# **DELAWARE**

# **TITLE X FAMILY PLANNING**

**PROGRAM GUIDELINES 2022-2023** 

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#### A. PURPOSE of DELAWARE'S TITLE X FAMILY PLANNING GUIDELINES

The purpose of these guidelines is to provide information, regarding polices and evidence based clinical practice guidelines for family planning services as a Subrecipient for the State of Delaware's Family Planning (FP) Program. The guidelines provide a foundation for the development of business practices, programming family planning services and clinical algorithms. The guidelines are intended for use by Subrecipients including DPH Clinics, that contract with the Delaware Division of Public Health's Family Planning Program Federal Title X funds to provide family planning services at the community level.

The Delaware Title X Family Planning Program background/summary provides policy and guidance for Sub-recipients to provide family planning services, centered upon the Title X statutes, Office of Population Affairs (OPA) Title X Guidelines, federal and state laws, regulations and annual funding process. The guidelines and forms are the basis for monitoring the Title X family planning projects.

The funded sub-recipient clinics are designed to address the unmet family planning needs of low-income women and men and provide access to populations with special health concerns. No one is denied services due to the inability to pay. These services include assisting individual's in determining the number and spacing of their children, all services are voluntary and non-coercive. The client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services from, or participation in, any other program that is offered by the sub-recipient. The services include a broad range of contraceptive methods, education and related preventive health services.

The Title X Family Planning guidelines are consistent with federal and state policies/procedures applicable to all sub-recipient agencies. DPH Family Planning provides resources to all personnel providing care as a sub-recipient in the Delaware Title X Family Planning Program.

https://www.hhs.gov/opa/guidelines/program-guidelines/program-requirements/index.html

The Title X Family Planning guidelines include the core-tenants of clinical services based upon the Providing Quality Family Planning Services (QFP) developed by the Centers for Disease Control and Prevention (CDC) and OPA. The QFP is intended for Sub-recipients across all practice settings as clinical evidenced based guidance for Title X Federal planning projects

\*If further clarification is required regarding clinical topics covered in the guidelines, please refer to Centers for Disease Control and Prevention Morbidity and Mortality Weekly Review (MMWR) Recommendations and Reports/ Vol. 63/ No.4, April 25, 2014.

\*\*Updated link at time the manual was distributed to providers in 2022 Providing Family Planning Services | CDC

\*\*\*The Title X project has a secure mailbox for our Title X sub-recipients and partner agencies. We welcome your comments and questions on the Guidelines. Please contact us at: dhss\_dph\_titlex@delaware.gov

As a Sub-Recipient with a Title X contract, each employee at your site(s), will sign the following statement.

I, \_\_\_\_\_ have read and understood the contents of this manual and will act in accordance with these policies and procedures while employed for a Sub-Recipient in Delaware's Title X Family Planning Program.

#### B. MANTENANCE of DELAWARE'S TITLE X FAMILY PLANNING GUIDELINES

The guidelines contain multiple sections for program administration, clinical and financial policies with a comprehensive appendix. The clinical section of the guidelines is reviewed and/or revised annually by the Title X Family Planning Quality Assurance Advanced Practice Registered Nurse (APRN). The program and fiscal policies are reviewed by the program director and additional Title X staff annually or as necessary to reflect federal or state requirements. The scheduled revision process does not preclude revisions at additional times, as federal and state policies are updated. As a Subrecipient provider for the Title X Program your agencies director, will receive a draft copy of the Title X Guidelines annually and may provide suggestions to the guidelines by email to the Title X Family Planning Director.

Policies which are updated are identified with the corresponding date(s). Any revised policies which are vital to operations will be sent via high priority email to the Subrecipients from the Title X Quality Assurance Advanced Practice Registered Nurse (APRN) with a read receipt.

Every effort is made to be sure Sub-recipients have the most current guidelines. The Title X Family Planning Guidelines are available in electronic format Link.

# C. <u>DELAWARE HEALTH and SOCIAL SERVICES MISSION, VISION and PRIORITIES</u>

#### **Mission Statement**

"To improve the quality of life for Delaware's citizens by promoting health and well-being, fostering self-sufficiency, and protecting vulnerable populations."

#### **Vision Statement**

"Together we provide quality services as we create a better future for the people of Delaware."

#### **Priorities:**

- α. Maximize Personal and Family Independence
- β. Be a self-correcting organization working to retool to keep pace with changing client needs and a changing service delivery environment

# D. <u>DELAWARE FAMILY PLANNING ORGANIZATIONAL STRUCTURE and</u> PROGRAM

The Family Planning Title X program is administered by the Delaware Department of Health and Social Services (DHSS), Division of Public Health (DPH), Section of Family Health Systems, Bureau of Adolescent and Reproductive Health, Family Planning Program (FP), with the agreement from the US Department of Health and Human Services, Office of Population Affairs.

The Bureau of Adolescent and Sexual and Reproductive Health is responsible for administering the Title X Grant from DHSS, Division of Public Health. This section of public health utilizes the core public health framework and principles to fulfill its responsibility for infrastructure building, population-based services, enabling services and direct health care for women men and adolescents. The bureau has the primary responsibility for program development and system planning. Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.

The purpose of FP is to assist individuals, couples, families and adolescents in identifying goals and develop a plan for the number and spacing of children if desired, and the means by which those goals may be achieved. These means include a broad range of acceptable and effective choices, methods education, which may range from choosing abstinence, to the use of other FP methods, or no method and (including contraceptive methods and natural FP or (other fertility awareness-based methods) and the management of infertility. FP services include preconception counseling, education, and general reproductive and fertility health care to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek FP services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. FP services are never coercive, are strictly voluntary. The client's acceptance of family planning services are voluntary, confidential, and must not be a prerequisite to eligibility for, or receipt of, any other services from, or participation in, any other program that is offered by the sub-recipient and DPHR&SH.

Delaware's family planning program sub-recipients must comply with the expectations regarding the provision of family planning services that can be found in the statute (Title X of the Public Health Service Act, 42 U.S.C. § 300 et seq.), the implementing regulations (42 CFR Part 59, Subpart A), and any applicable legislative mandates, and are expected to comply with additional program guidance. In addition, sterilization of clients as part of the Title X program must be consistent with 42 CFR Part 50, Subpart B ("Sterilization of Persons in Federally Assisted Family Planning Projects").

### E. FEDERALTITLE X MISSION and STRUCTURE

The Office of Population Affairs (OPA) promotes health across the reproductive lifespan through innovative, evidence-based adolescent health and family planning programs, services, strategic partnerships, evaluation, and research, Act 42 CFR Part 59, Subpart A.

OPA administers the Title X family planning program, the Teen Pregnancy Prevention program, and the Embryo Adoption Awareness program. OPA advises the Secretary and the Assistant Secretary for Health on a wide range of topics, including adolescent health, family planning, sterilization, and other population issues.

The Office of Population Affairs operates under the direction of the Deputy Assistant Secretary for Population Affairs, Jessica Swafford Marcella, M.P.A. who also serves as the Director of the Office of Adolescent Health.

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# TITLE X FEDERAL STATUES, REGULATIONS, and LEGISLATIVE MANDATES

#### 2021 Title X Final Rule

On October 4, 2021, the U.S. Department of Health and Human Services (HHS) Office of Population Affairs (OPA) amended the Title X Family Planning regulations to restore access to equitable, affordable, client-centered, quality family planning services for more Americans. Ensuring such access for all clients, especially for low-income clients, in the Title X program creates opportunities for realigning the nation's family planning program with nationally recognized standards of care and improving the health of communities that have been historically underserved. The 2021 regulations also reinforce the program's central tenets of quality, equity, and dignity for all individuals who seek Title X services and modernizes the more than 50-year-old program to better reflect the current healthcare system.

The U.S. Department of Health and Human Services (HHS) Office of Population Affairs (OPA) amends the Title X Family Planning regulations to restore access to equitable, affordable, client-centered, quality family planning services for more Americans.

#### Title X Statute-Five Major Provision of the Law

#### Title X of the Public Health Service Act, 42 U.S.C. 300, et seg. - PDF

- i. Section 1001 assist in the establishment and operation of voluntary family planning projects which provide a broad range of acceptable and effective family planning methods and related preventive health services that include natural family planning methods, infertility services, and services for adolescents; highly effective contraceptive methods; breast and cervical cancer screening and prevention services that correspond with nationally recognized standards of care; STD and HIV prevention education, counseling, testing, and referral; adolescent abstinence counseling; and other preventive health services. The broad range of services does not include abortion as a method of family planning.
- ii. Grants under Section 1003 provide training for personnel working in family planning services projects described under Section 1001. The purpose of this training is to promote and improve the delivery of family planning services
- iii. Grants under Section 1004 provide for projects for research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

Projects under this Section conduct data analysis and related research and evaluation on issues of interest to the family planning field, as well as research into specific topic areas related to service delivery improvement. Research on male reproductive health has been a focus of applied research activities since 1997. All research activities funded under Section 1004 support ensuring and improving the quality of family planning services.

- iv. Grants under section 1005 provided for the development and dissemination of informational and educational materials including the OPA website and the Title X family planning clinic locator database.
- v. Grants under section 1008 None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

# **TITLE X REGULATIONS**

Family Planning Program Regulations 42CFR59 Grants for Family Planning Services

- Subpart A Project Grants for Family Planning Services
- Subpart C Grants for Family Planning Service Training

Sterilization of Persons in Federally Assisted Family Planning Projects 42CFR50 Policies of General Applicability

• Subpart B - Sterilization of Persons in Federally Assisted Family Planning Project

The *Program Requirements for Title X Funded Family Planning Projects* were developed to assist current and prospective grantees in understanding and implementing the family planning grants program authorized by Title X of the PHS Act (42 U.S.C. 300 *et seq.*). The document is organized into 16 sections that describe the various requirements applicable to the Title X program, as set out in the Title X statute and implementing regulations (42 CFR part 59, subpart A), and in other applicable Federal statutes, regulations, and policies.

- χ. Priority given to persons from low-income families. Low-income family means family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 99020(2).
  - i. No charge will be made for services to persons from a low-income family (families whose annual incomes do not exceed 100 percent of the most recent federal poverty guidelines), except to the extent that payment will be made by a third party, including a government agency, which is authorized or under legal obligation to pay this charge.
  - ii. For persons whose annual family incomes do not exceed 250 percent of the federal poverty guidelines, charges must be based on a schedule of discounts, and individuals whose family incomes exceed 250 percent of the federal poverty guidelines are charged a schedule of fees designed to recover the reasonable cost of providing services.
  - iii. All Title X projects must have the ability to bill third parties (through public or private insurance) for the cost of services without the application of discounts, and reasonable efforts must be made to collect charges without jeopardizing client confidentiality. (42 CFR 59.11).
- 8. Family planning services include a broad range of medically approved services, which includes Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counselling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services and adolescent-friendly health services.

ε. Entities that provide only one method of family planning can participate as part of a project, as long as the entire project provides a broad range of family planning methods. A broad range of family planning services should include several categories of methods, such as: abstinence counseling, hormonal methods (oral contraceptives, rings and patches, injection, hormonal implants, intrauterine devices or systems), barrier methods (diaphragms, condoms), fertility

awareness-based methods and/or permanent sterilization. A "broad range" would not necessarily need to include all categories but should include hormonal methods since these are requested most frequently by clients and among the methods shown to be most effective in preventing pregnancy.

- φ. Family means a social unit composed of one person, or two or more persons living together as a household.
- γ. Services for adolescents must be provided as a part of the broad range of family planning services. Section 1001 of the statute requires that, to the extent practicable. Sub-Recipients should encourage family participation in family planning services projects. This is particularly important in relation to adolescents seeking family planning services. These services must be adolescent-friendly health services that are accessible, acceptable, equitable, appropriate and effective for adolescents, which include abstinence and ways to resist sexual coercion. Abstinence and family planning method selected and ways to resist sexual coercion are to be documented in the clients record.
- η. Adolescent may request confidential services without parent consent.
- 1. Basic infertility services and services to aid individuals and couples in achieving pregnancy also must be provided within the project as part of the broad range of family planning services. Pregnancy information and counseling must be provided in accordance with Title X regulations
- $\phi$ . Education must include STD risk reduction, contraceptive, reproductive life planning.
- κ. Services must be provided in a manner that protects the dignity of individuals, and services must be voluntary and free from coercion.
- λ. Sub-Recipients must not discriminate in the provision of services, on the basis of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status
- μ. Family planning medical services must be performed under the direction of a physician with special training or experience in family planning, and each family planning project must refer to other medical facilities when medically indicated, including in medical emergencies.

- v. Clinical services providers include physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.
- Care must be client-centered which is respectful of, and responsive to, individual client preference, need and values; client values guide all clinical decisions.
- $\pi$ . Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.
- Health equity is when all persons have the opportunity to attain their full health potential, and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.
- ρ. Inclusive is when all people are fully included and can actively participate in and benefit form family planning, including, but not limited to, individuals who belong to underservice communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americas and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; person who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.
- σ. Projects must also provide informational and educational programs that inform the community about the availability of services, and should promote participation in the development, implementation, and evaluation of the project by persons broadly representative of the community to be served.
- τ. Informational and educational materials made available through the project must be approved by an Advisory Committee that conforms to Title X regulations. The review of materials must take into account the educational and cultural background of individuals for whom the materials are intended, must consider the standards of the population or community, must ensure that the content is factually correct and is suitable for the intended population or community. The review and approval of such materials must be documented.
- υ. Section 1008 of the Act, as amended, requires, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."
- σ. Title X priority "Advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by

persistent poverty and inequality."

### FEDERAL LEGISLATIVE MANDATES

The following legislative mandates have been part of the Title X appropriations language for several years. Title X family planning services should include administrative, clinical, counseling, and referral services as well as training of staff necessary to ensure adherence to these requirements.

- None of the funds appropriated in this Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.
- Notwithstanding any other provision of law, no provider of services under Title
  X of the Public Health Service Act shall be exempt from any State law requiring
  notification or the reporting of child abuse, child molestation, sexual abuse,
  rape, or incest.
- That amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office."

OPA expectations each Sub-recipient will comply with applicable state laws in the proposed service area and will have project-wide monitoring and state-specific policies and procedures related to reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. These policies and procedures will include details related to:

- 1. Annual staff training on policies and procedures,
- 2. Implementation of policies,
- 3. Applicant monitoring throughout the project to ensure training and state-specific reporting is being followed, and
- 4. Maintenance of documentation concerning compliance. Each sub-recipient is expected to maintain a training log for each staff member providing Title X services.

These efforts will ensure clear understanding of and compliance with reporting processes, as well as permitting oversight and monitoring. In addition, any minor who presents with an STD, pregnancy, or any suspicion of abuse will be subject to preliminary screening to rule out victimization. Such screening is required for any individual who is under the age of consent in the State of the proposed service area.

### PROGRAM ELIGIBILITY

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

#### NON-DISCRIMINATION

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

#### NONDISCRIMINATION IN FEDERALLY ASSISTED PROGRAMS

In accordance with the Civil Rights Act we state the following:

No person under any program or activity provided in this facility, for which federal financial assistance is received, shall be excluded from participation in, be denied the benefit of, or otherwise be subjected to discrimination on the grounds of race, color, age, sex, creed, marital status, economic condition, sexual orientation, or disability. The Division of Public Health announces the right of any person to complain, should it be considered that any discriminatory practice is being carried out. You may contact: the Office for Civil Rights

# Region III - Philadelphia (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia)

Marlene Rey, Acting Regional Manager Office for Civil Rights U.S. Department of Health and Human Services 150 S. Independence Mall West Suite 372, Public Ledger Building Philadelphia, PA 19106-9111

Main Line (215) 861-4441 Hot Line (800) 368-1019 FAX (215) 861-4431 TDD (215) 861-4440

Sub-recipients must comply with ACA Section 1557 which prohibits discrimination based on race, color, national origin, sex, age or disability in health programs and activities that receive Federal funds. Section 1557 assists populations that have been most vulnerable to discrimination in health care and health coverage, including: women, members of the lesbian, gay, bisexual and transgender (LGBT) community, individuals with disabilities and individuals with limited English proficiency (LEP).

### **VOLUNTARY PARTICIPATION**

Client participation: all family planning services are provided solely on a voluntary basis. Individuals are not subjected to coercion or discrimination in the delivery of services, or coherence to use any particular method of family planning. Acceptance of family planning services is not a prerequisite to eligibility of any other services, assistance, or participation in any other program. Each Sub-recipient agency must have created a written policy regarding this statement. The language above must be included as part of each sub-receipts consent for treatment and must be part of the client record as a signed consent. Clients are encouraged to ask questions and may refuse a service or stop services at any time.

Staff participation in Title X: all family planning staff, sub-recipient agencies must be informed that they may be subject to prosecution under Federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure.

Sample voluntary participation acknowledgement of receipt is on the following page. Acknowledgement must be signed and maintained in personnel files at the sub recipient agency. Per the Public Health Service Act 42 CFR Part 59; IAC 641-74; QFP, 2014 Revised 2022

Sub-recipient agencies may use the Delaware Family Planning Form or modify to create their own specific form for use within the agency.

Services are to be provided without subjection individuals to any coercion to accept services or to employ or not employ any particular methods of family planning. (42 CFR § 59.5(a)(2))

| Participation                       | n Acknowledgement of Receipt of the Title X Voluntary  |
|-------------------------------------|--|
| information and I have read these   | ledge that I have received (Voluntary Participation) policies and been given the opportunity to ask I understand the information in these policies and |
| Employee's Name (print)             |  |
| Employee's Signature                | Date   |
| Supervisor's Signature              | Date   |
| Place the original copy of your age | ency's form in the employee's personnel file. Provide  |

a copy to the employee.

### CONFIDENTIALITY

Sub-recipients have safeguards to ensure client confidentiality. Information obtained by project staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality. Concern with respect to the confidentiality of information may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking or other similar reporting laws. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual. Each sub-recipient shall have a policy for indicating how clients are to be contacted to maintain confidentiality regarding their medical and financial information, which is to be documented in the client record. A confidentiality assurance statement must appear in the client's record.

Medical records are legally confidential and will be released per published HIPAA guidelines. Sub-Recipients' follow your agencies established procedures.

#### POLICY FOR TREATING & DISPENSING CONTRACEPTIVES TO MINORS

Clients under age 12 may not receive any medical treatment without the consent of a parent. This includes pregnancy testing, partial services for STD diagnosis/treatment or any GYN or contraceptive services. Clients under the age of 12 may receive counseling and non-prescription contraception such as condoms, film or foam. No Delaware laws restrict the distribution or use of contraceptives that can be purchased without a prescription (The Legal Handbook for Delaware Women, 1994). But, according to Delaware law, minors under the age of 12 must have parental consent to obtain contraceptives requiring a prescription (The Legal Handbook for Delaware Women, 1994).

Minors 12 years of age and above may be counseled and provided with a contraceptive method without parental consent (July 11, 1974 revision of the Delaware Code, Chapter 411, Volume 59, Laws of Delaware). When a medical provider does prescribe a contraceptive for a child between the ages of 12 and 18, the provider may notify the child's parents when it is believed to be medically necessary (13 Del. C. subsection 708,c).

## **CONFLICT of INTEREST**

Sub-recipient agencies must have established policies, regarding the Title X Requirement Public Health Service Act 42 CFR Part 59; IAC 641-74 Program Requirements for Title X Funded FP Projects, 2014; QFP, 2014. to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others

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

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

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

A sample conflict of interest form appears below.

| Sub-recipient agencies may use<br>create the specific form for use v   | he Delaware Family Planning Form or may modify t<br>thin the agency.   |
|--|--|
| I understand that my Title X posi<br>myself or for others. I have read | that I have received (Conflict of Interest) statement<br>on is not to be used for purposes of private gain for<br>his policy and been given the opportunity to ask<br>understand the information in this policy and adhere |
| Employee's Name (print)  |  |
| Employee's Signature   | Date   |
| Supervisor's Signature   | Date   |

Acknowledgement must be signed at onboarding, reviewed annually and

maintained in personnel files at the sub-recipient agency.

# **LIABILITY INSURANCE**

Sub-Recipients shall procure and maintain such insurance as is required by applicable federal and state law and regulation. Such insurance should include, but not be limited to, the following: liability insurance, fidelity bonding of persons entrusted with handling of funds, worker's compensation, unemployment insurance and professional liability.

Public Health Service Act 42 CFR Part 59; IAC 641-74

## FINANCIAL MANAGEMENT

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

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

- 1. Each sub-recipient maintains financial policies and procedures that can be referenced back to federal regulations as applicable.
- 2. Each sub-recipient maintains financial records and oversight documentation that demonstrates that the financial management practices within all project sites are aligned with Title X and other applicable regulations and contract requirements.

### **INCOME DETERMINATION**

Sub recipients must have a written policy concerning income determination. Sub-recipients may choose to require income verification for Title X clients. The rates are reasonable & necessary (42 CFR 59.5(b)(9). No charge will be made for services provided to any person from a low-income family whose income is at, or below, 100% of the Federal Poverty Level (FPL), except to the extent that payment will be made by a third party (including a Government agency) which is authorized to or is under legal obligation to pay this charge. Charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay. Charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent GSA Income Poverty Guidelines will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. Title X is the payor of last resort.

For the purpose of this policy income determination refers to the process of establishing client income to determine client placement on the schedule of discounts. Income may be self-reported. Clients that have lawful access to other valid means of income verification because they participation in another program may use those data rather than re-verify income. Clients who report they have no income are not required to prove absence of income

Family income should be assessed before determining where co-payments or additional fees are charged.

No charges for services may be made to a person from a family whose total annual income does not exceed 100 percent of the Income Poverty Guidelines, unless the payment is made by a third-party payer. However, charges will be made for services to persons other than those from low-income families. For persons, whose annual family income is between 100 and 250 percent of the Income Poverty Guidelines, charges must be on a sliding scale based on ability to pay; persons with income above that level should be charged full fees as described in the regulations.

Sub-recipients must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," IDPH means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. This does not include registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage.

Income determination for minors who request confidential family planning services shall be calculated solely on the minor's income. The Sub-recipient must, in those cases,

document in the minor's medical record the specific action taken by the provider to encourage the minor to involve his/her family (parents or guardians) in his/her decision to seek family planning services. If the provider has documented in the minors medical record a suspicion of child abuse or incest, and has consistent with and permitted by law, appropriately reported the situation, documentation of such encouragement is not required.

Sub-recipient project directors may choose to place the client on the sliding fee scale based on her annual income and ability to pay, for the purpose of payment for contraceptive services or methods only, where a woman has health insurance coverage through an employer that does not provide the contraceptive services or method sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage.

Low-income family also includes members of families who annual family income exceeds 100 percent of the FPL, but who, as determined by the project director, as unable, for good reasons, to pay for family planning services.

When reviewing the charging, billing, and collecting policies and procedures of Title X grantees, regional policies must ensure that family planning users whose documented income is at or below 100 percent of poverty (except when payment will be made by a third party) are not billed or in any way charged for the family planning services received from the grantee. Co-payments, registration fees, non-volunteer monetary contributions and similar activities which require the user to reimburse the grantee are interpreted as being charges for services and are thus subject to the requirements of the Title X regulations.

Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policy holders where the policy holder is someone other than the client.

Voluntary donations from clients are allowable; however, clients must not be pressured to make donations, and donations must not be a perquisite to the provision of services of supplies.

For further information or assistance with fee assessment, please contact the Title X Management Analyst at: 302-608-5758

### **FACILITIES and ACCESSIBILITY of SERVICES**

Clinic facilities should be adequate to provide family planning services which should be geographically accessible to the population served and should be available at times convenient to those seeking services. Services may be available outside of the usual business hours of 8:00 a.m. and 4:30 p.m. The setting and atmosphere of all facilities must ensure the privacy, confidentiality and maintain the dignity of clients during interviews, counseling sessions, and medical examinations. Adequate medical equipment must be supplied. The physical comfort of the clients and staff must receive due consideration. These requirements must be satisfied before the facility can qualify as a Title X Sub-recipient agency.

- Facilities should be clean and arranged to facilitate the comfort and privacy of clients.
- A comfortable gender-neutral waiting room, and adequate confidential reception area for interviews.
- Facilities must comply with 45CFRPart 84, which prohibits discrimination on the basis of handicap in Federally assisted programs. The facility should be readily accessible to person with disabilities who need program services.
- Sub-recipients must have a written process outlining their process reading disability protocol. As per section of law in the Rehabilitation Act, Section 504 protects qualified individuals with disabilities. Under this law, individuals with disabilities are defined as persons with a physical or mental impairment which substantially limits one or more major life activities. People who have a history of, or who are regarded as having a physical or mental impairment that substantially limits one or more major life activities. Major life activities include caring for one's self, walking, seeing, hearing, speaking, breathing, working, performing manual tasks, and learning. These clients must be provided with the extra time needed for the appointment when scheduling. They should have ample time to navigate the facility, and any assistance needed to ensure the visit is able to be completed in manner of dignity and respect.
- Notice of Privacy (HIPAA), Title X Services, Client Bill of Rights, and Human Trafficking signs/posters must be displayed in waiting room.
- Sub-recipients must comply with ACA Section 1557 which prohibits discrimination based on race, color, national origin, sex, age or disability in health programs and activities that receive Federal funds. Section 1557 assists populations that have been most vulnerable to discrimination in health care and health coverage, including: women, members of the lesbian, gay, bisexual and transgender (LGBT) community, individuals with disabilities and individuals with limited English proficiency (LEP).
- Sub-recipients must have a written process regarding disability protocol for their sites to include a process for if the person is blind, wheel chair bound, hard of hearing, deaf, or has any mobility issues.

### **PERSONNEL POLICIES**

Sub-recipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including, but not limited to, Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language.

Sub-recipients have written policies and procedures in place that provide evidence that there is no discrimination in personnel administration at its organizations and within its sub-recipient network. These policies should include, but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

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

## **REVIEW and APPROVAL of MEDICAL POLICIES**

#### SUB-RECIPIENT AGENCY POLICY REVIEW AND APPROVAL:

Each sub-recipient agency shall have a Family Planning Program medical director. The medical director will be a physician with education and experience in Family Planning. All clinical policies shall be reviewed annually by the sub-recipient agency Family Planning Program medical director.

The Title X Family Planning Program will review each sub-recipient agency's clinical policies every 3 years during site reviews. All sub-recipient policies will be submitted electronically to the Title X Family Planning Program by the date established in the annual contract.

Title X Family Planning Program State committee and approval:

At the Title X Family Planning Program State level, there is a medical advisory committee for the Family Planning Program. This committee, which should include representation from the clinical, administration and support staff, shall review current clinical policies annual and modify as appropriate and is overseen by the Department of Public Health's Medical Director. Other committee members include the Delaware Division of Public Health's Reproductive and Sexual Health clinics; Advanced Practice Nurse Practitioners and the Title X Family Planning's Quality Assurance Advanced Practice Nurse to provide recommendations based upon Title X Family Planning Guidance.

# POLICY FOR NEW SUB-RECPIENT STAFF OREINTATION and ANNUAL REQUIRED STAFF TRANSNING

Delaware Title X staff will provide an orientation to Title X for all new sub-recipient staff within six (6) months of the sub-recipient having a signed contract with Delaware Division of Public Health.

The orientation training will include:

- Family Planning overview, funding source, purpose and history of the program, services provided, clients served and program requirements
- Discussion of Delaware Title X Family Planning Program
- Orientation to Delaware Family Planning Program's website
- Orientation to Delaware's Title X Family Planning Guidelines

Additional trainings for Title X sub-recipients will be bi-annual and sub-recipients are encouraged to have at least three (3) staff members attend. If additional trainings are needed based upon site visit findings, those trainings will be individually scheduled with the sub-recipients.

### **SERVICE PLANS and PROTOCOLS**

The service plan is the component of a sub-recipient's annual health care plan which is developed by sub-recipient staff and the sub-recipient medical director which identifies the services to be provided to clients under Title X.

- All sub-recipient agencies must offer a broad range of effective and medically (FDA) approved family planning methods and services either on-site or by referral [59.5(a)(1)]. All sub-recipient agencies must have written clinical protocols approved and signed by the agency's medical director, which outline procedures for the provision of each service offered. Sub-recipient agencies must have written protocols available at each clinical site. The clinic staff must use approved protocols for the provision of all family planning services.
- Clinical protocols must be written in accordance with the QFP document,
  Delaware's Title X Family Planning Program Standards and Guidelines, State of
  Delaware laws and nationally recognized standards for medical care. Clinical
  Protocols must be current (i.e., updated within the past 12 months) and signed
  annually by the medical director. The Delaware Title X Family Planning
  Standards and Guidelines Manual must be available at each sub-recipient
  clinical site.

### **CLIENT EDUCATION**

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

- Counseling is non-coercive and informative, while prioritizing the holistic health needs and optimal wellbeing of the client, regardless of parenting intent, including participation of trusted adult.
- Client centered counseling is provided that is culturally sensitive, includes client priorities about pregnancy prevention, acceptability of methods, considers the relationship, partner comfort and function, and CDC Medical Eligibility Criteria and US Selected Practice Recommendations.
- Adolescent counseling will include information that normalizes abstinence for adolescents and not sexual activity, and clearly communicate the benefits of delaying sex or returning to a sexually risk-free status and support strong resistance skills as a way to opt out of unwanted sexual activity."
- When onboarding new staff, i.e support or medical, the following educational requirements below must be completed within 6 months of hire. Plus, several of the trainings must be reviewed annually. Sub-recipient staff must complete the required trainings in the RHTN system. The RHNTC system will be checked at 6 months and annually for the required trainings by the grantee's trainer educator.

# TITLE X FAMILY PLANNING ORIENTATION ONLINE TRAINING LINKS

- Title X Orientation RPNTC Links 62022 doc.
- Title X Orientation

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

- Make informed decisions about family planning;
- Use specific methods of contraception effectively and identify adverse effects;
- Discuss breast/testicular self-examination with appropriate disclaimers about efficacy;
- Reduce risk of transmission of sexually transmitted diseases and Human Immunodeficiency Virus (HIV);
- Understand the range of available services and the purpose and sequence of clinic procedures; and

- Understand the importance of recommended screening tests and other procedures involved in the family planning visits.
- Additional education should include information on reproductive health, health promotion/disease prevention, nutrition, exercise smoking cessation, alcohol and drug use.
- Any provider completing pregnancy testing and counseling must complete the educational requirement

Please use the link provided for additional information.

https://rhntc.org/

# REIVEW and APPROVAL OF INFORMATIONAL and EDUCATIONAL MATERIALS

The Delaware Title X Family Planning Program utilizes an Advisory Committee to review and approve the suitability of materials utilized for Sub-Recipients.

A written needs assessment is conducted annually to determine if any new literature is needed for Sub-Recipients by the Title X Trainer Educator and other Title X staff. A search is then conducted by the program to determine whether the in-house development of literature is necessary or whether it should be purchased from a vendor.

All literature that is developed or purchased is first reviewed by the program for readability, appropriateness, attractiveness, etc. Client literature is reviewed by the Information and Educational (I & E) Advisory Committee and the Division of Public Health's Office of Communications (OC) As per the 2016 Title X Federal Review, the grantee will utilize volunteers to form the committee members from various community agencies. There must be at least five members. The committee shall include broadly based representatives of the population or community for which the materials are intended. The purpose of the I & E review and assessment is to evaluate the literature's readability, cultural sensitivity and suitability, age appropriateness, technical accuracy, etc. All assessments (both I & E and OC) result in appropriate update, re-review and final approval of the literature. These steps are all documented and shared with the I & E membership prior to sending any literature to the printer and prior to the sale of the literature. Materials maybe electronic.

### Information and Education (I and E)/Advisory Committee:

#### **Materials Review Process**

Below is the step-by-step process for the appropriate review and approval of materials, brochures, posters, Public Service Ads and other communications of the Delaware Title X Family Planning Program within the Delaware Division of Public health (DPH). This process is prescribed for those materials and products subject to the Information and Education Committee requirements of the Federal Title X Program (42 CFR Part 59.5 (b) (10) and "Program Guidelines for Project Grants for Family Planning" as currently published by the United State Department of Health and Human Services, Office of Public Health and Science, Office of Population Affairs, Office of Family Planning).

 Wording, layout, graphics and other contents are initially reviewed internally within the State of Delaware for accuracy and acceptability by appropriate programs, such as: Family Planning administrative and clinical staff, DPH medical staff, Immunization Program staff, HIV Program staff, STD Program staff, and/or other program staff, as appropriate.

- 2 Materials under consideration for program use are shared with the Information and Education Committee members for review and input for acceptance, revision, or rejection.
- 3. As appropriate to the material's or product's intended use, materials under consideration may be tested for input, on a limited basis, at health fairs, through school-based health centers, clinics, or other avenues to ascertain appropriateness for specific targeted populations.
- 4. The results of appropriate review steps are documented through completion of review forms (Exhibits A and B) and/or I and E Committee Minutes.
- 5. The approval or rejection of all materials and products is documented on the I and E Materials Approval Master List (Exhibit C)

# Information and Education Brochure/Materials Review Survey Form Exhibit A

# (Preprinted, Stock Materials)

| Title of Brochure:  |     |    |
|---|-----|----|
| The above-named brochure was designed, or identified, to share important hea input and suggestions regarding the brochure are please requested. There are nanswers. |     |    |
| Please answer "Yes" or "No" for the following:  |     |    |
| Does this brochure get your attention?  | Yes | No |
| Is the appearance of the brochure reasonable?   | Yes | No |
| "I think this brochure, along with proper client education, would be beneficial."   | Yes | No |
| Do you feel the brochure information is helpful?  | Yes | No |
| Based on current practices, is the information in the brochure correct?   | Yes | No |
| If you said "No" to any question above, please tell us why:   |     |    |
|   |     |    |
|   |     |    |
|   |     |    |
| What is the main message from this brochure?  |     |    |
|   |     |    |
|   |     |    |
|   |     |    |
| Please list any known brochure(s) that would be a better choice for this topic.   |     |    |
|   |     |    |
|   |     |    |
|   |     |    |

**THANK YOU!** 

# Information and Education Brochure/Materials Review Survey Form Exhibit B

# (Drafted/Created Items)

| Title of Brochure:   |       |   |
|--|-------|---|
| The above-named brochure was designed, or identified, to share important health i suggestions regarding the brochure are please requested. There are no right or wro     |       |   |
| Please answer "Yes" or "No" for the following  |       |   |
| Does this brochure get your attention?   | YesNo |   |
| Is the appearance of the brochure reasonable?  | YesNo |   |
| "I think this brochure, along with proper client education, would be beneficial."  | YesNo |   |
| Do you feel the brochure information is helpful?   | YesNo |   |
| Based on current practices, is the information in the brochure correct?  | YesNo |   |
| If you said "No" to any question above, please tell us why:  |       |   |
|  |       | _ |
|  |       | _ |
|  |       |   |
| What is the main message from this brochure?   |       |   |
|  |       |   |
|  |       | _ |
|  |       | _ |
| What would make the brochure better?   |       |   |
|  |       |   |
|  |       | _ |
|  |       | _ |
| Please list any words or phrases from the brochure that you think people would find understand. Also, please list any substitute words or phrases that you feel would be | •     |   |
|  |       | _ |
|  |       |   |

**THANK YOU** 

# **Exhibit C**

# **I&E Brochure Materials Approval**

| Brochure/Material Name               | Approval Date | Comments                       |
|--------------------------------------|---------------|--------------------------------|
| Example: Family Planning<br>Handbook | 5/20/08       | Drafted item (Spanish version) |
|                                      |               |                                |
|                                      |               |                                |
|                                      |               |                                |
|                                      |               |                                |
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|                                      |               |                                |
|                                      |               |                                |
|                                      |               |                                |

### **COLLABORATIVE PLANNING and COMMUNITY ENGAGEMENT**

# **Community Participation and Community Education/Program Promotion Plan** (CPEP)

**Purpose:** Sub-recipients will develop a community engagement plan which ensures individuals selected from the community are cross cultural/diverse representative of the population served. These individuals should knowledgeable regarding the community's needs regarding family planning services. The plan will include shared decision making with your agency's leadership and the community representatives. The CPEP plan, is part of Title X Requirements 11.1, 11.2 and 11.3. The (CPEP) plan will include community engagement activities

Sub-recipients have written policies and procedures in place for ensuring that there is an opportunity for community participation in developing, implementing, and evaluating the project plan. 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: (a) engages diverse community members including adolescents and current clients, and (b) specifies ways that community members will be involved in efforts to develop, assess, and/or evaluate the program 3. Documentation demonstrates that the community engagement plan has been implemented (e.g., reports, meeting minutes, etc.).

As a sub-recipient (CPEP) plan can improve your agencies efficiency and effectiveness regarding family planning services and ensure community awareness of services provided.

- Sub-recipient agencies provide for community participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services. The goal of the Community Participation component of this plan is to address Section 11.1.
- Sub-recipient has responsibilities for ensuring that the community is aware of the
  objectives of the project and know about services. Sections 11.2 and 11.3 also
  detail that Community Education/Program Promotion activities should be
  based on an assessment of the needs of the community and that CPEP plans
  include implementation and evaluation strategies.

#### **Example CPEP Activities**

 Examples of activities which Sub-Recipient agencies may incorporate into their CPEP plan are included below. Note Sub-Recipient agencies should identify objectives and activities that apply to their specific context.

## **Community Participation Community Education/Program Promotion Conduct routine community** Conduct presentations to inform needs assessments. community partners (mental health and primary care providers, shelters, prisons, faith-based organizations, school personnel, parent groups, social service agencies, food pantries, and other community organizations) of services, locations, and hours. Note that NYSFPP does not fund implementation of Evidence Based Practice curriculum. Adolescent programs should be facilitated by CAPP/PREP whenever they are able. Conduct joint community needs Meet with community partners and assessments with community coalitions to discuss family planning program and potential partners – especially those also referral opportunities. funded by NYSDOH BWIAH (i.e., CAPP/PREP, MICHC, and Sexual **Violence Prevention Programs)** where service areas overlap. Administer client satisfaction Post up to date program information at a wide range of surveys and use results for program planning. community venues including virtual platforms (websites, social media, etc.) Collect feedback from clients Put out press releases.

through social media platforms.

| <ul> <li>Present at community meetings and solicit feedback.</li> <li>Community Participation</li> <li>Conduct a survey with community partners (mental health and primary care providers, shelters, prisons, faith-based organizations, school; personnel, parent groups, social service agencies, food pantries, and other community organizations).</li> <li>Distribute program information at community events.</li> <li>Provide clients with program information to share with peers.</li> </ul> | Develop mechanism for obtaining feedback from community members on agency FPP services and materials.     Mechanisms can include community advisory committee, youth advisory committee, patient advisory committee. | Distribute and post flyers.      |
|---|--|----------------------------------|
| <ul> <li>Conduct a survey with community partners (mental health and primary care providers, shelters, prisons, faith-based organizations, school; personnel, parent groups, social service agencies, food pantries, and other</li> <li>Provide clients with program information to share with peers.</li> </ul>  | i roooni at commanity mootingo   | Biothibato program imormation at |
| community partners (mental health and primary care providers, shelters, prisons, faith-based organizations, school; personnel, parent groups, social service agencies, food pantries, and other   | Community Participation  |                                  |
| Conduct focus groups with   | community partners (mental health and primary care providers, shelters, prisons, faith-based organizations,  |                                  |

# **Template Community Participation and Community Education/Program Promotion (CPEP) Plan**

The below template plan may be used to identify objectives and actions used by a Sub-Recipient to engage and educate the community. Sub-recipient agencies may adapt this template and add rows as needed.

| Objective |                    | Participation and Community Eduve relates to the Title X requireme |                | notion (CPEP) Plan |
|-----------|--------------------|--|----------------|--------------------|
|           |                    | ation [ ] community education/p                                    |                |                    |
| Timeline  | Target<br>Audience | Action Steps   | Responsibility | Evaluation         |
|           |                    |  |                |                    |
|           |                    |  |                |                    |
|           |                    |  |                |                    |
|           |                    |  |                |                    |
|           |                    |  |                |                    |
|           |                    |  |                |                    |
|           |                    |  |                |                    |

# MINIMUM STANDARDS of SERVICES GENERAL GUIDELINES

- 1. Services are provided solely on a voluntary basis and will not be made a prerequisite to eligibility for, or receipt of, any other services.
- 2. Services are provided without regard to religion, race, color, national origin, creed, handicap, sex, and number of pregnancies, marital status, age, contraceptive preference and sexual orientation.
- 3. Clients will be provided services in a manner, which protects the dignity of the individual.
- 4. Clients are assured of confidentiality.
- 5. Priority in the provision of services will be given to persons without alternate source of care.
- 6. Staff will encourage family participation in the decision of minors seeking family planning services.
- 7. Counseling will be provided on how to resist coercive attempts to engage in sexual activities with particular attention to minors.
- 8. Services and activities are focused on reproductive and sexual health concerns, including health promotion and education.
- 9. All diagnosis and treatment are provided by Physicians, Physicians Assistants, and Advanced Practice Nurses. Services are provided in accordance with guidelines, directives, and standards promulgated by the Division of Public Health, and generally accepted current standards of practice. These are in keeping with agency philosophy.
- 10. In accordance with Section 1008 of the Federal Title X regulations, none of the funds appropriated to the Delaware Women's Health Programs are used in any program where abortion is provided as a method of birth control.
- 11. Quality assurance is a joint responsibility of clinical and administrative staff within the Division of Public Health and each Sub-recipient agency.
- 12. The public should be informed of services provided, clinic hours and how to access care.
- 13. Clinics should be scheduled at varied times and locations in order to facilitate client accessibility.

- 14. Pregnancy testing is an integral service and should be available on a sliding fee scale at Sub-recipient site.
- 15. There should be established referral and follow-up systems.
- 16. Clinics should be conducted on an appointment basis to decrease client waiting time and to allow sufficient time for interviewing, counseling, teaching, screening, treatment and referral services. "Walk-in" clinics are encouraged.
- 17. Registered Nurses may administer and dispense medications under orders from the APRN and/or physician standing orders, in accordance with agency policy and state law.
- 18. Advanced Practice Registered Nurses (APRN) operate under agency-written medical protocols.

#### **SERVICES PROVIDED**

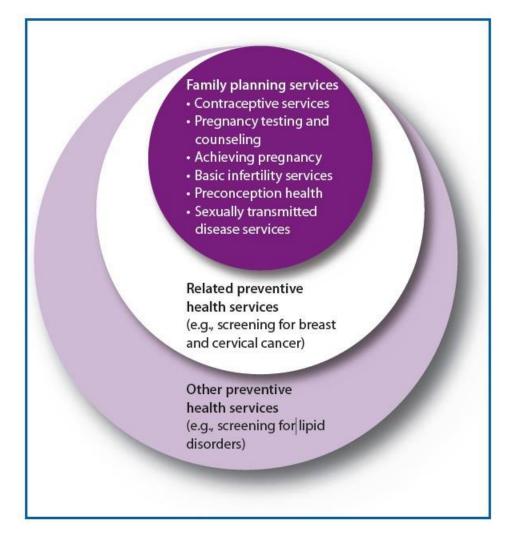
Services provided to Title X clients will lead to improved reproductive health outcomes.

- Accessibility: These recommendations address how to remove barriers to
  contraceptive use, use the family planning visit to provide access to a broader range
  of primary care and behavioral health services, use the primary care visit to provide
  access to contraceptive and other family planning services, and strengthen links to
  other sources of care. Acceptance of family planning services is not a prerequisite
  to eligibility of any other services, assistance, or participation in any other program.
  Each agency needs to create a policy regarding this statement. Clients are
  encouraged to ask questions and may refuse a service or stop service at any time.
- Client-centered: These recommendations encourage taking a client-centered approach by 1) highlighting that the client's primary purpose for visiting the service site is a clinic or other location where Title X services are provided to clients. must be respected, 2) noting the importance of confidential services and suggesting ways to provide them, 3) encouraging the availability of a broad range of contraceptive methods so that clients can make a selection based on their individual needs and preferences, and 4) reinforcing the need to deliver services in a culturally competent manner so as to meet the needs of all clients, including adolescents, those with limited English proficiency, those with disabilities, and those who are lesbian, gay, bisexual, transgender, or questioning their sexual identity (LGBTQ). Organizational policies, governance structures, and individual attitudes and practices all contribute to the cultural competence of a health-care entity and its staff. Cultural competency within a health-care setting refers to attitudes, practices, and policies that enable professionals to work effectively in cross-cultural situations (14–16).

- **Effectiveness:** These recommendations highlight the need for providers of family planning services to deliver high-quality care to all clients, including adolescents, LGBTQ persons, racial and ethnic minorities, clients with limited English proficiency, and persons living with disabilities.
- Equity: These recommendations highlight the need for providers of family planning services to deliver high-quality care to all clients, including adolescents, LGBTQ persons, racial and ethnic minorities, clients with limited English proficiency, and persons living with disabilities.
- **Safety:** These recommendations integrate other CDC recommendations about which contraceptive methods can be provided safely to women with various medical conditions and integrate CDC and U.S. Preventive Services Task Force (USPSTF) recommendations on STD, preconception, and related preventive health services.
- **Timeliness:** These recommendations highlight the importance of ensuring that services are provided to clients in a timely manner.
- **Efficiency.** These recommendations identify a core set of services that providers can focus on delivering, as well as ways to maximize the use of resources.
- **Value.** These recommendations highlight services (i.e., contraception and other clinical preventive services) that have been shown to be very cost-effective (17–19)
- Trauma-informed means a program, organization or system that is traumainformed realized the widespread impact of trauma and understands potential paths
  for recovery; recognizes the signs and symptoms of trauma in clients, families, staff,
  and others involved with the system; and responds by fully integrating knowledge
  about trauma into policies, procedures and practice, and seeks to actively resist retraumatization.

#### These services include:

- 1. Pregnancy testing and counseling
- 2. Achieving pregnancy
- 3. Basic infertility services
- 4. Preconception health
- Screening for breast and cervical cancer
- Management of minor GYN problems
- 7. Follow-up of abnormal findings as required by Program Policy or Federal Guidelines, including referral
- 8. Education and counseling
- History, physical assessment, and laboratory testing
- Administering, dispensing, or prescribing medications or contraceptives
- 11. Immunizations as per protocols.



- 12. HIV Risk Assessment, Education and Counseling; HIV Testing with Informed Consent
- 13. Psychosocial Assessment
- 14. Nutritional Assessment
- 15. Testing and treatment of STD's

In April 2014, Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the US Office of Population Affairs (QFP) - PDF (PDF - 1.18MB) was published as a CDC MMWR Recommendations and Reports. The QFP provide recommendations for use by all reproductive health and primary care providers with patients who are in need of services related to preventing or for achieving pregnancy.

https://www.hhs.gov/opa/guidelines/program-guidelines/program-requirements/index.html

# QFP updates links and verbiage.

<u>Update: Providing Family Planning Services | CDC</u>

<u>Update: Providing Quality Family Planning Services — Recommendations from</u>

CDC and the U.S. Office of Population Affairs, 2017

<u>Update: Providing Quality Family Planning Services — Recommendations from</u>

CDC and the U.S. Office of Population Affairs, 2015

## **CLIENT ENCOUNTERS**

The client's written general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2))

Client encounters with women and men of reproductive age may require different services (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STD services and related preventive health services).

Determine the clinical pathway;

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

For all clients, the following questions **must** be asked and documented to help determine what family planning services are most appropriate for the visit:

- What is the client's reason for the visit?
- Does the client have another source of primary health care?
- Does the client have a reproductive life plan or wants a pregnancy in the next year?
  - O Providers should assess the client's pregnancy intention or reproductive life planning by asking questions like: "Would you like to become pregnant in the next year?", "Have you thought about goals for having or not having children?", or "Do you plan to have children (or more children) in the future?", "How long would you like to wait before you become pregnant?" See One Key Question guidance at https://powertodecide.org/one-keyquestion or CDC Guidance at: https://www.cdc.gov/preconception/overview.html.
  - Providers should encourage family involvement/partner participation in reproductive life planning and family planning decisions where possible and appropriate.
- Client encounters with women and men of reproductive age should also include a
  Zika risk assessment, including asking about past and future travel plans for the
  client and partner(s).

#### Confidentiality

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

#### **Patient Consent**

- Sub-recipients must obtain written consent and indicate services are confidential, voluntary, and non-coercive when participation of family planning services. Family planning services is not a prerequisite to receipt of any other services offered. The consent must be obtained prior to providing services. All consents must appear in the client record.
- Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. (42 CFR § 59.5(a)(2))

#### **Laboratory Services**

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

#### FOR INITIAL HEALTH SCREENING VISITS:

#### History

- Complete medical and surgical history, including items necessary for safe provision of contraceptive methods:
  - Thromboembolic disease
  - Hepatic or renal disease
  - Breast and genital neoplasm
  - Cephalic and migraine with aurora
  - Diabetes and pre-diabetes
  - Hematologic disorder
  - Smoking habits
  - Allergies
  - Blood transfusion or blood products
  - Psychiatric or mental health history
  - Complete menstrual, obstetric and gynecologic history, including complications and unexpected pregnancy outcomes for females
  - Complete reproductive health history for males, including unexpected pregnancy outcomes
  - Sexual health assessment and contraceptive history
  - ST
  - Partner medical/risk history and age if available
  - Family history

- · Social history-smoking, drug use
- Immunizations
- Height
- Weight
- BMI
- Blood Pressure

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

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

**Physical Exam-** as required by contraceptive method chosen, evidenced based standards practice and clinical protocol.

Must include but is not limited to:

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

#### FOR PERIODIC HEALTH SCREENING VISITS

- An updated history or interim history is obtained, including:
  - Significant illnesses, surgeries or hospitalizations and medical care incurred since most recent visit at which a medical history was obtained or updated.
  - Update RLP as appropriate
  - Immunization history
  - · Review of method use, problems, barriers, satisfaction with method
  - Updated sexual assessment and social histories
  - Review of systems as indicated
  - Physical exam as indicated
  - Plan for continued use and follow up
  - If client requests an alternative method, follow initiation guidelines

#### Education should include: this list in not all-inclusive

- Information about all methods of contraception using a client centered approach.
   Basic reproductive anatomy and physiology if needed.
- Reproductive Life Planning at each visit
- Importance of FP to client's health
- Emergency contraception
- Clinic procedures
- Referrals as medically necessary or requested by client
- For adolescents: clients must receive counseling on parental involvement (or involvement of trusted adult if parental involvement is not an option), confidentiality, resisting attempts of sexual coercion, STI and HIV risk reduction. Adolescent counseling will include information that normalizes abstinence for adolescents and not sexual activity, and clearly communicates the benefits of

- delaying sex or returning to a sexually risk-free status and support strong resistance skills as a way to opt out of unwanted sexual activity."
- All counseling and education must be documented in the client record
- Contraceptive counseling is neutral, factual, and nondirective on each option. Counseling is non-coercive and informative, while prioritizing the holistic health needs and optimal wellbeing of the client, regardless of parenting intent, including participation of trusted adult.
- Client centered counseling is provided that is culturally sensitive, includes client priorities about pregnancy prevention, acceptability of methods, considers the relationship with partner(s)
- Universal education about relationship safety
- Abstinence and natural family planning for methods, include mechanism of action, effectiveness and failure rates, advantages, disadvantages, noncontraceptive benefits, STD protection, including HIV, side effect and potential complications, managing side effects, correct method use and discontinuation, resumption of menses when method discontinued for any method(s) interest is express.
- Discuss potential barriers to correct and consistent use with client.
- Male clients should also be provided information about female methods as well as emergency contraception when interest is expressed.
- Emergency procedures and contacts
- Reduction of risk of STI and HIV

#### Referral and Follow

Agency must have a planned mechanism for client follow-up;

- Referral for services beyond the scope of the agency is expected. Each Subrecipient is expected to have, by prior arrangement, providers, or agencies to which the client may be referred. These include Title X public health clinics and other Title X agencies, hospitals, voluntary organizations, and health service providers provided by other federal programs.
- If a Sub-recipient does not offer comprehensive primary health services onsite, the Sub-recipient must have a robust referral linkage with primary health providers.
- Provision of medications and/or supplies as needed. If a Sub-recipient Agency does not provide a contraceptive method on site that Sub-recipient will have a written policy for referring clients for that method.

Provided on the next 2 pages is a checklist of Family Planning and related preventive health services. Hard copies are provided when new agencies are onboarded and during the tri-annual site visit.

# Checklist

# Family planning and related preventive health services



| for wo                | omen                      | Family planning services  (provide services in accordance with the appropriate clinical recommendation) |  |                            |                                     |                              |                                    |
|-----------------------|---------------------------|---|--|----------------------------|-------------------------------------|------------------------------|------------------------------------|
|                       | Screening components      | Contraceptive services <sup>1</sup>   | Pregnancy<br>testing and<br>counseling | Basic infertility services | Preconception<br>health<br>services | STD<br>services <sup>2</sup> | Related preventive health services |
| History               | Reproductive life plan    | <b>✓</b>  | <b>✓</b>                               | ~                          | ~                                   | ~                            |                                    |
|                       | Medical history           | <b>✓</b>  | <b>~</b>                               | ~                          | <b>~</b>                            | <b>~</b>                     | <b>~</b>                           |
|                       | Current pregnancy status  | <b>✓</b>  |  |                            |                                     |                              |                                    |
|                       | Sexual health assessment  | <b>~</b>  |  | <b>~</b>                   | <b>~</b>                            | <b>~</b>                     |                                    |
|                       | Intimate partner violence |   |  |                            | <b>~</b>                            |                              |                                    |
|                       | Alcohol & other drug use  |   |  |                            | <b>✓</b>                            |                              |                                    |
|                       | Tobacco use               | ✓ (combined hormonal methods for clients >35 years)   |  |                            | <b>~</b>                            |                              |                                    |
|                       | Immunizations             |   |  |                            | ~                                   | <b>y</b> ⁴<br>(HPV & HBV)    |                                    |
|                       | Depression                |   |  |                            | ~                                   |                              |                                    |
|                       | Folic acid                |   |  |                            | <b>✓</b>                            |                              |                                    |
| Physical examination  | Height, weight & BMI      | ✓ (hormonal methods)³   |  | •                          | ~                                   |                              |                                    |
|                       | Blood pressure            | ✓ (combined hormonal methods)   |  |                            | <b>✓</b> 4                          |                              |                                    |
|                       | Clinical breast exam      |   |  | ~                          |                                     |                              | <b>✓</b> 4                         |
|                       | Pelvic exam               | ✓ (initiating diaphraam or IUD)   | ✓ (if clinically indicated)            | •                          |                                     |                              |                                    |
|                       | Signs of androgen excess  |   |  | ~                          |                                     |                              |                                    |
|                       | Thyroid exam              |   |  | <b>✓</b>                   |                                     |                              |                                    |
| Laboratory<br>testing | Pregnancy test            | ✓ (if clinically indicated)   | <b>~</b>                               |                            |                                     |                              |                                    |
|                       | Chlamydia                 | <b>→</b> 5  |  |                            |                                     | <b>✓</b> 4                   |                                    |
|                       | Gonorrhea                 | <b>→</b> 5  |  |                            |                                     | <b>✓</b> 4                   |                                    |
|                       | Syphilis                  |   |  |                            |                                     | <b>✓</b> 4                   |                                    |
|                       | HIV/AIDS                  |   |  |                            |                                     | <b>✓</b> 4                   |                                    |
|                       | Hepatitis C               |   |  |                            |                                     | <b>✓</b> 4                   |                                    |
|                       | Diabetes                  |   |  |                            | <b>y</b> 4                          |                              |                                    |
|                       | Cervical cytology         |   |  |                            |                                     |                              | <b>✓</b> 4                         |
|                       | Mammography               |   |  |                            |                                     |                              | <b>✓</b> 4                         |

**Source:** Centersfor Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from <a href="http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf">http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf</a>

**Abbreviations:** BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; IUD = intrauterine device; STD = sexually transmitted disease.

- 1 This table presents highlights from CDC's recommendations on contraceptive use. However, providers should consult appropriate guidelines when treating individual patients to obtain more detailed information about specific medical conditions and characteristics (Source: CDC, U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]).
- 2 STD services also promote preconception health but are listed separately here to highlight their importance in the context of all types of family planning visits. The services listed in this column are for women without symptoms suggestive of an STD.
- 3 Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (US Medical Eligibility Criteria 1) or generally can be used (US Medical Eligibility Criteria 2) among obese women. (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might beconcerned about weight change perceived to be associated with their contraceptive method.
- 4 Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of an infection or condition.
- 5 Mostwomendonotrequire additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at <a href="http://www.cdc.gov/std/treatment">http://www.cdc.gov/std/treatment</a>. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59[No. RR-12]). If awoman has not been screened according to guidelines, screening can be performed at the time of IUD insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. US medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

# **Checklist**

# Family planning and related preventive health services



# for men

|             |                          | Family planning services (provide services in accordance with the appropriate clinical recommendation) |                             |   |                             |                                       |
|-------------|--------------------------|--|-----------------------------|---|-----------------------------|---------------------------------------|
|             | Screening components     | Contraceptive services <sup>1</sup>  | Basic infertility services  | Preconception<br>health services <sup>2</sup> | STD services <sup>3</sup>   | Related preventive<br>health services |
| History     | Reproductive life plan   | <b>✓</b>   | <b>~</b>                    | <b>→</b>                                      | ~                           |                                       |
|             | Medical history          | <b>✓</b>   | <b>~</b>                    | <b>✓</b>                                      | <b>~</b>                    |                                       |
|             | Sexual health assessment | ~  | <b>~</b>                    | <b>✓</b>                                      | ~                           |                                       |
|             | Alcohol & other drug use |  |                             | <b>✓</b>                                      |                             |                                       |
|             | Tobacco use              |  |                             | <b>✓</b>                                      |                             |                                       |
|             | Immunizations            |  |                             | <b>✓</b>                                      | ✓ (HPV & HBV)⁴              |                                       |
|             | Depression               |  |                             | <b>✓</b>                                      |                             |                                       |
| Physical    | Height, weight & BMI     |  |                             | ~   |                             |                                       |
| examination | Blood pressure           |  |                             | <b>y</b> 4                                    |                             |                                       |
|             | Genital exam             |  | ✓ (if clinically indicated) |   | ✓ (if clinically indicated) | <b>y</b> 4                            |
| Laboratory  | Chlamydia                |  |                             |   | <b>y</b> 4                  |                                       |
| testing     | Gonorrhea                |  |                             |   | <b>✓</b> 4                  |                                       |
|             | Syphilis                 |  |                             |   | <b>y</b> 4                  |                                       |
|             | HIV/AIDS                 |  |                             |   | <b>~</b> 4                  |                                       |
|             | Hepatitis C              |  |                             |   | <b>✓</b> 4                  |                                       |
|             | Diabetes                 |  |                             | <b>↓</b> 4                                    |                             |                                       |

**Source:** Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from <a href="http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf">http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf</a>

**Abbreviations:** BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; STD = sexually transmitted disease.

This job aid was supported by the Office of Population Affairs (Grants FPTPA006030 & FPTPA006028-04-00). The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government

<sup>&</sup>lt;sup>1</sup> No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

<sup>&</sup>lt;sup>2</sup> The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199 [6 Suppl 2]:S389-95).

<sup>&</sup>lt;sup>3</sup> STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

<sup>&</sup>lt;sup>4</sup> Indicates that screening is suggested only for individuals at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

# MEDICAL RECORDS

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

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

#### CONTENT OF THE CLIENT RECORD

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

- Personal data:
- Confidentially assurance statement HIPAA Statement
- Medical history, physical exam, laboratory test orders, results, and follow-up;
- Treatment and special instructions:
- Scheduled revisits:
- Informed consents initial and annual updates;
- Refusal of services; and
- Allergies and untoward reactions to drug(s) recorded in a prominent and specific location.

The record must also contain reports of clinical findings, diagnostic and therapeutic orders, diagnoses and documentation of continuing care, referral, and follow-up. The record must include entries by counseling and social service staff where appropriate. Client financial information should be kept separated from the client clinical notes and client financial information should not be a barrier to client services.

# **CONFIDENTIALITY and RELEASE of RECORDS**

A confidentiality assurance statement must appear in the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality. HIV information should be handled according to law. When information is requested, agencies should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form, which does not identify particular individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care. Sub-recipients shall comply with Delaware Code Title 16 Health and Safety Regulatory Provisions concerning Public Health Chapter 12. Informed Consent and Confidentiality Sub chapter II. Confidential of Personal Health Information.

https://delcode.delaware.gov/title16/c012/sc02/index.shtml

## **EMERGIENCIES MEDICAL and NON-MEDICAL**

Sub-recipient agencies shall develop emergency guidelines, with input from their medical director, that reflect local resources. All staff must be trained in emergency procedures and must be familiar with the plans. Licensed medical staff providing direct client care must be trained in CPR and hold current certification. There must be a procedure in place for maintenance of emergency resuscitative drugs, supplies, and equipment.

#### **MEDICAL EMERGENCIES**

#### At a minimum, written protocols must address:

- Vaso-vagal reactions
- Anaphylaxis
- Syncope
- Cardiac arrest
- Shock
- Hemorrhage
- Respiratory difficulties

#### Protocols must also be in place for emergencies requiring:

- EMS transport
- After-hours management of contraceptive emergencies
- Clinic emergencies

Medical Emergencies DPH Standing Orders Appendix.... Sub-recipients may use as a reference for their medical emergency policy and protocols.

#### **NON-MEDICAL EMERGENCIES**

#### At a minimum, written protocols must address:

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

Emergency Follow-Up: Clients are to be instructed as to what they may do in case of an emergency outside of regular clinic hours. Clients should be referred to the emergency room of the hospital closest to them. See below list for 24-hour emergency service locations.

# **24 HOUR EMERGENCY SERVICE LOCATIONS:**

| COUNTY:     | FACILITY & ADDRESS  | PHONE NUMBER                     |
|-------------|---|----------------------------------|
| NEW CASTLE: | Christiana Hospital<br>4755 Ogletown/Stanton Road<br>Newark, DE 19711                           | 302-733-1000 Operator            |
|             | Christiana Care Middletown Emergency Department 621 Middletown Odessa Rd. Middletown, DE 19709  | 302-203-1300                     |
|             | St. Francis Hospital 7th & Clayton Streets Wilmington, DE 19805                                 | 302-421-4100 operator/4333<br>ER |
|             | Wilmington Hospital<br>501 West 14th Street<br>Wilmington, DE 19801                             | 302-428-4182 ER                  |
| KENT:       | Bay Health Medical<br>Center<br>Kent General Hospital<br>640 S. State Street<br>Dover, DE 19901 | 302-744-7121 ER                  |
|             | Bay Health Smyrna Emergency Center 401 N. Carter Road Smyrna, DE 19977                          | 302-659-2190 Operator            |
| SUSSEX:     | Beebe Hospital<br>424 Savannah Road<br>Lewes, DE 19958  | 302-645-3300 Operator/3289       |
|             | Milford<br>Hospital/Bayhealth<br>100 Wellness Way<br>Milford, DE 19963                          | 302-422-3311                     |
|             | TidalHealth<br>801 Middleford Road<br>Seaford, DE 199   | 302-629-6611 Operator/2555       |

# **REFERRALS and FOLLOW-UP**

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

Sub-recipients should complete a needs assessment annually and other activities. The needs assessment and other activities are to be documented, regarding social services and medical needs of the community to be served.

- Sub-recipients need to develop and implement plans to address the related social service and medical needs of clients as well as ancillary services needed to facilitate clinic attendance. Sub-recipients should have written collaborative agreements if needed for "external" agencies for clients for other social needs such as transportation, child care agencies, WIC etc.
- Sub-recipients will be monitored to ensure compliance with this requirement.
- Sub-recipients have policy and/or plan to address the related social service and medical needs of clients as well as ancillary services needed to facilitate clinic attendance

### 340B PROGRAM and PHARMACY GUIDELINES and LABELING

The purpose of the 340B program is to allow safety-net providers to stretch scarce federal resources as far as possible to reach more eligible patients and provide more comprehensive services. The 340B program is administered by the Office of Pharmacy Affairs at the federal Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services. Federal law mandates that drug manufacturers provide discounts on their drugs to certain health centers, known as covered entities, which primarily serve low income or medically underserved individuals. Covered entities are eligible for these discounts if they receive any one of a specified group of federal funding streams. Title X-funded health centers are among the covered entities that can receive these discounts. Other covered entities include federally qualified health centers (FQHCs) and FQHC look-alikes, Ryan White HIV/ AIDS program grantees, children's hospitals, disproportionate share hospitals, and Section 318-funded sexually transmitted disease (STD) clinics.

Each 340B eligible agency must have a 340B policy in place and will be review at agencies site visits. The following link gives a sample of a policy and procedure manual. <a href="https://rhntc.org/resources/demystifying-340b-frequently-asked-questions-webinar">https://rhntc.org/resources/demystifying-340b-frequently-asked-questions-webinar</a>

All entities covered by the 340B Drug Pricing Program are subject to audit by manufacturers or the federal government. It is important that your entity is compliant with the 340B requirements, as failing to do so can make your entity liable to manufacturers for refunds obtained through the program or removed from the 340B Program altogether.

https://rhntc.org/sites/default/files/resources/340b compliance tips 2017-12-08.pdf

A Title X Sub-recipient must have a signed contract with the Division of Public Health to be eligible to apply for 340B funding and have approval to apply from the Title X Director. Sub-recipient agencies must operate in accordance with Federal and Delaware laws relating to security and record keeping for drugs and devices. Delaware Title X Sub- recipients must have a policy to identify the person/persons responsible for pharmaceutical services, formulary procurement, storage, monitoring, and drug and device recalls management. The inventory, supply, logs and packaging and distribution of pharmaceuticals (including mailing) must be conducted in accordance with Delaware pharmacy laws and professional practice regulations.

Each facility shall maintain an adequate supply and variety of drugs and devices based upon each Sub-recipient's contract/agreement to effectively manage the contraceptive goals of their clients. Sub-recipients should also ensure access to other drugs or devices that are necessarily for the provision of other medical services within the scope of Title X.

Sub-recipients qualify as 340B users and must recertify annual with the Office of Pharmacy Affairs (HRSA) to continue to have access to 340 B drug purchases.

Delaware Title X Sub-recipient agencies must assure compliance with the provision of Section 340B of the PHS ACT that prohibit Drug Diversion and Double Discount/rebates.

See link below regarding registration

https://340bregistration.hrsa.gov/login

\*\*The Title X Family Planning Director can provide further guidance and assist regarding registration.

#### PHARMACY LABELING OF MEDICATIONS/SUPPLIES

Sub-recipients must comply with the Delaware Board of Pharmacy rules and regulations for clinics Title 24 Regulated Professions and Occupations Delaware Administrative Code Department of State Division of Professional Regulation 2500 Board of Pharmacy under section 12.1

As Sub-recipients must develop their pharmacy guidelines. Sub-recipients may utilize the Community and School Based Health Center Pharmacy Policies and Procedures Manual.

# **CHILD ABUSE REPORTING**

**Requirement to Report:** All clinic staff are expected to identify, document, and take steps to report known, or suspected, cases of child abuse, child neglect, human trafficking, and domestic/partner violence. Below are reporting and referral numbers:

Child Abuse Reporting Mandated (1-800-292-9582)
Human Trafficking Inquiries and Reporting (1-888-373-7888)
Domestic/Partner/Dating Violence Supports and Referral
Delaware Coalition Against Domestic Violence
New Castle County: 302-658-2958
Kent & Sussex Counties: 1-800-701-0456

Where clients, or staff, may need additional resource or referral information, the following central numbers are available:

Health & Human Service Information and Referrals in Delaware: 2-1-1Delaware Help Line: 1-800-560-3372 or text 302 231-1464

**Safeguards:** All reports must be made in accordance with State and Federal policies. Reports must be performed in a manner to assure the client's rights and safety are safeguarded, including:

- Privacy and Confidentiality,
- · Voluntary nature of services, and
- Physical protections (including separation from threatening entities and enlisting services of police and other authorities).

**Documentation:** Client records must include documentation of the time and date of each report, the entity to which the report was made, and information regarding completed forms and follow-up regarding the report. An example of Delaware's "Child Abuse/Neglect Mandatory Reporting Form" is copied at the end of this section.

#### Identification

Child Abuse (Physical): Indicators of physical abuse include:

- Human bite marks
- Bald spots
- Unexplained burns
- Rope burns on arms, legs, neck, or torso
- Unexplained fractures
- Unexplained lacerations, abrasions, or bruises

#### Behavioral indicators of physical abuse include:

- Wary of adult contact
- Apprehensive when other children cry
- Behavioral extremes: aggressiveness or withdrawal
- Overly compliant
- Afraid to go home
- Reports injury by parent
- Exhibits anxiety about normal behavior (i.e., napping)
- Complaints of soreness and moves awkwardly
- Destructive to self and others
- Early to school or stays late as if afraid to go home
- Accident prone
- Wears clothing that covers body when not appropriate
- Chronic runaway
- Cannot tolerate physical contact or touch

### Parental/Caretaker Indicators of Physical Abuse:

- Offers conflicting, unconvincing, or no explanation for the child's injury
- Describes the child as "evil" or in some other very negative way
- Uses harsh physical discipline with the child
- · Has history of abuse as a child

#### Child Abuse (Sexual), Child Indicators:

- Difficulty in walking or sitting
- Torn, stained or bloody clothing
- Pain or itching in the genital area
- Bruises or bleeding in the external genitals, vaginal or anal areas
- Frequent urinary or yeast infections
- Frequent unexplained sore throat

#### **Behavioral Indicators:**

- Unwilling to participate in certain physical activities
- Sudden drop in school performance
- Crying with no provocation
- Bizarre, sophisticated, or unusual sexual behavior or knowledge
- Anorexia
- Sexually provocative
- Poor peer relations
- Reports sexual abuse by caretaker

- Fear of or seductiveness towards males
- Suicide attempts
- Chronic runaways
- Early pregnancies

#### Parent/Caretaker Indicators of Sexual Abuse:

- Is unduly protective of the child or severely limits the child's contact with other children, especially of the opposite sex
- Is secretive and isolated
- Is jealous or controlling with family members
- There is evidence of a relationship between domestic violence batterers and sexual abusers

#### Child Abuse (Emotional): Child Indicators of Emotional Maltreatment

# **Physical Indicators:**

- Speech disorders
- Lags in physical development
- Failure to thrive
- · Asthma, severe allergies, or ulcers
- Substance abuse

#### **Behavioral Indicators:**

- Habit disorders (sucking, biting, rocking, etc.)
- Conduct disorders
- Neurotic traits
- Behavior extremes
- Complaint, passive
- Aggressive, demanding
- Overly adaptive behavior
- Inappropriately adult
- Inappropriately infantile
- Delinquent behaviors

#### Parent/Caretaker Indicators of Emotional Maltreatment

- Constantly blames, belittles, or berates the child
- Is unconcerned about the child and refuses to consider offers of help for the child's problems
- Overtly rejects the child

#### Other Considerations for Emotional Maltreatment

- Domestic violence includes, but is not limited to, physical or sexual abuse or threats of physical or sexual abuse and any other offense against the person committed by one parent against the other parent, against any child living in either parent's home or against any other adult living in the child's home.
- Children can witness domestic violence by sight or sound.
- Research suggests that in an estimated 30 to 60 percent of the families where domestic violence or child maltreatment is identified it is likely that both forms of abuse exist.

### **Child Neglect: Child Indicators of Neglect**

- Consistent hunger, poor hygiene, inappropriate dress
- Consistent lack of supervision, especially in dangerous activities or long periods
- Unattended physical problems or medical needs
- Abandonment
- Chronic lice
- Distended stomach, emaciated

#### **Behavioral Indicators**

- · Begging or stealing food
- Consistent fatigue, listlessness or falling asleep
- States there is no caretaker at home
- Frequent school absences or tardiness
- Destructive
- School dropout
- Early emancipation from family

#### **Parent Caretaker Indicators of Neglect**

- Appears to be indifferent to the child
- Seems apathetic or depressed
- Behaves irrationally or in a bizarre manner
- Is abusing alcohol or other drugs

#### **Domestic/Partner/Dating Abuse and Violence Indicators**

- Coercion or threats
- Intimidation
- Emotional abuse
- Isolation
- Minimizing, denying and blaming

- Questionable physical signs (including bruises, cuts, painful movements, broken or fractured bones)
- Using children
- Male privilege
- Economic abuse

# Delaware Division of Family Services Reporter Portal

The Delaware Division of Family Services Online Reporter Portal is designed to provide our Reporters the ability to report non-emergent information related to alleged child abuse and/or neglect.

Failure to provide complete information related to the situation and circumstance your reporting may delay a response in assessing the safety and well-being of the child/children and may also result in the report being screened out. If you should have concerns about electronic reporting please call the hotline at 1-800-292-9582 to make an oral report. Intake workers are available to assist you 24 hours a day / 365 days a year.

Open the hyperlink below to file a report.

Reporter Portal (force.com)

### **IMMUNIZATIONS**

Sub-recipient agencies should provide immunization for family planning clients when required per CDC Immunization Guidelines and within the terms of their Title X current contract/agreement. If Sub-recipients have limited vaccines due to the terms of their contract/agreement the clients are to be referred to appropriate providers.

Sub-recipient agencies should use patient assistance programs to assist with vaccines when they are available from the manufacturer.

Sub-recipients should consider being providers in Delaware's Department of Public Health Vaccine for Children Program (VFC) and comply with all VFC rules and requirements.

As VFC providers they shall enroll and participate in Delaware's Immunization Program Reporting Record System and comply with all rules and requirements.

For additional information refer to:

#### **Delaware's Immunization program website:**

https://dhss.delaware.gov/dhss//dph/dpc/immunize.html\_

https://www.cdc.gov/vaccines/schedules/index.html

https://delvax.dhss.delaware.gov/delvax/Login.aspx

# LIMITED ENGLISH PROFICIENCY/USE of INTERPRETERS

To ensure meaningful access, Sub-recipient agencies should provide language assistance resulting in accurate and effective communication for LEP clients at no cost to the client. Sub-recipient agencies shall implement strategies to provide services to those with LEP. Recipients of U.S. Department of Human Services funds, including Title X funds, must have policies in place for providing effective services to those with LEP in accordance with Title III at 28 C.F.R. Part 36 and Title IV of the Civil Rights Act of 1964 and 65 Federal Regulation 52761. Sub-recipients are required to have a written protocol outlining their agency's procedures and will be asked for a copy during the once every 3-year audit.

A client with limited English proficiency (LEP) cannot speak, read, write, or understand the English language at a level that permits him/her to interact effectively with health care and social service providers.

#### ASSESSING LANGUAGE ASSISTANCE NEEDS

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

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

Interpretation services include sign language or oral interpretive services and telephonic oral interpretive services. The sub-recipient agency is responsible for deterring the interrupters competency.

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

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

Sub-recipients should respect an LEP person's desire to use an interpreter of his or her own choosing (whether a professional interpreter, family member, or friend) in place of the free language services offered. Sub-recipients should consider issues of competence, appropriateness, conflicts of interest, and confidentiality in determining

| whether to respect the desire of the LEP person to use an interpreter of his or her own choosing. |
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# **EXCLUDED PROVIDERS**

The Delaware Title X Family Planning Program supports the Federal health care system to prevent Medicaid/Medicare fraud. As a Delaware Title X Family Planning Subrecipient your agency is required to assure all new employees are not listed as excluded providers under Medicaid/Medicare. This information must be documented in the staff's hiring human resources information during the Title X tri-annual site visits. <a href="https://oig.hhs.gov/exclusions/index.asp">https://oig.hhs.gov/exclusions/index.asp</a>

# **HUMAN TRAFFICKING**

# Standard Operating Procedure to Identify and Report Victims of Human Trafficking

#### **Definitions:**

- The Trafficking Victims Protections Act of 2000 is the first comprehensive federal law to address trafficking in persons.
  - Sex trafficking is the recruitment, harboring, transportation, provision, obtaining, patronizing or soliciting of a person for the purposes of a commercial sex act, in which the commercial sex act is induced by force, fraud, or coercion, or in which the person induced to perform such an act is 17 or younger.
  - Labor trafficking involves the recruitment, harboring, transportation, provision, or obtainment of a person through the use of force, fraud, or coercion for the purpose of involuntary servitude, peonage, debt bondage, or slavery.
  - https://humantraffickinghotline.org/what-human-trafficking/federal-law
- There are several pieces of Delaware legislation that also address human trafficking. See: <a href="https://legis.delaware.gov/BillDetail?LegislationId=22583">https://legis.delaware.gov/BillDetail?LegislationId=22583</a>,

MEANS PURPOSE ACTION Recruiting For the purposes of OR by **Involuntary Servitude** Harboring OR Force OR **Debt Bondage** OR Moving OR Fraud OR Slavery OR OR Obtaining Coercion Sexual Exploitation a person,

## **Trafficking Victims May:**

- Show signs of Traumatic Bonding
- Be in a state of crisis
- Display lack of emotion
- Downplay risks of existing health problems
- Refuse services
- Uncooperative or irritable
- Be distrusting of providers or law enforcement
- Not self-identify as victim

## Some Example Areas of Human Trafficking

Sex Trafficking

## **Hostess**" Bar/Club Operations

- Eastern European/Russian stripping or exotic dancing "Go-Go Clubs"
- Latino cantina bars
- Asian massage parlors/spas
- Strip Clubs

## Residential/Underground Brothel Settings

 Based in homes, apartments, hotel/motel rooms, trailer parks, mobile trailers, and other outdoor locations.

#### **Escort Services**

- Bar/Hotel-based
- Internet-based
- Private parties
- Boat cruises
- Phone chat lines

#### **Pimp-Controlled Prostitution**

- Hotel-based
- Internet-based
- Private parties
- Street-based
- Truck stops
- Other miscellaneous locations

Labor Trafficking

#### **Domestic Service Cases**

- Nannies
- Maids/Housekeepers

## **Small "Mom and Pop" Business Operations**

- Landscaping
- Nail salons
- Restaurants
- Industrial cleaning
- Construction
- Hospitality

## Peddling Rings / Sales Crews

- Magazine sales crews
- Flowers / Candy sales crews

#### **Large-Scale Labor Cases**

- Agricultural
- Factory settings (i.e., garments, food processing)
- Other large factory work environments (i.e., industrial welding



#### Sources:

Polaris Project for a World Without Slavery: https://polarisproject.org Human Trafficking hot line 1-888-373-7888

Delaware Child Abuse Recognition & Reporting Summit, February 1, 2011

Delaware Code, Title 19, Chapter 5, Sections 504, 506 and 507 (Specific to Child Labor Laws).

Delaware Code, Title 13, Chapter 7, Section 710, "Minors' consent to diagnostic and lawful therapeutic procedures relating to care and treatment for pregnancy or contagious diseases".

Delaware HB 116 (§787) (2007), "AN ACT RELATING TO CRIMINAL CONSEQUENCES OF CONDUCT THAT INVOLVES CERTAIN TRAFFICKING OF PERSONS AND INVOLUNTARY SERVITUDE".

<u>Human Trafficking: A Family Planning Perspective</u>, The Polaris Project, January 21, 2009 and September 22, 2011.

<u>2010 – 2011 Guide to Services for Older Delawarean's and Persons with Disabilities</u>, A Publication of Delaware's Aging and Disabilities Resource Center,

# CONTRACEPTIVE ACCESS in DIASTERS/PANDEMICS EMERGENCY REPLACEMENT OF CONTRACEPTION

All Sub-recipients will develop an emergency plan to assure the availability of prescriptions and nonprescription contraceptive methods for their clients during an emergency such as natural disasters, fires, flooding, tornados, hurricanes, earthquakes, ice storms and pandemics, manmade disasters hazardous issues and acts of terrorism.

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

Sub-recipients should replace per the client's last refill history and the agency should provide supplies equivalent to the number needed until the client can return to the Sub-recipient or another agency.

Updated 3/23/2020

#### Pandemic/Covid 19

## Frequently Asked Questions from Title X Family Planning Grantees about COVID19 Implications

#### **General Questions**

1. What is the best source for up-to-date information about COVID-19?

The best source for up-to-date information about COVID-19 is <a href="https://www.cdc.gov/coronavirus/2019-nCoV/index.html">https://www.cdc.gov/coronavirus/2019-nCoV/index.html</a>. This website is updated regularly and includes:

- General information
- Resources for the community
- Updates on COVID-19 cases across the U.S.
- Resources for healthcare professionals

We encourage all to sign up for email alerts on this website, so you can be sure to stay updated on new developments. Title X Family Planning services to our clients during this pandemic.

- Telehealth following Medicaid and State guidelines. (Billable to Title X)
- Mailing prescriptions and medications (BC) with a future scheduled appointment. (3-month scrip)
- Drive through services for medications (BC) with a future scheduled appointment. (3-month supply)
- Clients self-reporting blood pressures for extension scrips (provider discretion) documented.
- 30-day temporary non-enforcement of allowing other trained professionals (MA, RN, LPN) to offer options counseling. (To apply for a waiver, for this option your organization would have to contact the Family Planning Director in writing.
- As a sub-recipient a tele health consent form must be created and utilized. Each sub-recipient consent for treatment, must be part of the client record and signed. Suggested language for the consent; all family planning services are provided solely on a voluntary basis. Individuals are not subjected to coercion or discrimination in the delivery of services, or coherence to use any particular method of family planning. Acceptance of family planning services is not a prerequisite to eligibility of any other services, assistance, or participation in any other program. Clients are encouraged to ask questions and may refuse a service or stop services at any time.

## PROBHIBITION of ABORTION

Title X sub-recipients must be in full compliance with Section 1008 of the Title X statute, which prohibits abortion as a method of family planning, 42 CFR 59.5(a)(5), which prohibits projects from providing, promoting, referring for, or supporting abortion as a method of family planning, and 42 CFR 59.14(a)

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

All Sub-recipient contracts/agreements contain language stating that not Title X funds will be used in the provision of abortions or abortion related services.

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

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

Abortion Prohibition 1008 – The Prohibition of Abortion: None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

**Title X Guidelines:** Providers may offer pregnant women the opportunity to be provided nondirective pregnancy counseling information regarding each of the following options below; If requested; such information and counseling provided should be neutral, factual information on each of the following options except, with respect to any option(s) about which the pregnant woman indicate she does not wish to receive such information and counseling. (42CFR59.13(b)(1)(i).

- Prenatal care and delivery;
- Infant care, foster care, or adoption and
- Pregnancy termination

## **OPENING, MOVING or CLOSING CLINIC LOCATIONS**

The Office of Population Affairs (OPA) processes require approval and notification of changes in the scope of the Delaware Title X Family Planning Program. The change in scope should be approved by OPA prior to implementation, this include adding new Sub-recipients as a Title X provider. This policy addresses the procedure for requesting clinic closure, moves or additions of staff and engaging in any research projects.

If a Sub-recipient agency is considering closing a clinic site, moving a site, adding staff or engaging in any research projects the agency must notify the Title X Family Planning Program Director. The agency must also provide the following information and plan at least **60 days prior to the projected closure date**.

- Notify Title X Family Planning Program Director
- Provide a summary explanation as to why the site is being closed and what arrangements are being made to ensure the clients can continue with care
- Provide a list of other family planning service providers and clinic resources for clients. The list must include phone number(s) to call for an appointment.
- Contact other family planning providers in the service area as a courtesy to determine their capacity for additional clients.
- Inform clients regarding the closure. The client should sign a consent for release of their records. Consider poster closure information on social media sites.
- If referral agreement is developed between provides, include this information when notifying clients.
- Post sign in the clinic of the agency's plans regarding closure at least 30 days in advance.
- Accommodate clients for visits for contraceptive supplies needed to ensure sufficient coverage for their transition to another service provider.
- Ensure a mechanism is in place for follow-up with clients with abnormal lab results.
- Ensure all data from the clinic to be closed will be submitted for the FPAR
- Ensure any financial reports are available for review
- Notify the Title X Family Planning Director regarding the plan for the disposition of 340B medications and supplies.

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

- Location of existing clinic site and proposed new location
- Reason for changing the location

If the location must be moved due to an emergency the agency will notify the Family Planning Direct as soon as possible.

## **DATA USE and SHARING**

Sub-recipients must be in compliance with release and sharing of Title X data. The purpose is to assure that client personal identifiable informant remains strictly confidential. Sub-recipients shall not store or transfer non-public Stat of DE data outside of the U.S.

Sub-recipients shall use Title X data only for the purposes outlined within the contract and shall ensure that the minimum number of individuals have access to the information as necessary to complete program work.

Title X requirements state "All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals."

Therefore, Sub-recipients may only release their own agency family planning data in aggregate reports. No identifiable data may be released at any time. Identifiable data includes information that can directly or indirectly be used to establish the identity of a person, such as a name, address, or other information that can be linked to external information that allows for identification of the person.

Any sub-recipient hosting or maintaining clinical records or identifiable data and all IT staff with access to confidential or protected information must attest to the requirement of these safeguards in contract, Business Associate agreement or an attestation document in sub-recipient's current contract.

## **QUALITY ASSURANCE**

All Sub-recipients must develop a quality improvement (QI) plan. Quality Improvement (QI) is the use of a deliberate and continuous effort to achieve measurable improvements in the identified indicators of quality of care, which improves the health of the community. By improving the quality of care, family planning outcomes, such as reduced rates of unintended pregnancy, improved patient experiences, and reduced costs, are more likely to be achieved. The QI program is critical not only to the quality of care provided, but to standards and criteria, budget allocations, staffing patterns, clinic flow, and program planning. A quality improvement plan provides for ongoing evaluation of project personnel and services. The system should include:

- A set of administrative, fiscal, and clinical program standards
- A tracking system to identify clients for follow-up and/or continuing care including cervical cytology screening test results and necessary follow-up, mammography results and necessary follow up, laboratory tests and radiologic studies, pathology reports and any afterhours emergencies;
- Ongoing medical audits to determine compliance with agency protocols;
- Procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;
- Annual review of medical protocols to insure maintenance of current standards of care;
- A process to capture customer feedback to improve family planning care;
- Validating Family Planning Annual Data for the Family Planning Annual Report
- Annual quality improvement projects as deemed necessary.

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## **CLINICAL SERVICES INTRO**

Delaware's Title X Family Planning Clinical Standards and Guidelines were adapted from the following evidenced based practice guidelines. Providing Quality Family Planning Services (QFP), 2014 which provides recommendations developed collaboratively by the CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The QFP document describes how to provide quality family planning services to men and women. Quality health care is safe, effective, client-centered, timely, efficient, and equitable. The goal of family planning services is to assist individuals to achieve the desired number and spacing of children and to increase the changes children will be born healthy. Quality Title X family planning includes these attributes: confidentiality, safety, effectiveness, client-centered approach, timelessness, efficiency, accessibility, and equality and cost effectiveness. Quality family planning services include the following clinical elements:

- Contraceptive services
- Pregnancy testing education and counseling if desired by the client
- Achieving desired pregnancy (fertility awareness)
- Basic infertility services
- Preconception health services

Sub-recipients should be committed to offer all core family planning services (listed above), related preventive health services and referral for specialist care, as needed. Clients who are uninsured, underinsured or request confidential testing services are eligible for Title X services. Other preventive health services that are beyond the scope of Title X may be offered either on-site or by referral.

Sub-recipient agencies must implement policies that reflect current national standards of care for family planning clients. The national standards may include American Congress of Obstetricians and Gynecologists (ACOG) or American Society for Colposcopy and Cervical Pathology (ASCCP) and the US Preventive Services Task Force (USPSTF).

The Delaware Title X Guidelines are suggested standards/recommendations for Subrecipients who deliver family planning program services in Delaware. Sub recipients who are reimbursed by the Title X Delaware Family Planning Program, must follow policies and procedures as established by the Delaware Title X Family Planning Program.

The following section will contain clinic visit information for required documentation in the client record based upon the Delaware Division of Public Health criteria and the Centers for Disease Control and Prevention (CDC). (2014, April 25. Providing Quality

family planning services; Recommendations CDC and the U.S. Office Population Affairs. MMWR Morbidity and Mortality Weekly Reports.

**Source:** Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

This link includes the most recent updates

https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf\_Sub-Recipient agencies

must have treatment protocols regarding clinical services.

## **CLINIC VISIT: FEMALE, INCLUDING ADOLESCENTS**

**Reason for Visit**: Obtain and record the purpose of the visit for selecting a contraceptive method, and/or additional health concerns prompting the desire for health care if there is time allotted.

**Medical History** must be taken prior to prescribing contraception to ensure methods of contraception are safe for the client.

Medical history **must** include:

- Reproductive life plan
- Menstrual history
- Gynecologic history
- Obstetrical history
- Contraceptive use
- Allergies-medications/other
- Medications: current medications prescription OTC herbs supplements
- Immunizations: Date of last TDap, MMR or Rubella titer, Hepatitis B series, influence vaccine, varicella, pneumococcal, meningococcal, and other recommended vaccines such as HPV and use of Delaware Immunization Registry
- Recent intercourse
- Reproductive history
- Infectious or chronic health condition
- Zika risk assessment if indicated
- MPox risk assessment if indicated
- Other characteristics and exposures (e.g., age, postpartum, breastfeeding) that might affect the client's medical eligibility criteria (MEC) for contraceptive methods.
- Social history/risk behaviors substance use, tobacco, alcohol, injectable drugs, prescription drugs, illegal substances, how much/day, for how long
- Sexual history and risk assessment, partner(s) history. If client is a minor and there suspected abuse the age of the partner may need to be disclosed when making the mandatory report.
- Mental health, depression, family dynamics trauma
- Intimate partner violence

NOTE: Taking of a medical history **must** not be a barrier to making condoms available in the clinical setting (i.e., a preconception or any previous visit **must** not be a prerequisite for a client to obtain condoms).

## Physical and Laboratory Assessment

- For a female client, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP <120/80---screen each visit
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.
  - Height, weight, and BMI although not necessary before initiation contraceptive methods. As a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight, and BMI each visit.
  - Current pregnancy status: A provider may be reasonably certain that a woman is not pregnant is she has no S/S of pregnancy (either intrauterine or ectopic) and meets at least one of the following criteria:
    - <7 days since star of a normal menses;</li>
    - No sexual intercourse since the beginning of the last normal menses;
    - Has been using a reliable method of contraception correctly and consistently;
    - <7days since spontaneous or induced abortion;</li>
    - <4 weeks port partum; or</p>
    - <6 months postpartum, amenorrhoeic since delivery, and or exclusively or almost exclusively breast feeding (at least 85% of infant feedings are breast feedings).
  - Bimanual exam and cervical inspection (prior to IUD insertion, fitting diaphragm or cervical cap)
  - Pap screening and clinical breast exam (based on current recommendations for timing and testing components within in year of client being seen).
  - Chlamydia testing must be offered annually for all females < 25 years, sexually active women >25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year)
  - CT and GC testing must be available for clients requesting IUD insertion, if indicated.
  - Zika screening if indicated.

## CLIENT-CENTERED EDUCATION and COUNSELING

Contraceptive counseling is to help a client choose a method of contraception and understand how to use it correctly and consistently. Clients (adults and minors) who are undecided on a contraceptive method **must** be informed about all methods that can be used safely based on the 2016 CDC Medical Eligibility Criteria. When educating clients about the broad range of contraceptive methods, information **must** be medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a manner that is readily understood and retained. Documentation of education/counseling **must** be in the client's medical record.

Educating clients about contraceptive methods they can use safely includes the following:

- Method effectiveness
- Correct and consistent use of the method
- Benefits and Risks
- Potential Side effects
- Protection from STDs, including HIV
- Starting the method
- Danger signs
- Availability of emergency contraception (provide on-site or by prescription)
- Follow-up visit (as needed to obtain or maintain the selected method)

Quality client-centered contraceptive counseling includes the following:

- Establish and maintain rapport
- Assess the client's need and personalize the discussion
- Work with the client to establish a plan
- Provide information in a manner that can be understood by the client
- Confirm the client's understanding a. The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about effectiveness, risks, benefits, method use, protection from STDs and follow-up (QFP pages 45-46).

Contraceptive counseling must be documented in the client record (i.e., checkbox or written statement).

- Encourage partner communication about contraception, including understanding partner barriers (e.g., misperceptions) and general support for using a chosen method.
- A procedure consent form must be signed by the client prior to inserting an IUD or implant.
- Clinical evaluation of a client electing permanent sterilization should be guided by

the provider who performs the procedure.

• Provide Zika education and prevention strategies.

## **CONTRACEPTIVE COUNSELING for MINOR 12-17 YO**

Comprehensive information **must** be provided to minor clients about how to prevent pregnancy.

- It should not be assumed that minor clients seeking family planning services are sexually active. Avoiding sex (abstinence) is an effective way to prevent pregnancy and STDs and can be chosen as a method at any time in life.
- If the minor indicates that she or he will be sexually active, provide information about contraception and help her or him choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs/HIV. Long-acting reversible contraception (LARCs) are a safe and effective option for many minors, including those who have not been pregnant or given birth.
- Sub-recipients must offer confidential services to minors and must observe state
  mandatory reporting laws related to child abuse, neglect, and human trafficking.
  Minors must be informed that services are confidential, except that in special
  cases (e.g., child abuse) reporting is required.
- Sub-recipients must encourage communication between the minor and his or her parents, guardians, or trusted adult about sexual and reproductive health and his or her decision to seek services.
- Sub-recipients must provide counseling to minors on how to resist attempts to coerce them into engaging in sexual activities.

## **CLINIC VISIT: MALE, INCLUDING ADOLESCENTS**

**Reason for Visit:** Obtain and record the purpose of the visit for selecting a contraceptive method, and/or additional health concerns prompting the desire for health care if there is time allotted. The client may always return for an additional visit if required.

**Medical History:** must be taken prior to prescribing contraception to ensure methods of contraception are safe for the client.

#### **Medical history must include:**

- Reproductive life plan
- Use of condoms
- Allergies medications/other
- Medications
- Immunizations (Date of last TDap, MMR or Rubella titer, Hep b series, influence vaccine, varicella, pneumococcal, meningococcal and other recommended vaccines such as HPV and use of the Delaware Immunization Registry)
- · Recent intercourse
- Partner history (use of contraception, pregnant, has children, hada miscarriage or termination)
- Infectious or chronic health condition
- Zika risk assessment if indicated
- · Mpox risk assessment if indicated
- Contraceptive experiences and preferences
- Previous STD results if positive
- Sexual history and risk assessment partner(s) history and age

NOTE: Taking of a medical history **must** not be a barrier to making condoms available in the clinical setting (i.e., a formal visit **must** not be a prerequisite for a client to obtain condoms).

#### **Physical and Laboratory Assessment:**

- For male clients, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP<120/80---screen each visit</p>
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP>140/90 recheck at next visit or in 1 week and refer if sustained BP>140/90.
  - Height, weight and BMI although not necessary before initiation contraceptive methods. As a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight and BMI each visit.
  - For a male client, laboratory tests are not required unless indicated by history.
  - o Zika screening if indicated.
  - MPox screening if indicated

## **CLIENT CENTERED EDUCTION and COUNSELING**

Quality client-centered contraceptive counseling includes the following:

- Establish and maintain rapport
- Assess the client's need and personalize the discussion
- Work with the client to establish a plan
- Provide information in a manner that can be understood by the client
- Confirm the client's understanding. The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about effectiveness, risks, benefits, method use, protection from STDs and follow-up (QFP pages 45-46).

Contraceptive counseling must be documented in the client record (i.e., checkbox or written statement).

 When counseling male clients, discussion should include information about female-controlled methods where appropriate (including emergency contraception), encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STDs, including HIV.

## **Contraceptive Counseling for Minor 12-17 YO Clients**

Comprehensive information **must** be provided to minor clients about how to prevent pregnancy.

- It should not be assumed that minor clients seeking family planning services are sexually active. Avoiding sex (abstinence) is an effective way to prevent pregnancy and STDs and can be chosen as a method at any time in life.
- If the minor indicates that he will be sexually active, provide information about contraception and help him choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs/HIV. Long-acting reversible contraception (LARCs) are a safe and effective option for many minors, including those who have not been pregnant or given birth.
- Sub-recipients must offer confidential services to minors and must observe state
  mandatory reporting laws related to child abuse, neglect, and human trafficking.
  Minors must be informed that services are confidential, except that in special
  cases (e.g., child abuse) reporting is required.
- Sub-recipients **must** encourage communication between the minor and his or her parents, guardians, or trusted adult about sexual and reproductive health and his or her decision to seek services.
- Sub-recipients **must** provide counseling to minors on how to resist attempts to coerce them into engaging in sexual activities.

# CLINIC VISIT: CLIENTS RETURNING FOR METHOD CONTRACEPTIVE COUNSELING FOR MINOR 12-17YO

**Reason for Visit:** Obtain and record the purpose of visit returning for a contraceptive method, and/or additional health concerns prompting the desire for health care if there is time allotted. The client may always return for an additional visit if required. **Medical History: must** be updated prior to prescribing contraception to ensure current method of choice is safe for the client.

When providing contraceptives for returning clients, an assessment should include the following:

- Method concerns
- Method use (consistent, correct)
- Any changes in client's history (i.e., risk factors, medications)
- If appropriate, provide additional contraceptives and discuss a follow-upplan.
- Height, weight and BMI although not necessary for a return visit for a
  contraceptive method per the QFP. However, as a Sub-recipient for the
  Delaware Division of Public Health a client must receive height, weight and BMI
  each visit.
- For a female and male client, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP <120/80---screen each visit
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.

## **Contraceptive Counseling for Minor 12-17 YO Clients**

Comprehensive information **must** be provided to minor clients about how to prevent pregnancy.

- It should not be assumed that minor clients seeking family planning services are sexually active. Avoiding sex (abstinence) is an effective way to prevent pregnancy and STDs and can be chosen as a method at any time in life.
- If the minor indicates that he will be sexually active, provide information about contraception and help him choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs/HIV. Long-acting reversible contraception (LARCs) are a safe and effective option for many minors, including those who have not been pregnant or given birth.
- Sub-recipients **must** offer confidential services to minors and must observe state mandatory reporting laws related to child abuse, neglect and human trafficking. Minors **must** be informed that services are confidential, except that in special cases (e.g. child abuse) reporting is required.

- Sub-recipients **must** encourage communication between the minor and his or her parents, guardians or trusted adult about sexual and reproductive health and his or her decision to seek services.
- Sub-recipients and
  - □ DPHR&SH **must** provide counseling to minors on how to resist attempts to coerce them into engaging in sexual activities.

## STERILIZATION POLICY and COUNSELING GUIDELINES

Per Title X Guidelines, personnel working within the family planning project must be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2)

- 1. The decision for sterilization must be voluntary on the part of the individual wishing to be sterilized; that is the decision must be made without any coercion. The patient is to be given the necessary information to enable them to arrive at an informed decision. Counseling must include, but is not limited to, the information contained in this section.
- 2. An individual who counsels a patient for a sterilization procedure must offer to answer questions the individual to be sterilized may have concerning the procedures, and provide the patient with the following information:
  - Advise that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization.
  - A description of available alternative methods of family planning and birth control.
  - Advise that the sterilization should be considered permanent.
  - An explanation of the sterilization procedure.
  - A description of the discomforts and risks that may accompany and follow the performing of the procedure.
  - A description of the benefits or advantages that may be expected as a result of sterilization.
- 3. The following questions may help patients to come to a fully informed decision about sterilization.
  - Why do you want to be sterilized?
  - People who answer that they do not want more children and have thought this
    through carefully with regard to their lifestyle, etc. are usually good candidates for
    sterilization. Those who answer with reasons of concern for their spouse's
    health, emotional state, contraceptive problems, etc., may need more in-depth
    counseling.
  - What would you do if you lost your spouse (through death or divorce) or lost your children?
  - Do you have any other questions about sterilization?

4. Staff are encouraged to use the most current Contraceptive technology as a resource for information about sterilization procedures.

## **CLINIC VISIT: EMERGENCY CONTRACEPTION**

**Reason for Visit:** Obtain and record the purpose of visit for emergency contraception.

**Medical History:** should be obtained and EC prescribed for the following situations: no contraception used during intercourse, male condom slipped, broke or leaked, female condom diaphragm or cervical cap inserted incorrectly, missed contraceptive pills, more than 12 days late for Depo Provera injection, more than 2 days late starting vaginal ring or patch, error in coitus interruptus, error in period abstinence, IUD partially or totally expelled, exposure to a teratogen when not protected by effective contraception. **If indicated by the client's history, a negative pregnancy test to exclude a pre-existing pregnancy.** 

Emergency contraception has been found by the FDA to be safe and effective for use when initiated after unprotected intercourse.

- Birth control counseling should accompany or follow any method used for emergency contraception purpose in order to discourage women from using emergency contraception as a routine method of contraception.
- Methods can be
  - o Paragard IUD
  - o ella
  - o Plan B
- Chlamydia testing **should** be offered to females <25 years of age and to females > 25 years with risk factors.
- Height, weight, and BMI although not necessary for EC per the QFP.
   However, as a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight, and BMI each visit.
- For all female clients, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP <120/80---screen each visit
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.
- Chlamydia testing must be offered annually for all females < 25 years, sexually active women >25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year

## **CLINIC VISIT: PRECONCEPTION HEALTH MALE and FEMALE**

**Reason for Visit:** Obtain and record the purpose of visit for preconception health services. This visit can also be considered an initial visit.

#### **Medical History:** for **females**, **must** include:

- Reproductive life plan
- Sexual risk assessment
- Reproductive history
- History of prior pregnancy outcomes
- Environmental exposures
- Medications
- Genetic conditions
- Family history
- Intimate partner violence
- Social history/risk behaviors
- Immunization status
- Zika risk assessment
- MPox risk assessment

#### **Medical history** for **males must** include:

- Reproductive life plan
- Sexual health assessment
- Past medical and surgical history that impairs reproductive health
- Genetic conditions
- History of reproductive failures, or conditions that can reduce sperm quality (obesity, diabetes, varicocele
- Social history/risk behaviors
- Environmental exposures
- Immunization status
- Depression
- Zika risk assessment
- MPox risk assessment

#### **Physical Examination for all clients:**

- Height, weight, and BMI although not necessary for preconception services for males and females per the QFP. However, as a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight, and BMI each visit.
- For each client, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
  - If BP<120/80---screen each visit

■ If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP>140/90 recheck at next visit or in 1 week and refer if sustained BP>140/90.

## Laboratory testing must be recommended based on risk assessment:

- Diabetes screening (for type 2 diabetes in asymptomatic male and female adults)
- Zika screening if indicated.
- Mpox screening if indicated

#### Client Plan/Education:

- Some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).
- Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
- Avoid smoking, alcohol, and other drugs
- Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
- Offer/Refer for any needed STD screening (including HIV)
- Refer for age-appropriate vaccinations, if indicated
- Provide Zika education and prevention strategies
- Provide MPox education and prevention strategies

#### Referral:

- If client desires, refer for further diagnosis and treatment;
  - Refer male and female clients for additional services if screening results indicate presence of health condition or as indicated (i.e., tobacco cessation, obesity, diabetes, depression, immunizations).

## **CLINIC VISIT: ACHIEVING PREGNANCY**

Reason for Visit: Obtain and record the purpose of visit for achieving a pregnancy.

Medical History: Clients who have been trying to achieve pregnancy for 12 months or longer with regular unprotected intercourse should be offered basic infertility services. Services will be offered to clients who respond to the reproductive life plan questions stating they desire to become pregnant. Achieving pregnancy services include Identifying and assessing clients who desire pregnancy; providing counseling and education (including key messages on achieving pregnancy) and addressing misperceptions that many women, men, and minors have about fertility and infertility. Assessing and updating the client's physical, sexual, and medical history may reveal additional issues in the person's health history that need to be addressed. The results can also help determine the need for additional informant like fertility awareness or other health service such as: STD screening, preconception care, infertility series, possible need for Zika screening, and other preventative health services.

#### Client assessment includes:

- Reproductive life plan
- Sexual risk assessment
- Reproductive history
- History of prior pregnancy outcomes
- Environmental exposures
- Medications
- Genetic conditions
- Family history
- Intimate partner violence
- Social history/risk behaviors
- Immunizations
- Zika risk assessment

#### Medical history includes:

- Immunizations
- Medications
- Present infectious or chronic health conditions
- Genetic conditions
- Environmental exposures
- Social history/risk behaviors
- Sexual health and risk assessment
- Mental health
- Medical history for females must Include:
- Reproductive history
- Obstetrical/Gynecology history
- Family history

#### • Intimate partner violence

Medical history for **males must** include:

- Past medical or surgical history that might impair reproductive health
- Medical conditions associated with reproductive failure that could reduce sperm quality

#### Physical Examination for all clients:

- Height, weight, and BMI although not achieving pregnancy males and females per the QFP. However, as a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight, and BMI each visit.
- For each client, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP<120/80---screen each visit
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP>140/90 recheck at next visit or in 1 week and refer if sustained BP>140/90.

### Client education and counseling includes:

- Importance of regular preventive health and chronic disease management
- Some medications might be contraindicated in pregnancy and current medications will need to be reviewed by the prenatal care provider (obstetrician, physician, or midwife)
- Encourage daily supplement containing (400-800 mcg) of folic acid or a prenatal vitamin
- Avoid smoking, alcohol, and other drugs.
- Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
- Offer/refer for any needed STD screening, including HIV
- Offer/refer for age-appropriate vaccinations, as indicated
- Nutritional counseling and recommended weight loss if client is overweight
- If indicated provide Zika education and prevention strategies
- Counseling provided must be documented in the record

#### Education on maximizing fertility awareness and success includes:

 Fertility awareness/ Techniques to predict ovulation a. Education about peak days and signs of fertility (including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation)  Education on methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed.

### Lifestyle influences:

- Advise that vaginal intercourse every 1-2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant (women with regular menstrual cycles)
- Information that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five cups a day)
- Discourage smoking, alcohol, recreational drugs, and use of commercially available vaginal lubricants that may reduce fertility
- Education on Zika risks and the importance of Zika prevention for couples seeking pregnancy
- Encourage a daily supplement containing folic acid or prenatal vitamin
- Encourage males to avoid hot tubs

#### Referral:

 If desired, clients should be provided a current referral listing for further diagnosis and treatment.

## **CLINIC VISIT: PREGNANCY TESTING, DIAGNOSIS, and COUNSELING**

**Reason for Visit:** At the client's request or if the practitioner deems necessary.

Pregnancy testing is one of the most common reasons for a first visit to a family planning agency. It is important to use this occasion as an entry point for providing education and counseling about family planning services. Sub-recipient's written protocol and procedure **must** be current, available, and consistent with national standards of care.

#### Pregnancy diagnosis services include:

- General Consent for Services
- Reproductive Life Plan Discussion
- Medical history (including chronic medical illnesses, physical disability, psychiatric illness)
- Zika risk assessment
- Pregnancy testing (qualitative urine with high sensitivity)
- Pregnancy test results **must** be given to the client in person
- Counseling and referral resource list as appropriate
- Chlamydia testing must be offered to females annually<25 years of age and to females>25 years with risk factors.
- Height, weight, and BMI although not required for pregnancy testing per the QFP. However, as a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight and BMI each visit.
- For client, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP<120/80---screen each visit
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP>140/90 recheck at next visit or in 1 week and refer if sustained BP>140/90.

#### If the **pregnancy test is positive**, the clinical visit should include:

- An estimation of gestational age.
  - If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination may be needed to help assess gestational age.
- Information on the normal signs and symptoms of early pregnancy
- Instructions on when to report any concerns to a provider for further evaluation
- Clients with a positive pregnancy test **should** be referred to a health care provider for medically necessary prenatal health care.
- If ectopic pregnancy or other pregnancy abnormalities or emergency situations are suspected, the client must be referred for immediate diagnosis and management.
- Sub-recipients may not perform, promote, refer for, or support abortion as a

- method of family planning. However, except for medical emergencies or in the case of rape or incest.
- If there will be delays in obtaining prenatal care of more than 2 months, pregnant women with risk factors should be offered STD testing (including HIV).
- Sub-recipients should assess the client's social support and provide appropriate counseling or social service resources.

For clients with a **positive pregnancy test**, a **licensed nurse** should confirm the pregnancy test result and provide basic factual information regarding the client's pregnancy management options including:

- If the client is using hormone contraceptive to discontinue immediately
- Provide information regarding early and continuous prenatal care and pregnancy problem symptoms, including when to seek medical attention.
- Clients should be provided initial prenatal education about medication use in pregnancy, prenatal vitamins folic acid, lifestyle, diet and nutrition, all education is documented in the clients' record.
- Information on adoption, including local or statewide resources
- Acknowledge that termination is an option, provide basic information on the procedures (medical and surgical)

Information on maintaining a healthy pregnancy should include:

- Advise that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy should be reviewed by a prenatal care provider.
- Encourage a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
- Encourage avoiding smoking, alcohol, and other drugs.
- Encourage avoiding eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish).
- Recommend age-appropriate vaccinations if indicated.
- Recommend Zika screening if indicated.

Clients with a **negative pregnancy diagnosis** and do not want to become pregnant should be offered information about family planning services as indicated, such as:

- The value of making a reproductive life plan.
- Contraceptive services (or scheduled for an appointment).
- Counseling to explore why the client thought she was pregnant and sought pregnancy testing services.
- Assessed for difficulties using her current method of contraception, if indicated.

Women who are not pregnant and who are trying to become pregnant **must** be offered information about family planning, as indicated, such as:

• Services to help achieve pregnancy or basic infertility services

- Preconception health education
- STD services
- Reproductive life plan
- Zika education and prevention strategies

# CLINIC VIST: BASIC INFERTILITY SERVICES > 35YO FEMALE and MALE

**Reason for Visit:** At the client's request, basic infertility care is part of the core family planning services. Infertility is defined as the failure of a couple to achieve pregnancy after 12 months or longer of unprotected intercourse.

Sub-recipients should have a current written protocol and procedure, available and consistent with national standards of care.

Infertility visit to a family planning clinic focuses on determining potential causes of the inability to achieve pregnancy and making any needed referrals for specialist care. Evaluation of both partners should begin at the same time. Earlier evaluation (6 months of regular unprotected intercourse) is justified for:

- Women aged >35 years
- Those with a history of oligo-amenorrhea (infrequent menstruation)
- Those with known or suspected uterine or tubal disease or endometriosis
- Those with a partner known to be sub-fertile (the condition of being less than normally fertile though still capable of effecting fertilization).

Understanding the client's reproductive life plan and difficulty in achieving pregnancy. Medical history **must** include:

- Past surgeries
- Previous hospitalizations
- Serious illnesses or injuries
- Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders)
- Childhood disorders
- Cervical cancer screening results and any follow-uptreatment
- Medication
- Allergies
- Social history/risk behaviors
- Family history of reproductive failures
- Reproductive history (i.e., time trying to achieve pregnancy; coital frequency and timing)
- Level of fertility awareness
- Previous evaluation and treatment results; gravidity, parity, pregnancy

- outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea
- Sexual history (pelvic inflammatory disease, history of/exposure to STDs)
- Review of systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)
- Zika risk assessment
- Mpox risk assessment

#### Physical Examination for all clients:

- Height, weight, and BMI not indicated for males and females for basic infertility services per the QFP. However, as a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight, and BMI each visit.
- For each client, the following **must** be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP<120/80---screen each visit
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP>140/90 recheck at next visit or in 1 week and refer if sustained BP>140/90.

## if clinically indicated:

- Thyroid examination (i.e., enlargement, nodule, or tenderness)
- Clinical breast examination (CBE)
- Signs of androgen excess
- A pelvic examination (i.e., pelvic, or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity).

Basic Infertility Care for Men. Infertility services provided to the male partner of an infertile couple should include

- Client's reproductive life plan
- Medical history must include:
- Reproductive history (methods of contraception, coital frequency and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).
- Medical illnesses (e.g., diabetes mellitus)
- Prior surgeries
- Past infections
- Medications (prescription and nonprescription)
- Allergies
- Lifestyle exposures
- Sexual health assessment
- Female partners' history (pelvic inflammatory disease, STDs, and

## problems with sexual dysfunction)

- · Zika risk assessment
- Mpox risk assessment

## A physical examination **must be offered if clinically indicated**:

- Examination of the penis (including the location of the urethral meatus)
- Palpation of the testes and measurement of their size
- Presence and consistency of both the vas deferens and epididymis
- Presence of a varicocele
- Secondary sex characteristics

Male clients concerned about their fertility should be offered a semen analysis via laboratory requisition at the client's expense. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, postejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.

#### Infertility Counseling

Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam. Provide Zika education and prevention strategies.

#### Referral:

 Clients (female and male) must be referred for further diagnosis and treatment if indicated or requested.

## **CLINIC VISIT: SEXUALLY TRANSMITTED INFECTION SERVICES**

**Reason for Visit:** Obtain and record the purpose of visit for sexually transmitted infections (STD's) services. Clients should be made aware that whenever they have unprotected sexual contact (no barrier method is used), they are exposed to the possibility of an STD.

Screening and treatment must follow current Center for Disease Control and Prevention STD Treatment and HIV testing guidelines. This may include clients who are uninsured, underinsured or request confidential testing services. Guidelines ensure all clients are treated in a timely manner and appropriate follow-up measures are provided.

- Assess client's Reproductive Life Plan
- Medical history
  - Allergies
  - Medications
  - Medical conditions
  - Sexual health assessment, based on gender identify, current anatomy and sexual behavior (partners, practices, protection, past history of STDs, pregnancy prevention)
  - Intimate Partner Violence
  - Assess possibility of Human Trafficking
  - o Immunizations (Hep.B, HPV)
  - Zika risk assessment
  - MPox assessment
- Physical Exam as indicated (based on history or S/S)
- Height, weight and BMI is not indicated for males and females for STD services per the QFP. However, as a Sub-recipient for the Delaware Division of Public Health a client must receive height, weight and BMI each visit.
- For each client, the following must be provided:
  - o BP Screen each visit per Delaware Division of Public Health
    - If BP<120/80---screen each visit
    - If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit if average BP>140/90 recheck at next visit or in 1 week and refer if sustained BP>140/90.
- Laboratory testing: (specimens must be sent to the State of Delaware's Public Health lab.)
  - Chlamydia and Gonorrhea (CT & GC); All client's potential sites of exposure should be tested per history.
  - Testing must be offered annually for all females< 25 years.</li>
  - Sexually active women > 25 years with risk factors (infected partner, partner with other concurrent partner, symptoms history of STD or multiple partners in the last year, inconsistent condom use, sex work, drug use, those

- who reside in high prevalence areas, should be offered testing.
- Clients who test positive for CT/GC should be re-tested 3 months following treatment for early detection of reinfection. Clients who do not present at 3 months for re-test should be re-tested the next time they present for services in the 12 months following treatment of the initial infection.
- All males with S/S suggestive of CT/GC or partner with CT/GC.
- All males who have sex with males (MSM) should be tested.
- CT/GC screening for males can be considered at sites with high prevalence (adolescent clinics, correctional facilities, STD clinics) or males who have sex with males (MSM).
- Syphilis
  - Testing should be offered for male and female clients at high risk:
- MSM.
- Commercial sex workers,
- Person who exchange sex for drugs,
  - Those in adult correctional facilities,
  - Living in high prevalence
  - o HIV/AIDS
    - Testing is recommended for everyone between the ages of 13 and 64 get tested for HIV at least once.
    - Annual testing of certain risk factors: Use the link below
    - Getting Tested | Testing | HIV Basics | HIV/AIDS | CDC
  - Herpes Simplex Virus (HSV) Screening
    - Routine screening of asymptomatic clients for genital herpes simplex virus (HSV) infection is not recommended in the general population
    - Testing, counseling and treatment of symptomatic clients (i.e., presence of genital lesions), should follow current CDC guidelines.

#### Hepatitis C

- Testing should be recommended once for female and male clients without risks (if born during 1945-1965). If testing is positive, refer for additional care and management of HCV infection and related conditions. Assess for alcohol use and refer for intervention if indicated.
- Clients with high-risk behaviors /conditions (e.g., past or current injection of illegal drugs, HIV infected) should be

recommended to have annual testing.

#### Hepatitis B

- Screening is not recommended for the general population.
- Testing should be recommended for high-risk populations (persons from high prevalence areas, homeless, HIV positive, IV drug users, MSM, Hep.B household contacts.)

#### Zika Virus

- Risk assessment questions should be asked of all clients. Has the client or partner(s) traveled to a Zika impacted area in the past 8 months?
- Consider referral for testing if sexually active and seeking pregnancy as appropriate.
- All clients should be educated regarding Zika risks and prevention strategies.

#### Mpox

- Risk assessment for client with a rash located or near the genitals, or hands, feet, chest or mouth. S/S fever, chills, swollen lymph nodes, exhaustion, muscle aches, headache, respiratory symptoms.
- Exposure or potential exposure
- You are a man who has sex with other men, or if you are a transgender or nonbinary person and in the past 6 months have had any of the following:
  - A new diagnosis of one or more sexually transmitted diseases including acute HIV, chancroid, chlamydia, gonorrhea, or syphilis.
  - More than one sex partner.
- You are a person who in the past 6 months has had any of the following: Sex at a commercial sex venue, event or in a area where monkeypox transmission is occurring.
- Consider vaccination before exposure, if already exposed ideally within 4 days.

#### Counseling

- Educate on risk reduction and available testing or referral for testing.
- Encourage vaccination for HPV and Hepatitis B if indicated
- Encourage condom use to prevent STD/HIV infection
- Encourage clients with STDs to:
- Notify their sex partners and urge them to seek medical evaluation and treatment
- Refrain from unprotected sexual intercourse during the period of STD treatment
- Return for re-testing in 3 months if indicated

Educate on Zika risks and prevention strategies.

#### Referral

- Clients with Hepatitis C and HIV infection should be linked to medical care and treatments.
- Client should be provided needed immunizations. Sub-recipients should have robust linkages of they do not provide family practice care within their settings.

<sup>\*</sup>Prescribing information is located in the APRN Family Planning Guidelines from the Delaware Division of Public Health.

## **CLINIC VISIT: GYNECOLOGIC SERVICES**

Sub-recipient agencies should provide for the diagnosis and treatment of minor gynecology problems to avoid fragmentation or lack of health care for clients with these conditions. Written protocols and operating procedures **must** be available, current, and consistent with national standards of care.

Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine dip stick testing.

## **CLINIC VISIT: RELATED PREVENTIVE HEALTH SERVICES**

REASON FOR VISIT: Obtain and record the purpose for the visit for clients seeking cervical cytology, clinical breast exam (CBE) or referral for mammography. This should be clients without a primary care provide, the client should be linked to a primary care provider.

MEDICAL HISTORY: USPSTF recommends that women be asked about family history that would be suggestive of an *increased risk for deleterious mutations in BRCA1 or BRCA2 genes* (e.g. receiving a breast cancer diagnosis at an early age, bilateral breast cancer, history of both breast and ovarian cancer, presence of breast cancer in one or more female family members, multiple cases of breast cancer in the family, both breast and ovarian cancer in the family, one or more family members with two primary cases of cancer, and Ashkenazi background). Women with identified risk(s) should be referred for genetic counseling and evaluation for BRCA testing (Grade B). The USPSTF also recommends that women at increased risk for breast cancer *should be counseled about risk-reducing medications* (Grade B).

CERVICAL CYTOLOGY: Clients seeking services at FP clinics may expect/prefer to obtain cervical cancer screening services at that location, providers should provide cervical cancer screening to clients receiving related preventive health services.

Providers should follow USPSTF recommendations to screen women with cervical cytology screening:

Pap testing as indicated:

Age 21-29 every 3 years' cervical cytology alone, regardless of their sexual history or HPV vaccination. Annual pelvic exams may still be indicated.

Age 30-65 every 3 years with cervical cytology alone

Age 30-65 every 5 years with hrHPV alone, or;

Age 30-65 every 5 years with hrHPV testing in combination with cytology co-testing, regardless of their sexually history or HPV vaccination. End screening at age 65 for women with adequate prior screening and are

not otherwise at risk for cervical cancer.

High-risk women (immune-compromised, prior CIN 2 results or higher) should start screening when sexually active or by 21 years if HIV positive. Otherwise, start at age 21. Thereafter, screen annually and extend to every three years if three tests are negative. From age 30 onward, perform cytology every year until three normal tests, then every three years or cytology plus high-risk HPV testing every three years. Continue lifelong screening.

Sub-recipients may choose to follow ACOG standards as well. Cervical cytology no longer is recommended on an annual basis. Further, it is not recommended (Grade D) for women aged <21 years. Women with abnormal test results should be treated in accordance with professional standards of care, which may include colposcopy. The

need for cervical cytology should not delay initiation or hinder continuation of a contraceptive method. Providers should also follow ACOG and AAP recommendations that a genital exam should accompany a cervical cancer screening to inspect for any suspicious lesions or other signs that might indicate an undiagnosed STD.

\*Additional information for Pap testing is located Standing Orders Section from the Delaware Division of Public Health.

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

## CLINICAL BREAST EXAMINATION (CBE)

Despite a lack of definitive data for or against, clinical breast examination has the potential to detect palpable breast cancer and can be recommended. Patients should be informed there is not enough evidence to balance the benefits and risks of screening. If a client requests a clinical breast exam it should be performed.

ACOG recommends:

Age >19 annually

ACS recommends:
20-39 every 3 years
>40 annually

However, the USPSTF recommendation for CBE is an (I) and clients should be informed that there is insufficient evidence to assess the balance of benefits and harms of the service.

\*Additional information for abnormal breast findings/information is located in the Standing Orders Section from the Delaware Division of Public Health.

#### **MAMMOGRAPHY**

Providers should follow USPSTF recommendations to screen women aged 50–74 years on a biennial basis; they should screen women aged <50 years if other conditions support providing the service to an individual patient.

## **CLINIC VISIT: EXPEDITED PARTNER THERAPY EPT**

EPT in Delaware is available to clinicians as an option for partner treatment. EPT represents an additional strategy for partner management that does not replace other strategies. Sub-recipients should provide EPT after obtaining the client's history and when the client requires treatment for chlamydia and gonorrhea.

REASON FOR VISIT: obtain client history when a client requires treatment for chlamydia and gonorrhea. The provider should recommend any sexual partners in the past 60 days be treated. Ideally partner(s) should attend the clinic to be evaluated, examined, and tested, counseled, and treated by a medical provider. However, if the partner is unable or unwilling to seek medical care EPT can be offered.

#### Counseling

Educate on risk reduction and available testing and referral for testing Encourage vaccination for HPV and Hepatitis B if indicated Encourage condom use to prevent STD/HIV infection Return for re-testing in 3 months or at next visit. Educate on Zika risk and prevention strategies.

For additional information please use the link provided. <a href="https://www.dhss.delaware.gov/dhss/dph/dpc/ept.html">https://www.dhss.delaware.gov/dhss/dph/dpc/ept.html</a> STI Screening Recommendations (cdc.gov)

## REPRODUCTIVE LIFE PLAN

A reproductive life plan is a set of goals about having or not having children Since the reproductive capacity of individuals spans almost four decades, optimizing health before and between pregnancies requires the full participation of all segments of health care. Part of the reproductive life plan includes goals to improve personal health. Individuals should be reminded of the fact whenever one is sexually active, the possibility of pregnancy must be considered.

#### THE REPRODUCTIVE LIFE PLAN

A reproductive life plan (RPL) should include a discussion of whether a client is planning to parent, what actions can be taken to prevent that from happening before they are ready, and what steps can be taken to protect their fertility. Clients should be encouraged to consider the following and help them build a plan that is right for them.

- Do you plan to have a child in the next year or two?
- Where do you see yourself in five years?
- Do you want to be a parent one day?
- If no, what will you do to prevent pregnancy?
- If yes, how old do you want to be when you have your first child?
   How many children do you want?
   How far about would you like them to be?
- · Have you discussed this with your partner?
- Have you discussed this with your parents?
- How do you plan ahead financially to be a parent?
   What kinds of things do you need to think about?
- What are you plans after finishing school?
- If you experienced a pregnancy before you are ready, what will you do?

#### RESOURCES:

https://dethrives.com/wp-content/uploads/2014/09/1-DE-MLMPW-Booklet\_8.12.14.pdf/

https://teens.dethrives.com/

## **CONCLUSION**

In conclusion, the Title X Guidelines document is the framework which outlines federal and state policies and procedures for all Title X contracted providers, to ensure high quality, safe, evidenced based family planning services. The Title X Guidelines must be available at all clinical locations for appropriate staff.

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