care component operates under the responsibility of a physician with experience or special training in family planning <i>(42 CFR 59.5 (b) (6))</i> • Sub-recipient offers a broad range of acceptable/effective FDA approved contraceptive methods on-site or by referral <i>(Title X Statute, Section 1001; 42 CFR 59.5 (a)(1))</i> <ul style="list-style-type: none"> 1) Methods include natural family planning <i>(Title X Statute, Section 1001; 42 CFR 59.5 (a)(1))</i> 2) Sub-recipient service system provides family planning services to adolescents <i>(Title X Statute, Section 1001; 42 CFR 59.5 (a) (1))</i> 	<p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p>		

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B. Service Plan and Protocols			
1. Sub-recipient's service plan has been successfully implemented			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Sub-recipient provides the full range of services as outlined in the service plan (per approved grant application) • Written clinical protocols are in place at each service delivery site and are consistent with Title X Guidelines and nationally recognized standards for medical care <ul style="list-style-type: none"> 1) Service site clinical protocols and plans for education are signed off by the Medical Director and approved by the grantee 2) Sub-recipient has a mechanism in place to assure that protocols are current and reviewed and updated regularly 	<p>M</p> <p>M</p> <p>M</p> <p>S</p>		

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C. Procedural Outline			
1. Based on the reason for the visit, the following services are offered in accordance with QFP and properly documented in the client medical record			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Education • Counseling • Informed consent (General) • History • Physical assessment (when warranted) • Laboratory testing • Follow up and referrals 	M M M M M M M		
2. The following components, appropriate to the purpose of the visit, must be offered and documented in the clients' medical record:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Client return visits (<i>excluding routine supply visits</i>) include an assessment of the client's health status, current complaints, and evaluation of birth control method, and opportunity to change methods. 	S		

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D. Emergencies			
1. Written protocols for medical emergencies are current and include the following situations:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Vaso-vagal reactions/syncope (<i>fainting</i>) • Anaphylaxis (<i>severe allergic reactions</i>) • Cardiac arrest/respiratory difficulties • Shock/Hemorrhage (<i>uncontrolled bleeding</i>) • Emergencies requiring EMS transport • After hours emergencies and management of contraceptive emergencies 	M M M M M M		
2. Staff is prepared to manage clinic-based emergencies (e.g., fire, vandalism)			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Training for emergencies is available to staff 	S		

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E. Referrals and Follow-Up			
1. Sub-recipient provides for coordination and use of referral arrangements <i>(42 CFR 59.5 (b) (2))</i>			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Formal referral agreements are in place • Referrals for care beyond the scope of the project (e.g., non-family planning, emergency care, etc) are made consistent with Title X requirements • Sub-recipient maintains a current referral list <i>(42 CFR 59.5 (b) (8))</i> • Referral list includes health care providers, local health departments, hospitals, voluntary agencies, and health services projects, and other federal programs 	M M M M		

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A. Required Services			
1. Sub-recipient provides services on a voluntary basis			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Written informed consent is obtained prior to services • Consent form is language appropriate, i.e., written in a language understood by the client or translated and witnessed by an interpreter • There is a process in place for ensuring and documenting client understanding of: <ol style="list-style-type: none"> 1) Contraception benefits and risks 2) Effectiveness (including correct use) 3) Potential side effects 4) Complications 5) Discontinuation issues 6) Danger signs of method chosen 	<p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p>		

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<p>2. Sterilization complies with federal requirements: <i>(42 CFR Part 50, Subpart B)</i></p>			
<ul style="list-style-type: none"> • Federally approved consent form is used <i>(Found in the Appendix to 42 CFR Part 50, Subpart B, Section 50.201)</i> • Required signatures are secured. These include: <ol style="list-style-type: none"> 1) Individual sterilized 2) Interpreter 3) Person who obtains consent 4) Physician obtaining consent 	<p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p>		
B. Client Education			
<p>1. Education services offered allow client to make informed decisions and take positive health actions. When appropriate, this includes:</p>			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Information needed to make informed decisions about family planning, including reproductive health care plan • Actions to reduce transmission of HIV and STDs/STIs • Health promotion/disease prevention information (i.e., nutrition, exercise, smoking cessation, alcohol/drug use, domestic violence, and sexual abuse) 	<p>M</p> <p>M</p> <p>S</p>		

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C. Counseling			
1. Counseling services comply with Title X requirements:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Documentation of counseling is included in client record • Counselors are sufficiently knowledgeable to provide accurate information regarding the benefits and risk, safety, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the various contraceptive methods <ol style="list-style-type: none"> 1) Counselors should be objective, nonjudgmental, culturally aware, and sensitive to individual differences of clients 2) Counselors should be knowledgeable about other services offered by the clinic <p><i>Note: If the sub-recipient uses checklists for documenting required counseling components, a detailed written protocol for what is included in that counseling should be reviewed</i></p>	<p>M</p> <p>M</p> <p>S</p> <p>S</p>		

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2. Method counseling is provided, when indicated , and includes:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Results of physical exam and lab studies, if appropriate M • Effective use of contraceptive methods, benefits, and efficacy of the methods M • Possible side effects/complications M • How to discontinue the method selected and information regarding back-up method used M • Planned return schedule M • Emergency 24-hour telephone number M • Location where emergency services can be obtained M • Appropriate referral for additional services, if needed M 			
3. Project offers STD/STI and HIV prevention education according to nationally recognized standards:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • There is evidence STD/STI and HIV prevention education is available to clients at all sites. At a minimum, this includes: <ul style="list-style-type: none"> 1) Education about HIV infection and AIDS M 2) Information on risks, infection prevention, and referral services M 3) Discussion on personal risk and risk reduction strategies M 			

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D. History, Physical Assessment, and Lab Testing			
1. History: Information related to client medical histories are consistent with Title X requirements:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • A complete medical history is documented for both female and male clients and updated at subsequent clinical visits. Complete medical history must include: <ol style="list-style-type: none"> 1) Past medical history (<i>i.e., significant illnesses, hospitalization, surgery, blood transfusions or exposure to blood products, and chronic or acute medical conditions</i>) 2) Allergies 3) Current medications (<i>including OTC medications</i>) 4) Tobacco, alcohol, and drug use (<i>both prescription and other drugs</i>) 5) Immunization and Rubella status 6) Review of systems 7) Pertinent history of immediate family members 8) Partner history (<i>i.e., injectable drug use, multiple partners, risk history for STDs/STIs and HIV, sex with men, sex with women, or both</i>) 	<p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p>		

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<ul style="list-style-type: none"> • FEMALE reproductive history must include the following: <ol style="list-style-type: none"> 1) Contraceptive use past and current (including adverse effects) 2) Menstrual history 3) Sexual history 4) Obstetrical/Gynecological history 5) STD/STI, including HBV 6) HIV infection 7) Pap testing history 	<p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p>		
<ul style="list-style-type: none"> • MALE reproductive health history must include the following: <ol style="list-style-type: none"> 1) Sexual history 2) STD/STI, including HBV 3) HIV infection 4) Urological conditions 	<p>M</p> <p>M</p> <p>M</p> <p>M</p>		

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2. Physical Assessment			<i>Write/Type Comments in the space below</i>
<p>Information related to female and male physical assessments is consistent with national standards for care (e.g., ACOG, ACS, ASCCP, USPSTF) as appropriate:</p> <ul style="list-style-type: none"> • INITIAL FEMALE physical assessment should include: <ol style="list-style-type: none"> 1) Height/weight 2) STD/STI and HIV screening, as indicated <ol style="list-style-type: none"> a) If services are not provided on-site, documentation of appropriate referral for those at risk should be noted in client's chart 3) Clinic must stress the importance of and provide for health maintenance screening. This includes: <ol style="list-style-type: none"> a) Blood pressure b) Breast exam, if appropriate c) Pap testing, if appropriate d) STD/STI and HIV screening • INITIAL MALE physical assessment should include: <ol style="list-style-type: none"> 1) Height/weight 2) STD/STI and HIV screening, as indicated 3) Clinic encourages and provides for health maintenance screening procedures for male clients. This includes: <ol style="list-style-type: none"> a) Blood pressure 	<p>M</p> <p>S</p> <p>S</p> <p>S</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>S</p> <p>S</p> <p>S</p>		

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3. Laboratory Testing: Information related to client laboratory testing are consistent with Title X requirements:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • The sub-recipient provides on-site pregnancy testing M • The sub-recipient provides the following tests when require by the specific contraceptive method (<i>FDA or prescribing recommendations</i>) or according to screening recommendations as stipulated in QFP <ul style="list-style-type: none"> 1) Gonorrhea and chlamydia testing M 2) Diabetes testing M 3) Hepatitis B testing M 4) Syphilis serology (VDRL, RPR) M 5) HIV testing M • Clients are notified of abnormal lab test results <ul style="list-style-type: none"> 1) Notification procedure maintains client confidentiality M 			

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4. Revisits are individualized and based on client need as required by Title X:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Revisit schedules must be based on client need for: <ol style="list-style-type: none"> 1) Education 2) Counseling 3) Clinical care beyond that provided at previous visit • First time users of hormonal methods, IUDs, diaphragms, and cervical caps should be scheduled for early revisit 	M M M S		
E. Fertility Regulation			
1. Reversible Contraception complies with Title X requirements:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • When indicated, clients are given more than one method to minimize the risks of STDs/STIs, HIV and pregnancy • Consistent and correct use of condoms is encouraged, as appropriate 	S S		

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2. Permanent Contraception (<i>Sterilization</i>) complies with Title X requirements: (<i>42 CFR Part 50, Subpart B</i>)			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Counseling and consent process must assure that the client’s decision to undergo sterilization is completely voluntary • Federal sterilization regulations must be complied with when sterilization is performed or arranged for by the project 	M M		
F. Infertility Services			
1. Sub-recipient provides basic infertility services			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Level I basic services include: <ol style="list-style-type: none"> 1) Initial infertility interview 2) Education 3) Physical examination 4) Counseling 5) Referral • Sub-recipient provides Level II infertility services (<i>e.g., semen analysis, assessment of ovulatory function and postcoital testing, etc.</i>) • Sub-recipient does <u>not</u> provide Level III infertility services 	M M M M M O M		

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G. Pregnancy Diagnosis and Counseling			
1. Sub-recipient provides pregnancy diagnosis consistent with Title X regulations: <i>(42 CFR 59.5 (a) (5))</i>			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Pregnancy diagnosis and counseling is provided to all clients in need of these services • Pregnancy diagnosis includes: <ol style="list-style-type: none"> 1) History 2) Pregnancy testing 3) Physical assessment (including pelvic exam) <ul style="list-style-type: none"> ○ When gestational age cannot be determined the provider counsels the client on the importance of receiving an exam as soon as possible, preferable within 15 days • If ectopic pregnancy is suspected, the client is referred for immediate diagnosis and treatment 	<p>M</p> <p>M</p> <p>M</p> <p>S</p> <p>M</p> <p>M</p>		

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2. Sub-recipient provides pregnancy testing and counseling consistent with Title X regulations: <i>(42 CFR 59.5 (a) (5))</i>			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Clients with a positive pregnancy test: <ol style="list-style-type: none"> 1) Pregnant clients are offered the opportunity for counseling on pregnancy options, including: <ul style="list-style-type: none"> ○ Prenatal care and delivery ○ Infant care, foster care, or adoption ○ Pregnancy termination 2) Options counseling is provided as neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any options(s) about which the pregnant woman indicated she does not wish to receive such information and counseling 3) Clients electing to continue their pregnancy are: <ul style="list-style-type: none"> ○ Referred for early prenatal care ○ Provided information on good health practices during early pregnancy (<i>e.g., good nutrition, avoidance of smoking, drugs, alcohol, x-rays</i>) • Clients with a negative pregnancy test are given information about the availability of contraceptive and infertility services, as appropriate 	<p>M M M M</p> <p>S S</p> <p>S</p>		

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H. Adolescent Services			
1. Sub-recipient provides contraceptives services to adolescents consistent with Title X requirements: <i>(Title X Statute Section 1001)</i>			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Sub-recipient ensures appointments for services to adolescents are provided as soon as possible • Sub-recipient complies with state requirements regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest • Adolescents seeking contraceptive services are informed about all methods of contraception • Adolescents are informed of the following: <ul style="list-style-type: none"> 1) Abstinence 2) Contraceptive options 3) Safer sex practices • Counseling sessions and needed follow-up are confidential • Services provided to minors are confidential and do not need written consent of parents or guardians • There is no evidence that parents or guardians are notified before or after a minor has requested and received Title X services, without the minor's consent 	<p>S</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>M</p>		

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<ul style="list-style-type: none"> Policies and procedures must be in place to provide counseling to minors on how to resist coercive attempts to engage in sexual activities 	M		
I. Related Services (Optional Services)			
1. If optional services are offered, skilled personnel and equipment are available:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> Sub-recipient provides for the diagnosis and treatment of minor gynecologic problems (vaginitis, UTI, etc.) Sub-recipient provides for detection and treatment of the more common STDs/STIs (e.g., GC, syphilis, chlamydia, HIV) Gonorrhea and chlamydia tests are made available for clients requesting IUD insertions If testing is done, sub-recipient must comply with state and local STD/STI reporting requirements When treatment for minor gynecologic problems or more common STDs/STIs is provided on-site, appropriate follow-up measures are undertaken 	S S M M M		

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J. Special Counseling			
1. Sub-recipient meets the Title X requirements for special counseling:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • When indicated, clients are offered appropriate counseling and referral for the following: <ol style="list-style-type: none"> 1) Future planned pregnancies/preconception counseling 2) Management of a current pregnancy 3) Other concerns (e.g., substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) 	<p>S</p> <p>S</p> <p>S</p>		

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K. Pharmaceuticals			
1. Sub-recipient meets Title X requirements as they relate to pharmaceuticals:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • Each facility maintains an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients • Sub-recipient maintains the necessary drugs or devices for the provision of any other services it includes within the scope of the Title X project 	M M		
L. Medical Records			
1. Sub-recipient meets Title X requirements as they relate to medical records:			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • A medical record is established for each client who obtains clinical services 	M		

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<ul style="list-style-type: none"> • Medical records are retained in accordance with accepted medical standards and state laws Records must be: <ul style="list-style-type: none"> 1) Complete, legible, and accurate. (<i>Telephone encounters of a clinical nature are documented</i>) 2) Signed by the clinician (<i>name, title, date</i>) 3) Readily accessible 4) Systematically organized to facilitate prompt retrieval of information 5) Confidential, safeguarded against loss or use by unauthorized persons • Content of Client Record: Record must contain sufficient information to identify the client, indicate contact information, justify clinical diagnosis, and warrant the treatment and end results. The required content includes: <ul style="list-style-type: none"> 1) Personal data 2) Scheduled revisits 3) Medical history, physical exam, clinical findings, diagnostic/laboratory orders, results, and treatment 4) Documentation of continuing care, referral, and follow up 5) Informed consent(s) 6) Refusal of services 	<p>M</p>		

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<ul style="list-style-type: none"> 7) Allergy and drug reactions 8) Medical record allows for entries by counseling and social service staff • Confidentiality and release of records <ul style="list-style-type: none"> 1) A confidentiality assurance statement must appear in the client's record 2) A written consent of the client is required for 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 • Sub-recipient has a mechanism to expedite the transfer of medical records to other providers upon client's request 	<p>M</p> <p>M</p> <p>M</p> <p>M</p> <p>S</p>		

M = Must S = Should

Rev. March 2015, from Interim Program Review Tool- August 2014

P:FPRH/monitor tools/FPRH Clinical Services

**WASHINGTON STATE DEPARTMENT OF HEALTH
FAMILY PLANNING AND REPRODUCTIVE HEALTH
ON-SITE MONITOR TOOL FOR TITLE X AGENCIES**

Criteria for Compliance	C	NC	Comments/Documentation/Explanation
M. Quality Assurance			
1. Sub-recipient has a quality assurance system in place that provides for ongoing evaluation of project personnel and services			<i>Write/Type Comments in the space below</i>
<ul style="list-style-type: none"> • The quality assurance system includes: <ol style="list-style-type: none"> 1. An established set of clinical, administrative, and programmatic standards by which conformity is maintained 2. A tracking system to identify clients in need of follow-up and/or continuing care 3. Ongoing medical audits to determine conformity with agency protocols 4. Peer review procedures to evaluate individual clinician performance 5. Periodic review and update of medical protocols 6. A process to elicit consumer feedback 7. Ongoing and systematic documentation of QA activities 	S S S S S S		

M = Must S = Should
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DOH 349-001