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# Family Planning Program Manual

**VDH DH DEPARTMENT** OF HEALTH



July 2020

Dear Family Planning Sub-recipient:

The Virginia Department of Health Family Planning Manual has been revised to reflect the most recent Title X regulations, Quality Family Planning (QFP) service guidelines, and Virginia State laws applicable to the provision of family planning services. This manual reflects the minimum acceptable level of care and has been approved by the Family Planning Medical Advisory Committee, the Office of Family Health Services Director, and the Family Planning Program Supervisor. VDH does not permit deviation from policies that are required by its funding agencies and governmental regulations. VDH policies are found on the VDH FP webpage.

Effective May 1, 2020, all materials outlined in the VDH Family Planning Manual have been approved by the VDH leadership. Any additions or revisions made after this date will be approved and distributed individually.

VDH staff will make updates to this document every two years. It is the responsibility of the sub-recipients Family Planning Coordinator to ensure appropriate staff have read and reviewed the updated manual, and sign the "Signature Page" annually.

If you have any questions or see an area for improvement, please send your comments to: Reproductivehealth@vdh.virginia.gov

We thank you for your partnership and your service to Virginians.

Sincerely,

The VDH's Family Planning Program

# Signature Page

### Virginia Department of Health MANUAL REVIEW

### July 2020

The Family Planning Manual must be reviewed and signed annually by the contractor's Family Planning Coordinator. It is the responsibility of the Family Planning Coordinator to ensure all staff working on the Title X program, are up-to-date with Title X policy and procedure.

Signature pages must be available for review during VDH site visits.

With the signature below, the contracted Title X agency authorizes that it has read and implemented required elements into the contracted program.

Name

Title

Date

The only person required to sign the Manual is the current Title X, Family Planning Coordinator. However, all family planning staff are required to read the manual annually.

# Virginia and Federal Title X Overview

The Virginia Department of Health (VDH) Family Planning Program (FPP) is governed by the regulations and guidelines enacted by Congress under the Title X Population Research and Voluntary Family Planning Programs section of the Family Planning Services and Populations Research Act of 1970 (Public Law 91-572). All VDH family planning sites must adhere to the Program Requirements for Title X Funded Family Planning Projects, which articulate the federal statutory and regulatory requirements of the Title X family planning program. Furthermore, all VDH family planning sites must adhere to the regulations governing project grants for family planning services (42 CFR part 59, subpart A), as amended by the Final Rule (Compliance with Statutory Program Integrity Requirements) and its compliance dates.

All VDH family planning sites must also adhere to Providing Quality Family Planning Services (QFP) service guidelines, developed by the Centers for Disease Control and Prevention (CDC) and Office of Population Affairs (OPA). The QFP provides clinical recommendations for providing family planning services in a manner that is consistent with the best current scientific evidence.

VDH family planning sites should refer to these documents for guidance and clarification as needed.

### Title X Providers & Sub-Recipients

The U.S. Department of Health and Human Services' Office of Population Affairs (OPA) oversees the Title X program. OPA funds a network of family planning centers which serve about 4.0 million clients a year. Services are provided through state, county, and local health departments; community health centers; and hospital-based, school-based, faith-based, other private nonprofits. Title X staff are specially trained to meet the contraceptive needs of individuals with limited English proficiency, teenagers, and those confronting complex medical and personal issues such as substance abuse, disability, homelessness or intimate partner violence.

If a site identifies a potential sub-recipient agency, they should refer that agency to the VDH FPP to discuss the possibility of establishing a contract. Sites cannot enter nor end such agreements without first notifying the VDH FPP Supervisor and receiving approval.

### Scope of Services

Since 1970, Title X Family Planning clinics have played a critical role in ensuring access to a broad range of family planning and related preventive health services for millions of low-income or uninsured individuals. In addition to contraceptive services and counseling, Title X-supported clinics provide a number of important preventive health services:

- Patient education and counseling
- Contraceptive services
- Pelvic examinations
- Achieving pregnancy
- Breast and cervical cancer screening according to nationally recognized standards of care
- Sexually transmitted disease (STD) and Human Immunodeficiency Virus (HIV) prevention education, counseling, testing and referral
- Basic infertility services

By law, Title X funds may not be used for programs in which abortion is a method of family planning. The Title X family planning program is intended to assist individuals in determining the number and spacing of their children. This promotes positive birth outcomes and healthy families. The education, counseling and medical services available in Title X-funded clinic settings assist in achieving these goals.

# Federal and Virginia Title X Overview

### VDH Mission, Values & Beliefs

The VDH FPP is administered by the Division of Child and Family Health housed within the Office of Family Health Services at the Virginia Department of Health.

The mission of the VDH FPP is to provide quality reproductive health services to vulnerable populations in Virginia regardless of ability to pay. Clinical services are to be provided on a voluntary basis, in a confidential and caring atmosphere, and in the most effective and efficient manner possible. VDH's role is to provide ongoing quality assurance, evaluation, and policy development to family planning programs across the state. VDH ensures compliance by conducting clinical and fiscal audits, developing and monitoring local work plans, offering regular technical assistance calls, and providing one-on-one technical assistance as necessary.

VDH values and believes that:

- All persons should have the opportunity to determine the number and spacing of their children.
- Reproductive health care and family planning should be provided without regard to race, sex, religion, national origin, age, marital status, language, sexual orientation, gender identity, ability status, or financial status.
- The decision to use family planning services should be made on a voluntary basis.
- Patients should receive information, counseling, and medical services before conception, and these services should remain continually available.
- Individuals should receive sufficient scientific information to make informed decisions about family planning.
- Individuals have the right to family planning services that are confidential and non-judgmental and provided with respect to privacy, dignity and individuality.
- People of all genders have the right, and are encouraged, to seek family planning and reproductive health services.
- Persons providing family planning services must seek continuing education, training and information and strive to provide the highest quality of care.

There is no single answer to solving the problem of unintended pregnancy. Proven strategies include ensuring access to services, providing evidence-based, comprehensive sex education in schools, and promoting reproductive life planning and positive youth development activities. Family planning health centers provide services that allow all people freedom to choose when and if they want to have children, reducing unintended pregnancy and protecting the welfare of the state. The Title X program has received bipartisan support over the years and continues to be an integral piece of the public health system nationally and in Virginia.

# Legal Issues

### Informed Consent

Family planning sites must obtain the client's written voluntary informed consent before providing any clinical services. The consent form must be written in a language that is understood by the client. If staff assess the client is unable to give informed consent (i.e. because of an intellectual disability), then written informed consent must be given by the parent or legal guardian if the client is a minor, or a legal guardian if the client is an adult.

A written consent for general services must be obtained at the initial visit, then reviewed and explained to the client as necessary. Separate consent is also required for certain other procedures, including but not limited to immunizations, colposcopy, IUD insertions and removals, etc.

Before signing the consent form, the client must receive the appropriate education, and have the opportunity to ask and receive answers to any and all questions. This includes questions about the consent form or any services, supplies or procedures. Staff must be confident that the client understands the content of both the education and consent form.

All consent forms must include the signature of the client, the signature of the person obtaining consent and the date. All consent forms must be kept in the client's medical record.

### Voluntary Participation

Family planning services must be provided without regard to an individual's religion, race, color, national origin, language, ability status, age, sex, gender identity, sexual orientation, number of pregnancies, marital status, citizenship status, veteran status, contraception preference, or ability to pay. When a staff member signs the Family Planning Manual Signature Page, they are indicating that they understand all policies and procedures outlined in this manual, including but not limited to:

- The use of Title X FP services by any individual must be solely on a voluntary basis.
- Individuals seeking Title X FP services must not be subject to coercion to receive such services.
- Individuals seeking Title X FP services must not be subject to coercion to receive or use any particular method of family planning.
- Using FP funds in programs where abortion is a method of family planning is prohibited. Title X funds cannot be used for an abortion or abortion-related services.
- Acceptance of FP services by an individual must not be a prerequisite to eligibility for, or receipt of, any other services or assistance from or participation in any other health department or community programs.
- Any personnel who coerce or endeavor to coerce any individual to undergo abortion or permanent sterilization procedure may be subject to prosecution under Federal law. This may result in a fine, imprisonment, or both.
- Personnel must encourage family participation in the decision of minors to seek family planning services and counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.

### Confidentiality and Minor Confidentiality

FP personnel must assure and respect client confidentiality and provide safeguards to protect against any invasion of personal privacy. All client information obtained by the project staff related to clients receiving services is protected under the HIPAA guidelines and regulations. Otherwise, client information may only be disclosed in the form of aggregate data that does not identify the individual.

At all times, personnel must preserve the confidentiality of all clients in every aspect of their family planning care, even within the clinic setting and with billing transactions. HIPAA guidelines must always be followed.

Financial eligibility for services and determination of charges must be done in a manner that assures confidentiality and privacy.

Personnel must inform clients fully about the limits of confidentiality in a given situation, when confidentiality may be broken, the purposes for which information is obtained, and how information may be used within the confines of the program.

Clients must be advised that they have the right to specify how the family planning program staff may contact them. Clients have the right to designate themselves as a Do Not Contact client; however, they must be advised about the possibility of abnormal test results and the need for further confidential contact in these cases to ensure the health of the client.

Personnel must obtain written consent from the client prior to the photocopying of and/or the releasing of medical records outside the health department system. Staff must make efforts to assure confidentiality of the client's family planning record while it is being photocopied.

The client's written consent must also be obtained prior to taping or recording any family planning activities. The client's verbal consent must be obtained before permitting third party observation of the clinic visit. The client must be informed that they have the right to allow or deny their partner's presence when receiving family planning services. If the partner is present, the client must also have some time alone with the clinician.

Resident physicians and/or medical, nursing, nurse practitioner, certified nurse midwife, or physician assistant students may perform examinations as a component of their training. Clients must be informed of their training status prior to the examination.

### Minor Confidentiality

Minors must be assured that all aspects of their care are confidential, and that if follow-up is necessary, every effort will be made to assure their privacy and confidentiality.

### Liability Coverage

The VDH FPP must ensure the existence of adequate liability coverage for all segments of the family planning program, including the provision of service.

### Human Subjects Clearance and Research Projects

The VDH FPP must adhere to the legal requirements governing human subjects' research. Sub-recipients must inform the FPP Supervisor of any research projects requiring Internal Review Board (IRB) approval involving Title X FP clients. The research proposal must be presented to the FPP Supervisor prior to initiation of any planned research activities in the field. The agency's IRB policy must be followed.

### Compliance with State Mandated Reporting Laws on Child Abuse, Child Molestation, Sexual Abuse, Rape, or Incest

Persons who are mandated to report are defined in VA Code 63.2-1509 *Requirement that certain injuries to children be reported by physicians, nurses, teachers, etc.; penalty for failure to report.* Sub-recipients are expected to follow the procedures outlined in VA Code 63.2-1509 regarding any suspected cases of child abuse and/or neglect.

### Non-Discrimination

Services must be provided without regard to an individual's religion, race, color, national origin, language, ability status, age, sex, gender identity, sexual orientation, number of pregnancies, marital status, citizenship status, veteran status, contraception preference, or ability to pay. Services must be provided without the imposition of any durational residency requirement or a requirement that the client be referred by a physician.

### Clients With Limited English Proficiency

Title VI of the Civil Rights Act of 1964 requires any agency that receives federal funding is required to provide interpreters for persons with limited English proficiency, provide easily understood materials and post signage in languages of commonly encountered non-English speaking groups represented in the service area. The United States Department of Health and Human Services provides guidance to federal financial assistance recipients regarding Title VI Prohibition against National Origin Discrimination Affecting Limited English Proficient Persons.

Ideally, a professional medical interpreter will be made available on-site to provide interpretation services. The clinic may hire a professional interpreter or may utilize a trained volunteer interpreter. Alternatively, a clinic staff member who speaks the language in question may be used as an interpreter for the client. A family member or friend is not considered an ideal interpreter due to the sensitive nature of the care being provided, and because the clinic has no way to assure that the family member or friend is qualified to interpret medical information. If a client chooses to provide their own interpreter, and the service provider determines at any point during the service that the client's interpreter is not competent in this role, the service provider should obtain the services of a competent interpreter.

# Legal Issues

### Clients with Disabilities

Provisions must be made to accommodate people with disabilities in accordance with the requirements of the Americans with Disabilities Act.

Clinics should make an effort to provide interpreters who are fluent in sign language. If an on-site interpreter is not available, health centers may consult the guidance for requesting an interpreter at a state agency provided by the Virginia Department of Deaf and Hard of Hearing.

### Physical Separation of Title X and Non-Title X Activities

Title X projects must be organized so that they are physically and financially separate from prohibited activities. Title X projects must have objective integrity and independence from prohibited activities including:

a) Separate, accurate accounting records;;

b) The degree of separation from facilities (e.g., treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;;

c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

VDH ensures compliance with this regulation by:

- 1. Reviewing current financial practices; VDH's Title X providers do not provide abortions.
- 2. Determining which sites, if any, need support in improving financial separation practices to be in full compliance with 2019 Regulations; VDH's Title X providers do not provide abortions.
- 3. Determining which sites, if any, will require physical separation due to co-location of Title X services and abortion services; VDH's Title X providers are not co-located with abortion services.
- 4. Meeting with site directors to discuss strategies for physical separation ; VDH's Title X providers are not co-located with abortion services.
- 5. Working with sites on an individual basis to implement financial separation plans and physical separation plans; VDH's Title X providers do not provide abortions and are not co-located with abortion services.

# **Clinical Management**

### Clinic Schedules and Appointments

Clients must be informed of clinic routine hours of operation. These hours must be posted in the clinic where they are clearly visible to clients, potential clients, and visitors. Clients should be advised of the telephone number to call for appointments, a telephone number to be used in case of a problem when the office is closed, and where to access emergency contraception if needed. Appointment reminders (postcards, phone calls, text messages, etc.) should be sent to clients several days before the appointment, if possible.

Any client who could potentially experience or cause an unintended pregnancy, regardless of age, gender identity, or sexual orientation, may be classified as a family planning client. If an established client does not return to the clinic for three years, they must be classified as a new client when they return.

Appointments should be offered at convenient times for clients and should be offered during evenings and/or weekends in addition to during the day. Appointments should be scheduled in the order of the client's request for services; however, if a client has urgent concerns, is experiencing an emergency, or needs to be seen immediately, sites should try to see them the same day. Sites may opt to use telemedicine when appropriate using a HIPAA-compliant platform. If this is not possible, the client should be referred to the nearest hospital emergency room, community health center, or private provider. A clinic's schedule should include a certain number of slots each day to accommodate walk-ins and/or clients with urgent needs.

Services must be prioritized for clients most in need of services, including adolescents. Attempts should be made to schedule their appointments as soon as possible. Appointments for clients most in need of services should be made within one week.

Each office must establish procedures for managing clients who arrive late for their scheduled appointments. Clients who arrive late for their appointment should be offered the option of rescheduling the appointment for another day or waiting until all scheduled clients are seen. If the client chooses to reschedule, they should be offered any contraceptives they may need until their rescheduled appointment. It is never appropriate to let a client run out of contraceptives while waiting for an appointment.

Client wait time during the visit is expected to be minimal and not to exceed actual services time. For comprehensive visits, the total client visit time should not exceed 90 minutes. Clients should be served as closely as possible to their scheduled appointment time.

### **Gynecologic Services**

The VDH FPP provides for the diagnosis and treatment of minor gynecologic problems in family planning clinics so as to avoid fragmentation or lack of health care for clients with these conditions.

Complex procedures, such as colposcopy and biopsy, may be offered to family planning clients provided that family planning clinicians performing these services have specialized training and equipment.

All family planning sites must maintain a current list of provider referral sites for clients needing advanced gynecological services.

# **Clinical Management**

### **Referrals**

FP sites must provide medical services related to FP, as well as, necessary referrals to other medical facilities when medically indicated, including emergencies that require referral. Projects are not responsible for the cost of this care outside the scope of the Title X project. Family planning staff should update referral lists at least annually and solicit feedback from clients regarding their satisfaction with referral providers.

- Sites making referrals to another provider should have a written MOA/MOU. If not, staff must call ahead to verify the site has the capacity to accept the client prior to making the referral.
- Sites must maintain referral and resource lists of health care providers, social service providers, and other support programs that could benefit Title X patients. Referral and resource lists must be reviewed for accuracy annually and updated as needed; proof of an updated referral/resource list will be requested during program site visits.
- Clients should be given a choice of providers from which to select when possible.
- When a client is referred for non-family planning or emergency clinical care, FP staff must:
  - 1. Provide client with a written list of current referral options;
  - 2. Solicit an acceptable way to notify the client in case follow-up is needed;
  - 3. Advise minors that confidentiality cannot be guaranteed once referred to another agency or program;
  - 4. Make arrangements for the provision of client information to the referral provider. Staff should obtain the client's consent to such arrangement, except as may be necessary to provide services to the client or as required by law, with the appropriate safeguards for confidentiality;
  - 5. Advise the client on their responsibility in complying with the referral;
  - 6. Counsel the client on the importance of such referral and the agreed upon method of follow-up;
  - 7. Assess clients on their satisfaction level with their referral providers; and if the client refuses to accept the referral after counseling, document the refusal in the medical record.

### **Abnormal Findings**

Sites must follow-up on any abnormal clinical findings or test results. In the event that the client's needs extend beyond the scope of the family planning program, clients must be referred to other providers for care.

### Eligibility. Billing and Charges

VDH FPP provides services to all clients in accordance with the eligibility guidelines stipulated by its funding source. Family planning clients must not be denied services or subjected to any variation in quality of services due to an inability to pay.

A schedule of discounts, based on ability to pay, is required for individuals with family incomes between 101% and 250% of the Federal Poverty Level (FPL). All family planning clients, including minors, must be charged for all services according to sliding scale.

A financial eligibility screening must be done for every family planning client. At the time of services, clients who are responsible to pay for their services must be given bills directly. In cases where a third party is responsible, and the client doesn't desire confidentiality, bills must be submitted to that third party, and must show total charges without applying any discount. In such cases, bills to clients must show total charges less any allowable discounts.

Clients who lose birth control supplies will be charged for replacements according to the sliding fee schedule.

Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.

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.

### Eligibility. Billing and Charges

### Non-Chargeable Services

Clients at 100% of the Federal Poverty Level (FPL) and below must not be charged for any family planning services, contraceptive supplies, or copayment fees.

### Third Party Payers

Medicaid and private health insurance plans must be billed for family planning clients who have coverage, unless doing so would jeopardize client confidentiality.

### Minors

When providing services to minors, whether or not they have requested confidential services, charges for services must not present a barrier to receiving services. A financial eligibility screening must be completed for every family planning client, including minors. Minors accompanied by a parent(s) to the clinic should be screened using the income of that parent(s), unless confidentiality is requested.

For minors requesting confidential family planning services, an income eligibility screening must be completed, and the client's charges will be calculated based on an economic unit of one. Charges must be based solely on the income actually available to the minor, such as wages from part-time employment, stipends and allowances paid directly to the minor. Those services normally provided by the parents/guardians, such as food, shelter, transportation, etc., should not be included in determining the minor's income. Under certain circumstances where confidentiality is restricted to limited members of the family (e.g. one parent is aware of the minor seeking services but the other is not), and the minor's confidentiality would be breached in seeking the full charge, the charges must be based solely on the minor's income.

If a minor is receiving confidential services and has income of their own to pay for services, then the client should be handed an invoice for services while in the clinic. If the client lives with parent(s) or guardian(s), then an invoice should not be sent to the client's mailing address. If the client becomes delinquent in their payments, then the client should be given a delinquency notice at the next visit and each subsequent visit until the delinquency is resolved. Under no circumstances should a client who lives with their parent(s) or guardian(s) be referred to an outside collection agency.

For minors not requesting confidential family planning services, third party payers may not be billed. Insurance coverage by a third party is considered part of the non-confidential minor's ability to pay.

### College Students

College students claiming to be dependents of their parents must provide income eligibility based on family income. If the college student notes confidentiality as a concern, or if the college student is not claiming to be a dependent of their parents, charges must be based solely on the client's income as an economic unit of one.

# **Clinical Management**

### Personnel

Sites must establish and maintain personnel policies that comply with federal and state requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title I of the Americans with Disabilities Act. The personnel policies will include, but will not be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures. All personnel records must be confidentially maintained.

Family planning personnel should be broadly representative of all significant elements of the population to be served by the project, and must be sensitive to and able to deal effectively with the cultural and other characteristics of the client population.

New family planning program staff will be provided with an appropriate orientation by experienced family planning staff. A list of required training and competencies is found on VDH FP webpage.

Family planning personnel must be informed that they may be subject to persecution under federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure. There must be a signed consent in each family planning employee's personnel folder indicating they have been informed and are aware of this federal law.

The clinical care component of the family planning program is operated under the direction of a medical director who is a Virginia licensed physician.

Clinical staff must be limited to individuals who are licensed to practice in Virginia and are qualified for the positions for which they are appointed. Licenses of applicants for positions requiring licensure must be verified prior to employment, and documentation of current licensure must be maintained. Clinical personnel subject to licensure or certification by the Commonwealth of Virginia shall have a current license on file or documentation of such on file at the appropriate office. This includes physicians, nurses, nurse practitioners, certified nurse midwives, physician assistants, pharmacists, laboratory personnel and licensed counselors/social workers.

Certified nurse midwives shall practice in consultation with a licensed physician in accordance with a practice agreement between the nurse practitioner and the physician. The practice agreement must address the availability of the physician for routine and urgent consultation on patient care. The certified nurse midwife is responsible for maintaining the agreement and providing it to the Virginia Board of Nursing and Virginia Board of Medicine upon request.

### Supplies & Pharmaceuticals

Sites must maintain the equipment and supplies necessary to provide safe, comprehensive family planning services in accordance with all program guidelines. Family planning offices are expected to follow all federal and state infection control regulations.

All service sites must adhere to federal and state laws for the security, prescribing, labeling, dispensing and record keeping for prescription drugs and devices. The inventory, supply and provision of pharmaceuticals must be in compliance with state pharmacy laws and professional practice regulations.

Only authorized personnel may dispense medications at the family planning site. The VDH FPP encourages sites to write prescriptions for clients when appropriate (i.e. not a barrier for client, client has insurance, etc.). However, each site reserves the right to dispense medications on-site based on available resources. All requirements for packaging and dispensing of medications as defined and directed by the Virginia State Board of Pharmacy shall be adhered to.

Each family planning service site must maintain an adequate inventory of pharmaceuticals to manage the needs of its family planning clients. Medications must be stored in a locked cabinet or room to which only designated staff has access. Refrigerated medications must be labeled for clinic use only and must be stored in a refrigerator labeled for clinical use only.

VA Code 38.2-3407.5:2. Reimbursements for dispensing hormonal contraceptives ensures that all private health insurance plans in Virginia cover up to a 12-month supply of hormonal contraception at one time. This law went into effect on JJuly 1, 2017, though insurance companies had until JJanuary 1, 2018 to be in compliance.

### 340B

Sites receiving Title X funds are eligible for 340B drug discount pricing. The 340B program is managed by the federal Human Resources and Services Administration (HRSA). 340B medications offered through the Title X program must only be used for family planning clients. In order to be considered a family planning client, the client must have a medical record with mandatory family planning components clearly documented. If these criteria are not met, the client's visit cannot be counted as a family planning encounter, and this client is not eligible for 340B drug discount pricing.

Sites are responsible for completing the 340B recertification process for each family planning service site annually. Failure to re-certify will result in a loss of the 340B drug pricing discount for the offending site. Recertification can only be completed by the designated Authorizing Official (AO). A designated AO and primary contact person must be identified and their contact information kept current within the 340B database. Any other changes to the 340B database (e.g. changing AO, changing primary contact information, adding a site, etc.) must be reported to the Family Planning Program, as the Title X database must be updated in conjunction.

### Adding or Closing Clinical Sites/Change in Scope

A Change in Scope occurs when a Title X clinical site proposes to change the objectives, aims, or purposes previously identified in the approved application. Opening and/or clinical sites is considered a Change in Scope, as is transferring services to another agency. These changes require a formal request from the Family Planning Title X Program Supervisor to the Office of Population Affairs (OPA). Sites must notify the VDH FPP regarding plans to add new sites, close existing sites, or transfer services to another agency in advance. No changes may be made without prior approval by the Family Planning Supervisor.

A Change in Scope request can take a few months, and VDH will only submit a Change of Scope request on behalf of the agency twice a year. Therefore, sites should plan accordingly and notify the FPP as soon as possible. If a new site is not officially added to the Title X project in this manner, that site cannot use Title X 340B medications. Once the request is approved by OPA, the FPP staff will provide the steps needed to begin or close a service site.

Sites wishing to begin or end services must submit the following information to the FPP Supervisor:

- Name of location
- Description of the geographic area and population served which may be affected by the change in scope
- How the need for change was determined
- How the addition will address the overall need for services in the area
- Anticipated start date of service provision
- Anticipated number of patients to be served

### **Emergency Management**

All family planning clinics must have a written plan for the management of emergencies, and clinic facilities must meet applicable standards established by federal, state, and local governments (e.g., local fire, building, and licensing codes). Health and safety issues within the facility fall under the authority of the Occupational Safety and Health Administration (OSHA). The basic requirements of these regulations include, but are not limited to the following:

### Clinical site emergencies

- 1. All family planning sites must have a written protocol for 9-1-1 medical emergencies and transport.
- 2. Each family planning site must have a current emergency cart/box/bag easily accessible by all licensed family planning staff. This cart/box/bag must be checked monthly for outdated medications and supplies.
- 3. All family planning program staff must be familiar with the emergency plans and protocol and locations of portable cardiac defibrillators (AED).
- 4. Appropriate training, including initial and ongoing training in CPR and OSHA blood borne precautions must be made available to staff and training documented in personnel files.

### Disaster plans (e.g. fire, bomb, terrorism, earthquake, etc.)

- 1. Staff must be able to identify emergency evacuation routes.
- 2. In the event of the need to evacuate the building, each examination room must have a building evacuation route map posted in a visible location.
- 3. Building exits must be well marked and free from barriers/easily accessed by staff and clients.
- 4. Staff must complete training and understand their role in an emergency or natural disaster.

### Mandatory Title X Family Planning Components

**BRIEF BACKGROUND:** A clinic visit must meet certain criteria in order to be considered a Title X encounter. Clients can only be identified as Title X users if the required Title X components (Box 1) are clearly documented in the medical record. Without these required components, the client must not be counted in the Title X FPAR system.

**Procedure/Directive:** Any person who can experience or cause an unintended pregnancy, regardless of their sexual orientation or gender identity, is eligible for Title X services, and should receive documented Title X counseling. A client may only be counted as a Title X client when the mandatory components are documented in the medical record.

Box 1. Mandatory Components of Title X Family Planning Encounter

The following <u>must</u> be clearly documented for a visit to be considered a Title X FP encounter:

- Medical History
- Physical/medical assessment as needed and related to contraceptive use (blood pressure and/or weight is acceptable). Refer to the <u>CDC's Medical Eligibility Criteria</u> and <u>US Selected Practice Recommendations (US SPR) for Contraceptive Use</u> for further guidance
- <u>Reproductive life plan</u>
- Contraceptive counseling, including method effectiveness, side effects, etc.
- The client's chosen method of contraception
  - Note: A client is not required to leave with any particular method of contraception in order to receive Title X services. Rather, their chosen method of contraception must be documented in the medical record, even if the client chooses "abstinence," "no method," or "condoms."
- STI risk reduction counseling
- Sexual coercion assessment, based on the client's needs (See Box 2)
- Minor counseling for clients under under 18 years old (See **Box 3**)

Box 2. Key Components of Sexual Coercion Counseling

All clients must be counseled on how to resist coercive attempts to engage in sexual activities, regardless of age.

Suggested topics:

- Emphasize that sexual activity should always be a personal, positive, empowered choice.
- Define sexual coercion as a feeling, situation, or atmosphere where emotional and physical control leads to sexual abuse, rape, or a person feeling that they have no choice but to submit to sexual activity.
- Discuss the various types of sexual coercion, including sexual trauma, sexual violence, rape, intimate partner violence, and human trafficking.
- Discuss ways to negotiate with a partner those sexual activities that they will or will not engage in within their relationship.
- Assess for reproductive coercion (behavior that interferes with contraception use and pregnancy).

### Mandatory Title X Family Planning Components

Box 3. Key Components of Minor Counseling

- Limits of confidentiality
  - Assure the minor of their confidentiality, situations when confidentiality may be broken, and that family member consent is not required to receive Title X services
- Family/Trusted adult involvement
  - Encourage minors to involve their families or trusted adults in their health care, including family planning.
  - Explore who, other than the clinic, is aware of the minor's family planning visit.
  - Explore with the client the likelihood of families noticing changes caused by a chosen method, and how the client might respond if approached.
- Sexual coercion
  - How to resist coercive attempts to engage in sexual activities
- Acceptable ways for the clinic to contact the minor when necessary.

### Family Planning Examinations and Preventive Health Services

**BRIEF BACKGROUND:** FP services may be the only source of health care for many people of reproductive health age. Therefore, it is imperative that FP sites offer preventative health services to all FP clients, regardless of gender identity or sexual orientation.

**PROCEDURE / DIRECTIVES:** All Title X visits must have each of the mandatory FP components clearly documented in order to count as a Title X encounter. Refer to the Mandatory FP Components to ensure that each visit meets the Title X requirements. Clients have the right to refuse any service.

- 1. The Family Planning National Training Center's Family Planning and Preventive Services Checklist should be used as a guide for FP visits.
- 2. All visits and revisits must be individualized and based on:
  - a. Client needs
  - b. Reason for the client's visit
  - c. Current clinical guidelines and recommendations
- 3. Care must be taken to ensure that unnecessary barriers do not delay the initiation of effective contraception. Refer to FP Timing of Initiation Guidelines for more information.
- 4. The VDH FPP adheres to the most recent American College of Obstetricians and Gynecologists (ACOG) and American Society of Colposcopy and Cervical Pathology (ASCCP) guidelines for cervical cancer screening and management. There is no medical benefit to requiring a routine pelvic examination or cervical cytology prior to initiating hormonal contraception. The prospect of such an examination may deter a client, especially an adolescent, from having a clinical visit.
- 5. FP services for male clients, like any other client, must be individualized based on client needs, the reason for the client's visit, and current clinical guidelines and recommendations. Staff are encouraged to frame the conversation around the client's intent for parenthood/pregnancy; reproductive health plan including strategies to achieve healthy pregnancy or avoid unintended pregnancy; STI risk reduction; initiation of contraception, such as condoms and/or reliance on partner's birth control method, if desired; as well as counseling and education related to immunization status. For additional information, consult the U.S. Department of Health and Human Services' Preventive Male Sexual and Reproductive Health Care: Recommendations for Clinical Practices.

### Timing of Contraceptive Method Initiation

**BRIEF BACKGROUND:** The goal of the FPP is to improve pregnancy planning and prevent unwanted pregnancy. Initiating an effective contraceptive method on the day of visit is expected, whenever possible.

**PROCEDURE / DIRECTIVES:** It is the policy of the FPP to initiate use of oral contraceptives, Depo Provera, the patch, the vaginal ring, or condoms on the day the client presents for contraception. The implant or an IUD may require a bridging method and a return visit, depending on the client's circumstances.

- 1. The type of exam, history taking, and testing a client receives must depend on the method requested and the type of visit.
- 2. FP sites will determine the dosage and number of subsequent cycles it will provide on-site based on that site's resources and the client's circumstances.
- 3. The clinician may offer emergency contraception (EC) if the client has had unprotected intercourse 5 or less days prior to presentation.
- 4. All family planning clients not using a LARC must be offered prophylactic EC.

### Box 1. How to be Reasonably Certain a Woman is not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is < 7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is < 7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority

[>85%] of feeds are breastfeeds), amenorrheic, and < 6 months postpartum

If the client meets CDC criteria for reasonable certainty (Box 1), an appropriate method must be started on the day of visit. If the client is not started on their chosen method, medical record documentation must explain why. If the client has been abstinent or only had protected intercourse for 2 weeks, an appropriate method may be initiated:

- a. On the same day of visit
- b. Using Sunday start
- c. On the first day of next menstrual period
- 1. Initiation of LARCs in these circumstances is at the clinician's judgement and availability. However, IUDs are not an appropriate choice when there is the possibility of pregnancy.
- 2. Consideration for incidents of unprotected intercourse:
  - a. If a woman has had unprotected sex in the five days prior to visit, EC must be offered even if she had other unprotected sex before that. As with all FP services, the client may decide whether or not to accept it. All forms of contraception, except the IUD, are appropriate to start the same day or next day if Plan B is given.
  - b. If the client has had sex in the past 72 hours, the copper IUD may be placed as EC.
  - c. If Ulipristal (UPA) is used for EC, the client must wait 5 days before beginning hormonal contraceptive.
  - d. If the woman has had unprotected sex outside of the window for EC, for the majority of women, the benefits of starting contraception outweigh the risks.
- 3. Depending on the circumstances, a patient may be encouraged to return for a second UPT, or she may be counseled to take a home pregnancy test in 3 weeks.

### **Basic Infertility Services**

**BRIEF BACKGROUND:** Infertility is defined as the failure of a couple to conceive after 12 months or longer of regular, unprotected intercourse or after 6 months for women:

- Over age 35
- With oligomenorrhea
- A history of known or suspected uterine or tubal disease or endometriosis
- With a partner known to be subfertile

**PROCEDURE/DIRECTIVES:** All FP sites must provide Level 1 infertility services. Refer to National Family Planning Training Center's Basic Infertility Checklist for more detailed information regarding Level 1 infertility services. Level 2 and Level 3 services include sophisticated infertility testing by gynecologists and reproductive endocrinologists who specialize in assisted reproductive technology. Level 2 and Level 3 services are beyond the scope of Title X FP services, therefore clients requiring these services must be referred to an outside provider.

# Clinical

### **Contraceptive Methods**

**BRIEF BACKGROUND:** The goal of the VDH FPP is to reduce the number of unintended pregnancies in Virginia.

**MEDICAL ELIGIBILITY CRITERIA:** For an up-to-date, detailed list of contraindications for contraception, consult the most recent CDC US Medical Eligibility Criteria for Contraceptive Use.

- U.S. MEC 4=A condition that represents an unacceptable health risk if contraceptive method is used.
- U.S. MEC 3=A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- U.S. MEC 2=A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- U.S. MEC 1=A condition for which there is no restriction for the use of the contraceptive method.

**PROCEDURE/DIRECTIVES:** For evidence-based guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate, refer to the current CDC U.S. Selected Practice Recommendations for Contraceptive Use.

- 1. FP sites must provide a broad range of contraceptives, including emergency contraception.
- 2. FP sites not carrying each method must have a formal (written) referral agreement for any method not provided.
- 3. FP sites that have referral agreements with other Title X sites must reimburse the providing site for staff/clinician time and the contraceptive method.
- 4. FP sites will determine the dosage and number of subsequent cycles it will provide on-site based on that site's resources and the client's circumstances.
- 5. Prescriptions may be written for contraceptives on the clinic formulary or on the client's insurance plan formulary. Accepting a prescription must not pose a barrier for the client.
- 6. Education and information regarding sterilization must be provided for all clients, if indicated or requested. Sites must maintain a list of community providers where clients can be referred for sterilization.
- 7. FP staff must assess the client's knowledge of their chosen method and provide additional information as appropriate.
  - a. Review Family Planning National Training Center's (FPNTC) Explaining Contraception Job Aid for counseling information on the chosen method.
  - b. Provide patient-centered, tiered-effectiveness method counseling.
  - c. Offer the client written instructions and/or materials, but only distribute them at the client's request. Refer to the VDH FP webpage for approved patient education materials.
  - d. Counsel client that only condoms protect against sexually transmitted infections (STIs). Offer condoms and encourage use with each sex act.
  - e. Offer emergency contraception prophylactically to any clients not using a LARC, but the client may decide whether or not to accept it.

Availability and Charges: A broad range of contraceptive methods must be made available for FP clients. Sites must charge clients according to their approved sliding fee scale. Income Level A clients must never be charged a fee for FP services or supplies.

### Emergency Contraception (EC)

**BRIEF BACKGROUND:** Emergency contraception (EC) refers to contraceptive methods that can be used after unprotected sexual intercourse to prevent pregnancy. The most commonly used options for EC include the levonorgestrel-only regimen (Plan B One-Step and its generic varieties) and Ulipristal (UPA). Another option includes the insertion of a copper IUD (Cu IUD).

EC is the only way to reduce pregnancy risk in circumstances of rape, mechanical failure, or a lapse in contraception. Family planning clinics in the federally funded Title X program received explicit authorization to provide emergency contraception treatment in April 1997.

- 1. EC is not an abortion, and will not disrupt a pregnancy that is already established. No single mechanism of action has been established for emergency contraception; rather, the mode of action varies according to the menstrual cycle on which sexual intercourse occurs, the time in the menstrual cycle that the emergency contraception is administered, and the type of EC. UPA and the levonorgestrel-only regimen have been shown to inhibit or delay ovulation as well as inhibit the movement of sperm. Review of literature confirms that EC is unlikely to prevent implantation of a fertilized egg.
- 2. The copper in the Cu IUD enhances its effectiveness by interfering with sperm movement, egg fertilization, and by possibly preventing implantation. The Cu IUD can prevent pregnancy after sexual intercourse, and is ineffective after implantation. The Cu IUD is not an abortifacient.

**MEDICAL ELIGIBILITY CRITERIA:** There are multiple contraindications for the use of estrogen-containing products, many of which require detailed explanations to determine whether the condition is an absolute contraindication or one in which estrogen may be carefully prescribed in certain situations. For an up-to-date, detailed list of contraindications for combined hormonal contraception, consult the most recent US Medical Eligibility Criteria for Contraceptive Use.

- U.S. MEC 4=A condition that represents an unacceptable health risk if the contraceptive method is used.
- U.S. MEC 3=A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- U.S. MEC 2=A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- U.S. MEC 1=A condition for which there is no restriction for the use of the contraceptive method.

**PROCEDURE / DIRECTIVES:** Clinical sites are expected to provide EC on site.

- 1. Review Family Planning National Training Center (FPNTC)'s Explaining Contraception Job Aid for counseling information. Offer the client written instructions and/or materials, but only distribute them at the client's request. Refer to the VDH FP webpage for approved patient education materials.
- 2. Counsel client that EC does not protect against sexually transmitted infections (STIs). Offer condoms and encourage use with each sex act.
- 3. When possible, the client should be seen in the clinic that day and started on a contraceptive method.

### Emergency Contraception (EC)

### Eligibility

FP staff must assist in determining a client's eligibility for EC. The client should provide the date of their last menstrual period (or date of recent delivery or abortion), whether the last menstrual period was normal, the date and time of the most recent act of unprotected intercourse, and whether any other acts of unprotected intercourse have occurred since her last menstrual period.

### Other Considerations

Patients who have been raped should be encouraged to go to an emergency room so that evidence may be collected, and appropriate treatment given. EC is available at most emergency rooms.

Clients using UPA as their choice of EC must wait five days before the initiation of hormonal contraception. A non-hormonal back-up method will be required for seven days.

### Availability and Charges

Emergency contraception must be available for all family planning clients. Family planning clients receiving EC must be charged according to their approved sliding fee scale. Clients under the 100% FPL must never be charged a fee for family planning services or supplies.

### Minor Counseling

**BRIEF BACKGROUND:** The purpose of counseling in the FP setting is to assist individuals and couples in reaching an informed decision regarding their reproductive health. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

**PROCEDURE / DIRECTIVES:** All Title X clinic sites must provide documented counseling that encourages family participation in the decision of minors to seek FP services, as well as counseling on how to resist attempts to coerce minors into engaging in sexual activities. Sites may not require written consent of guardians for the provision of FP services to minors, nor can FP staff notify a parent or guardian before or after a minor has received Title X services. Minors must receive appropriate referrals beyond the scope of Title X FP services when appropriate. When such referrals are made, FP staff must inform the minor that parental/guardian consent may be needed for those services.

### Key Components of Minor Counseling

- Limits of confidentiality
  - Assure the minor of their confidentiality, situations when confidentiality may be broken, and that family member consent is not required to receive Title X services
- Family/Trusted adult involvement
  - Encourage minors to involve their families or trusted adults in their health care, including family planning.
  - Explore who, other than the clinic, is aware of the minor's family planning visit.
  - Explore with the client the likelihood of families noticing changes caused by a chosen method, and how the client might respond if approached.
- Sexual coercion
  - How to resist coercive attempts to engage in sexual activities
- Acceptable ways for the clinic to contact the minor when necessary

### Key Components of Sexual Coercion Counseling

All clients must be counseled on how to resist coercive attempts to engage in sexual activities, regardless of age. Suggested topics:

- Emphasize that sexual activity should always be a personal, positive, empowered choice.
- Define sexual coercion as a feeling, situation, or atmosphere where emotional and physical control leads to sexual abuse, rape, or a person feeling that they have no choice but to submit to sexual activity.
- Discuss the various types of sexual coercion, including sexual trauma, sexual violence, rape, intimate partner violence, and human trafficking.
- Discuss ways to negotiate with a partner those sexual activities that they will or will not engage in within their relationship.
- Assess for reproductive coercion (behavior that interferes with contraception use and pregnancy).

# Clinical

### **Minor Counseling**

### Key Components of Family Involvement/Trusted Adult Counseling

The goal of family involvement/trusted adult counseling is to encourage minors to seek input from their family or a trusted adult when making decisions about their sexual health. When youth have open, supportive communication with their families about their sexual health, they tend to experience healthier outcomes. Use counseling skills, such as open-ended questions, to explore the minor's family dynamic and how comfortable the minor is in discussing these issues.

Examples of open-ended questions to use to introduce adult/family involvement:

- How comfortable are your parents/trusted adult with your sexuality? (What do they think?)
- Tell me about sexuality discussions you've had with your parents/trusted adult.
- Even if they are uncomfortable, how do your parents/trusted adult handle your questions about sexuality? (*How do they communicate?*)

Be aware that there may be circumstances when family involvement is not advisable at the time, such as:

- Violence in the family
- Parents have rigid or poor communication skills
- Parents have clearly stated their opposition to the client
- Hints of any of the above

Do not assume that a minor's situation will always remain the same. Revisit the issue at subsequent visits. For example, ask, "Has there been any change...

- ...in your parents'/trusted adult's position on you coming here?"
- ...in your parents'/trusted adult's position about your sexual behaviors?"
- ...in your parents'/trusted adult's position on your choice of partners?"
- ...in your comfort level in talking with your parents/trusted adult?"

### Patient Centered Counseling

**BRIEF BACKGROUND:** The purpose of counseling in the FP setting is to assist individuals and couples in reaching an informed decision regarding their reproductive health. This includes planning and spacing births, choice of preferred contraception and services which contribute to positive birth outcomes and improved health for adults and their infants. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest. Patient-centered counseling encourages client decision-making and responsibility.

**PROCEDURE / DIRECTIVES:** FP staff must adapt the discussion to each client. Persons who provide education/ counseling must be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware, and able to create an environment in which the client feels comfortable discussing personal information.

- 1. FP staff must use patient-centered counseling.
- 2. FP staff must help clients:
  - Explore, express and manage their feelings;
  - Define alternatives;
  - See circumstances realistically;
  - Cope with anxieties and pain;
  - Mobilize for action on a decision; and
  - Recognize and draw on their own strengths and support systems.
  - A variety of tools to assist staff with patient-centered counseling is located on the FP webpage under Tools.

### Other Considerations

In some cases, the type of counseling needed by the client is beyond the scope of that which can be provided on a short-term basis in the FP clinic. In these cases, clinic staff must maintain a list of referral resources for meeting the client's long-term counseling needs. Refer to the Clinical Management section of the FP Manual for more information.

### Pregnancy Counseling

**BRIEF BACKGROUND:** Pregnancy testing is one of the most common reasons for a first visit to a FP clinic. It is important to use this opportunity as an entry point for providing education and counseling about FP and reproductive health.

**PROCEDURE/DIRECTIVES:** All FP clinics must have pregnancy tests of high sensitivity and offer pregnancy testing on site. Serum quantitative hCG should be considered if repeat urine pregnancy tests are negative in spite of evidence suggesting possible pregnancy. Pregnancy diagnosis and pregnancy options must be offered to all clients in need of this service. FP providers must provide objective, factual and non-directive information on pregnancy options.

- 1. FP clinic sites must maintain a referral list and a separate resource list for clients receiving a pregnancy test.
- 2. The referral list must include prenatal care providers.
  - a. The resource list must include a variety of services, such as mental health, substance use, primary care, food assistance, abortion, etc. Abortion providers listed on the resource list cannot be designated as abortion providers.
  - b. All clients receiving a positive pregnancy test result are expected to receive information about a wide variety of services, and thus must receive both a referral list and a resource list.
  - c. Document all pregnancy tests. Clients with positive results must be provided with a referral list and a resource list.
- 3. When giving a positive test result, FP staff members may share the result with the client, and then state that the client's options are parenting, adoption, and abortion. The staff member must share the referral list and the resource list with the client. Clients with follow up questions about prenatal care, adoption, or abortion must be referred to a clinician.
- 4. Anyone calling a FP clinic requesting information on pregnancy options must be referred to a clinician.
- 5. Each clinic site must have patient education for all pregnancy options available. Pregnancy counseling tools and pregnancy options resources may be found on the VDH FP webpage.
- 6. Pregnancy resource centers/Crisis pregnancy centers are community-based organizations that provide material and emotional support to pregnant people throughout the state. Because VDH FP sites are expected to practice patient-centered counseling, pregnancy resource centers are an appropriate resource for patients choosing parenting or adoption. Pregnancy resource centers are not an appropriate resource for clients who choose abortion or are unsure about their decision, and this resource must not be shared with clients who have expressed this.

### Postpartum Visits

**BRIEF BACKGROUND:** The weeks following birth are important for both the mother and infant's long-term health and wellbeing. In order to optimize the health of women and infants, the American College of Obstetricians and Gynecologists (ACOG) states that postpartum care should be an ongoing process, not just a single encounter. ACOG recommends that all women make contact with their OB/GYN or other obstetric care provider within the first three weeks postpartum. This initial assessment should be followed up with a comprehensive postpartum visit no later than 12 weeks after birth.

**PROCEDURE/DIRECTIVES:** To best meet the needs of women during the postpartum period, the timing of the comprehensive visit should be individualized and patient-centered; changes in insurance coverage after delivery should be taken into account.

- 1. If a site undertakes responsibility for postpartum care, an assessment of the patient's physical, social, and psychological well-being must be conducted.
- 2. Sites are not expected to implement all practices recommended in ACOG's current Committee Opinion on Optimizing Postpartum Care. However, ACOG's current Committee Opinion on postpartum care must be used as a guide when drafting local policies.

### Sexual Violence, Intimate Partner Violence, and Human Trafficking Counseling

**BRIEF BACKGROUND:** Given the prevalence of violence in the United States, FP sites will likely encounter clients who have experienced sexual violence, intimate partner violence, and/or human trafficking. Survivors of violence may need extensive counseling and care that a FP clinic is not equipped to provide on-site, and FP sites must be prepared to offer compassionate counseling and referrals for these clients

**PROCEDURE/DIRECTIVES:** All FP staff must be knowledgeable and up to date on state and local sexual assault laws, sexual abuse laws, mandatory reporting, and human trafficking laws. Sites must have written policies/protocols for handling sexual violence and/or intimate partner violence disclosures from clients during clinic visits.

A client stating that they have experienced sexual violence, intimate partner violence, and/or human trafficking should always be given the number of the local violence service agency. Clinic staff may also assist the client in accessing other support systems in the community. FP sites must assure that staff is providing accurate information and resources to survivors in a sensitive manner, and may contact the FPP for technical assistance.

- 1. FP sites must provide universal screening to all clients for potential abuse and violence.
- 2. Clients disclosing a history of violence must be assessed for ongoing violence to determine if the client is in immediate danger.
- 3. Clients who have experienced rape within EC's window period of effectiveness must be offered EC.
- 4. Clients disclosing a history of violence must be assessed for reproductive coercion during contraceptive methods counseling.
- 5. Clients disclosing a history of violence should be offered testing for STIs, including HIV.
- 6. FP provides must document any allegations of sexual or intimate partner violence, as well as any physical evidence of violence that they observe.
- 7. FP sites must share information with these clients about the local violence service agency.
- 8. FP sites should share information about local Emergency Departments with clients over 18 who disclose that they have been sexually assaulted. Clients should be informed that a police report is not required in order to collect forensic evidence, which should be collected as soon as possible in case the client decides to press charges or make a police report at a later date. For clients under 18, FP staff must follow state mandatory reporting laws. It is important to note that Emergency Departments are required by law to report any sexual assault they evaluate. Hospitals must have the consent of a parent or legal guardian to evaluate and treat anyone under 18 years of age. Emancipated minors may provide consent for themselves.
- 9. Healthcare professionals in Virginia are not legally required to report cases of intimate partner violence to law enforcement. If the provider files a report, they must never file a report without the client's knowledge and consent, and careful safety planning.
- 10. Federal law requieres state child welfare agencies to report suspected cases of human trafficking to law enforcement. FP sites must provide universal screening to all clients for potential abuse and violence, and report any cases of suspected abuse or neglect to DSS in accordance with State law.

### Additional Information

Virginia Sexual and Domestic Violence Action Alliance: http://www.vsdvalliance.org/

Local violence service agencies: http://www.vsdvalliance.org/resources-helpayuda/get-help/

Virginia Sexual Assault Laws: https://law.lis.virginia.gov/vacodefull/title18.2/chapter4/article7/

Virginia Anti-Violence Project: https://virginiaavp.org/

Teen Dating Violence: https://www.loveisrespect.org/

Virginia Human Trafficking Data and Resources: https://humantraffickinghotline.org/state/virginia

Polaris Project (National Human Trafficking Hotline): https://polarisproject.org/

Preventing Sex Trafficking and Strengthening Families Act of 2014: https://www.ncsl.org/research/humanservices/preventing-sex-trafficking-and-strengthening-families-act-of-2014.aspx

### Reproductive Life Plan/Preconception Counseling

**BRIEF BACKGROUND:** Reproductive life planning includes discussing your life goals as they relate to childbearing. It helps both women and men think about if and when they would like to have children. It can also increase awareness of how a person's current behaviors can affect their health, future fertility and birth outcomes in the future. **PROCEDURE / DIRECTIVES:** All clinic sites must discuss and document the client's reproductive life plan. Preconception counseling must be offered based on the client's reproductive life plan. All Title X clients, regardless of gender identity or sexual orientation, must be assessed for a reproductive life plan, and the reproductive life plan must then be used to guide the client's care. Assessment and documentation of the reproductive life plan is a mandatory Title X component.

- 1. As reproductive life plan counseling is expected to be tailored to the individual client, a standard set of prescribed questions is not recommended. Refer to the *Family Planning National Training Center's Asking Clients about their Reproductive Life Goals* for sample questions.
- 2. Staff must tailor the counseling based on the client's answers and needs.
- 3. Document reproductive life plan/conception health counseling in the client's medical record.

### Sexually Transmitted Infection (STI) and HIV

**BRIEF BACKGROUND:** The incidence and prevalence of STIs, particularly among adolescents, requires that family planning projects provide education/counseling and information about common STIs and HIV/AIDS.

**PROCEDURE/DIRECTIVES:** Family planning sites must make the detection and treatment of common STIs available to all family planning clients. Family planning sites must offer risk assessment, testing, and treatment for common STIs, including HIV/AIDS. Treatment should be provided on-site when possible, and the appropriate follow-up measures must be undertaken.

Family planning sites must follow the current Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases Treatment Guidelines and Centers for Disease Control and Prevention (CDC) Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services for STI testing and treatment. Clients must be informed of state policies concerning mandatory STI reporting and partner notification requirements. Family planning sites must comply with state and local reporting requirements.

### Sexually Transmitted Infections and HIV Counseling:

Family planning clients must receive thorough and accurate counseling on STIs and HIV. STI/HIV counseling refers to an individualized, face-to-face, dialogue with a client about their risks for acquiring STIs/HIV. At a minimum, counseling should include the following:

- Education about STIs, HIV infection, and AIDS
- Education about the relationship between HPV and cervical cancer
- Information on risks and infection prevention; and referral services
- STI and HIV risk reduction strategies
- STI and HIV testing locations

Clients, especially those at risk for STIs/HIV, should be encouraged to use condoms in addition to another method of contraception. Barriers to condom use should also be reviewed. This information should be reinforced at all subsequent visits. Documentation of all counseling provided must be included in the client's medical record.

### Substance Use/Abuse

**BRIEF BACKGROUND:** Scientific evidence demonstrates that clients with substance use disorder experience healthier outcomes when their condition is identified early, they receive appropriate counseling, and they receive an appropriate referral for treatment.

**PROCEDURE/DIRECTIVES:** FP sites must screen, assess, and identify clients with substance use disorder and assist with connecting them to community-based resources for appropriate care.

- 1. FP sites must maintain an updated list of local resources for clients with suspected or confirmed substance use disorder.
- 2. Clients should be assessed for a history of substance use. Any drug or alcohol abuse should be noted and discussed with the client.
- 3. Virginia's Behavioral Health Risks Screening Tool is a standardized instrument intended to screen pregnant, postpartum and women of childbearing age for depression, substance use and/or experiences of intimate partner violence. A positive result requires further assessment and an automatic referral for additional services. This tool is optional for use.
- 4. Given the relationship between substance use and unprotected sex, contraception and barrier methods should be discussed with clients with a history of substance use.

Some signs and symptoms of substance abuse include:

**Physical Findings:** evidence of intravenous drug use; alcohol on the breath; scars and injuries; hypertension; tachycardia or bradycardia; tremors; slurred speech; self-neglect or poor hygiene; liver or renal disease; runny nose; chronic cough; cheilosis; nervous mannerisms (e.g. frequent licking of the lips, jitters, foot tapping); pinpoint or dilated pupils; reproductive dysfunction (e.g. irregular menses, miscarriage, infertility, fetal alcohol syndrome, hypogonadism).

<u>Psychological Findings:</u> memory loss; depression; anxiety; panic; paranoia; unexplained mood swings; personality changes; intellectual changes; sexual risk taking; dishonesty; unreliability.

### Providing Family Planning Care in the Context of Zika

**BRIEF BACKGROUND:** The goal of the VDH FPP is to help patients make informed decisions about pregnancy and childbirth in the context of Zika. Zika virus can be acquired from mosquitoes or from sex with a person who has the virus, and can be passed from a pregnant women to her fetus. Zika can cause a serious birth defect called microcephaly, as well as other problems such as absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth.

**PROCEDURE/DIRECTIVES:** As Zika information is updated, the CDC publishes new research findings and clinical recommendations. Providers are encouraged to check the Office of Population Affairs or the Family Planning National Training Center websites to ensure use of the most current information and toolkit versions.

- 1. All non-pregnant clients of reproductive age should be screened for exposure to Zika virus and educated about the risks of infection during pregnancy, regardless of their gender.
- 2. If the client is not pregnant or does not desire a pregnancy, offer contraception using patient-centered tieredeffectiveness counseling.
- 3. Inform the client that using contraception consistently and correctly can prevent pregnancy.
- 4. Condoms can reduce the chance of acquiring Zika from sex, if used consistently and correctly.
- 5. Not having sex can eliminate the risk of sexual transmission of ZZika infection, although there may still be risk of mosquito-borne transmission.

# Quality Assurance, Staff Training & Technical Assistance

### Staff Orientation and Training

All sub-recipients must have an established orientation and training program for all staff, including specific family planning training. It is recommended that all staff working for the program be oriented to the Title X program, including staff that provides medical interpretation and/or translation for the program. In addition:

- There must be routine training of staff on Federal and state requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as human trafficking
- It is suggested that all personnel have the option to attend continuing education based on an assessment of training needs, quality assurance indicators, and changing regulations/requirements.
- All training and continuing education should be documented and kept on file. It is recommended that orientation and other employment related to continuing education be documented in employees' personnel files.



### Training and Technical Assistance

It is the responsibility of the local family planning staff in collaboration with the FPP to provide training for all Title X family planning personnel. All FP staff must complete the initial Title X Orientation and any additional training required by the FPP. FP staff should participate in continuing education related to their job duties, and documentation of such education should be maintained and accessible for review upon site visits. Failure to complete mandatory trainings could result in a loss of Title X funding.

- 1. The Family Planning National Training Center (FPNTC) is the official training site for the VDH FPP.
  - a. The National Clinical Training Center for Family Planning is a national training and technical assistance centers funded by the Office of Population Affairs to provide the most up-to-date and latest evidenced-based, quality training nationwide for family planning clinicians:
    - i. Administrative training: https://www.fpntc.org/
    - ii. Clinical training: http://www.ctcfp.org/clinical-training/
- 2. Staff must complete all training as required by the FPP and seek out additional training as needed.
- 3. FP sites must allow time each month for staff to complete required FP training
- 4. FP sites must monitor staff completion of Title X trainings, and retain documentation of Title X trainings for the current project period.
- 5. The VDH FPP is available for consultation and technical assistance by phone, email, or video conference, and encourages sites to utilize these resources.
- 6. FP sites may request on-site technical assistance as needed by contacting the VDH FPP.
- 7. Attend Title X Sub-Recipient Quarterly Webinars.

# Quality Assurance, Staff Training & Technical Assistance

### **Staff Orientation**

Program Staff Orientation to Title X Family Planning

Staff Member Name: \_\_\_\_\_

Position: \_\_\_\_\_

FQHC: \_\_\_\_\_

Hire Date: \_\_\_\_\_\_

	ORIENTATION ACTIVITY	TIMELINE	REQUIRED STAFF	DATE COMPLETED & INITIALS
Title X Orientation				
1.	Review the VDH FP Manual	Within 30 days of hire	All FP Staff	
2.	Review VDH FP Webpage	Within 30 days of hire	All FP Staff	
3.	Complete FPNTC Title X Orientation and print certificate.	Within 6 months of hire	All FP Staff	
4.	Review Title X Program Guidelines	Within 30 days of hire	All FP Staff	
5.	Review current Title X Key Issues and Program Priorities	Within 30 days of hire	All FP Staff	
6.	Review Agency Title X Work Plan	Within 30 days of hire	All FP Staff	
7.	Review current CDC Recommendation for Providing Quality Family Planning Services (QFP)	Within 60 days of hire	All FP Staff	
8.	Review current CDC Medical Eligibility Criteria (MEC)	Within 60 days of hire	All FP Staff	
9.	Review current CDC Selected Practice Recommendations for Contraceptive use (USSPR)	Within 60 days of hire	All FP Staff	
10.	Review current CDC STD Treatment Guidelines	Within 60 days of hire	All FP Staff	
11.	Review CDC Recommendations for Providing Quality STD Clinical Services	Within 60 days of hire	All FP Staff	
12.	Attend FP trainings as appropriate	Ongoing	TBD	

The Family Planning Orientation has been completed as outlined above.

Family Planning Coordinator Printed Name and Title

Family Planning Coordinator Signature

# Quality Assurance

### Overview

**BRIEF BACKGROUND:** The purpose of the VDH FPP quality assurance system is to provide ongoing monitoring and evaluation of Title X family planning personnel and services.

**PROCEDURE/DIRECTIVES:** It is the policy of the VDH FPP to have quality assurance processes in place to ensure that service sites are providing Title X family planning services consistent with Title X legislative mandates and program requirements, relevant federal and state statutes, local agency guidelines, and other established professional standards, with the expressed purpose of meeting the needs of clients. The VDH FPP provides oversight of service sites through annual work plans, quarterly progress reports, client satisfaction surveys, medical record audits, and Title X family planning program reviews.

- 1. The FPP will assure program consistency by maintaining clinical, administrative and programmatic standards. This requirement is accomplished through the VDH FPP Policy Manual, and regularly assessed through medical record audits, Title X Site Reviews, and routine reviews of clinical data. Information about medical records audits is below.
- 2. FP sites will create a system to identify patients in need of follow-up and/or continuing care.
- 3. FP sites will regularly monitor clinic show rates with the goal of maintaining an 80% patient show rate. If no show rates remain above 20% at any location, the family planning clinic should consider double booking patient slots or adjusting clinic hours.
- 4. FP sites must develop a system for regularly soliciting consumer feedback, such as patient satisfaction surveys.

### Medical Record Audit:

The FP medical record audit is a critical part of the VDH FPP quality assurance system. Medical record audits must evaluate the care provided to a variety of FP clients. Sites must provide appropriate follow-up for identified deficiencies (e.g. staff training, mock chart audits, etc.)

- 1. Monthly medical record audits are required for all sites providing Title X services.
- 2. A minimum of ten (10) charts per site shall be audited a month using.
- 3. Charts must be randomly selected from FP clients served within the past 12 months, and pulled from all clinic sites.
- 4. Sites must maintain the chart audit results and documentation of appropriate follow-up for the current Title X project period.

### Family Planning Community Outreach, Education, & Project Promotion

**BRIEF BACKGROUND:** Community outreach, education, and engagement activities are a critical component of the VDH FPP quality assurance system. Title X FP sites must develop, maintain, and evaluate a process for engaging the communities served by the FP project, and then use community feedback to inform and evaluate local FP efforts.

**PROCEDURE/DIRECTIVES:** Title X FP services must be patient-centered and provided based on client and community needs. FP sites must provide community education to enhance community understanding of the objectives of Title X services, make known the availability of services to potential clients, and encourage continued participation by persons who may benefit from services.

### Community Awareness and Access

Family planning sites are expected to conduct a periodic needs assessment with regard to awareness of and need for access to family planning services in the community. It is acceptable to use a site or local community organization's assessment as long as reproductive health metrics are included. Assessments must be conducted at least once per project period (i.e. every 3 years). Sites must have a written community education and service promotion plan, as well as documentation that the plan has been implemented (e.g., media spots/materials developed, event photos, participant logs, and monitoring reports). The plan must (a) state that the purpose is 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, (b) promote the use of family planning among those with unmet need, (c) utilize an appropriate range of methods to reach the community, and (d) include an evaluation strategy. Documentation that an evaluation has been conducted, and that program activities have been modified in response must be a part of the plan.

### Community Education

Family planning sites must develop a written community engagement, education, and service promotion plan based on the results of then needs assessment. The plan must (a) state that the purpose is 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, (b) promote the use of family planning among those with unmet need, (c) utilize an appropriate range of methods to reach the community, and (d) include an evaluation strategy.

Sites must develop a work plan regarding community engagement and education with appropriate planning details, implementation details, and evaluation outcomes for that site, and then incorporate this work plan into their annual work plan submitted to VDH FPP.

### Collaborative Planning and Community Engagement

Sites must have procedures in place to ensure that there is an opportunity for community participation in developing, implementing, and evaluating their Title X program. Participants should include individuals who are broadly representative of the population to be served, and who are knowledgeable about the community's needs for family planning services. The community engagement plan must engage diverse community members including adolescents and current clients, and specify ways that community members will be involved in efforts to develop, assess, and/or evaluate the program. Documentation must demonstrate that the community engagement plan has been implemented (e.g., reports, meeting minutes, etc.).

### Family Planning Community Outreach, Education, & Project Promotion

### FP Client Feedbackk

In addition to Patient Satisfaction Surveys, VDH FP clients may be referred to VDH's LiveWell website to leave feedback for the FPP.

### Information & Education (I&E) Committee

The purpose of the I&E Committee is to review and approve all informational and educational materials that are given to VDH Title X FP clients. An I&E Committee must adhere to the following characteristics/requirements:

- Consist of at least 5 but no more than 9 committee members;;
- Be broadly representative of the community in which the family planning program is implemented;
- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- Consider the cultural norms of the population or community to be served with respect to such materials;
- Review the content of the materials 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 (i.e. educational value, literacy level/understandability, cultural competence, and moral standards as appropriate to the community); and
- Establish a written record of its determinations (meeting minutes and summary of materials reviewed).

The VDH FPP partners with a state-level coalition to meet this requirement, and posts all approved materials on the VDH FP webpage. FP sites are encouraged to work with the family planning program supervisor to submit prospective materials to this coalition for approval. Family planning sites may choose to have a local advisory board or committee serve as its IE Committee instead. This is allowable as long as the pre-existing group meets the requirements listed above. Following:

- A list of local committee members and each member's age, race, and ethnicity;
- A copy of each of the print materials reviewed and a listing of any videos and/or DVDs;
- Copies of each Informational Educational Materials Review Evaluation Worksheet completed by committee members during the review; and
- A copy of the sign-in sheet for the review.

### Patient Education Materials

Clinical sites must have all Title X patient education materials approved by the I&E Committee and VDH FPP prior to sharing with patients. Federal grant support must be acknowledged in any publication for which Title X funds were used (even partly). This involves placing a brief statement on any family planning brochures, educational materials or flyers produced by sites.

Ex. "This brochure was developed (in part) with federal funds from the Office of Population Affairs grant number FPHAxxxxx."

### Family Planning Medical Advisor Committee (FPMAC)

The Family Planning Medical Advisory Committee consists of medical experts from across the Virginia Department of Health's (VDH) Title X network, including but not limited to physicians, nurse practitioners, and Family Planning Program staff. The role of the FPMAC is to establish and review ongoing policies and guidelines for the VDH FPP. The FPMAC is also responsible for reviewing materials approved by the I&E Committee for factual, technical, and clinical accuracy.

# Quality Assurance

### Title X Site Visits

**BRIEF BACKGROUND:** The purpose of the family planning quality assurance process is to ensure that service sites are providing Title X family planning services consistent with Title X legislative mandates and program requirements, relevant federal and state statutes, VDH guidelines, and other established professional standards, with the expressed purpose of meeting the needs of clients. The Title X Site Review provides an opportunity for face-to-face interaction between program administrative staff, clients and service providers in the local setting.

Title X family planning clinics are subject to site reviews and medical record audits by authorized state and federal personnel. This includes but is not limited to the review of service records, policies and procedures, staffing, training, job descriptions, and licensure verification.

**PROCEDURE/DIRECTIVES:** The family planning review team will monitor all Title X family planning clinics at least once per project period (i.e. every three years). Family planning clinics must comply with audits of medical records, financial and accounting practices, and any other documents that are conducted by state and federal personnel, or other persons duly authorized by the VDH. The family planning review team must be given access to all information related to Title X family planning program services to ensure patient care is provided in accordance with Federal and State regulations and guidelines, as well as current evidence-based practice standards. The current site visit review tool is available on the VDH FP webpage.

### VDH Site Visit Process

The VDH family planning site review process is a continuous process between the administrative office and the local service sites. The site review process includes an administrative, clinical, and fiscal review. Formal site visits are conducted on a rotating basis at least every three years, and as needed. When possible, the FPP will provide written notification of a scheduled site visit at least 30 days in advance. An agenda listing required staff and site visit documents and the Program Review Tool will be sent upon notification of an upcoming site visit.

For site review purposes, documents such as patient surveys, training logs, chart audit forms, etc. need only be kept for the current project period. Please note that sites may be required to retain documents longer for VDH's Internal Audit Team, and should contact VDH Internal Audit directly with any concerns. The Quality Assurance Nurse Supervisor, Fiscal Auditor, and any other Review Team member(s) reserve the right to request any other pertinent family planning documents not listed previously.

The site visit elements include the following (in no particular order):

- Introductions
- Administrative Review
- Fiscal Review
- Clinical Review
- Clinic Observation (sites must ensure sites have clients scheduled during review)
- Record review
- Interviews staff and patients
- Exit conference
- Written site review report
- Corrective Action Plan (CAP)

Upon completion of the FP site review, the review team will draft a formal written report with findings and recommendations. Staff will receive the review team's completed program review tool, a written report, and a corrective action plan (CAP) spreadsheet. Staff is expected to respond to the report with the completed CAP spreadsheet within 30 days of receipt. Once the CAP is accepted by the FPP, a follow-up review will be scheduled by the review team.

# **Ouality Assurance**

### Title X Site Visit

### Findings

Findings are broken up into three types and color-coded by severity. Red indicates a Title X Finding, which is the most serious. Title X findings require immediate correction as failure to correct these findings could result in the loss of VDH's Title X award. Yellow indicates an agency finding, and green indicates a FPP finding. Each finding must be addressed in the final CAP.

### Corrective Action Plan (CAP)

The FPP review team will complete the first step.

- State the finding/observation Ex. Title X Finding 1, Section 9, Project Services and Clients, 9.8 Range of Family Planning Methods (#1 sites must:
- 2. Create clear, simple, measurable activities/actions steps to correct the finding (i.e. the corrective action). These steps are not the same as the evaluation.

Ex. Ensure 100% of medical records have clear documentation by:

- a. Reviewing FP Mandatory Component Guidelines during staff meeting
- b. Ensure new staff are trained on mandatory components
- c. Conduct monthly chart audits to identify compliance
- 3. List the individual(s) responsible Ex. FP Coordinator, NP, MD
- 4. Provide an achievable timeline
  - Ex. Mo/Day/Year
- 5. Evaluate/monitor the progress of the CAP

Ex. 100% Medical record audits will show documentation of mandatory components, training will show all staff aware of mandatory components, staff attendance list and minutes show training occurred.

This version was updated August 2020.