MARYLAND STATE
FAMILY PLANNING PROGRAM

ADMINISTRATIVE GUIDELINES

2007

CENTER FOR MATERNAL AND CHILD HEALTH
FAMILY HEALTH ADMINISTRATION
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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REVIEW OF

MARYLAND STATE FAMILY PLANNING PROGRAM
ADMINISTRATIVE GUIDELINES
2007

I have reviewed the Maryland State Family Planning Program Administrative Guidelines.

Name	Date

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INTRODUCTION

I. BACKGROUND

> Family planning remains a keystone in attaining a national goal aimed at achieving planned, wanted pregnancies and preventing unintended pregnancies. Family planning services provide opportunities for individuals to receive medical advice and assistance in controlling if and when they get pregnant and for health providers to offer health education and related medical care.@
>
> *Healthy People 2010, Conference Edition*
> U.S. Department of Health and Human Services

Maryland has a long tradition for ensuring the availability and accessibility of family planning services. In 1966, the Maryland State Board of Health and Mental Hygiene issued a policy statement strongly endorsing family planning as an integral part of preventive health care and recommended that the service be offered by all local health departments. As a result, family planning services became available in all 24 Maryland subdivisions.

In 1970, Title X of the Public Health Service Act, Section 1001 (Public Law 91-572), was passed by Congress. The Maryland Department of Health and Mental Hygiene received its first grant from the Title X Federal Family Planning Program that year. The grant enabled the Department to expand family planning services throughout the state. The Department has proudly served as the Title X grantee in Maryland for more than 35 years.

The Maryland State Family Planning Program is directed by the Center for Maternal and Child Health, Family Health Administration, Maryland Department of Health and Mental Hygiene. The Program provides services to Maryland citizens through a family planning health delivery system consisting of local health departments and community-based agencies.

Over this period of time, the Maryland state government has generously supported family planning services with additional State general funds. A number of innovative projects, several of which are nationally recognized, have resulted from this support. The Program oversees efforts with an interdisciplinary team of health care professionals with expertise from a broad range of fields including obstetrics and gynecology, public health, nursing, epidemiology, social work, health education, and fiscal administration. Furthermore, the Program draws on institutional and private sector reproductive health expertise from around the state in order to make the Program as technically strong and as community-oriented as possible.

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II. PHILOSOPHY

1. MISSION

The mission of the Maryland State Family Planning Program is to reduce unintended pregnancies and to improve pregnancy outcomes by assuring that comprehensive, quality family planning services are available and accessible to Maryland citizens in need. This is consistent with the Title X Federal Family Planning Program mission "to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children."

2. MANDATES

The Center for Maternal and Child Health is responsible for carrying out federal and state mandates for improving the health of women, newborns, children, and adolescents. A major goal is to reduce maternal, infant, and child mortality and morbidity, with a focus on low income populations. Integral to this process is the development and implementation of a plan to assure statewide availability and accessibility to high quality comprehensive reproductive health care.

Mandates for accomplishing the mission include:

a. Title X of the Public Health Service Act of 1970 states that its purpose is the provision of contraceptive services and information in order to help lower the incidence of unintended pregnancy, to improve maternal health by doing so, and to prevent recourse to abortion. Title X authorizes project grants to public and private, nonprofit organizations for the provision of family planning services (including natural family planning and infertility services) to all who need them, with priority given to low-income persons.

b. Title V of the Social Security Act has authorized the Maternal and Child Health Services Programs since 1935. Title V was continued with changes by the Omnibus Budget Reconciliation Act (OBRA) of 1989 (PL 101-239). The 1935 Act delineates the basic mission of Title V: "The State Plan will incorporate by reference documents showing with respect to maternal and child health services programs the establishment in the State Agency, under the direction of a program director, of a separate organizational unit charged primarily with responsibilities in the field of maternal and child health and including at least planning, promoting, and coordinating of maternal and child health services and the administration of the unit and its staff as provided under the State Plan." The 1989 amended Act further clarifies the purposes of Title V: (1) to provide and assure mothers and children (especially those with low income or limited availability to services) access to quality maternal and child health services; (2) to reduce infant mortality and to promote the health of mothers and infants by providing prenatal, delivery, and postpartum care for low income, at-risk pregnant

women.

c. Health-General, Article 18, Section 107 of the Annotated Code of Maryland states: "The Secretary (of Health and Mental Hygiene) shall devise and institute means to prevent and control infant mortality; diseases of pregnancy; diseases of childbirth; diseases of infancy; diseases of early childhood; and promote the welfare and hygiene of maternity and infancy."

3. BELIEFS AND PRINCIPLES

The fundamental belief underlying the Maryland State Family Planning Program is that every pregnancy should be a planned and wanted one. The guiding principle of the Program is that all men and women should be able to have the number of children they want, when they want to have them. Consistent with this principle are the following expectations:

a. That no one is denied family planning services because of the inability to pay and that priority is given to persons from low income families
b. That counseling includes all family planning options
c. That services are provided without regard to religion, race, color, national origin, disabling condition, age, sex, number of pregnancies, or marital status
d. That counseling is conducted in a supportive and non-coercive manner that protects the dignity of the individual
e. That counseling includes information on the prevention of HIV/AIDS and other sexually transmitted diseases
f. That counseling of adolescents includes emphasis on abstinence and resisting sexual coercion and encouragement of parental involvement
g. That health care providers, from both the public and private sectors, work in partnership to address the issues
h. That community members are consulted in the design and implementation of the program

4. APPROACH

The Center for Maternal and Child Health approaches the needs of reproductive age women and men, newborns, children, and adolescents from a public health perspective. This perspective focuses on both population-based and personal care services.

a. Population-based functions include:

(1) data collection and analysis
(2) needs assessment
(3) standards setting and quality assurance
(4) health promotion and education
(5) monitoring and evaluation
(6) program and policy development

b. Personal care services include the provision of:

(1) family planning care
(2) preconception health care
(3) prenatal care
(4) primary health care
(5) preventive health care
(6) case management services
(7) risk appropriate referrals

INTRODUCTION

III. PROGRAM GOALS AND FEDERAL PRIORITIES

The goals of the Maryland State Family Planning Program are:

Goal 1: To assure statewide availability of family planning services

Goal 2: To assure access to family planning services for underserved populations in need

Goal 3: To improve the comprehensiveness of family planning services

Goal 4: To improve the quality of family planning services

Goal 5: To improve management of program resources

Goal 6: To promote community awareness of the benefits of family planning

Goal 7: To reduce unintended pregnancies in Maryland

These goals are consistent with the Title X Program Priorities:

1. Assuring ongoing high quality family planning and related preventive health services that will improve the overall health of Individuals.

2. Assuring access to 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 that corresponds with nationally recognized standards of care; STD and HIV prevention education, counseling and testing; extramarital abstinence education and counseling; and other preventive health services. The broad range of services does not include abortion as a method of family planning.

3. Encouraging participation of families, parents, and/or other adults acting in the role of parents in the decision of minors to seek family planning services, including activities that promote positive family relationships.

4. Improving the health of individuals and communities by partnering with community-based organizations (CBOs) and faith-based organizations (FBOs), and other public health providers that work with vulnerable or at-risk populations.

5. Promoting individual and community health by emphasizing family planning and related preventive health services for hard-to-reach populations, such as the uninsured or under-insured individuals, males, persons with limited English proficiency, adolescents, and other vulnerable or at-risk populations.

INTRODUCTION

IV. PURPOSE

This document, the *Maryland State Family Planning Program Administrative Guidelines 2006*, has been developed by the Center for Maternal and Child Health, Family Health Administration, Department of Health and Mental Hygiene. Its purpose is to assist local health departments and contract agencies in implementing programmatic policies and procedures that are in compliance with state requirements and the Title X *Program Guidelines for Project Grants for Family Planning Services* which were issued by the Office of Population Affairs, U.S. Department of Health and Human Services, in January 2001. A copy of the Title X *Program Guidelines* is found in Appendix A.

This document is divided into two parts. The first part includes the Introduction and specific guidelines covering topics pertinent to the administration of family planning and reproductive health programs. The second part consists of Appendices, which, in addition to the *Program Guidelines for Project Grants for Family Planning Services*, include other programmatic and reference materials.

Throughout these *Guidelines*, in accordance with the definitions in the *Program Guidelines for Project Grants for Family Planning Services,* the word "must" indicates *mandatory* program policy. "Should" indicates *recommended* program policy. The words "may" and "can" indicate suggestions for consideration. "Delegate agencies" are local health departments and other organizations that provide services under contractual arrangements with the Center for Maternal and Child Health (CMCH). "Agencies under contract" are private, non-profit agencies that operate either under contract to CMCH or to a local health department.

ADOLESCENT SERVICES

The Title X Program Guidelines Section 8.7 requires that:

- *Adolescent clients require skilled counseling and age-appropriate information. Appointments should be available to them… as soon as possible.*

- *Abstinence as well as contraceptive and safer sex practice options… must be discussed with all adolescents.*

- *Adolescents must be assured that counseling sessions are confidential (with certain exceptions. See the "Consent for Family Planning Services" at* http://fha.state.md.us/mch/html/clinical_guidelines.cfm)

- *Counselors should encourage family involvement in the decision of adolescents to seek family planning services and provide counseling to minors on resisting attempts to coerce minors into engaging in sexual activities.*

- *Title X projects may not require written consent of parents or guardians for the provision of services to minors.*

Providing services to adolescent clients is a priority of the Maryland State Family Planning Program. The following guidelines address Title X requirements and specific features of Maryland's program:

Positive Youth Development Approach

Interactions by family planning staff with adolescents should incorporate positive youth development principles, which have been shown to have a beneficial effect on risk-reduction among teens. The basic tenets of the skills-based, positive youth development approach as formulated by the National Research Council and Institute of Medicine are:

- Ensure that engagement with young people is grounded in knowledge of adolescent growth and development.
- Build strong, healthy adult-youth relationships.
- Have a clear and well-articulated philosophy of youth.
- Recognize the strengths of youth and support educational and other avenues of achievement.
- Recognize and utilize the resources of the community.
- Actively involve youth in the program.
- Help youth to build and practice skills.

Settings that promote positive youth development are:

- Physically and psychologically safe.
- Organizationally appropriate.
- Purveyors of affirmative social norms.
- Providers of opportunities for connection and skill building.
- Supportive of worthwhile goals.
- Dedicated to the integration of community, school and family.

Perhaps the most salient feature of the positive youth development approach is its vision of young people as resources, rather than problems. Family planning staff have a unique opportunity to convey regard and respect for the adolescent as he or she seeks to assume responsibility for an important component of adult healthcare.

Consent and Confidentiality

1. In Maryland, adolescents may consent on their own for family planning services. The Maryland Minors Consent Law can be found in the Appendix. All health care providers should be thoroughly familiar with the law.

2. The section titled **INFORMED CONSENT** in this manual discusses the confidentiality issues within the Consent for Family Planning, DHMH 1216, which may be found in the Appendix and on the CMCH website at http://fha.state.md.us/mch/html/clinical_guidelines.cfm. The Family Planning Individualized Contact Plan, DHMH 1269, or an equivalent form developed locally, should be used with adolescents who do not wish to be contacted at home.

Access and Availability of Services

1. Appointments should be made available to adolescents for counseling and/or medical services as soon as possible. Access can be facilitated by having teen clinic sessions or special hours for adolescents. Leaving slots open on the appointment schedule and having afternoon walk-in hours can also help.

2. Teens may be more likely to access services if they do not have to undergo a pelvic examination at their first visit. The section of these guidelines titled **DEFERRAL OF PHYSICAL EXAMINATION** discusses the deferral of the initial physical examination for adolescents requesting hormonal (or other) contraceptives. In addition, annual examinations for teens (and adults) may also be deferred in certain situations.

Counseling

1. It is the hallmark of publicly funded family planning programs that clients receive counseling and education, along with medical services and supplies.

For adolescents, the need for information and support and the opportunity for influencing health choices over a lifetime are clear.

2. Reproductive health services for youths must include age-appropriate counseling and education in the following areas:

   - Encouraging family participation in sexuality discussions and in the decision of the young person to seek family planning services;
   - Encouraging abstinence and the delay of sexual activities;
   - Promoting the use of family planning and related preventive health services;
   - Supporting the adolescent in resisting attempts to coerce him or her into engaging in sexual activities.

3. Additionally, all family planning clinics are required to offer HIV/AIDS education, counseling and testing either on-site or by referral. When any or all HIV/AIDS prevention services are offered on-site, prevention information should incorporate the "ABC" message for teens, as follows:

   - "A" is for abstinence;
   - "B" is for being faithful;
   - "C" is for condom use, when a youth's behaviors put him or her at risk for HIV/AIDS.

4. When a teen comes to the clinic with or without a parent, friend or other family member, issues of consent, confidentiality and its limits must be discussed at the earliest opportunity. It is important to explain that teens have a right to receive confidential services but that health care providers are mandated to report suspected instances of child abuse and neglect to the proper authorities. Similarly, young clients and family members must be made aware that confidentiality does not extend to information about suicide, homicide and certain life-threatening activities or serious medical conditions.

5. When a teen comes to the clinic alone or with someone other than a parent, he or she should be asked whether a parent is aware of the visit. Unless there is reason to believe that the teen would be in danger from the parent or that the parent would interfere with the teen's access to care, clinic staff should encourage the teen to consider parental involvement. When a teen is unable or unwilling to involve a parent, he or she should be encouraged to involve some other supportive, adult family member. Encouragement of the family involvement should be documented in the youth's record at every visit.

6. Whenever a provider discusses the client's sexual history, it is important to ask whether any sexual activity has been forced or coerced. All teens should be given the message that force and coercion have no place in sexual relationships and may be illegal. Informational materials and referrals

to community resources that deal with domestic and sexual violence, including law enforcement, should be readily available. The Maryland Network Against Domestic Violence (MNADV) and the Maryland Coalition Against Sexual Assault (MCASA) can provide statewide information on laws as well as national and local resources. To contact MNADV, go to www.MNADV.org or call 1-800-MDHELPS. To contact MCASA, go to www.mcasa.org or call 1-800-983 RAPE.

7. It is essential to support and reinforce positive choices for teens. Obtaining educational and medical services from a family planning clinic is a positive choice for sexually active teens and/or those who wish to be better prepared to make sexual choices. Other positive choices a teen may make involve delaying sexual activities and observing the ABC message in terms of preventing HIV/AIDS and other sexually transmitted diseases.

8. When a teen has disclosed child abuse or neglect, including child sexual abuse, the provider must make a report to the appropriate authorities according to legal requirements. (Please see the section of these guidelines titled **MANDATED REPORTING OF CHILD ABUSE AND NEGLECT**).

9. A minor may disclose violent or sexually exploitive behavior that does not meet the definition for child abuse such as dating violence, sexual assault or sexual activity with a partner who is significantly older and is neither a family or household member nor an individual with temporary or permanent, past or present responsibility for the care, custody or supervision of the minor. When this occurs, the client should be advised that clinic staff are there to help any teen who requests assistance. The adolescent may need support in seeking the involvement of a parent or family member and/or in accessing community resources, including law enforcement or emergency medical facilities and shelters. Each clinic must maintain a list of resources and, when available, brochures and flyers issued by national and local programs. At a teen's request, a staff member may assist in making connections. Please see the section of these guidelines titled **FAMILY AND INTIMATE PARTNER VIOLENCE (FIPV).**

10. Document all counseling, reports, referrals and referral information in the adolescent's chart.

11. It is impossible to know what information from a family planning session may be retained by a client or when any individual may be ready to act on information provided. Document all counseling, reports, referrals and referral information in the adolescent's chart. Thus, it may be advisable to provide age-appropriate counseling repeatedly when visits occur more frequently than annually.

Primary References

Family Law Article, §5-704, and Criminal Law Article, §3-304, 3-305, 3-306, 3-307 and 3-308, Annotated Code of Maryland

APPOINTMENT SYSTEM

1. A well-maintained and monitored appointment system is one of the most important characteristics of a smoothly operating clinic for the following reasons:

    a. Client waiting time is minimized and staff contact time with clients is maximized.

    b. Back-ups in the clinic flow are reduced or eliminated.

    c. Clients with special needs may be matched with the most appropriate staff resources.

2. Key factors for an effective appointment system are:

    a. Management/staff control

    b. Management/staff support

    c. Good clerical procedures

    d. Clinician punctuality

    e. Client punctuality

3. Appointment systems must be well-structured and all staff should comply with policies and procedures with few exceptions.

4. The structure, policies and procedures of the system should be in written form and available to staff and clients. When making changes to the appointment system, it is wise to post this information and inform all callers at least a month ahead of the scheduled change.

6. Clients should be encouraged to take responsibility for making their own appointments and for notifying the clinic when they need to cancel their appointments.

7. To minimize no-shows, appointments should optimally be scheduled no more than four weeks in advance.

8. If appointments must be made more than four weeks in advance, when confidentiality concerns do not preclude them, reminder postcards or telephone calls one to two days before the appointment should be considered.

9. Clients should be served as closely as possible to their appointment time.

10. At all stations, clients should be served in order. If more than one client has the same appointment time, the client with the earliest arrival time should be seen first.

11. The appointment system should accommodate a limited number of walk-in clients.

12. If a client walks in for service without an appointment, he/she should be given an appointment for the earliest possible time. If no appointment is available for the current day, the charge nurse should see the client for triage and possible referral.

13. Clients requesting emergency contraception must be seen as soon as possible on a same-day, walk-in basis. Limiting the time interval between the episode of unprotected sexual intercourse and the first dose of emergency contraception is critical for the success of this treatment.

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

The Title X Program guidelines Section 10.1 requires that:

Projects are expected to follow applicable Federal and state guidelines regarding infection control.

The following guidelines address this requirement:

1. An Exposure Control Plan must be developed by each local health department and contract agency in accordance with the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, the Maryland Occupational Safety and Health Act, Title 09, Subtitle 12, 09.12.31, and DHMH Policy 03.02.01, The HIV Policy for DHMH Facilities, version effective April 15, 2002. Guidance for developing such a plan is available from the Maryland Institute for Emergency Medical Services Systems (MIEMSS) at 1-800-762-7157 or on-line at www.miemss.org/InfectDisease.htm.

2. All staff included in the Exposure Control Plan are considered to be affected staff. Affected staff should be aware of the location of the written Exposure Control Plan at each clinic site. They are required to follow Plan requirements, use personal protective equipment as directed by their employer and attend an annual Exposure Control Plan training update. Documentation of staff attendance at the annual update must be kept on file.

3. The Maryland Department of Health and Mental Hygiene requires the use of Universal Precautions for infection control in all state facilities and contract agencies. Standard Precautions contain a synthesis of the major features of Universal Precautions for blood and body fluids and Body Substance Isolation. Under these requirements, gloves must always be worn when handling body fluids of all types.

4. All affected staff must be offered and receive Hepatitis B immunization, except those that have been previously immunized or decline in writing.

5. All staff must report any exposure incidents immediately to their supervisor or designee for appropriate management.

6. Copies of DHMH Policy 03.02.01 on HIV, available on-line at www.dhmh.state.md.us/pdf/030201e-sof.pdf, should be available at each local health department and contract agency. Providers should also have copies of the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard 29 CFR 1910.1030, available on-line from MIEMSS at http://miemss.umaryland.edu/InfectDisease.htm. Finally, each provider should have copies of MMWR Vol. 54 (RR-09): 1-17, dated September 30, 2005, the Updated U.S. Public Health Service Guidelines for the

Management of Occupational Exposures to HIV and Recommendations for Post-Exposure Prophylaxis. The latter may be accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm.

CHAPERONES

The Maryland Board of Physicians suggests that some clients, particularly female ones, may wish to have a chaperone present in the examination room with the clinician during "more intimate examinations."[1] The Maryland State Family Planning Program supports the use of chaperones during examinations for the following reasons:

- A chaperone provides comfort and support to the client.
- A chaperone provides protection for the clinician in situations where words and/or actions might be misconstrued or used as a basis for litigation.
- A chaperone provides protection for the client in the event of unprofessional behavior by a clinician.

Ideally, an aide or assistant to the clinician serves as chaperone. The Center for Maternal and Child Health advocates aide/assistant support for all nurse clinicians and physician clinicians for clinic efficiency. The use of a trained assistant allows clinicians to utilize clinical skills and expertise most effectively in client management. In addition to serving as a chaperone, the assistant performs supportive functions such as room and specimen preparation and assists the clinician in maintaining a clean and uncontaminated environment.

CMCH guidelines for the use of chaperones are as follows:

1. A chaperone should be in the examination room with the clinician whenever the client is in any state of undress.

2. A chaperone must be present in the examination room regardless of whether the client and clinician are of the same or opposite gender.

3. Ideally, the chaperone is an employee who also serves as an aide/assistant to the clinician; however, a trained volunteer whose presence serves as support to the client and protection for the clinician is also acceptable.

4. A member of the client's family or a friend who has accompanied the client as his/her personal support should not be designated to serve as chaperone.

5. The name of any chaperone present during the physical examination must be recorded in the medical record, as a signature in the space provided on either the FAMILY PLANNING INITIAL RECORD (DHMH 4398), the FAMILY PLANNING INTERVAL RECORD (DHMH 4400) or the FAMILY PLANNING COLPOSCOPY RECORD (DHMH 1175).

[1] "Boundary Violation – Sexual Misconduct;" Maryland Board of Physicians website, www.mbp.state.md.us/pages/bound_violation.html, copyright 2003.

CLINIC FACILITIES

The Title X Program Guidelines Section 6.4 requires that:

> *Facilities should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours.*
>
> *Facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet applicable standards established by federal, state, and local governments (e.g., local fire, building and licensing codes).*
>
> *Projects must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap in federally assisted programs and activities…Projects must also comply with any applicable provisions of the Americans With Disabilities Act (Public Law 101-336).*

The Title X Program Guidelines Section 10.1 requires that:

> *Projects are expected to follow applicable Federal and state regulations regarding infection control.*

The following guidelines address these requirements:

1. The location of the facility, number of examining rooms, and physical arrangements will be determined by local conditions and size of the patient population.

2. Facilities and equipment must meet the requirements of local codes. These general requirements should be maintained regardless of facility size:

    a. The heating plant, electrical system, and fire protection procedures must meet the requirements of local codes.

    b. Water and waste disposal systems must be provided in accordance with the local regulations.

    c. The facility must be safe and sanitary. Provision must be made for the disabled in accordance with the provisions of the Americans with Disabilities Act (ADA).

    d. Lighting levels in all areas should be adequate.

    e. There should be adequate ventilation through the use of windows,

mechanical ventilation, or a combination of both.

f. There should be a comfortable waiting room with an area for client reception and registration that affords adequate privacy for clients to disclose personal information without discomfort. There should be a sign posted stating that parents or guardians are responsible for small children. Magazines and other reading materials appropriate for the client population should be in the waiting areas. There should be an area where clients can watch educational videos.

g. There should be a sufficient number of single, private examining rooms, each furnished with the following items:

Examination table with suitable disposable covers
Examination light
Table for equipment
Gynecologic examination equipment and supplies (suggested supplies: Acetic acid, pH paper, TCA, normal saline and KOH)
Stool for the examiner
Chair for the client
Small desk or table for writing
Storage cabinet
Sink

h. Expiration dates on all medical supplies must be clearly labeled and a monitoring system should be in place.

i. The foot end of the examination table must always be positioned away from the door to ensure client privacy.

j. Each clinic must have a container with basic supplies and equipment for managing on-site medical emergencies and must have written plans and procedures for managing such occurrences. A designated person must be responsible for evaluation on a regular basis to ensure that supplies are current and complete.

k. There must be adequate toilet facilities, including a sink, for the clients. Separate toilet facilities with a sink should be provided for the staff.

l. The client dressing area should be in the examining room or adjacent to it, to ensure privacy. Clients in examination gowns must not be seated in public areas while awaiting examination.

m. There should be a designated area or utility room where laboratory tests such as pregnancy tests and microscopic exams can be

performed. This area should be equipped with the following items:

A sharps container and gloves at each work station
Hand-washing facilities/ sink
Closed cabinets for storage
Locked medicine cabinets
Refrigerator (The temperature should register between 34-42EF or 2-8EC; a temperature monitoring system should be in place.)
Waste receptacle
Current CLIA License posted

n. There must be offices or space in which privacy is assured for interviewing and counseling as well as for discussions about income validation and fee assessment.

o. There should be secure facilities for conducting administrative functions such as data entry, record processing, maintenance and storage.

3. The following components should be provided whenever possible:

a. A conference room for client and staff education. If a separate room is not available, the waiting room may be used.

b. Space where children accompanying the client can safely play.

4. After each clinic session the examination rooms must be cleaned according to written protocol. The entire clinic facility must be cleaned thoroughly on a daily basis.

5. Record of maintenance for equipment such as microscope, autoclave and BP cuffs should be maintained.

CLINIC OPERATIONS

The Title X Program Guidelines Section 5.2 requires that:

Every Project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the [federal] Privacy Act.

The Title X Program Guidelines Section 5.3 requires that:

Grantees must establish policies to prevent employees, consultants, or members of governing or advisory boards from using their positions for purposes of private gain for themselves or for others.

The Title X Program Guidelines Section 5.4 requires that:

Grantees and/or delegates/contractors should ensure the existence of adequate liability coverage for all segments of the projects… including all individuals providing services.

1. All family planning clinics should have the following key components:

    a. A well-organized strategy for service;
    b. Clearly articulated personnel policies and procedures that describe work standards and include prohibitions against conflict of interest;
    c. Privacy and confidentiality safeguards;
    d. Adequate liability coverage;
    e. Customer-oriented front-line personnel; and
    f. Customer-friendly systems.

2. All staff should be service-oriented.

3. Job standards should be developed for all clinic positions. Position descriptions must be detailed and specific, e.g., the receptionist job description should describe how the incumbent is to greet and interact with the clients.

4. The number of hours of family planning clinic time and the number of clinic sessions per week or month should depend on the need in the community and available clinic space. Assessment of clinic hours should be an ongoing process. Evening and Saturday hours are encouraged when it is determined that they would meet community needs.

5. The system for client registration and sign-in must assure client confidentiality. Similarly, counseling and fee assessment must be conducted in areas that afford adequate privacy.

6. The maximum time any client spends in the clinic should be approximately 60 minutes. Variation in time spent in clinic depends on the complexity of the visit. A client should be informed that her initial visit will be longer than her subsequent visits because extra time is needed for history-taking and teaching.

7. All clients are to be offered and encouraged to take the HIV screening test.

8. Fewer stations and therefore fewer different staff members in the clinic flow are better for the client. Clinic operations should be client-centered.

9. A confidential procedure must be established to allow for client notification and adequate follow-up of abnormal laboratory results.

10. Clients who fail to keep their appointments should be contacted and offered new appointments.

11. There must be a system to ensure a prompt and accurate method of contacting clients in case of a manufacturer recall of any contraceptive. Family planning clinics must keep an electronic or hand-written medication log that includes each client's name and/or other identifying information, date, medication and lot number.

12. The clinic hours should be posted. Also, information about where the client should go for care after hours should be posted and/or given to the client.

13. Services must include routine gynecologic and preventive care along with counseling, education and referral. Colposcopy and certain basic types of infertility testing may be provided when clinicians trained in these specialty areas are available.

14. Pregnancy diagnosis and counseling must be provided to all clients in need of this service. An abbreviated pregnancy test record includes, at a minimum, a Clinic Visit Record (CVR) and an encounter form that must be completed for each client at the time of the visit.

15. Requests for emergency contraception must be managed expeditiously through direct client contact or appropriate referral.

16. Client satisfaction surveys must be conducted at least annually to help evaluate the effectiveness of clinic operations. Findings from the surveys should inform quality improvement efforts.

CLINICIAN CREDENTIALS

The Title X Program Guidelines Section 6.5 requires that:

- *The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning.*

- *Licenses of applicants for positions requiring licensure are verified prior to employment and that there is documentation that licenses are kept current.*

- *Protocols exist that provide all project personnel with guidelines for client care.*

The following guidelines address these requirements:

1. The clinical care component of Maryland State Family Planning Program is under the direction of the Medical Director, Family Planning and Reproductive Health, Center for Maternal and Child Health, Maryland Department of Health and Mental Hygiene. This position is held by a board certified obstetrician/gynecologist.

2. Local health departments and agencies under contract may utilize local qualified physicians, nurse practitioners and nurse midwives for rendering technical assistance, clinical services, and consultation.

3. Confidential medical credentials files for clinicians employed by the Center for Maternal and Child Health are maintained at the Center for Maternal and Child Health. The credentials (including appropriate state licensure and certification) of each new clinician hired by local health departments and contract agencies must be verified prior to employment and reviewed at least annually.

5. All family planning sites have been issued the *Maryland State Family Planning Program Clinical Guidelines – 2005* and the *Maryland State Family Planning Program Administrative Guidelines - 2007*. They are also available on the CMCH website at www.fha.state.md.us/mch (click on Family Planning and Reproductive Health.) Incoming staff must acknowledge in writing that they have familiarized themselves with these materials by signing the signature page at the beginning of the Guidelines.

CLINICIAN CREDENTIALS

The Title X Program Guidelines Section 6.5 requires that:

- *The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning.*

- *Licenses of applicants for positions requiring licensure are verified prior to employment and that there is documentation that licenses are kept current.*

- *Protocols exist that provide all project personnel with guidelines for client care.*

The following guidelines address these requirements:

1. The clinical care component of Maryland State Family Planning Program is under the direction of the Medical Director, Family Planning and Reproductive Health, Center for Maternal and Child Health, Maryland Department of Health and Mental Hygiene. This position is held by a board certified obstetrician/gynecologist.

2. Local health departments and agencies under contract may utilize local qualified physicians, nurse practitioners and nurse midwives for rendering technical assistance, clinical services, and consultation.

3. Confidential medical credentials files for clinicians employed by the Center for Maternal and Child Health are maintained at the Center for Maternal and Child Health. The credentials (including appropriate state licensure and certification) of each new clinician hired by local health departments and contract agencies must be verified prior to employment and reviewed at least annually.

5. All family planning sites have been issued the *Maryland State Family Planning Program Clinical Guidelines – 2005* and the *Maryland State Family Planning Program Administrative Guidelines - 2007*. They are also available on the CMCH website at www.fha.state.md.us/mch (click on Family Planning and Reproductive Health.) Incoming staff must acknowledge in writing that they have familiarized themselves with these materials by signing the signature page at the beginning of the Guidelines.

COMMUNITY INVOLVEMENT, EDUCATION AND OUTREACH

The Title X Program Guidelines Section 6.9 requires that:

- *Title X grantees and delegate/contract agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services…*

  The I&E advisory committee may serve the community participation function if it meets the above requirements, or a separate group may be identified. The community participation committee must meet annually or more often as appropriate.

- *Each family planning project must provide for community education programs… This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.*

- *To facilitate community awareness of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community… Promotion activities should be reviewed annually and be responsive to the changing needs of the community.*

The following guidelines address these requirements:

1. Outreach in the Maryland Family Planning Program is characterized by "reaching out" and "reaching in." "Reaching out" is the effort that the family planning program, the local health departments and agencies under contract make to educate and inform the community about the clinical, educational, and counseling services that are available. This kind of education and outreach is often focused on specific groups, such as adolescents and their parents, immigrants, non-English speaking individuals, clients in STD clinics, participants in substance abuse programs and homeless men and women.

   "Reaching in" describes the process used to hear from members of the community about the availability, quality and acceptability of family planning services. Through the participation in customer satisfaction surveys and focus groups, the family planning client provides valuable information to the family planning program.

2. Agencies typically have diverse ways of connecting within their communities to assess needs and promote family planning services. Delegate agencies

must convene an informational and educational (I&E) materials review committee at least annually consisting of diverse members of the community to advise family planning staff on the suitability of materials provided to or viewed by clients. Ideally, these committees link the agency with others who are knowledgeable about the needs of the community for affordable family planning and reproductive health services. For more information about informational and educational review committees, please see the section of these guidelines titled **INFORMATIONAL AND EDUCATIONAL (I&E) MATERIALS REVIEW**.

3. Examples of education and outreach efforts undertaken by the Center for Maternal and Child Health (CMCH), local health departments and agencies under contract include:

   a. Participation in conferences, health fairs and other events in the community and in schools;
   b. Presentation of classes and workshops, for professionals or for local adults and teens; and
   c. Inviting individuals and groups to attend an activity or event at a clinic, such as a focus group or an open house.

4. A record should be kept of all community education and outreach efforts. Staff should evaluate the effectiveness of the efforts. Local health departments must submit a Health Education Report to CMCH by March 31st each year describing education and outreach activities for the preceding twelve months. Reports should follow the Community Health Education Annual Report Format which can be found in the Appendix or by clicking on the Family Planning Administrative Guidelines (Appendix) at the Web site of the Center for Maternal and Child Health at www.fha.state.md.us/mch . Completed reports should be sent to:

   Ms. Sharon Wongus, Coordinator of Special Health Programs
   Center for Maternal and Child Health
   Department of Health and Mental Hygiene
   201 West Preston St., Room 309
   Baltimore, MD 21201

   Questions may be directed to Ms. Wongus at 410-767-5068 or e-mailed to wonguss@dhmh.state.md.us.

   Generally, health education and outreach reporting requirements for agencies under contract are spelled out under the terms of the contract.

CONFIDENTIALITY

The Title X Program Guidelines Section 5.2 requires that:

- *No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual…*

The following guidelines address this requirement:

1. Clients have certain rights to privacy under federal and state law when receiving medical services. Providers are required to comply with all applicable state and federal laws.

2. Under Maryland law, an individual under the age of 18 may consent on his or her own behalf to confidential family planning services and certain other medical treatment; however, a doctor providing the treatment, or his or her designee, may notify the minor's parents. For example, a doctor in a family planning clinic may decide it is necessary to notify a minor's parents when the minor has been found to have a serious health problem and the minor does not return to the clinic for treatment.

3. When a serving an adolescent or adult client who does not wish to be contacted by phone or by mail at home or at other stipulated locations, providers should ask the client to sign a **FAMILY PLANNING INDIVIDUALIZED CONTACT PLAN, DHMH 1269,** or an equivalent local form. This form, which can be found in the Appendix and on the CMCH website at http://fha.state.md.us/mch/html/clinical_guidelines.cfm provides space where the client can identify a special contact plan. An example of such a plan would be "Please call and leave me a message at my boyfriend Jack Brown's house. His number is 410-555-5555." The client must be informed that, in the event that a serious health problem is identified, the clinic will make every attempt possible to contact the client, which could mean abrogating confidentiality. For more information on confidentiality issues and the contact plan, please see the section in these Guidelines titled **INFORMED CONSENT**.

4. Health care providers are required to report suspected child abuse or neglect. When they make a report of suspected maltreatment in good faith, they are protected under the law from civil or criminal liability pertaining to abrogation of confidentiality. For more information about reporting child abuse and neglect, please see the section in these

guidelines titled **MANDATED REPORTING OF CHILD ABUSE AND NEGLECT**.

5. Examinations and interviews with clients in which personal and financial information is exchanged must be conducted in settings that afford adequate privacy.

6. When confidential information is to be forwarded to another provider or agency, the client must sign a form authorizing the release of confidential information. The DHMH INDIVIDUAL'S AUTHORIZATION or an equivalent HIPAA-compliant form should be used for this purpose. The DHMH INDIVIDUAL'S AUTHORIZATION form, which can be found in the Appendix, is available for staff of local health departments to download from the DHMH intranet at http://indhmh/hipaa.

DATA COLLECTION AND REPORTING

Overview

The Maryland State Family Planning Program in the Center for Maternal and Child Health collects data from local health departments and agencies under contract in order to:

- Establish a profile of the client population served
- Identify emerging trends in needs and services
- Allocate resources based on data-driven decisions
- Demonstrate the need for funding support
- Meet federal and state reporting requirements
- Provide accountability for funds received

CMCH includes aggregate client, visit, and lab data in the federal Title X Family Planning Annual Report (FPAR) and in the state Reproductive Health Data Report. Aggregate STD lab results are shared with the Infertility Prevention Project (IPP) and may be shared within the Maryland Department of Health and Mental Hygiene, as appropriate.

The Data System

Since April 1, 2005, Ahlers and Associates (Ahlers) of Waco, Texas has been the contracted vendor for family planning data collection for the Center for Maternal and Child Health (CMCH). Local health departments and agencies under contract must use the Ahlers Family Planning program, a commercial off-the-shelf pc-based system designed for Title X data collection and reporting, or a comparable, approved third-party system for collection of data. In most clinics, information is entered from the Maryland Clinic Visit Record (CVR) form into the Ahlers software. When lab results are received, they are entered directly into the software. Each provider electronically transmits the collected data to Ahlers once a month. Clinics using other, approved third-party systems must also submit their data monthly to Ahlers in the approved data format with the approved edit checks.

CMCH reviews the CVR data collection form annually and may add, modify, or remove data elements in order to meet the evolving needs of the family planning program. Any changes to the CVR and/or the Ahlers software are completed by Ahlers. Clinics using approved, third-party systems are responsible for any changes to their systems that may be necessary in order to meet new family planning data collection and reporting requirements.

All visit and lab results for a calendar year must be transmitted by January 31 of the following year in order to be accurately reported in FPAR. (e.g., All visit and lab data for visits completed between January 1, 2006 and December 31, 2006 must be transmitted to Ahlers by January 31, 2007.) Data/record audits are conducted

by CMCH as a part of the Clinical and Administrative Site Review Process to verify the data reported by service providers.

In addition to the basic module that tracks client demographics, clinic visits, services provided and lab results, the Ahlers system offers the following additional modules to support the administration of family planning programs:

- Appointment Scheduling;
- Client Billing;
- Insurance Billing;
- Pharmacy Inventory and Dispensing; and
- Case Management.

Procedures to protect the confidentiality of client information must be in place when using any data system. For example, access to the data should be restricted to appropriate staff; password protection for data files should be used if necessary; and data entry computers should not be left unattended when data files are open.

Ahlers furnishes certain reports to providers and to CMCH on a monthly basis to support quality control within the system. Other reports may be created by visiting the Ahlers website at http://ahlerssoftware.com, or by requesting them through the CMCH Database Specialist, Debbie Walpole. Ms. Walpole may be contacted at (410) 767-5665 or by e-mail at dwalpole@dhmh.state.md.us.

Definitions

For purposes of reporting family planning data, the following definitions, found in the *Title X Family Planning Annual Report: Forms and Instructions* are used:

- A **Family Planning Encounter**, or visit, is "a documented, face-to-face contact between an individual and a family planning provider that takes place in a…family planning service site. The purpose of a family planning encounter - whether clinical or non-clinical – is to provide family planning and related preventive health services to female and male clients who want to avoid unintended pregnancies or achieve intended pregnancies... A written record of the services provided… must be documented in the client record." *Only face-to-face contacts documented in a medical or health record can be counted as encounters or visits.*

  When an established, ongoing client receives a service during a visit that does not pertain to avoiding unintended pregnancy or achieving an intended pregnancy, the visit may be counted as a family planning encounter. Even if an established, ongoing client has been sterilized but continues to seek gynecological or related preventive health care at the clinic, his or her visit may be counted as a family planning encounter. When, however, a first-time client receives gynecological or related preventive health services, and does

not receive services related to preventing or achieving pregnancy, the visit may not be counted as a family planning encounter. Similarly, when a post-menopausal client receives gynecological or related preventive health services, the visit may not be counted as a family planning encounter.

- A **Family Planning User**, or client, is "an individual who has at least one family planning encounter at a… service site during the [one year] reporting period." An individual may be counted as a client *only once* during the reporting period.

- Providers are individuals who staff family planning facilities. They are divided into two groups, clinical and non-clinical services providers.

    - **Clinical Services Providers** are those "who are trained and permitted by state-specific regulations to perform *all aspects* of the user (male and female) physical assessment... [They] are able to offer client education, counseling, referral, follow-up, and/or clinical services (physical assessment, treatment, and management) relating to a client's proposed or adopted method of contraception, general reproductive health or infertility treatment." Included are physicians, physician assistants, nurse practitioners, certified nurse midwives and other licensed health providers, such as registered nurses (RN).

    - **Non-Clinical Services Providers** are "other agency staff… that are able to offer client education, counseling, referral and/or follow-up services… [and] perform or obtain samples for routine laboratory tests…, and perform routine clinical procedures that may include some aspects of the user physical assessment."

- A **Family Planning Service Site** is "an established unit" where family planning staff provides family planning services to family planning users. Established units include clinics, hospital outpatient departments, homeless shelters, detention and correctional facilities, and other locations such as mobile vans or schools. The home of a client may not be considered a family planning service site for the purposes of this program.

<u>Conclusion</u>

The data collection and reporting system of the Maryland State Family Planning Program was put into place to serve a variety of local, state and federal needs. Every effort was made when the system was installed to tailor it to each provider. Providers needing support for any reason may contact Ahlers at 800-888-1836.

DEFERRAL OF PHYSICAL EXAMINATION

The Title X Program Guidelines section 8.3 requires that:

- *Physical examination and related prevention services should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless if in the clinician's judgment there is a compelling reason for extending the deferral.*

- *All deferrals, including the reason(s) for deferral, must be documented in the client record.*

The following guidelines address these requirements:

In order to reduce barriers to care and improve access to contraceptives, the option of deferring the physical examination (including the pelvic examination) may be used for adolescents and women who are on their menstrual periods or who decline the examination for personal reasons. Deferral of the physical examination can be done for the initial examination or for subsequent annual examinations.

1. Assessment should include a medical history, blood pressure, weight, urine screen, and, in the case of deferral of an initial visit or if indicated on deferral of an annual examination a urine pregnancy test.

2. Age appropriate counseling should be done regarding oral, injectable and other contraceptives, the pelvic examination, and the prevention of sexually transmitted diseases. Appropriate informed consent forms should be discussed and completed. Parental involvement should be encouraged and supported with adolescent clients.

3. The clinician may elect to perform portions of the physical examination if necessary to rule out pregnancy or obtain additional information on conditions which would contraindicate the use of hormonal contraception.

4. If the assessment appears satisfactory, the clinician may initiate or continue contraception and the remainder of the physical examination (including the complete pelvic examination) may be deferred for up to 3 months.

5. Hormonal contraception will be initiated according to the *Maryland Family Planning Clinical Guidelines- 2005*.

6. A return visit for the pelvic examination must be completed within 3 months. If the client fails to keep her return appointment, follow-up contact must be made in the appropriate manner.

7. Whenever the pelvic examination is deferred, the client's record should be appropriately documented. Continuation of hormonal contraception without a completed pelvic examination past 6 months requires documentation of the specific circumstances that, in the clinician's judgment, justified the extended deferral.

EDUCATION AND COUNSELING

The Title X Program Guidelines Section 8.1 requires that:

- *Agencies must have written plans for client education that include goals and content outlines to ensure the consistency and accuracy of the 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.*

The Title X Program Guidelines Section 8.2 requires that:

- *The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services.*

- *Documentation of counseling must be included in the client's record.*

The Title X Program Guidelines Section 9.3 requires that:

- *Clients should be offered appropriate counseling and referral as indicated regarding future planned pregnancies, management of a current pregnancy, and other individual concerns (e.g. substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) as indicated.*

- *Preconception counseling should be provided if the client's history indicates a desired pregnancy in the future.*

The following guidelines address these requirements:

GENERAL GUIDELINES FOR EDUCATION AND COUNSELING

1. Client education is critical to contraceptive success.

2. Education and counseling should be offered in an objective, non-judgmental fashion and be based upon an assessment of the client's level of knowledge and comprehension, past experience with family planning, resources, family situation, coping ability, learning style and linguistic and cultural needs.

3. Health education services and counseling **must** provide clients with the

information needed to:

a. Make informed decisions about family planning.

b. Use specific methods of contraception with knowledge of the methods' effectiveness, benefits, risks, and adverse effects.

c. Perform breast/testicular self-examinations.

d. Reduce risk of transmission of STDs and HIV.

e. Understand the range of available services and the purpose and sequence of clinic procedures.

f. Understand the importance of recommended screening tests and other procedures involved in the family planning visit.

4. Clients **should** be offered information about:

a. Basic reproductive anatomy and physiology
b. Domestic violence, sexual coercion and sexual abuse
c. Smoking cessation
d. Sexuality
e. Alcohol and drug abuse
f. Health promotion/disease prevention
g. Exercise, nutrition, and stress reduction
h. Infertility

5. Individualized education is generally more effective than group education and may also be more efficient.

6. Involving the sexual partner of the client in the education and counseling process when it is appropriate and possible to do so will normally enhance success.

7. Many people learn better if the material is presented visually. Education may include: a video or DVD explaining clinic procedures; flip charts of male and female reproductive systems; samples of each contraceptive method; a speculum; and/or a breast model.

8. Appropriate print materials (brochures, pamphlets, fact sheets, consent forms) should be reviewed with the client. Topics or sentences that particularly pertain to the individual client may be circled for increased emphasis.

9. It is recommended that an educational flow sheet be used for

documentation of education and counseling completed, and the client's response. This flow sheet can also be used to suggest topics for the client's future education and counseling.

PRECONCEPTION COUNSELING

Preconception counseling can help clients decide on the advisability and timing of pregnancy, assess and possibly reduce risks, and reinforce the lifestyle habits that promote a healthy mother and infant. All women of reproductive age should receive preconception health information.

Clinical information on preconception counseling can be found in the Maryland State Family Planning Clinical Guidelines – 2005 at http://fha.state.md.us/mch/html/clinical_guidelines.cfm

INFERTILITY COUNSELING

All clinics must offer at least basic (Level I) infertility services, which include an initial infertility interview, education, physical examination, counseling, and appropriate referral. However, Level II and Level III infertility services are beyond the scope of services offered by the Maryland State Family Planning Program. The following centers are referral resources for infertility:

University of Maryland Hospital
Gynecology, Endocrinology and Infertility Clinic
410-328-6640

Johns Hopkins Hospital
Gynecologic, Infertility and Endocrine Clinic
410-955-5191

Clinical information on infertility can be found in the Maryland State Family Planning Clinical Guidelines – 2005 at http://fha.state.md.us/mch/html/clinical_guidelines.cfm

GENETIC COUNSELING

Information gathered when completing the family planning initial record may assist in assessing the client's need for genetic counseling and evaluation. The clinician and other staff members should be alert to any indication of genetic disorders or conditions in a client that may lead to birth defects.

Extensive genetic counseling and evaluation are beyond the scope of the Maryland State Family Planning Program; therefore, a referral systems should be in place for those that require such services. The Office for Genetics and Children with Special Health Care Needs at DHMH can facilitate referral for in-depth personalized

counseling. You may call the Office for Genetics and Children with Special Health Care Needs at 410-767-6730, or 1-800-638-8864 or visit their website at www.fha.state.md.us/genetics. Additionally, the following centers are referral resources:

University of Maryland Hospital
Prenatal Diagnostic Center
410-328-3335

Johns Hopkins Hospital
Prenatal Diagnostic Center
410-955-3091

Sinai Hospital
Prenatal Diagnostic Center
410-601-5853

EMERGENCIES AND SAFETY

The Title X Program Guidelines Section 7.3 requires that:

> *All projects must…have written plans and procedures for the management of on-site medical emergencies. At a minimum…Protocols must address vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties.*
>
> *[Written] protocols must also be in place for emergencies requiring transport, after-hours management of contraceptive emergencies, and clinic emergencies. All project staff must be familiar with these plans.*
>
> *Appropriate training, including training in CPR, should be available to all staff.*

The Title X Program Guidelines Section 10.1 requires that:

> *Projects are expected to follow applicable Federal and state regulations regarding infection control.*

The following guidelines address these requirements:

1. Written protocols for emergency care must be reviewed annually.

2. A designated staff member must check the emergency supply cart or box at least monthly. The staff member must check inventory and expiration dates, and reorder supplies as needed. The sign-off sheet must be clearly visible on or near the cart or box.

3. The facility must post and make available to all personnel an ongoing plan specifying procedures to be followed in case of fire, disaster, or other emergency. A designated staff member must complete and document fire and safety inspection. This would include checking that the EXIT signs are clearly visible and that the fire extinguishers have been recharged on an annual basis. Fire and disaster drills should be conducted at least annually. All local health departments and contract agencies must follow all county and state laws pertaining to fire and safety.

4. Specific security procedures must be written to detail measures to ensure the physical safety of clients and staff in case of suspicious or violent behavior. Staff must receive training on these procedures.

5. All clinical staff must maintain continuous, basic CPR certification by attending training sessions every two years. A record of each individual's CPR re-certification must be maintained.

6. All staff must be familiar with the procedures to use following an exposure incident (i.e. parenteral or per mucosal exposure to blood or other potentially infectious material) as outlined in the provider's Bloodborne Pathogen Exposure Control Plan. Please also see BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN in these Guidelines.

7. For local health departments only, all guidelines issued by the DHMH Risk Management Program must be followed. The DHMH Risk Management Program is located in Room 111 at 201 W. Preston St., Baltimore, MD 21201. Its website can be found at :http://dhmh.md.gov/ohr/riskmgt/index.htm You can call the Risk Management Coordinator at 410-767-5689, if you have questions or need the name of your local health department Risk Management Program Coordinator.

8. Individual jurisdictions should be contacted for their own contingency plans for medication dispensing.

FEE ASSESSMENT AND COLLECTION

The Title X Program Guidelines Section 6.3 requires that:

- *Clients must not be denied services or subject to any variation in quality of services because of the inability to pay.*
- *Charges must be based on a cost analysis of all services provided.*
- *Clients whose documented income is at or below 100% of the Federal poverty level must not be charged.*
- *A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees must be waived for individuals with family incomes above this amount who…are unable, for good cause, to pay for family planning services.*
- *Projects must bill all third parties authorized or legally obligated to pay for services.*
- *Bills to third parties must show total charges without applying any discount.*
- *Bills to clients must show total charges less any allowable discounts.*
- *Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.*
- *Reasonable efforts to collect charges without jeopardizing client confidentiality must be made.*
- *<u>Voluntary</u> donations from clients are permissible. However, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies.*
- *Client income should be re-evaluated at least annually.*

Fee Assessment and collection are areas of operation in which both state and federal requirements apply. Guidance on state requirements may be found in the Department of Health and Mental Hygiene *Human Services Agreement Manual* (HSAM093005.doc) and the *Local Health Department Funding System Manual* (LHDFundSystManual.doc), which can be found on-line at www.dhmh.state.md.us/forms/sf_gacct.htm .

The following information addresses fee assessment, billing and collections issues for clients who pay out of pocket as well as those with Medicaid or other third party insurance coverage:

1. **HealthChoice Medicaid Program:** HealthChoice is the name of Maryland's Medicaid Managed Care Program. Care is rendered to Medicaid recipients by managed care organizations (MCO). Federal law permits Medicaid recipients to receive family planning services from any qualified provider. HealthChoice members may self-refer for family planning services without prior authorization or approval with the exception of sterilization procedures.

   To verify a client's eligibility and the name of the MCO, one may call the Eligibility Verification System (EVS) at 1-866-710-1447. HealthChoice enrollees and providers may contact 1-800-284-4510 with questions and problems. Provider information, including the MARYLAND MEDICAL ASSISTANCE OB/GYN/FAMILY PLANNING SERVICES PROVIDER MANUAL is also found on-line at www.emdhealthchoice.org/providerinfo/.

   The scope of services covered under the family planning self-referral provision is limited to those services required for contraceptive management. The ICD-9 diagnosis code (V25) must be indicated on the claim form in order for the MCO to recognize that the CPT Evaluation and Management code is related to a family planning service. For information on CPT codes that must be used to bill MCOs for these services, consult the MARYLAND MEDICAL ASSISTANCE OB/GYN/FAMILY PLANNING SERVICES PROVIDER MANUAL, page 24 .0.

   MCOs must pay providers for pharmacy items and laboratory services when the service is provided on-site in connection with the self-referral service. For example, MCOs must reimburse medical providers directly for the administration of Depo-Provera™ from a stock supply of the drug. This eliminates an unnecessary barrier to care which is created when a member is asked to go to an outside pharmacy to get Depo-Provera™ and return to the provider's office for the injection.

2. **Medical Assistance client not enrolled in HealthChoice:** If the client has an MA card and is not yet enrolled in an MCO, the billing should be under the fee for service basis using the county's service specific rate for that service. Verify eligibility as noted above. The bill should be submitted directly to the Medical Assistance Program at DHMH.

3. **Maryland Medicaid Family Planning Program:** There is a special category of Medicaid coverage for low-income women who previously had Maryland Children's Health Program (MCHP) coverage due to pregnancy. These women receive a Family Planning Program MA card (purple and white card) that is valid for up to five years for family planning services only, unless they become eligible for another Medical Assistance program, no longer need contraception because of permanent sterilization, no longer live in Maryland, voluntarily request to be disenrolled, or no longer meet income eligibility requirements after two or more years of enrollment. Verify eligibility

as noted above. The CMS 1500 form is sent to the Medical Assistance Program at DHMH. Call 1-800-456-8900 if you need coding information or have questions about this program.

4. **Maryland Primary Adult Care (PAC) Program:** This is another special category of Medicaid coverage for certain low-income adults not covered by Medicare. Those enrolled receive both primary care and pharmacy services. Family planning services are available under this program, with the exception of sterilizations. PAC participants select or are assigned to an MCO. Those interested in learning more about the PAC program may call 1-800-226-2142 or go to www.dhmh.state.md.us/mma/pac/index.htm.

5. **Fees for all other client visits:** Fees for all other client visits (non-Medicaid) are assessed using the DHMH *Ability to Pay Scale*. The *Ability to Pay Scale* is based on federal poverty levels established each February and, in accordance with Title X requirements, stipulates that there is no charge for family planning services rendered to individuals with incomes at or below 100% of the federal poverty level. A revised schedule goes into effect each July. The current schedule may be viewed on-line at www.dhmh.state.md.us/pca/html/forms2.htm#1stset.

   Local health departments and their sub-vendors must adhere to schedules of charges based upon cost reporting and approved annually in the CPT format. Agencies funded under certain CMCH contracts or grants also charge according to fee schedules based upon cost reporting and approved annually.

   At the suggestion of Region III of the Title X program, we have developed a suggested script for determining the fee an individual should pay for services. This suggested script can be found in Appendix G .

6. ***Non-Chargeable Services List*:** Along with these **Guidelines**, refer to the current DHMH *Non-Chargeable Services List* (updated each fiscal year) at www.dhmh.state.md.us/pca/html/forms2.htm#1stset for information on family planning services that are non-chargeable except, in certain cases, to Medicaid or other third party insurers.

   a. No charge should be made when a client is asked to return because of the failure of the clinic to complete all of the required tests or examinations at a previous visit. An example of a "no charge visit" is a return visit for a repeat Pap test due to lack of endocervical cells on the previous test.

   b. There is no charge for **pregnancy testing** when no other service is provided. Donations may be accepted but not solicited. When pregnancy testing is included with other services, the visit is

chargeable based on the level of service(s) rendered.

c. **Birth control pills are non-chargeable;** however pill pick-up in local health department or other settings where the client sees the nurse at the time of the pick-up may be charged as a brief nurse visit (99211).

d. **There is no charge for the Emergency Contraceptive (EC) Pill.**

There is no charge to the patient if a pregnancy test is done when Emergency Contraception is provided. A visit for Emergency Contraceptives that only requires completion of the DHMH 4522 EC record would be a non-chargeable visit. A pregnancy test is optional. The EC Pill is provided free of charge whether supplied by the State or purchased by the LHD with grant money provided by the State.

e. **Depo-Provera™ for private pay clients with incomes at or below 250% of the federal poverty level:**

The Depo-Provera™ order visit is chargeable at the full rate to Medicaid, third party payers and to private pay clients on the sliding fee scale. The drug is chargeable to Medicaid and other third party payers at full cost. For private pay clients with incomes at or below federal poverty level, there is no cost of the drug; however, the cost of the visit for each injection is based on the level of service. The subsequent annual visits are chargeable based on the level of service and the client's ability to pay.

7. Record Keeping:

Title X requires that the income of each service recipient be assessed at least annually. According to guidance issued by the Office of Population Affairs (OPA) in March 2006:

> "Title X projects may request proof of income, but they may not require it. Thus, if a client has no proof of income, but provides self-declaration of income, the Title X project should accept the self-declaration and charge the client based upon what he or she has declared. Title X projects may not assess the client at 100% of the charge because they do not have proof of income, as this may present a barrier to the receipt of services."

According to the DHMH *Local Health Department Funding System Manual 2130.08,* an individual financial record must be established for each recipient of services or chargeable person including, when available, documents appropriate to the verification of income, expenses, allowances and

exemptions. If a Title X client states that he or she is not able or willing to make such documents available, the client's statement should be documented in the record and the record should reflect that income verification was established by means of self-declaration in accordance with Title X requirements.

The *Local Health Department Funding System Manual* further stipulates that "documentation of reductions to ability to pay determinations must include things like: tax returns, pay stubs, unemployment insurance applications or other reasonable relevant documentation." However, when services are provided under Title X, such documentation may be requested, but may not be required. When documentation of ability to pay is not provided by a Title X client whose self-declaration establishes a fee reduction, the record should reflect that, in accordance with Title X requirements, income verification was requested but not made available.

8. Fee Collection

DHMH Policy 3205 establishes certain requirements for collection by local health departments of accounts declared by the Health Officer to be delinquent. Once an account has been designated delinquent, it must be transferred to the Central Collection Unit, Department of Budget and Fiscal Planning (CCU). However, Title X precludes any practice that may constitute a barrier to the receipt of services, such as the assignment of the account of a service recipient to a collection agency. For some "do's and don'ts" pertaining to fee collection, please see the "Fee Assessment Script," which is included in the Appendix to these Guidelines

9. Policy Clarifying Fee Collection for Minors:

When providing services to minors, whether confidential or non-confidential, agency policies concerning fee assessment and charging for services must not present a barrier to the client's receiving services.

Charges to minors who receive confidential services must be based on the income of the minor. The client's income alone shall be used to determine the client's fiscal responsibility for all family planning services.

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

Unit.

For charges to non-confidential minors, the family's income may be considered in determining the charge for services. The minor must specifically indicate that confidentiality is not a concern and that her parent(s) may be contacted concerning fees and insurance coverage.

If a minor client is non-confidential, third party payment, such as private health insurance or HealthChoice, may be accessed. Insurance coverage by a third party is considered part of the non-confidential minor's ability to pay.

10. Policy on Donations:

Voluntary donations from clients are permissible. However, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements. If a notice is posted to indicate that donations are acceptable, the notice should not be written to imply a specific amount.

FAMILY AND INTIMATE PARTNER VIOLENCE

Family and intimate partner violence (FIPV) includes physical, sexual and psychological assault and/or coercion within a current or past family, cohabiting or dating relationship. It is also known as domestic violence. It may be an isolated event, when the perpetrator lacks continuing access to the victim; however, more frequently it is a pattern of ongoing behavior. The goal of such behavior is achieving compliance from or control over the victim. A child or adolescent may be the actual or intended target of a violent act, or may become traumatized by witnessing abusive behavior. A high proportion of those who behave violently with an adult partner also abuse children within the family. Children may come to believe that violence is an acceptable way of dealing with problems or conflicts. They may also be more likely to enter into abusive relationships as they mature.

Most violence toward a partner is perpetrated by a male against a female; however, male-to-male, female-to-male and female-to-female violence is known to occur as well. FIPV can result in injury, death or chronic illness. Some victims are at greatest risk when they try to leave the situation or have separated from the abuser.

Medical professionals need to view interpersonal violence as a health problem. Appropriate health care management of all women includes universal screening for family or intimate partner violence.

Many women who have been victimized are reluctant or unable to get help. Some are literally held captive, and others may not have the money or means of transportation to leave. Cultural, ethnic and/or religious influences may affect a woman's response to violent behavior and her awareness of viable options.

Maryland does not have mandatory reporting requirements for domestic violence. In this state, mandatory reporting is required only for abuse or neglect of a child or abuse, neglect or exploitation of a vulnerable adult. A vulnerable adult is defined as a person aged 18 or older who lacks the physical or mental capacity to provide for his or her daily needs. In other situations involving interpersonal violence, it is the responsibility of the victim to report the abuse to the proper authorities. However, whenever any health care provider treats a person for an injury that was caused by or shows evidence of having been caused by any type of gunshot, the police must be notified.

For additional information on mandated reporting of child abuse and neglect and counseling teens on sexual coercion and sexual assault, please also refer to the sections of these guidelines titled **MANDATED REPORTING OF CHILD ABUSE AND NEGLECT** and **ADOLESCENT SERVICES**. FIPV guidelines for providers are as follows:

1. All clients should be educated to increase their awareness of violence as a health problem. This information should be part of their health care education and counseling.

2. Family planning clients should be screened for current or previous FIPV during initial visits. Screening should be updated at least annually thereafter. Information about a person's prior experience of physical, psychological or sexual violence may have bearing upon current or future health and wellbeing.

3. Clients should be informed about the level of confidentiality they may expect in response to any disclosure they may make. Requirements for mandated reporting of child abuse or neglect should be clearly stated, including the requirement that maltreatment be reported even when it occurred when an adult was still a child.

4. Screening should be carried out in private. Direct, specific questions should be phrased in order to make them nonjudgmental and as non-threatening as possible. For example, a provider may ask:

   - Has anyone close to you ever threatened to hurt you?
   - Has anyone ever hit, kicked, choked or hurt you physically?
   - Has anyone, including your partner, ever forced you to have sex?
   - Are you afraid of your partner?

5. Health care providers should accurately document any problems or complaints of abuse, or physical evidence of violence.

6. The possibility of FIPV should be considered when a client's explanation for an injury does not seem plausible, when there has been a delay in seeking medical care or when an individual presents with vague complaints for which there is no other plausible explanation.

7. Cultural competency is important, and questions should be asked in the client's primary language when possible.

8. Validation, empathy and concern are appropriate responses to disclosures about victimization.

9. Upon learning of an incident or pattern of domestic violence, a provider needs to assess the current safety of the client. If the client was victimized in the past and is no longer at risk, a referral for counseling may be indicated. If there is violence in a current relationship, a provider should attempt to establish a safety plan with the client and make referrals to community resources. Each clinic should maintain listings with contact information for local law enforcement, shelters and other agencies that serve victims of domestic violence and counselors. The Maryland Network Against Domestic Violence (MNADV) and the Maryland Coalition Against Sexual Assault (MCASA) can provide statewide information on laws as well as national and local resources.

To contact MNADV, go to www.MNADV.org or call 1-800-MD HELPS. To contact MCASA, go to www.mcasa.org or call 1-800-983 RAPE. Providers should maintain respect for the right of each individual to determine his or her own course of action. If a client does not wish to seek counseling or involve the authorities, it may be helpful to promote the importance of a social support system.

10. Women are sometimes under the mistaken impression that violence will stop during pregnancy. It is important to advise such clients that research has not shown this to be true. In fact, abusive behavior is likely to continue unabated or increase.

11. When a woman fears that her partner may respond violently if he discovers that she has come to the clinic, it is likely that the provider will wish to recommend an undetectable method of contraception such as injectable progestin (Depo-Provera®).

12. When a provider suspects or is told that an adolescent client has experienced violence, sexual coercion and/or assault that is not reportable to Child Protective Services or law enforcement, the provider should seek to engage the young person in safety planning. Counseling may also be appropriate on ways to avoid sexual coercion. The client should be given information about ways to contact local victims' services programs, emergency medical facilities and law enforcement.

Primary References

JSI Research and Training Institute. *Family and Intimate Partner Violence: Resource Guide for Integrating Services into Family Planning Clinics*. September 2004.

Details about the laws concerning Domestic Violence can be found in the Annotated Code of Maryland, Family Law Article, §4-501 to §4-530.

Details about the laws concerning sexual assault and rape can be found in the Annotated Code of Maryland, Criminal Law Article, §3-304. §3-305, §3-306, §3-307 and §3-308.

INFORMATIONAL AND EDUCATIONAL (I&E) MATERIALS REVIEW

The Title X Program Guidelines Section 6.8 requires that:

- *An advisory committee of five to nine members… who are broadly representative of the community must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X.*

The following guidelines address this requirement:

There are many sources of informational and educational materials suitable for use in family planning clinics. For example, Office of Population Affairs Clearinghouse has a number of educational publications available free of charge for download from their website at http://opa.osophs.dhhs.gov/pubs/publications.html. You may also order up to 20 hard copies of any item free of charge through the website or by calling the Clearinghouse at 866-640-7827.

Whether materials have been obtained from an outside source or created in-house, they are subject to informational and educational review procedures established under Title X. The Maryland State Family Planning Program has a two-tiered informational and educational review process. At the local level, I&E review committees operate to assess materials in use at facilities within the community served. The materials and findings of local committees are then submitted to the Central I&E Review Committee, which meets at the Center for Maternal and Child Health (CMCH) to provide a second, statewide level of review.

1. Each local health department and other delegate agency must have an information and education review process. Central to that process is the local I&E review committee consisting of 5 to 9 members. Members of the committee must be representative of the community served. Every effort should be made to include clients. Committees are strengthened when they successfully incorporate members of various ages, drawn from diverse sectors of the service delivery community.

2. The committee must meet at least annually to review all materials distributed to or viewed by clients in order to determine the appropriateness and consistency of the content. Examples of materials that must be reviewed are handouts pertaining to fees, referral lists, videos and DVDs to be used in the waiting room and brochures that describe contraceptive methods.

3. The Committee should consider whether information directed to clients is factually correct, current, culturally sensitive and suitable for the population served. Written materials that are clear, direct and easy to read are preferable. Publications that are illustrated with drawings or photographs

enhance readability and increase eye appeal.

4. There must be a written record of Committee determinations. The **Informational & Educational Materials Review Evaluation Worksheet** should be used for this purpose. The **Worksheet** is available in the Appendix and or by clicking on the Family Planning Administrative Guidelines (Appendix) at the Web site of the Center for Maternal and Child Health at www.fha.state.md.us/mch .

5. After the local I&E Review Committee has completed its work, a packet containing the following items must be submitted to the Central I&E Review Committee at CMCH:
   - A list of local committee members;
   - A copy of each of the print materials reviewed and a listing of any videos and/or DVDs;
   - Photocopies of each **Informational & Educational Materials Review Evaluation Worksheet** completed by committee members during the review; and
   - A photocopy of the sign-in sheet for the review.

   Packets containing materials reviewed during the previous 12 month period should be submitted no later than March 31st to:

   Ms. Sharon Wongus, Coordinator of Special Health Programs
   Center for Maternal and Child Health
   Department of Health and Mental Hygiene
   201 West Preston St., Room 309
   Baltimore, MD 21201

   Questions about the I&E review process may be directed to Ms. Wongus at 410-767-5068 or to wonguss@dhmh.state.md.us.

INFORMED CONSENT

The Title X Program Guidelines Section 8.1 requires that:

- *Written informed consent, specific to the contraceptive method, must be signed before a prescription contraceptive method is provided.*
- *The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter.*
- *To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen.*
- *The signed informed consent form must be a part of the client's record.*
- *The method-specific consent form should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method.*

The following guidelines address these requirements:

INTRODUCTION

Obtaining informed consent is an educational process and the consent form documents that process. Pragmatically, a client who understands her or his contraceptive method will be more likely to use it safely and effectively. Ethically, every person has a right to complete information about products and services that can affect health. Legally, the clinic staff must provide adequate information to help the client reach a reasonable and informed decision about health options.

Informed consent consists of seven basic elements. The "BRAIDED method" (Contraceptive Technology, 18th revised edition, 2004, Chapter 10, page 264) can be helpful in remembering the components of good counseling.

Benefits of the method
Risks of the method
Alternatives to the method
Inquiries about the method are the client's right and responsibility
Decision to withdraw from using the method without penalty is the client's right at any time
Explanation of the method is owed the client
Documentation that the staff member has covered each of the previous six points

GENERAL GUIDELINES

1. A written consent for general family planning services must be obtained at the initial visit. It should be obtained again every four years for continuing clients or if there is a break in service of one year or greater.

2. Each consent form must be signed and dated by the client and witnessed and signed and dated by a staff member after thorough counseling and review of the information on the form.

3. A written consent for a specific procedure (such as IUD insertion) needs to be obtained only at the time of the procedure.

4. The FDA-approved and manufacturer-supplied pamphlet must be given to the client for all hormonal methods and the IUD. This action should be documented.

5. The client may be given a copy of each consent, if requested.

6. If the physician or nurse-clinician believes that a client is unable to give informed consent (for example, because of mental disability), then written informed consent must be given by the parent or legal guardian if the client is a minor, or a legal guardian if the client is an adult.

7. The consent forms listed below (1 through 9) can be found in the Appendix and are also available on the CMCH website at http://fha.state.md.us/mch/html/clinical_guidelines.cfm

8. Local programs may use additional consent forms. Please notify the Medical Director, Family Planning and Reproductive Health at CMCH if you choose to use additional forms.

MARYLAND STATE FAMILY PLANNING PROGRAM CONSENT FORMS

The following consent forms or forms containing equivalent information must be used in Maryland State Family Planning Program family planning clinics:

1. **CONSENT FOR FAMILY PLANNING SERVICES, DHMH 1216** -This form is to be read, discussed, signed and witnessed, during the education session, at the initial visit. It must be reviewed, signed, and dated every four years or anytime there is a break in service of one year or more.

2. **CONSENT FOR ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS), DHMH 1217)**

a. This form must be reviewed, signed and witnessed when the client selects the method either initially or after a break in service of one year or greater.

b. A sample FDA approved information pamphlet from a pill package should be shown to the client during the education session. The client will receive the FDA approved Information pamphlet contained in her pill package at the end of her clinic visit.

3. **CONSENT FOR PLAN B® EMERGENCY CONTRACEPTIVE PILLS, DHMH 4523**

4. **CONSENT FOR DEPOT MEDROXYPROGESTERONE ACETATE (DMPA), DHMH 4479**

5. **CONSENT FOR INTRAUTERINE DEVICE - PARAGARD®, DHMH 4670**

6. **CONSENT FOR ORTHO EVRA® - CONTRACEPTIVE PATCH, DHMH 4616**

7. **CONSENT FOR NUVARING® - VAGINAL CONTRACEPTIVE RING, DHMH 4661**

8. **FAMILY PLANNING INDIVIDUALIZED CONTACT PLAN, DHMH 1269**

This agreement may be used whenever an adult or adolescent client does not want to be contacted by telephone or letter at his or her home address. The section that calls for a special plan requires that the client identifies workable arrangements for contact. An example of a special plan would be: "Call my boyfriend Jack Brown's house (410-284-2699) and leave a message for me." It is important that a client who does not want to be contacted understands that completion of the special plan section, while not required, enhances the likelihood that the clinic will be able to comply with his or her wishes.

Inability to contact a confidential client for follow-up regarding a serious health problem may be a reason to break confidentiality. The need for a current special contact arrangement should be discussed with the client at the initial visit, annually and any time the clinic may have to reach the client following a visit. If the client states that the plan originally identified will no longer work, cross out the plan and rewrite, initial, date, etc?) When a client informs the clinic that he or she no longer needs special confidentiality, indicate this at the bottom of the previously completed form.

Under the law in Maryland, a minor may consent on his or her own behalf to

certain types of medical treatment including family planning services. For details, see the Maryland Minor's Consent Law, (Health-General Article, Section 20-102) which can be found in the Appendix and is available by clicking on the Family Planning Administrative Guidelines (Appendix) at the Web site of the Center for Maternal and Child Health at www.fha.state.md.us/mch .

9. **COLPOSCOPIC EXAMINATION CONSENT DHMH, 4174A**

10. **CRYOTHERAPY CONSENT, DHMH 4174B**

11. **CONSENT FOR IMPLANON™- SUNDERMAL CONTRACEPTIVE IMPLANT, DHMH 4672**

OTHER CONSENT FORMS

CONSENT FOR STERILIZATION, HHS-687 (11/03) – The federal consent for sterilization form is used when a local provider completes the pre-procedure counseling for a man who will undergo a vasectomy through the Maryland State Family Planning Program at Planned Parenthood of Maryland's Towson clinic. Forms may be downloaded from the Office of Population Affairs Clearinghouse website at http://opa.osophs.dhhs.gov/pubs/publications.html. You may also order up to 20 copies free of charge through the website or by calling the Clearinghouse at 1-866-640-7827. The forms, which must be completed 30 days in advance of the procedure, are available in English and Spanish. For more information, please see the section in these guidelines titled **STERILIZATION.**

References:

Hatcher, Robert A. et al., Contraceptive Technology. Eighteenth Revised Edition. (N.Y.: Ardent Media, Inc., 2004) p. 264.

The American College of Obstetricians and Gynecologists, Guidelines for Women's Health Care (Washington DC: The American College of Obstetricians and Gynecologists, 1996) p. 38.

MALE INVOLVEMENT

With rare exceptions, (e.g., a clinic conducted in a female institutional setting), it is expected that all providers will serve both male and female clients. Services should include a sexual history, an age-appropriate physical exam and laboratory testing and related counseling and education about general and sexual health as well as contraceptive methods and sexually transmitted diseases (STD), including HIV/AIDS.

Staff members who are untrained or those who are inexperienced and lack confidence in serving male clients should be referred for appropriate training. TRAINING 3, the agency funded to provide training and technical assistance to Title X programs in federal Region III, frequently offers workshops on various aspects of male involvement. TRAINING 3 offerings and schedules are listed on its website at www.training3info.org. Also, the Family Planning Chief Nurse Consultant at CMCH acts as liaison for the Maryland State Family Planning Program with TRAINING 3 and other training programs and organizations. He or she makes training announcements available at quarterly Regional Consultants and Nursing Staff Advisory Workgroup (RCANSAW) meetings and can be contacted by calling (410) 767-6713. In addition, local programs can request Technical Assistance or targeted local trainings in the provision of male services from TRAINING 3. Contact the Family Planning Chief Nurse Consultant for further information in this area.

Clinician training in the provision of male reproductive health services may be obtained from a number of sources. The Region III STD/HIV Prevention Training Center in Baltimore offers clinician training on a regular basis in the area of male STD/Reproductive Health examinations. This training meets the requirements of the Maryland Board of Nursing for documentation of clinical competency in this area of advanced practice for certified nurse midwives and women's health nurse practitioners. In addition, the Title X-supported Clinical Training Center for Family Planning (CTCFP) and TRAINING 3 are resources for opportunities to enhance clinician skills in the provision of male services in family planning clinics. The Family Planning Chief Nurse Consultant can provide additional information regarding Board of Nursing Advanced Practice requirements for providing male reproductive health care and clinician training resources.

Once adequate training has occurred, mentoring by a more experienced employee and observation of exams and counseling during clinics may help to support those who are new to the practice of involving males in family planning services. TRAINING 3 and CTCFP also support the training of clinicians to function as preceptors to local clinicians and programs to further increase the comfort level of staff in providing services to males.

MANDATED REPORTING OF CHILD ABUSE AND NEGLECT

All health care workers acting in their professional capacity are mandated to report information that otherwise would be confidential when they suspect child abuse or neglect. (Please see **Family Law Article, §5-704, Annotated Code of Maryland** in the Appendix). In Maryland, reports are required even when a previously maltreated child is now an adult.

Workers are protected from civil liability and criminal penalty when making a report in good faith. Alternatively, they could be subject to sanctions from their professional licensing boards if they knowingly fail to report.

A child is defined as an individual under the age of 18. Child abuse includes physical injury or mental injury under circumstances indicating that a child's health or welfare is harmed or at substantial risk of harm and sexual abuse, with or without physical injury, perpetrated upon a child by a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for supervision of the child.

Child neglect means the failure to provide proper care and attention to the child under circumstances that the child's health or welfare is harmed or placed at substantial risk of harm. It includes leaving the child unattended and mental injury or substantial risk of mental injury that is caused by failure to provide proper care and attention to the child.

When the perpetrator of a physical or sexual assault is an individual **other than**

A. a family or household member or
B. someone with temporary or permanent, current or past care, custody or responsibility for the supervision of the child,

the mandated reporting requirement does not apply. In fact, a provider could risk licensing or criminal penalties or civil liability for violating the confidentiality of a client were the provider to make a report in a situation that falls outside the mandated reporting law. In Maryland, statutory rape is not reportable unless the perpetrator is a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for the supervision of the minor. However, even when it is not reportable, a sexual relationship between an adolescent and an older adolescent or adult may raise concerns that sexual coercion is occurring. Family planning providers are required to counsel minors about ways to resist attempts to coerce them into engaging in sexual activities. In addition to counseling, referrals to sexual assault programs or other types of assistance may be offered.

Guidelines for mandated reporters are as follows:

1. Under Maryland's mandated reporting law, after a health care provider has learned about a suspected incident or incidents of child maltreatment, a report to the appropriate authorities is required.

2. An oral report of child physical or sexual abuse must be made as soon as possible to Child Protective Services (CPS) or the appropriate law enforcement agency.

3. An oral report of neglect or mental injury must be made as soon as possible to CPS.

4. The head of the public health agency in which the provider is employed should be informed of an abuse or neglect report immediately.

5. Within 48 hours, a written report of abuse or neglect must be sent to CPS and, if the report concerns child abuse, a copy must also be sent to the State's Attorney. Reports may be made on the **DHR/SSA 180**. **DHR/SSA 180** reporting forms and statewide contact information about CPS may be found on-line at www.dhr.state.md.us/cps (under Mandated Reporters.)

6. When the mandated reporting law does not apply in cases of statutory rape, dating violence or sexual assault, a young person may need assistance in accessing a variety of medical, including mental health, and community services. At a minimum, the client should be counseled about safety, parental involvement and ways to resist sexual coercion. The youth should be urged to take advantage of local victims' services programs. Referral to emergency medical facilities and/or local law enforcement authorities may also be appropriate.

Primary References

Family Law Article, §5-704, Annotated Code of Maryland
Criminal Law Article, §3-304, 3-306, 3-307, 3-308, Annotated Code of Maryland

NEEDS ASSESSMENT

The Title X Program Guidelines Section 3.2 requires that:

- *An assessment of the need for family planning services must be conducted prior to applying for a competitive grant award.*

- *Grantees should perform periodic reassessment of service needs.*

The following guidelines address these requirements:

1. Data collection is an integral part of needs assessment. Service providers must use the Ahlers data system or an approved, third party system for collection of data. Please see **DATA COLLECTION AND REPORTING** for additional information on data collection requirements.

2. Service providers should identify emerging trends in family planning in their respective service delivery areas through solicitation of consumer input and community involvement. Client satisfaction surveys and local advisory councils are means of obtaining this information.

3. Service providers should send representatives to the Regional Consultants and Nursing Staff Advisory Workgroup (RCANSAW) quarterly meetings as a means of sharing information, assessing needs, and discussing issues that impact the provision of family planning services throughout the state.

4. Periodic reassessment of needs should be done through all components of the needs assessment process: data analysis, consumer and community input, and professional feedback through RCANSAW and other meeting and networking opportunities.

5. The needs assessment process is used to determine future directions of the program as a whole and to develop a work plan designed to meet identified needs.

NURSE DISPENSING IN LOCAL HEALTH DEPARTMENT CLINICS

The Maryland Board of Physicians Declaratory Ruling 01-1 RE: POLICY AND PROCEDURE FOR REGISTERED NURSES DISPENSING PRESCRIPTION AND OVER THE COUNTER DRUGS AND DEVICES IN PUBLIC HEALTH CLINICAL PRACTICE SETTINGS states that:

…A physician employed by the Department of Health and Mental Hygiene or a local health department may delegate dispensing authority to certain registered nurses who have received approved training to dispense drugs and devices in a safe and legal manner.

In order to establish a uniform standard of practice in local health departments throughout Maryland, in 1999 the Board of Physicians issued a Declaratory Ruling that allows physicians employed by the Department of Health and Mental Hygiene (DHMH) or a local health department to delegate the authority to dispense medications to public health nurses who have been specially trained to do so. Drugs and devices dispensed under the policy must be from an approved formulary and dispensed in a manner specifically prescribed by the Declaratory Ruling.

The formulary established under the Declaratory Ruling is kept current by a Committee on Nurse Dispensing convened by the Department of Health and Mental Hygiene and composed of one representative designated by the Secretary along with one representative from each of the Boards of Pharmacy, Nursing and Physicians as well as a representative from the Maryland Council of Public Health Nurse Directors and a volunteer pharmacist from the community. Local health officers are responsible for obtaining the approval of the Committee on Nurse Dispensing for the formulary and for any changes or additions to the formulary.

Registered nurses who dispense drugs and devices in local health departments are expected to complete an approved training course that includes instructions in the following areas:

- Drugs and devices that can be dispensed under the Ruling;
- Steps in dispensing;
- Local health department dispensing policies and procedures;
- Storage, packaging, labeling and disposal of drugs and devices;
- Inventory;
- Drug interaction management;
- Patient consultation;
- Record keeping;
- Legal aspects of dispensing;
- Procedures for minimizing general medication errors; and
- Reviews of pharmacology, therapeutics and side effects of drugs on the approved formulary.

Shortly after issuance of the Declaratory Ruling, “Train the Trainer” sessions were

conducted to prepare nurses from local health departments to train other nurses in their facilities.

Local health officers or their designees are charged with the responsibility for maintaining the standards and procedures set forth in the Declaratory Ruling and for conducting an annual review of dispensing-related activities. They must also assure that adequate safeguards are in place to ensure:

- The confidentiality of patients' drug records;
- That no additional fee is charged for dispensing drugs or devices;
- That a licensed pharmacist is available for consultation; and,
- That up-to-date drug references are available to the registered nurses who dispense medications.

Nurses authorized to dispense medications under the Ruling must comply with a number of specific requirements enumerated in the policy document, which can be found in the Appendix.

ORIENTATION, EDUCATION, AND TRAINING OF STAFF

The Title X Program Guidelines Section 6.6 requires that:

X *Projects must provide for the orientation and in-service training of all project personnel.*

X *All project personnel should participate in continuing education related to their activities.*

X *Documentation of continuing education should be maintained.*

The following guidelines address these requirements:

1. Policy

All new family planning staff will complete a formal program orientation within three months of their employment. The orientation will include information on federal and state requirements, clinical and administrative responsibilities and ethical issues.

2. Goals

The basic goal of an orientation is to assist the new employee in acquiring the necessary knowledge and skills to effectively perform his/her job.

3. Standards/guidelines for family planning orientation programs

a. Each local program will identify a coordinator/advisor/mentor with overall responsibility for planning and supervising the orientation of each new staff member.

b. Each local program will have an indexed and tabbed orientation manual tailored to their specific departmental needs that includes at a minimum:

(1) Goals and objectives

(2) Substantive topics with detail in outline form

(3) Teaching methods and activities for each topic area

(4) Checklist form to be used by the new staff member and the coordinator to monitor progress

(5) Evaluation forms: one for the new staff member and one for

the coordinator.

c. A manual developed with funding from the Office of Population Affairs entitled **Orientation to Family Planning** is available from Development Systems, Inc. of Kansas City, Missouri. Copies of this orientation manual were made available by TRAINING 3 and sent free of charge to all Maryland State Family Planning clinics operating in 2004. Although they are no longer available free of charge, copies may be ordered from Development Systems from their website at www.devsys.org/html/main.html, or by phone at 816-561-5050.

d. The program will be logically ordered, evenly paced, and may vary in length from one to three months.

e. The program will include observation, observed practice, and return demonstration of all tasks and procedures.

f. The new staff member will accompany at least two clients through an entire clinic visit.

g. The checklist and orientation evaluation forms will be placed in the employee's personnel file.

h. Consultation and technical assistance for orientation is available from the CMCH central office staff and the regional nurse consultants.

i. Documentation of each staff member's completed orientation program should be in a location easily accessible for review during the Clinical and Administrative Site Review Process.

4. Continuing education and training

Agencies should have a written training/in-service policy for staff. Local policies for education and training should be reviewed and updated annually. Records must be maintained of all training events that each staff member has attended. The family planning supervisor should assure that all staff members are continuously updated on current family planning issues. Some specific training resources include the following:

a. All family planning staff are encouraged to attend the annual statewide CMCH Reproductive Health Update usually held in the Spring. It features nationally known speakers on family planning and related topics.

b. Family planning staff are also encouraged to take advantage of

CMCH and TRAINING 3 sponsored workshops on a variety of topics held in Maryland, the surrounding states and Washington D.C. They are scheduled throughout the year. Staff may be included on the TRAINING 3 mailing list by contacting TRAINING 3, Family Planning Council, Suite 1000, 260 South Broad Street, Philadelphia, PA 19102. The telephone number is 215-985-2600 and their FAX number is 215-732-1252. Information about TRAINING 3 can also be found on their website at www.training3info.org.

c. Local health departments and agencies under contract conduct frequent in-services and workshops. Information about speakers and topics is often shared with other programs at Regional Consultants and Nursing Staff Advisory Workgroup (RCANSAW) meetings.

d. CMCH staff and clinical consultants are available for technical assistance and training events.

QUALITY ASSURANCE – CUSTOMER SATISFACTION SURVEYS

The Title X Program Guidelines Section 10.4 requires that:

> *A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality assurance system should include…a process to elicit consumer feedback.*

The following guidelines address the requirements for establishment of a quality assurance process to obtain consumer feedback. Information about that part of the quality assurance system that examines the standards, facilities and performance of the program on a continuous basis, can be found in the section entitled **QUALITY ASSURANCE - THE MARYLAND STATE FAMILY PLANNING PROGRAM CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS (QA Site Review Process 072106)**

Two types of customer satisfaction survey are conducted in the Maryland State Family Planning Program: The Family Planning Report Card and the Internal Customer Satisfaction Survey.

The Family Planning Report Card

The Family Planning Report Card is the name given to a brief client satisfaction measure administered during a one-month period in family planning clinics at least annually, preferably semi-annually.

The Family Planning Report Card is distributed to providers and is also available in English and Spanish on the CMCH website. It is short (taking no more than 7-10 minutes to complete) and easy to read. All questions are simple and direct, and the format is designed with data processing in mind. Providers using the Family Planning Report Card are instructed that they may insert questions of local interest on the form following the questions that are standard for all facilities. In jurisdictions with significant populations of clients who speak neither English nor Spanish, providers should furnish translations in accordance with the DHMH Policy on Limited English Proficiency. Reports on findings from local customer satisfactions surveys are maintained with other quality assurance materials at sites and forwarded to CMCH annually. Insights gained through the surveys should inform quality improvement efforts.

Copies of the Family Planning Report Card can be found in Appendix and on the CMCH website at www.fha.state.md.us/mch (click on Family Planning and Reproductive Health, Family Planning Administrative Guidelines, Appendix.)

Customer Satisfaction Survey

Staff of the Maryland State Family Planning Program at CMCH manage the statewide program and provide a variety of clinical and administrative services to providers. One way in which CMCH staff are able to evaluate the effectiveness of those services is by inviting providers to respond to a survey designed especially for internal customers. The survey, which is brief and user-friendly, is posted periodically on the Internet on Survey Monkey. It is intended to be a confidential survey. The only identifying information that will be asked is the region of the State where the responder works. Results from the survey are evaluated and used to improve program quality and enhance communication. A copy of the internal Customer Satisfaction Survey can be found in the Appendix and on the CMCH website at www.fha.state.me.us/mch (click on Family Planning and Reproductive Health, Family Planning Administrative Guidelines, Appendix.)

QUALITY ASSURANCE – THE MARYLAND STATE FAMILY PLANNING PROGRAM CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

The Title X Program Guidelines Section 10.4 requires that:

> *A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality assurance system should include:*
>
> - *An established set of clinical, administrative, and programmatic standards by which conformity [is]… maintained;*
> - *A tracking system to identify clients in need of follow-up and/or continuing care;*
> - *Ongoing audits to determine conformity with agency protocols;*
> - *Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate any needed corrective action when deficiencies are noted;*
> - *Periodic review of medical protocols to insure maintenance of current standards of care;*
> - *A process to elicit consumer feedback; and*
> - *Ongoing and systematic documentation of quality assurance activities.*

The following guidelines address the requirements for establishment of a system that employs peer review and audits to examine the standards, facilities and performance of the program on a continuous basis. The requirement for developing a process to obtain consumer feedback is dealt with in the Section entitled **QUALITY ASSURANCE – CUSTOMER SATISFACTION SURVEYS**.

1. The Maryland State Family Planning Program Clinical and Administrative Site Review Process maintains a schedule of site reviews and medical record audits of all participating service sites. Each site receives an annual review, conducted either by one or more clinician consultants from the Center for Maternal and Child Health (CMCH) or by staff of the clinic or delegate agency itself. Standard forms that are periodically updated document all components of the process, which assesses compliance with state and federal regulations and quality client care standards. Contract facilities are reviewed annually by either CMCH or delegate agency staff. Schedules are generated at CMCH and copies of the written summary of each review are maintained both at the local site and at CMCH. When deficiencies are identified, follow-up, which may include ongoing monitoring in addition to corrective measures, involves both CMCH and local staff.

2. Depending on the type of family planning service site, the annual review may include a clinic site review (including physical inspection and review of administrative/clinical policies and procedures), chart review, and

observation of a client visit. In addition, medical record audits of specific topics or data elements, performed exclusively by CMCH reviewers, may be performed on a requested percentage of client records meeting identified audit criteria.

3. All local health departments and agencies under contract are expected to augment the Maryland State Family Planning Program Clinical and Administrative Site Review Process with locally developed, implemented and documented quality assurance activities. Such activities should be conducted regularly and provide opportunities for staff input. One staff member at each service site should be designated as the Quality Assurance Coordinator.

4. The Maryland State Family Planning Program Site Review Process Planning Team, chaired by the CMCH Chief Nurse Consultant for Family Planning and Reproductive Health or his/her designee, meets on a monthly basis to administer and oversee the operation and ongoing development of this quality assurance program. In addition, members of the Planning Team are available to provide Technical Assistance and consultation in meeting Quality Assurance Site Review Process requirements.

A full description of the Maryland State Family Planning Program Clinical and Administrative Site Review Process, along with copies of the forms, may be found in the Appendix.

RECORDS AND RECORDS MANAGEMENT

The Title X Program Guidelines Section 5.2 requires that:

> *No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual.*

The Title X Program Guidelines Section 10.3 requires that:

> *Projects must establish a medical record for every client who obtains clinical services. That record must be maintained in accordance with accepted medical standards and State laws with regard to record retention.*
>
> *The record must… contain reports of clinical findings, diagnostic and therapeutic orders, and documentation of continuing care, referral and follow-up. Client financial information should be kept separate from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.*
>
> *HIV information should be handled according to law, and kept separate whenever possible.*
>
> *Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite the continuity of care.*

The Title X Program Guidelines also establishes specific requirements for history-taking, physical assessments, laboratory testing and revisits, which are set forth in Section 8.3.

The following guidelines address these requirements:

1. The Maryland State Family Planning Program has developed medical record forms that are consistent with the requirements of Title X, the Health Information Portability and Accountability Act (HIPAA) and state and federal policies pertaining to the provision of services to individuals with limited English proficiency (LEP). Forms developed centrally for local use include the following:

    - FAMILY PLANNING INITIAL RECORD (DHMH 4398)
    - FAMILY PLANNING FLOW RECORD (DHMH 4399)
    - FAMILY PLANNING INTERVAL RECORD (DHMH 4400)
    - FAMILY PLANNING PLAN B EMERGENCY CONTRACEPTION

RECORD (DHMH 4522)
- PREGNANCY TESTING ENCOUNTER RECORD (DHMH 4648)
- FAMILY PLANNING COLPOSCOPY RECORD (DHMH1175)
- CHRONOLOGIC COLPOSCOPY FLOW RECORD (DHMH1176)

Copies of these forms may be found in the Appendix and are also located on the Center for Maternal and Child Health website at http://fha.state.md.us/mch/html/clinical_guidelines.cfm

Medical information should be maintained separately from financial information. If only one record is established per client, financial information should be filed in its own section, separate from medical information, and should under no circumstances affect the amount or quality of care received by the client.

HIV information should be kept separate to the extent possible.

2. Service providers may use alternate forms but the content of each form must equal the content of the corresponding DHMH form. The DHMH form may be modified for local use, although content may not be eliminated. Electronic versions of forms for local modification may be requested from the Medical Director or Chief Nurse Consultant for the Family Planning and Reproductive Health Program at (410) 767-6713.

3. Each clinic must maintain an accurate medical record for every client. The medical record should be legible, concise, cogent, and complete. All encounters should be recorded either on the FAMILY PLANNING INITIAL RECORD (DHMH 4398 or equivalent) or on the FAMILY PLANNING INTERVAL RECORD (DHMH 4400 or equivalent) or on a continuation sheet. All staff including non-medical personnel, should record every client encounter (including telephone calls), reason for encounter, and all instructions given and plans made. Each entry must be dated and signed. Black ballpoint pen should be used. **Family Planning staff should neither highlight nor underline any portion of the medical record.** Removable tags or stickers may be used to alert clinicians or other staff to the need to address a specific area of the record.

4. Medical records should be easily accessible at all times. A system should be in place that insures that if the record is not in a file cabinet it is easily located. As much as possible, medical records should be stored in a file cabinet unless the client is in the clinic session or a staff member is actively working on follow-up related to the client.

5. Medical records are confidential and the staff must safeguard record information against loss or use by unauthorized persons. Medical records should be securely locked in file cabinets or in a locked room at night.

6. Records should be tabbed for ease in recording and finding information. The usual sections for tabbing are the following:

   FAMILY PLANNING FLOW RECORD (DHMH 4399)
   History and Physical (DHMH 4398 and DHMH 4400)
   Nurses Notes (continuation notes or progress notes)
   Laboratory
   Consents
   Correspondence, e.g., past medical reports and releases of information
   Educational Flow Sheet (if providers wish to develop such a form for local use)

7. Chronological or reverse chronological order should be maintained for all additional pages or reports entered into the record over time. Items attached to particular pages of the record should be firmly secured using staples or tape, not paper clips.

8. In the laboratory section of the record there should be a clearly identified separate sheet for each type of laboratory test performed. Like tests should be grouped together, e.g. all gonorrhea tests listed together, all cytology tests listed together, all Chlamydia tests listed together. Laboratory slips should be filed in chronological or reverse chronological order within these test groups in the laboratory section of the record.

9. The *Local Health Departments Funding System Manual,* available on-line at www.dhmh.state.md.us/forms/sf_gacct.htm (LHDFundStstManual.doc Section 2211.02), states that "…records must be maintained for five years and until all audit requirements are met, unless a longer retention period is required by federal, state, or local requirements and then destroyed if no longer needed." In the case of local health department family planning records, a longer retention period is required. The Records Retention and Disposal Schedule (Schedule No. 1518) of the Department of General Services Records Management Division issued in 1993 states that local health department family planning case files should be retained for ten years after the last entry, then destroyed. It also states that records of children (under age 18) should be retained for ten years or until the client reaches age twenty-four, whichever is greater, then destroyed. Schedule No. 1519 is available from the Department of General Services Records Management Division at 410-799-1930.

10. Record retention in contract agencies is governed by the terms of the contract.

11. There must be a written policy for protection and release of records. Written consent of the client, or the responsible person acting on his or her behalf, is

required for the release of medical information, in accordance with state and federal law and regulation. Transferring medical records from one health department to another or between any other health care facilities can only be accomplished with the client's written consent. For additional information on this topic, please see the **CONFIDENTIALITY** section.

REFERRAL FOR PRIMARY CARE

1. Everyone receiving family planning services should be encouraged to have a primary care provider. All clients should be asked if they have a primary care provider and if so, this information should be recorded in the client's medical record. If a client does not have a provider, the client should be encouraged to obtain one and should be given appropriate referral information.

2. The Primary Adult Care (PAC) Program offers primary care services to individuals 19 and over with limited incomes. PAC replaces the Maryland Pharmacy Assistance Program (MPAP) and the Maryland Primary Care Program. All those who were enrolled in either the Maryland Primary Care Program or MPAP were automatically transferred to Primary Adult Care. Participants in the PAC program are enrolled in a Managed Care Organization (MCO) and are entitled to receive all family planning services except for sterilization. They may select any provider for family planning who participates in Medicaid. Clients wishing information about the PAC program may be advised to call 1-800-226-2142 or they may go to www.dhmh.state.md.us/mma/pac/index.htm on the Internet.

3. Clients enrolled in Medicaid's Maryland Family Planning Program (purple and white cardholders) who do not have a primary care provider must be referred for primary care services. Depending upon current income and age, some may be eligible for the Primary Adult Care (PAC) Program. To access information about PAC, find out if they meet the income guidelines and obtain application materials, clients may call 1-800-226-2142 or go to www.dhmh.state.md.us/mma/pac/index.htm. If they are eligible for the PAC Program and decide to join, they will have to give up their Medicaid Family Planning card and will subsequently not be eligible to receive a sterilization through the PAC Program.

4. All purple and white cardholders may access primary care services at Federally Qualified Health Centers (FQHC) or Maryland Qualified Health Centers (MQHC). If there is no health center available locally, the client should be referred to another resource for primary care services. All referrals must be documented. Counseling and/or written materials given to purple and white card holders should include information that will help them access primary care services and provide the location and phone number of the nearest health center or alternative resource.

6. Information about FQHCs, MQHCs and other resources for primary care services for low income and/or uninsured individuals and families can be found on-line at www.fha.state.md.us/ohpp/pco/html/mdhlthctrs.cfm .

REFERRALS AND FOLLOW-UP FOR LABORATORY AND/OR SPECIAL TESTS

The Title X Program Guidelines Section 7.4 requires that:

- *Agencies provide all family planning services [required by Title X] either on-site or by referral. When required services are to be provided by referral… [there must be] formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.*

- *Agencies must have written policies/procedures for follow-up on referrals that are made as a result of abnormal physical examination or laboratory test findings.*

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

    - *Make arrangements for the provision of pertinent client information to the referral provider… with appropriate safeguards for confidentiality;*
    - *Advise [the] client on their responsibility in complying with the referral; and*
    - *Counsel [the] client on the importance of such referral and the agreed upon method of follow-up.*

  [Local health departments and agencies under contract] are not responsible for the cost of this care.

- *Agencies must maintain a current list of health care providers, local health and human services departments, hospitals , voluntary agencies, and health services projects… to be used for referral purposes.*

The Title X Program Guidelines Section 8.3 requires that:

- *A procedure which addresses client confidentiality must be established to allow for client notification and adequate follow-up of abnormal laboratory results.*

The following guidelines address these requirements:

1. A tracking system must be maintained to ensure the appropriate submission of specimens and timely receipt of results.

2. During or after each clinic session the laboratory work completed and

special tests ordered should be recorded in the system. A designated staff person should check the system at regular intervals to see if laboratory results have been returned. The laboratory or medical center should be contacted for test reports or results that are overdue.

3. Specific recommendations written by laboratory personnel for action should be considered along with a thorough review of the record by the clinician. Interpretations or impressions written by laboratory personnel on lab slips should **not** be highlighted or underlined by the family planning staff.

4. Clinics may use a tickler box system, computer program or workbook to help follow up abnormal laboratory results and/or special referrals.

5. There is a standard, minimum follow-up procedure for notifying a client of abnormal results of any type, which is as follows:

   a. One or two telephone contacts are attempted.
   b. If telephone contact attempts are unsuccessful, a letter is sent.
   c. If there is no response to the letter, a certified letter requiring a returned receipt with the client's signature is sent. If the certified letter is returned "unclaimed," some agencies follow up with a home visit, although a visit is not required.

   The entire follow-up should be reasonably prompt with contact or resolution accomplished by one month. If the client does not respond in 7 to 10 days to any step in the process, the next step should be initiated. Careful documentation of all actions should be completed in the medical record.

   Confidentiality procedures must be strictly observed during the notification process. From the outset, the client's record should be flagged so that, should the client call or come into the clinic, all staff are aware that efforts to reach the client are in progress.

6. All follow-up of laboratory tests must be rigorously documented. The date that the test was done, the date the report was received and results of the test should be recorded in the client's medical record and in the laboratory log. If follow-up is necessary, the client should be contacted as described above, and documentation should be entered into the laboratory log or equivalent system, and into the medical record. A similar procedure must be initiated when abnormal mammogram results are received.

7. Local health departments and delegate agencies must have written referral and follow-up procedures. Referral resources should be evaluated and updated periodically. Referrals are most effectively completed with the use

of a printed referral form. The form is either mailed to the referral provider or given to the client to hand-carry to the new appointment.

8. The time and manner of referral and follow-up depend upon the nature of the problem for which the referral was made. For example:

   a. Emergency referrals (e.g., possible ectopic pregnancy) should be made immediately with the referral provider. Follow-up by the clinic staff and documentation of the outcome should occur within 24 to 48 hours.

   b. Urgent referrals (e.g., solitary breast nodule) should be followed up within six weeks with the client.

   c. Essential referrals (e.g., hypertension) should be followed up with the client, the timing to depend on professional judgment.

   d. Discretionary referrals (made at the request of the client) should be followed up with the client at the next clinic visit.

9. Certain lab results must be reported electronically to the Family Planning and Reproductive Health data system contractor, Ahlers and Associates, in a timely fashion to be included in Maryland's federal Family Planning Annual Report (FPAR).

RESEARCH PROJECTS AND PUBLICATIONS

The Title X Program Guidelines Section 5.5 requires that:

> *Grantees considering clinical or sociological research using Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable.*
>
> *Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources in any segment of the project.*

The Title X Program Guidelines Section 6.10 requires that:

> *Grantees should ensure that publications developed under Title X do not contain information which is contrary to program requirements or to accepted clinical practice.*

The following guidelines address these requirements:

1. All DHMH facilities must comply with DHMH requirements for research. Information on DHMH requirements can be found at http://www.dhmh.state.md.us/oig/irb.

2. Local health departments and contract agencies must send written notification of any planned research activities to the Chief, Family Planning and Reproductive Health or his/her designee at CMCH prior to the initiation of such activities. This notification must include the following:

    a. A description of the project, including plans to comply with legal requirements pertaining to human subjects of research, especially the method for obtaining informed consent;
    b. Documentation of approval by an Institutional Review Board (IRB); and/or
    c. Indication of when the researcher(s) plan to submit an application to the DHMH IRB. All applications to the DHMH IRB must be processed through the Center for Maternal and Child Health. Application instructions and forms may be downloaded from the website referenced in 1, above.

3. The Chief, Family Planning and Reproductive Health will inform the federal Region III office in Philadelphia in writing of all planned research with IRB approval.

4. Information concerning rights of people who participate in research and federal regulations on using humans in medical or behavioral research may be obtained by calling 1-866-447-4777 or by writing:

Office for Human Research Protections (OHRP)
1101 Wootton Pkwy. Room 200
Rockville, MD 20852

Current information about ethical issues and research with human participants is also available from OHRP on the Internet at Http://www.hhs.gov/ohrp.

5. Any provider planning to publish materials based upon activities conducted under funding from the Center for Maternal and Child Health should contact the Chief, Family Planning and Reproductive Health or his/her designee to ensure that the publication complies with all relevant federal and DHMH requirements.

RESOURCES

The Maryland State Family Planning Program is part of a network of public and private non-profit programs serving and advocating for individuals in need of access to low or no-cost health care. Clients benefit when the connections among programs function to educate, inform and enlarge the pool of resources available to providers.

When providers reproduce and distribute materials found on the Internet or otherwise obtained from outside sources, it is important that they observe copyright restrictions. Also, when materials are reproduced for distribution to clients, they should be submitted to the local Informational and Educational (I&E) Review Committee for approval.

The following list of resources, although not exhaustive, includes organizations and programs that have proven to be of value to members of the public health community.

Name	**Phone Number**	**Website**
Maryland Center for Maternal and Child Health	410-767-6713	www.fha.state.md.us/mch
Maryland Pregnancy Risk Assessment Monitoring System (PRAMS)	410-767-6713	http://www.fha.state.md.us/mch/prams/index.cfm
Maryland Emergency Contraception website	1-877-994-6432	www.plannedparenthoodmd.org (click on Emergency Contraception)
Maryland Department of Human Resources – Child Protective Services	410-767-7112	www.dhr.state.md.us/cps
Maryland Medicaid Family Planning Program	1-800-456-8900	www.dhmh.state.md.us/mma/mchp
Center for Medicaid and	1-877-486-2048	www.cms.hhs.gov

Name	Phone Number	Website
Medicare Services (CMS)		
Office of Population Affairs (OPA) Office of Family Planning	240-453-8822	http://opa.osophs.dhhs.gov/grants.html
OPA Clearinghouse	1-866-640-7827	http://opa.osophs.dhhs.gov/clearinghouse.html
Centers for Disease Control	1-800-311-3435	www.cdc.gov
Guttmacher Institute	212–248-1111, or 202–296-4012	www.guttmacher.org
Kaiser Family Foundation	Headquarters: 650-854-9400 Wash. D.C. Office 202-347-5270	www.kff.org
American College of Obstetricians and Gynecologists	202-638-5577	www.acog.org
American Medical Women's Association	1-800-995-AMWA	www.amwa-doc.org
Managing Contraception	770-887-8383	www.managingcontraception.com
National Family Planning and Reproductive Health Association (NFPRHA)	202-293-3114	www.nfprha.org
Office for Victims of Crime Resource Center U.S. Department of	1-800-627-6872	www.ojp.usdoj.gov/ovc

Name	Phone Number	Website
Justice		
National Sexual Violence Resource Center	1-877-739-3895	www.nsvrc.org
Maryland Coalition Against Sexual Assault (MCASA)	410-974-4507 1-800-983-RAPE	www.mcasa.org
Maryland Network Against Domestic Violence (MNADV)	1-800-MDHELPS	www.mnadv.org
University of Washington information on medical care for those from other cultures	206-598-7498	http://depts.washington.edu/pfes/cultureclues.html
Health and Health Care in Schools	202-466-3396	www.healthinschools.org
Agency for Healthcare Research and Quality	301-427-1364	www.ahrq.gov
Agency for Health Care Policy and Research	301-427-1364	http://www.ahrq.gov/consumer/
U.S. Census	301-763-6440	www.census.gov
Promising Practices Network	301-393-0411 ext.7172	www.promisingpractices.net
National Campaign to Prevent Teen Pregnancy	202-478-8500	www.teenpregnancy.org

Name	Phone Number	Website
Planned Parenthood Federation of America (PPFA)	1-800-230-PLAN 1-800-230-7256 (medical questions)	www.ppfa.org
Federal Grants Forms Download	202-619-0257	http://www.hhs.gov/forms/
State Family Planning Administrators (SFPA)	202-293-2114	www.sfpainfo.org
The Urban Institute	202-833-7200	www.urban.org
Sexuality Information and Education Council of the U.S. (SEICUS)	732-445-7929	www.siecus.org
Association of Reproductive Health Professionals (ARHP)	202-466-3825	www.arhp.org
American Public Health Association (APHA)	202-777-2534	www.apha.org
National Center for Education in Maternal and Child Health	202-784-9770	www.ncemch.org
Child Trends	202-572-6000	www.childtrends.org
Kids Count	410-547-6600	http://www.kidscount.org/sld/databook.jsp
OPA Abstinence website		www.4parents.gov
Cyclebeads	1-877-290-5399	www.cyclebeads.com
Office of Minority Health Resource Center	1-800-444-6472	www.omhrc.gov
Sex, ETC.	732-445-7929	www.sxetc.org

Name	Phone Number	Website
(teen newsletter of the Network for Family Life Education)		
Sexuality and You website	N/A	http://www.sexualityandu.ca/home_e.aspx
Center for Law and Social Policy (CLASP)	202-906-8000	www.clasp.org
Healthy Teen Network)	1-202-547-8814	http://www.healthyteennetwork.org/
New York Online Access to Health (NOAH)	N/A	www.noah-health.org
The National Center for Cultural Competence (NCCC)	1-800-788-2066 or 202-687-5387	http://gucdc.georgetown.edu
National Council on Interpreting in Health Care (NCIHC)	Fax 707-541-0437	www.ncihc.org
SPIRAL: website for health information in Asian languages	1-800-338-7657	http://spiral.tufts.edu
Foreign-born Information and Referral Network (FIRN)	410-992-1923 1-888-399-3476	www.firnonline.org/
National Council for Adoption	703-299-6633	http://www.adoptioncouncil.org/
Preventing Perinatal HIV Transmission – A Clinician's	Elisabeth Liebow, MPH 410-887-3134	www.baltimorecountymd.gov/go/perinatal

Name	Phone Number	Website
Toolkit		
Medical Management of HIV Infection – Dr. John Bartlett	A more recent edition of this book may be available from the publisher. Periodically the Web site is updated to the most recent edition.	www.bartletthiv.org

SERVICES FOR CLIENTS WITH LIMITED ENGLISH PROFICIENCY (LEP)

The Title X Program Guidelines Section 6.5 requires that:

> *Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to and able to deal effectively with the cultural and other characteristics of the client population.*

The Title X Family Planning Annual Report: Forms and Instructions - Effective January 2005 defines the following terms used in collecting data about client demographics and services:

- *Limited English Proficiency (LEP) – Refers to clients whose native or dominant language is not English and whose skills in listening to, speaking, reading, or writing English are such that they derive little benefit from family planning and related preventive health services provided in English.*

- *English Proficiency – Refers to an individual's adeptness at English, as indicated by reading skills (the ability to comprehend and interpret text); listening skills (the ability to understand verbal expressions of the language); writing skills (the ability to produce written text with content and format); and speaking skills (the ability to use oral language appropriately and effectively).*

- *Native Language – Refers to the language or dialect first learned by an individual or first used by the parent/guardian with a child. The terms "native" and "primary" language are used interchangeably.*

- *Dominant Language – Refers to the language or dialect an individual best understands and with which he or she is most comfortable. A person may be dominant in one language in some situations and dominant in another language in other situations.*

- *Interpreter Competence – Competency to interpret does not necessarily mean formal certification as an interpreter, although certification is helpful. To be considered competent, interpreters must:*
    - *Demonstrate proficiency in and ability to communicate information accurately in both English and in the other language, and identify and employ the appropriate mode of interpreting;*
    - *Have knowledge in both languages of any specialized family planning or reproductive health terms or concepts, and of any particularized vocabulary and phraseology used in the LEP person's country of origin;*
    - *Understand and follow confidentiality and impartiality rules to the same extent as the recipient employee for whom they are interpreting and/or to the extent their position requires; and*

- *Understand and adhere to their role as interpreter without deviating into other roles—such as counselor or legal advisor—where such deviation would be inappropriate.*

Family planning providers are required to serve individuals with limited English proficiency (LEP) in a manner that is sensitive to cultural and linguistic differences. In order to ensure that Title X grantees and delegate agencies are familiar with federal requirements for serving LEP persons, the Office of Population Affairs (OPA) included copies of Health and Human Services (HHS) LEP policy documents in Appendix 7 of the *Title X Family Planning Annual Report: Forms and Instructions – Effective January 2005*. They are also available on-line as follows:

- *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (http://www.hhs.gov/ocr/lep/lep_guidance080403.pdf).*
- *HHS Provides Written Guidance for Health and Human Services Providers to Ensure Language Assistance for Persons with Limited English Skills (http://www.hhs.gov/ocr/lep/press.html).*

In accordance with federal and state law, the Maryland Department of Health and Mental Hygiene (DHMH) has issued LEP requirements for providers of family planning and other public health services funded by the Department. DHMH Policy 02.06.07 on Equal access to DHMH Services by Individuals with Limited English Proficiency can be found in the Appendix and on-line at http://www.dhmh.state.md.us/policies/pdf/020607-sof.pdf . In addition to requiring that services to an LEP person be provided with the assistance of an appropriately trained interpreter, the policy states that certain "'vital documents' [must] be translated into any language spoken by a LEP group that constitutes 3% of the overall population within a specified geographic area under specified circumstances." "Vital Documents" are defined as those "that individuals applying for services or benefits from a covered entity must understand, respond to or complete in order to access the services/benefits or continue to receive the services or benefits…[and] that inform the participant of his/her rights…"

Each provider agency should have a written policy for providing services to clients who do not speak English. It is difficult for a clinician or a nurse to provide medical or nursing services without the assistance of an adequate interpreter. Ideally, a professional medical interpreter will be made available on site to provide interpretation services. The service provider may hire a professional interpreter or may utilize a trained volunteer interpreter. Alternatively, a bi-lingual clinic staff member who is appropriately trained may be used as an interpreter for the client. If these options are not possible, the clinic may want to utilize services available through a series of State of Maryland contracts.

All state, county and municipal governments and other agencies receiving state funds may procure services from the following contractors:

Lionbridge Global Solutions II, Inc.: **BPO #050B7800036**
PRIMARY CONTRACTOR: Onsite Interpretation Services

Schreiber Translations, Inc.: **BPO #050B7800035**
PRIMARY CONTRACTOR: Written Document Translation Services

CTS LanguageLink: **BPO #050B7800015**
PRIMARY CONTRACTOR: Telephonic Interpretation Services
SECONDARY CONTRACTOR: Onsite Interpretation Services; *and*
Written Document Translation Services

Additional information about onsite interpretation, telephonic interpretation and written document translation can be found at the following Web site and in the Appendix:

http://dbm.maryland.gov/dbm_publishing/public_content/dbm_search/procurement/using_language_int_svcs/language_interpretation_contacts.html .

A family member or friend of a client is not considered an ideal interpreter due to the sensitive nature of the health care being provided and because the clinic has no way to assure that the family member or friend is qualified to interpret medical information. Such an individual should only be used when the LEP person requests it and when it is concluded that the use of that family member or friend would not detract from the effectiveness of the services provided. Whenever an LEP person asks to use his or her own interpreter, it should be noted in the medical record.

SERVICES FOR CLIENTS WITH SPECIAL NEEDS

The Title X Program Guidelines Section 6.4 requires that:

> *Projects must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap in Federally assisted programs and activities, and which requires [that] they are readily accessible to people with disabilities…Projects must also comply with any applicable provisions of the Americans With Disabilities Act (Public Law 101-336).*

1. All local health departments and contract agencies should have a written policy and plan pertaining to services for disabled clients. The plan should include information on referral to the closest facility offering the necessary accommodation when a clinic cannot serve a particular individual for any reason. At a minimum, the plan should address service delivery to the following clients:

    a. Clients who are wheelchair dependant or who have any special needs due to physical disability.
    b. Clients who are hearing impaired: Clinics should make an effort to provide interpreters who know sign language. Another source of help may be the Maryland Relay Service (MRS), which is a telephone service that gives people with hearing and/or speech impairments the ability to communicate by telephone. The number is 1-800-735-2258. There is no additional fee for local calls and long distance calls are billed at reduced rates. For more information call the Customer Service Center at 1-800-676-3777 or the Maryland Department of Budget and Management Telecommunications Access of Maryland at 1-800-552-7724.

2. Questions about services for the disabled may be addressed to the DHMH Office of Equal Opportunity Programs (OEOP) OEOP information may be found on-line at http://dhmh.state.md.us/oeop/ or by calling 410-767-6600.

STERILIZATION

The Title X Program Guidelines Section 8.4 requires that:

- *The counseling and consent process must assure that the client's decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures.*

- *Federal sterilization regulations, which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project. (Appendix A)*

Clinical guidance on sterilization for males and for females can be found in the *Maryland Family Planning Clinical Guidelines – 2005* (*http://www.fha.state.md.us/mch/html/clinical_guidelines.cfm*). The guidance that follows pertains to the process of counseling and referring the client, obtaining informed consent where appropriate, processing the consent form and assisting in scheduling the procedure.

VASECTOMY

Since 1994, the Maryland Family Planning Program has funded vasectomy procedures for a limited number of Maryland men aged 21 or older who desire this method of contraception but cannot afford it. The procedures are performed at the Planned Parenthood of Maryland Towson Clinic. Counseling and consent, which must be completed at least 30 days prior to the procedure, may be provided either at the Towson facility or at any other Maryland State Family Planning Program clinic site.

To obtain information about vasectomy services offered by Planned Parenthood of Maryland and funded by the Maryland State Family Planning Program, go to www.plannedparenthoodmd.org on the Internet or call the Towson facility at 410-665-9775.

Counseling

The client may receive vasectomy counseling at any local Maryland State Family Planning Program clinic or from the staff at Planned Parenthood of Maryland at Towson where the procedure will be performed. When the counseling is performed locally, the prospective vasectomy patient signs the consent form at the conclusion of the session and hand-carries the original to the Towson clinic on the day of the procedure.

Patient education tools may be used in order to assist with vasectomy counseling. Planned Parenthood of Maryland publishes a brochure describing the procedure

and what patients may expect following the surgery. To request copies of the brochure, call the Towson clinic at the number provided above. The Office of Population Affairs (OPA) Clearinghouse also offers educational brochures in English and Spanish free of charge. Clearinghouse publications and other materials, including Information for Men - Your Sterilization Operation and Información para el Hombre sobre la Operación para la Esterilización, may be downloaded from the website at http://opa.osophs.dhhs.gov/pubs/publications.html. You may also order up to 20 hard copies free of charge through the website or by calling the Clearinghouse at 866-640-7827.

Vasectomy counseling will include information about the "no-scalpel" procedure, advantages, disadvantages, permanency, the availability of other contraceptive options for the client and his partner and the post-operative semen analysis.

Consent

The Federal Sterilization Consent (OMB 0937-0166) must be used when a client chooses sterilization through the Maryland State Family Planning Program partnership with Planned Parenthood of Maryland. It is available in English or Spanish for download or to order from the OPA Clearinghouse according to the instructions provided above. It must be signed by the client and witnessed by staff. If the client signed the consent at a local clinic, he must bring the original with him to Planned Parenthood's Towson facility on the day of the procedure.

It is important to remember that vasectomies funded through federal government programs such as the Title X program and Medicaid or Medicare require that there be a **30**-day waiting period between the date the consent was signed and the date of the vasectomy. Once signed, the consent form is effective for **180** days from the date of the signature.

Scheduling the Appointment

The client himself must call Planned Parenthood of Maryland at Towson to schedule his appointment. During this phone call, a short interview will be conducted to screen for the presence of contraindications to surgery. The client will have the option to receive his pre-op physical at any one of the 8 sites of Planned Parenthood of Maryland listed below or on the day of surgery. The pre-op physical fee is on a sliding fee scale.

Release of Medical Information

If the local provider wants vasectomy information returned, the provider must forward a release of information form signed by the client to Planned Parenthood of Maryland. The INDIVIDUAL'S AUTHORIZATION form which can be found by staff of local health departments on the DHMH Intranet at http://indhmh/hipaa/html/guideandforms.html or an alternative HIPAA-compliant

release form is acceptable.

Financial Eligibility Determination

The contact person at Planned Parenthood of Maryland will explain the fee assessment eligibility process when the client calls to make the vasectomy appointment. The fee schedule utilized for vasectomy is a sliding fee scale that is approved by the Maryland Department of Health and Mental Hygiene.

TUBAL LIGATION REFERRAL

The Maryland State Family Planning Program does not fund tubal ligation surgeries. However, clients seeking information about sterilization should be counseled by staff regarding the advantages and disadvantages of tubal ligation, its permanency, and the availability of other contraceptive options. Patient education tools may be used in order to assist with tubal ligation counseling. The Office of Population Affairs (OPA) Clearinghouse offers the following brochure on female sterilization: Information for Women - Your Sterilization Operation (in Spanish, Información para la Mujer sobre la Operatión para la Esterilización.) It can be downloaded from the Office of Population Affairs website at http://opa.osophs.dhhs.gov/pubs/publications.html. You may also order up to 20 hard copies free of charge through the website or by calling the Clearinghouse at 1-866-640-7827.

Clinics should have a current list of local providers for referral. Women who are in the Maryland Medical Assistance Family Planning (Purple and White Card) Program are eligible for tubal ligation if they are 21 years or older. The women can choose any doctor or clinic that accepts Medical Assistance. The telephone number to obtain information about providers who accept Medical Assistance is 1-800-456-8900. Women in the Primary Adult Care (PAC) program are not eligible for tubal ligation.

SUPPLIES AND PURCHASING

The Title X Program Guidelines Section 10.2 requires that:

> *Agencies must be operated in accordance with Federal and State laws relating to security and record keeping for drugs and devices. Inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice patterns.*
>
> *It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients.*

The following guidelines address these requirements:

1. Each family planning clinic must offer all approved methods of family planning either directly or through referral.

2. It is essential that adequate supplies of a wide range of approved contraceptive methods be kept at each clinic site.

3. All Maryland State Family Planning providers are eligible to purchase contraceptives and related supplies under the 340B Public Health Pricing Program operated by the Office of Pharmacy Affairs (OPA) at the Health Resources and Services Administration (HRSA), US Department of Health and Human Services (HHS). Enrollment in the 340B Program enables providers to purchase contraceptive supplies and related medications at designated public health prices. Whenever a provider joins or leaves the Maryland State Family Planning Program, the Chief, Family Planning and Reproductive Health or his/her designee at CMCH notifies OPA. At the beginning of each quarter, OPA updates the 340B List, using information gathered from grantees during the previous 90 days. Pharmaceutical companies and distributors consult the list, which appears on the OPA website at http://www.hrsa.gov/opa In addition to the 340 B PHS prices, clinic managers should understand that some contraceptives (e.g., NuvaRing and Implanon) can only be ordered at the 340 B price through the 340 B Prime Vendor Program. In order to join the Prime Vendor Program, a clinic must be a member of the 340 B Program and take an extra step to sign up for the 340 B Prime Vendor Program. Information about this program can be found at www.340Bpvp.org

4. Widely used contraceptives and related medications and materials can be ordered by local health departments at reduced prices through state-solicited contracts. Most state contracts are solicited and awarded annually, although new contracts may be added periodically during the year as the need arises. Local department fiscal offices or purchasing departments have access to

information about current contracts including the names of products that are available, contract numbers, unit costs, names and addresses of suppliers and contract expiration dates (http://dgsweb.dgs.state.md.us/activeBPO/comm_medequip.html .) Some contracts specify a minimum amount for an order. Ordering and paying for supplies is the responsibility of the family planning program in each individual jurisdiction. Health department programs may also order outside of these contracts, if desired, as long as the supplies are approved family planning items. Note: The Cardinal Distribution Contract with the State of Maryland is called the Prime Vendor Pharmaceutical Contract. This is not the same as the 340 B Prime Vendor Program with HealthCare Purchasing Partners International (HPPI).

Contract providers may find it useful to participate in purchasing cooperatives such as the California Pharmaceutical Purchasing Cooperative. Information about such cooperatives can be found on the Internet.

5. Funding permitting, CMCH staff are sometimes able to make stocks of certain contraceptive supplies available at no cost to providers. When clinics use these supplies, it is essential that they be furnished to clients free of charge.

6. There must be written inventory control procedures for clinic supplies and pharmaceutical materials. There should be a designated person responsible for maintaining current documentation on supplies.

Voluntary Participation

The Title X Program Guidelines Section 5.1 requires that:

Use by any individual of project services must be solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use or not to use any particular method of family planning. Acceptance of services must not be a prerequisite to eligibility for, or receipt of, any other service or assistance from or participation in any other programs…

Project personnel 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.

As part of the orientation received prior to assuming their duties in the facility, all family planning staff members employed by local health departments and contract agencies must be informed of Title X requirements pertaining to voluntary participation. Managers and supervisors should ensure that all individuals working in the family planning setting have an opportunity to read and discuss materials on this subject. A statement acknowledging the staff member's awareness and understanding of the voluntary participation policy should be maintained in his or her personnel file. This Voluntary Participation Policy Acknowledgement form, found in the Appendix, or a similar document may be used for this purpose.

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Appendix A

Program Guidelines
For Project Grants
For Family Planning Services

Program Guidelines For Project Grants For Family Planning Services

United States Department of Health and Human Services
Office of Public Health and Science
Office of Population Affairs
Office of Family Planning
4350 East West Highway, Suite 200
Bethesda, Maryland 20814

January 2001

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Attachments

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Resource Documents

PART I

1.0 Introduction to the Program Guidelines

This document, *Program Guidelines for Project Grants for Family Planning Services (*Guidelines), has been developed by the Office of Population Affairs (OPA), U.S. Department of Health and Human Services (DHHS), to assist current and prospective grantees in understanding and utilizing the family planning services grants program authorized by Title X of the Public Health Service Act, 42 U.S.C. 300, et seq. The Office of Population Affairs also provides more detailed guidance, updated clinical information and clarification of specific program issues in the form of periodic Program Instructions to the Regional Offices.

This document is organized into two parts. Part I (sections 1-6) covers project management and administration, including the grant application and award process. Part II (sections 7-11) covers client services and clinic management.

Reference is made throughout the document to specific sections of the Title X law and implementing regulations, which are contained in *Attachments A and B,* respectively. (Reference to specific sections of the regulations will appear in brackets, e.g., [45 CFR Part 74, Subpart C].) Federal sterilization regulations are contained in *Attachment C.* The DHHS regional offices are listed in *Attachment D.* Selected other materials that provide additional guidance in specific areas are classified as *Resource Documents.*

1.1 DEFINITIONS

Throughout this document, the word "must" indicates *mandatory* program policy. "Should" indicates *recommended* program policy relating to components of family planning and project management that the project is urged to utilize in order to fulfill the intent of Title X. The words "can" and "may" indicate suggestions for consideration by individual projects.

The "grantee" is the entity that receives a Federal grant and assumes legal and financial responsibility and accountability for the awarded funds and for the performance of the activities approved for funding. The "project" consists of those activities described in the grant application and supported under the approved budget. "Delegate/contract agencies" are those entities that provide family planning services with Title X funds under a negotiated, written agreement with a grantee. "Service sites" are those locations where services actually are provided by the grantee or delegate/contract agency.

2.0 The Law, Regulations, and Guidelines

To enable persons who want to obtain family planning care to have access to such services, Congress enacted the Family Planning Services and Population Research Act of 1970 (Public Law 91-572), which added Title X, "Population Research and Voluntary Family Planning Programs" to the Public Health Service Act. Section 1001 of the Act (as amended) authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)" (*see Attachment A*). The mission of Title X is to provide individuals the information and means to exercise personal choice in determining the number and spacing of their children.

The regulations governing Title X [42 CFR Part 59, Subpart A] set out the requirements of the Secretary, Department of Health and Human Services, for the provision of family planning services funded under Title X and implement the statute as authorized under Section 1001 of the Public Health Service Act. Prospective applicants and grantees should refer to the regulations (*see Attachment B*). This document, *Program Guidelines for Project Grants for Family Planning Services*, interprets the law and regulations in operational terms and provides a general orientation to the Federal perspective on family planning.

3.0 The Application Process

3.1 ELIGIBILITY

Any public or nonprofit private entity located in a state (which, by definition, includes the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands [Midway, Wake, et al.], the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services project grant [59.2, 59.3].

To promote the purposes of Section 1001 of the Act in the most cost effective and efficient manner, grants will be made to public and non-profit private entities to foster projects most responsive to local needs. A non-profit private agency, institution, or organization must furnish evidence of its non-profit status in accordance with instructions accompanying the project grant application form. Under the law, grants cannot be made to entities that propose to offer only a single method or an unduly limited number of family planning methods. A facility or entity offering a single method can receive assistance under Title X by participating as a delegate/contract agency in an approvable project that offers a broad range of acceptable and effective medically approved family planning methods and services [59.5(a)(1)].

3.2 NEEDS ASSESSMENT

An assessment of the need for family planning services must be conducted prior to applying for a competitive grant award. The needs assessment documents the need for family planning services for persons in the service area and should include:

- Description of the geographic area including a discussion of potential geographic, topographic, and other related barriers to service;
- Demographic description of the service area including objective data pertaining to individuals in need of family planning services, maternal and infant morbidity/mortality rates, birth rates and rates of unintended pregnancies by age groups, poverty status of the populations to be served, cultural and linguistic barriers to services, etc.;
- Description of existing services and need for additional family planning services to meet community/cultural needs;
- Need indicators that include rates of STDs and HIV prevalence (including perinatal infection rates) in the grantee area;
- Identification and descriptions of linkages with other resources related to reproductive health; and
- Identification and discussion of high priority populations and target areas.

Grantees should perform periodic reassessment of service needs. Competitive grant applications must include a full and updated needs assessment.

3.3 THE APPLICATION

The Department of Health and Human Services' Office of Population Affairs administers the Title X Family Planning Program through the DHHS Regional Offices. An annual announcement of the availability of Title X service grant funds sets forth specific application requirements and evaluation criteria. Applications must be submitted to the Office of Grants Management for Family Planning Services on the form required by the Department. The application forms are available from the Office of Grants Management for Family Planning Services. Assistance regarding programmatic aspects of proposal preparation is available from the Regional Office. For assistance with administrative and budgeting aspects of proposal preparation, contact the Office of Grants Management for Family Planning Services.

Unless otherwise instructed, applicants are to respond to the standard instructions contained in the application kit and to the PHS supplemental instructions. An application must contain:

- a needs assessment
- a narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the requirements of the law and regulations;
- a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested [59.4(c)(2)] and which is consistent with the terms of Section 1006 of the Act, as implemented by regulation [59.7(b)];
- a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project;
- project objectives that are specific, realistic, and measurable; and
- other pertinent information as required [59.4(c)(4)].

The application must address all points contained in section 59.7(a) of the regulations, which are the criteria DHHS Regional Offices will use to decide which family planning projects to fund and in what amount. The application shall not include activities that cannot be funded under Title X, such as abortion, fundraising, or lobbying activities.

3.4 PROJECT REQUIREMENTS

Projects must adhere to:

- Section 59.5 and all other applicable provisions of the regulations, which list the requirements to be met by each project supported by Title X.
- The applicable requirements of these *Program Guidelines for Project Grants for Family Planning Services.*
- Other Federal regulations which apply to grants made under Title X [59.10]. For assistance in identifying other relevant regulations, contact the Regional Office.

3.5 NOTICE OF GRANT AWARD

The notice of grant award will inform the grantee how long DHHS intends to support the project without requiring it to recompete for funds [59.8]. This period of funding is called the "project period." The project will be funded in increments called "budget periods." The budget period is normally twelve months, although shorter or longer budget periods may be established for compelling administrative or programmatic reasons.

4.0 Grant Administration

All grantees must comply with the applicable legislative, regulatory and administrative requirements described in the *Public Health Service Grants Policy Statement*. A copy of the *Public Health Service Grants Policy Statement* may be obtained from the Office of Grants Management for Family Planning Services.

5.0 Legal Issues

5.1 VOLUNTARY PARTICIPATION

Use by any individual of project services must be solely on a voluntary basis. Individuals must not be subjected to coercion to receive services or to use or not to use any particular method of family planning. Acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other service or assistance from or participation in any other programs of the applicant [59.5(a)(2)].

Project personnel 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.

5.2 CONFIDENTIALITY

Every project must assure client confidentiality and provide safeguards for individuals against the invasion of personal privacy, as required by the Privacy Act. No information obtained by the project staff about individuals receiving services may be disclosed without the individual's written consent, except as required by law or as necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual [59.11].

5.3 CONFLICT OF INTEREST

Grantees must establish policies to prevent employees, consultants, or members of governing or advisory bodies from using their positions for purposes of private gain for themselves or for others.

5.4 LIABILITY COVERAGE

Grantees and/or delegates/contractors should ensure the existence of adequate liability coverage for all segments of the project funded under the grant, including all individuals providing services. Governing boards should obtain liability coverage for their members.

5.5 HUMAN SUBJECTS CLEARANCE (RESEARCH)

Grantees considering clinical or sociological research using Title X clients as subjects must adhere to the legal requirements governing human subjects research at 45 CFR Part 46, as applicable. A copy of these regulations may be obtained from the Regional Office. Grantees must advise the Regional Office in writing of research projects involving Title X clients or resources in any segment of the project.

6.0 Project Management

6.1 STRUCTURE OF THE GRANTEE

Family planning services under Title X grant authority may be offered by grantees directly and/or by delegate/contract agencies operating under the umbrella of the grantee. However, the grantee is responsible for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided by delegate/contract agencies. Grantees must therefore have a negotiated, written agreement with each delegate/contract agency and establish written standards and guidelines for all delegated project activities consistent with the appropriate section(s) of the *Program Guidelines for Project Grants for Family Planning Services,* as well as other applicable requirements such as Subpart C of 45 CFR Part 74, or Subpart C of 45 CFR Part 92. If a delegate/contract agency wishes to subcontract any of its responsibilities or services, a written negotiated agreement that is consistent with Title X requirements and approved by the grantee must be maintained by the delegate/contractor. Delegate/contract agencies should be invited to participate in the establishment of grantee standards and guidelines.

6.2 PLANNING AND EVALUATION

All projects receiving Title X funds must provide services of high quality and be competently and efficiently administered. To meet these requirements, each competitive application must include a plan which identifies overall goals and specific measurable objectives for the project period. The objectives may be directed to all clients or to specific groups of clients and must be consistent with Title X objectives. The plan must include an evaluation component that addresses and defines indicators by which the project intends to evaluate itself.

6.3 FINANCIAL MANAGEMENT

Grantees must maintain a financial management system that meets the standards specified in Subpart C of 45 CFR Part 74 or Subpart C of 45 CFR Part 92, as applicable, as well as any other requirements imposed by the Notice of Grant Award, and which complies with Federal standards to safeguard the use of funds. Documentation and records of all income and expenditures must be maintained as required.

! Charges, Billing, and Collections

A grantee is responsible for the implementation of policies and procedures for charging, billing, and collecting funds for the services provided by the project. The policies and procedures should be approved by the governing authority or board of the grantee and the Regional Office.

Clients must not be denied project services or be subjected to any variation in quality of services because of the inability to pay. Billing and collection procedures must have the following characteristics:

(1) Charges must be based on a cost analysis of all services provided by the project. At the time of services, clients who are responsible for paying any fee for their services must be given bills directly. In cases where a third party is responsible, bills must be submitted to that party.

(2) A schedule of discounts must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. A schedule of discounts is required for individuals with family incomes between 101% and 250% of the Federal poverty level. Fees must be waived for individuals with family incomes above this amount who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.

(3) Clients whose documented income is at or below 100% of the Federal poverty

level must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services.

(4) Individual eligibility for a discount must be documented in the client's financial record.

(5) Bills to third parties must show total charges without applying any discount.

(6) Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement with the Title XIX or the Title XX state agency at either the grantee level or delegate/contract agency level is required.

(7) Bills to clients must show total charges less any allowable discounts.

(8) Eligibility for discounts for minors who receive confidential services must be based on the income of the minor.

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

(10) A method for the "aging" of outstanding accounts must be established.

(11) Voluntary donations from clients are permissible. However, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements set out above.

(12) Client income should be re-evaluated at least annually.

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

! Financial Audit

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

6.4 FACILITIES AND ACCESSIBILITY OF SERVICES

Facilities in which project services are provided should be geographically accessible to the population served and should be available at times convenient to those seeking services, i.e., they should have evening and/or weekend hours in addition to daytime hours. The facilities should be adequate to provide the necessary services and should be designed to ensure comfort and privacy for clients and to expedite the work of the staff. Facilities must meet applicable standards established by the Federal, state and local governments (e.g., local fire, building and licensing codes).

Projects must comply with 45 CFR Part 84, which prohibits discrimination on the basis of handicap in Federally assisted programs and activities, and which requires, among other things, that recipients of Federal funds operate their Federally assisted programs so that, when viewed in their entirety, they are readily accessible to people with disabilities. A copy of Part 84 may be obtained from the Regional office. Projects must also comply with any applicable provisions of the Americans With Disabilities Act (Public Law 101-336).

Emergency situations may occur at any time. All projects must therefore have written plans and procedures for the management of emergencies.

6.5 PERSONNEL

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

Grantees must also ensure that:

- Projects are administered by a qualified project director;
- The clinical care component of the project operates under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning;
- Protocols exist that provide all project personnel with guidelines for client care;

- Personnel records are kept confidential;

- Licenses of applicants for positions requiring licensure are verified prior to employment and that there is documentation that licenses are kept current.

6.6 TRAINING AND TECHNICAL ASSISTANCE

Projects must provide for the orientation and in-service training of all project personnel, including the staffs of delegate agencies and service sites. All project personnel should participate in continuing education related to their activities. Documentation of continuing education should be maintained and used in evaluating the scope and effectiveness of the staff training program.

Training through regional training centers is available to all projects under the Title X program. In addition to training, grantees may receive technical assistance for specific project activities. Technical assistance is provided by contract from the OPA and administered through the Regional Office. Information on training and technical assistance is available from the Regional Office.

6.7 REPORTING REQUIREMENTS

Grantees must:

(1) comply with the financial and other reporting requirements of 45 CFR Part 74 or 45 CFR Part 92, as applicable; and

(2) comply with other reporting requirements as required by DHHS.

6.8 REVIEW AND APPROVAL OF INFORMATIONAL AND EDUCATIONAL MATERIALS

An advisory committee of five to nine members (the size of the committee can differ from these limits with written documentation and approval from the Regional Office) who are broadly representative of the community must review and approve all informational and educational (I&E) materials developed or made available under the project prior to their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X. Oversight responsibility for the I&E committee(s) rests with the grantee. The grantee may delegate the I & E operations for the review and approval of materials to delegate/contract agencies.

The I&E committee(s) must:

- Consider the educational and cultural backgrounds of the individuals to whom the materials are addressed;
- Consider the standards of the population or community to be served with respect to such materials;
- Review the content of the material to assure that the information is factually correct;
- Determine whether the material is suitable for the population or community to which it is to be made available; and
- Establish a written record of its determinations [59.6].

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

6.9 COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

Boards and advisory committees for family planning services should be broadly representative of the population served.

! Community Participation

Title X grantees and delegate/contract agencies must provide an opportunity for participation in the development, implementation, and evaluation of the project (1) by persons broadly representative of all significant elements of the population to be served, and (2) by persons in the community knowledgeable about the community's needs for family planning services [59.5(b)(10)].

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

! Community Education

Each family planning project must provide for community education programs [59.5(b)(3)]. This should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

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

! Project Promotion

To facilitate community awareness of and access to family planning services, projects must establish and implement planned activities whereby their services are made known to the community [59.5(b)(3)]. Projects should review a range of strategies and assess the availability of existing resources and materials. Promotion activities should be reviewed annually and be responsive to the changing needs of the community. For more information, contact the Regional Offices.

6.10 PUBLICATIONS AND COPYRIGHT

Unless otherwise stipulated, publications resulting from activities conducted under the grant need not be submitted to DHHS for prior approval. The word "publication" is defined to include computer software. Grantees should ensure that publications developed under Title X do not contain information which is contrary to program requirements or to accepted clinical practice. Federal grant support must be acknowledged in any publication. Except as otherwise provided in the conditions of the grant award, the author is free to arrange for copyright without DHHS approval of publications, films, or similar materials developed from work supported by DHHS. Restrictions on motion picture film production are outlined in the *Public Health Service Grants Policy Statement*. Any such copyrighted materials shall be subject to a royalty-free, non-exclusive, and irrevocable right of the Government to reproduce, publish, or otherwise use such materials for Federal purposes and to authorize others to do so [45 CFR 74.36][45 CFR 92.34].

6.11 INVENTIONS OR DISCOVERIES

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

PART II

7.0 Client Services

Projects funded under Title X must provide clinical, informational, educational, social and referral services relating to family planning to clients who want such services. All projects must offer a broad range of acceptable and effective medically approved family planning methods and services either on-site or by referral [59.5(a)(1)]. Projects should make available to clients all methods of contraception approved by the Federal Food and Drug Administration.

Part II of this document has been developed to assist grantees in determining those services which will be provided to fulfill the mission of Title X.

- Projects must provide services stipulated in the law or regulations, or which are required by these Guidelines for the provision of high quality family planning services.

- Projects may also provide those services that are intended to promote the reproductive and general health care of the family planning client population.

7.1 SERVICE PLANS AND PROTOCOLS

The service plan is the component of the grantee's project plan, as set forth in the competitive application, which identifies those services to be provided to clients under Title X by the project. As part of the project plan, all grantees must assure that delegate/contractors have written clinical protocols and plans for client education, approved by the grantee and signed by the service site Medical Director, which outline procedures for the provision of each service offered and which are in accordance with state laws. Clinical protocols must be consistent with the requirements of these Guidelines.

Under exceptional circumstances, a waiver from a particular requirement may be obtained from the Regional Office upon written request from a grantee. In submitting a request for an exception, the grantee must provide epidemiologic, clinical, and other supportive data to justify the request and the duration of the waiver.

7.2 PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence in which they are provided, will depend upon the type of visit and the nature of the service requested. However, the following components must be offered to and documented on all clients at the initial visit:

Education

- Presentation of relevant information and educational materials, based upon client needs and knowledge;

Counseling

- Interactive process in which a client is assisted in making an informed choice;

Informed Consent

- Explanation of all procedures and obtaining a general consent covering examination and treatment and, where applicable, a method specific informed consent form;

History

- Obtaining of a personal and family medical and social history;

Examination

- Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

- Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

- Planned mechanism for client follow-up;
- Performance of any necessary clinical procedures;
- Provision of medications and/or supplies as needed; and
- Provision of referrals as needed.

Return visits, with the exception of routine supply visits, should include an assessment of the client's health status, current complaints, and evaluation of birth control method, as well as an opportunity to change methods. The following components must be offered to and documented on all clients at the return visit:

History

- Updating a personal and family medical and social history;

Examination

- Performance of a physical examination and any necessary clinical procedures, as indicated;

Laboratory Testing

- Performance of routine and other indicated laboratory tests;

Follow-up & Referrals

- Planned mechanism for client follow-up;
- Performance of any necessary clinical procedures;
- Provision of medications and/or supplies as needed; and
- Provision of referrals as needed.

7.3 EMERGENCIES

Emergency situations involving clients and/or staff may occur at any time. All projects must therefore have written plans for the management of on-site medical emergencies. At a minimum, written protocols must address vaso-vagal reactions, anaphylaxis, syncope, cardiac arrest, shock, hemorrhage, and respiratory difficulties. Protocols must also be in place for emergencies requiring transport, after-hours management of contraceptive emergencies, and clinic emergencies. All project staff must be familiar with these plans. Appropriate training, including training in CPR, should be available to staff.

7.4 REFERRALS AND FOLLOW-UP

Grantees must assure that delegate/contract agencies provide all family planning services listed in Section 8.0 under "Required Services," either on-site or by referral. When required services are to be provided by referral, the grantee must establish formal arrangements with a referral agency for the provision of services and reimbursement of costs, as appropriate.

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

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

- Make arrangements for the provision of pertinent client information to the referral provider. Agencies must obtain client's consent to such arrangements, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality;

- Advise client on their responsibility in complying with the referral; and

- Counsel client on the importance of such referral and the agreed upon method of follow-up.

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

8.0 Required Services

The services contained in this section must be provided by all projects funded under Title X.

The client's written informed voluntary consent to receive services must be obtained prior to the client receiving any clinical services. In addition, if a client chooses a prescription method of contraception, a method-specific consent form must be obtained and updated routinely at subsequent visits to reflect current information about that method.

8.1 CLIENT EDUCATION

Grantees and/or delegate/contract 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.

Education services must provide clients with the information needed to:

- Make informed decisions about family planning;
- Use specific methods of contraception and identify adverse effects;
- Perform breast/testicular self examination;
- 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 visit.

Clients should be offered information about basic female and male reproductive anatomy and physiology, and the value of fertility regulation in maintaining individual and family health. Additional education should include information on reproductive health and health promotion/disease prevention, including nutrition, exercise, smoking cessation, alcohol and drug abuse, domestic violence and sexual abuse.

! Method-Specific Informed Consent

Written informed consent, specific to the contraceptive method, must be signed before a prescription contraceptive method is provided. Prior to implementation, informed consent forms should be approved by the service site Medical Director.

The consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. To provide informed consent for contraception, the client must receive information on the benefits and risks, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the contraceptive method chosen. Specific education and consent forms for the contraceptive method provided must be part of

the project's service plan.

The signed informed consent form must be a part of the client's record. All consent forms should contain a statement that the client has been counseled, provided with the appropriate informational material, and understands the content of both. The method-specific consent form should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method.

Federal sterilization regulations [42 CFR Part 50, Subpart B], which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.2 COUNSELING

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, nonjudgmental, sensitive to the rights and differences of clients as individuals, culturally aware and able to create an environment in which the client feels comfortable discussing personal information. The counselor must be sufficiently knowledgeable to provide accurate information regarding the benefits and risk, safety, effectiveness, potential side effects, complications, discontinuation issues and danger signs of the various contraceptive methods. Additionally, the counselor should be knowledgeable about the other services offered by the agency. Documentation of counseling must be included in the client's record.

! Method Counseling

Method counseling refers to an individualized dialogue with a client that covers the following:

- Results of physical exam and lab studies;
- Effective use of contraceptive methods, including natural family planning (NFP), and the benefit and efficacy of the methods;
- Possible side effects/complications;
- How to discontinue the method selected and information regarding back-up

method use, including the use of certain oral contraceptives as post-coital emergency contraception;

- Planned return schedule;
- Emergency 24-hour telephone number;
- Location where emergency services can be obtained; and
- Appropriate referral for additional services as needed.

! Sexually Transmitted Disease (STD) and HIV Counseling

All clients must receive thorough and accurate counseling on STDs and HIV. STD/HIV counseling refers to an individualized dialogue with a client in which there is discussion of personal risks for STDs/HIV, and the steps to be taken by the individual to reduce risk, if necessary. Persons found to have behaviors which currently put them at risk for STD/HIV must be given advice regarding risk reduction and must be advised whether clinical evaluation is indicated. All projects must offer, at a minimum, education about HIV infection and AIDS, information on risks and infection prevention, and referral services. On an optional basis, clinics may also provide HIV risk assessment, counseling and testing by specially trained staff. When the project does not offer these optional services, the project must provide the client with a list of health care providers who can provide these services.

8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING

! History

At the initial comprehensive clinical visit, a complete medical history must be obtained on all female and male clients. Pertinent history must be updated at subsequent clinical visits. The comprehensive medical history must address at least the following areas:

- Significant illnesses; hospitalizations; surgery; blood transfusion or exposure to blood products; and chronic or acute medical conditions;
- Allergies;
- Current use of prescription and over-the-counter medications;
- Extent of use of tobacco, alcohol, and other drugs;

- Immunization and Rubella status;
- Review of systems;
- Pertinent history of immediate family members; and
- Partner history
  - injectable drug use
  - multiple partners
  - risk history for STDs and HIV
  - bisexuality.

Histories of reproductive function in female clients must include at least the following:

- Contraceptive use past and current (including adverse effects);
- Menstrual history;
- Sexual history;
- Obstetrical history;
- Gynecological conditions;
- Sexually transmitted diseases, including HBV;
- HIV;
- Pap smear history (date of last Pap, any abnormal Pap, treatment); and
- In utero exposure to diethylstilbestrol (DES).

Histories of reproductive function in male clients must include at least the following:

- Sexual history;
- Sexually transmitted diseases (including HBV);

- HIV; and
- Urological conditions.

! Physical Assessment (female)

For many clients, family planning programs are their only continuing source of health information and clinical care. Therefore, an initial complete physical examination, including height and weight, examination of the thyroid, heart, lungs, extremities, breasts, abdomen, pelvis, and rectum, should be performed.

While most client services will necessarily relate to fertility regulation, family planning clinics must provide and encourage clients to use health maintenance screening procedures, initially and as indicated. Clinics must provide and stress the importance of the following to all clients:

- Blood pressure evaluation;
- Breast exam;
- Pelvic examination which includes vulvar evaluation and bimanual exam;
- Pap smear;
- Colo-rectal cancer screening in individuals over 40; and
- STD and HIVscreening, as indicated.

Following counseling about the importance of the above preventive services, if a client chooses to decline or defer a service, this should be documented in their record. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or procedures.

All physical examination and laboratory test requirements stipulated in the prescribing information for specific methods of contraception must be followed. Physical examination and related prevention services should not be deferred beyond 3 months after the initial visit, and in no case may be deferred beyond 6 months, unless if in the clinician's judgment there is a compelling reason for extending the deferral. All deferrals, including the reason(s) for deferral, must be documented in the client record. Project protocols should be developed accordingly.

! Physical Assessment (male)

Family planning clinics also may be an important source of reproductive health care for male clients. Physical examination should be made available to male clients, including height and weight, examination of the thyroid, heart, lungs, breasts, abdomen, extremities, genitals and rectum. Examination should also include palpation of the prostate, as appropriate, and instructions in self-examination of the testes. Clinics should stress the importance of the following to male clients:

- Blood pressure evaluation;
- Colo-rectal cancer screening in individuals over 40; and
- STD and HIVscreening, as indicated.

! Laboratory Testing

Specific laboratory tests are required for the provision of specific methods of contraception. Laboratory tests can also be important indicators of client health status and useful for diagnostic purposes. Pregnancy testing must be provided onsite. The following laboratory procedures must be provided to clients if required in the provision of a contraceptive method, and may be provided for the maintenance of health status and/or diagnostic purposes, either on-site or by referral:

- Anemia assessment
- Gonorrhea and chlamydia test
- Vaginal wetmount
- Diabetes testing
- Cholesterol and lipids
- Hepatitis B testing
- Syphilis serology (VDRL, RPR)
- Rubella titer
- Urinalysis

- HIV testing

• Notification of Abnormal Lab Results

A procedure which addresses client confidentiality must be established to allow for client notification and adequate follow-up of abnormal laboratory results.

• Other Laboratory Services or Procedures

Other procedures and lab tests may be indicated for some clients and may be provided on-site or by referral.

! Revisits

Revisit schedules must be individualized based upon the client's need for education, counseling, and clinical care beyond that provided at the initial and annual visit.

Clients selecting hormonal contraceptives, intrauterine devices (IUDs), cervical caps, or diaphragms for the first time should be scheduled for a revisit as appropriate after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information or clarification. A new or established client who chooses to continue a method already in use need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

8.4 FERTILITY REGULATION

! Reversible Contraception

Currently, the reversible methods of contraception include barrier methods (female and male), IUDs, fertility awareness methods, natural family planning, and hormonal methods (injectables, implants, orals). Certain oral contraceptive regimens have been found by the Federal Food and Drug Administration to be safe and effective for use as postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. More than one method of contraception can be used simultaneously by a client and may be particularly indicated to minimize the risks of STDs/HIV and pregnancy. Consistent and correct use of condoms should be encouraged for all persons at risk for STDs/HIV.

! Permanent Contraception

The counseling and consent process must assure that the client's decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal sterilization regulations, which address informed consent requirements, must be complied with when a sterilization procedure is performed or arranged for by the project (see Attachment C).

8.5 INFERTILITY SERVICES

Grantees must make basic infertility services available to women and men desiring such services. Infertility services are categorized as follows:

- *Level I* Includes initial infertility interview, education, physical examination, counseling, and appropriate referral.
- *Level II* Includes such testing as semen analysis, assessment of ovulatory function and postcoital testing.
- *Level III* More sophisticated and complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Level II infertility services may be offered in projects with clinicians who have special training in infertility. Level III services are considered to be beyond the scope of Title X program.

8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Projects must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most common reasons for a first visit to the family planning facility. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects should have available a pregnancy test of high sensitivity. If the medical examination cannot be performed in conjunction with the laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, referral for early initiation of prenatal care should be made. Clients planning to carry their pregnancies

to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays). For clients with a negative pregnancy diagnosis, the cause of delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.

Projects must offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

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

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling [59.5(a)(5)].

Clients who are found not to be pregnant should be given information about the availability of contraceptive and infertility services, as appropriate.

8.7 ADOLESCENT SERVICES

Adolescent clients require skilled counseling and age-appropriate information. Appointments should be available to them for counseling and clinical services as soon as possible.

Adolescents seeking contraceptive services must be informed about all methods of contraception. Abstinence as well as contraceptive and safer sex practice options to reduce risks for STD/HIV and pregnancy must be discussed with all adolescents. It is important not to assume that adolescents are sexually active simply because they have come for family planning services. As the contraceptive needs of adolescents frequently change, counseling should prepare them to use a variety of methods effectively.

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

8.8 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

The children of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility related risks. As part of the medical history, clients born between 1940 and 1970 should be asked if their mothers took estrogens during pregnancy. Clients prenatally exposed to exogenous estrogens should receive information/education and special screening either on-site or by referral.

9.0 Related Services

The following related health services, which can improve quality of care, may be offered if skilled personnel and equipment are available.

9.1 GYNECOLOGIC SERVICES

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of health care for clients with these conditions. 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. More complex procedures, such as colposcopy, may be offered, provided that clinicians performing these services have specialized training.

9.2 SEXUALLY TRANSMITTED DISEASES (STD) AND HIV/AIDS

The increasing incidence and prevalence of STDs, particularly among adolescents, requires that family planning projects increase their efforts to provide education and information about the more common STDs and HIV/AIDS. Projects should make available detection and treatment of the more common STDs. At-risk clients should be urged to undergo examination and treatment as indicated, either directly or by referral. When treatment is provided on-site, appropriate follow-up measures must be undertaken.

Gonorrhea and chlamydia tests must be available for clients requesting IUD insertion. Tests for gonorrhea, syphilis, chlamydia and HIV should be provided as indicated by client request or evidence of increased risk for infection.

Grantees and/or delegate contract agencies must comply with state and local STD reporting requirements.

9.3 SPECIAL COUNSELING

Clients should be offered appropriate counseling and referral as indicated regarding future planned pregnancies, management of a current pregnancy, and other individual concerns (e.g., substance use and abuse, sexual abuse, domestic violence, genetic issues, nutrition, sexual concerns, etc.) as indicated. Preconceptional counseling should be provided if the client's history indicates a desired pregnancy in the future.

9.4 GENETIC INFORMATION AND REFERRAL

Basic information regarding genetic conditions should be offered to family planning clients who request or are in need of such services. Extensive genetic counseling and evaluation is beyond the scope of the Title X program. Referral systems should be in place for those who require further genetic counseling and evaluation

9.5 HEALTH PROMOTION/DISEASE PREVENTION

Family planning programs should, whenever possible, provide or coordinate access to services intended to promote health and prevent disease. Programs are encouraged to assess the health problems prevalent in the populations they serve and to develop strategies to address them.

9.6 POSTPARTUM CARE

Family planning programs may provide postpartum care in collaboration with local agencies or institutions which provide prenatal and/or intrapartum care. If a family planning program undertakes responsibility for postpartum care, such care should be directed toward assessment of the woman's physical health, initiation of contraception if desired, and counseling and education related to parenting, breast feeding, infant care, and family adjustment.

10.0 Clinic Management

10.1 EQUIPMENT AND SUPPLIES

Equipment and supplies must be appropriate to the type of care offered by the project. Projects are expected to follow applicable Federal and state regulations regarding infection control.

10.2 PHARMACEUTICALS

Agencies must be operated in accordance with Federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations.

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

10.3 MEDICAL RECORDS

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

- Complete, legible and accurate, including documentation of telephone encounters of a clinical nature;
- Signed by the clinician and other appropriately trained health professionals making entries, including 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 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, justify the clinical impression or diagnosis, and warrant the treatment and end results. The required content of the medical record includes:

- Personal data;
- Medical history, physical exam, laboratory test orders, results, and follow-up;
- Treatment and special instructions;
- Scheduled revisits;
- Informed consents;
- 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, and documentation of continuing care, referral, and follow-up. The record must allow for entries by counseling and social service staff. Projects should maintain a problem list at the front of each chart listing identified problems to facilitate continuing evaluation and follow-up. Client financial information should be kept separate from the client medical record. If included in the medical record, client financial information should not be a barrier to client services.

! Confidentiality and Release of Records

A confidentiality assurance statement must appear in the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality [59.11]. HIV information should be handled according to law, and kept separate whenever possible. 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.

10.4 QUALITY ASSURANCE AND AUDIT

A quality assurance system must be in place that provides for ongoing evaluation of project personnel and services. The quality assurance system should include:

- An established set of clinical, administrative and programmatic standards by which conformity would be maintained;
- A tracking system to identify clients in need of follow-up and/or continuing care;
- Ongoing medical audits to determine conformity with agency protocols;
- Peer review procedures to evaluate individual clinician performance, to provide feedback to providers, and to initiate corrective action when deficiencies are noted;
- Periodic review of medical protocols to insure maintenance of current standards of care;
- A process to elicit consumer feedback; and
- Ongoing and systematic documentation of quality assurance activities.

TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001 [300]

(a)The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family [1] participation in projects assisted under this subsection.

(b)In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c)The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d)For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973, $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976;
$115,000,000 for the fiscal year ending September 30, 1977;
$136,400,000 for the fiscal year ending September 30, 1978;
$200,000,000 for the fiscal year ending September 30, 1979;
$230,000,000 for the fiscal year ending September 30, 1980;
$264,500,000 for the fiscal year ending September 30, 1981;
$126,510,000 for the fiscal year ending September 30, 1982;
$139,200,000 for the fiscal year ending September 30, 1983;
$150,030,000 for the fiscal year ending September 30, 1984; and
$158,400,000 for the fiscal year ending September 30, 1985.

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[1] So in law. See section 931(b)(I) of Public Law 97-35 (95 Stat. 570). Probably should be "family".

FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES

SEC. 1002 [300a]

(a)The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b)The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c)For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d)For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS

SEC. 1003 [300a-1]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

RESEARCH

SEC. 1004 [300a-2]

The Secretary may -

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

INFORMATIONAL AND EDUCATIONAL MATERIALS

SEC. 1005 [300a-3]

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

REGULATIONS AND PAYMENTS

SEC. 1006 [300a-4]

(a)Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b)Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c)A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that--

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in

accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

VOLUNTARY PARTICIPATION

SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

PROHIBITION OF ABORTION

SEC. 1008 [1] [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

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[1] Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.232 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure
45 CFR part 16—Procedures of the Departmental Grant Appeals Board
45 CFR part 46—Protection of human subjects
45 CFR part 74—Administration of grants
45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
45 CFR part 81—Practice and procedure for hearings under part 80 of this title
45 CFR part 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Service Act
45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying

[49 FR 38116, Sept. 27, 1984. Redesignated and amended at 61 FR 6131, Feb. 16, 1996]

§ 58.233 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6131, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 58.234 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

Subparts E–F [Reserved]

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

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Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a–4.

SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, *et al.*), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and

may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family 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.

(8) Provide that 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, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral

[1] Section 205 of Pub. L. 94-63 states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both."

to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) 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.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for 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 others in the community knowledgeable about the community's needs for family planning services.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients, and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of nonfederal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and

Human Services effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title
45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance
45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

AUTHORITY: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-1.

SOURCE: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

§ 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a–1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

§ 59.202 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act.

(b) *State* means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.

(c) *Nonprofit* private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(d) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Training* means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

§ 59.203 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: *Provided,* That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

§ 59.204 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a-1, and 300a-4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

§ 59.205 Project requirements.

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

[1] Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

§ 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to

program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by Subpart Q of 35 CFR part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

(1) Return travel to the trainee's point of origin.

(2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation impelmenting such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the

approval of the President (45 CFR part 80).

§59.210 Inventions or discoveries.

Any grant award pursuant to §59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§59.212 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) *Accounting for grant-related income*—(1) *Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or

assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.213 [Reserved]

§ 59.214 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 59.215 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:
A General.
B Cash Depositories.
C Bonding and Insurance.
D Retention and Custodial Requirements for Records.
F Grant-Related Income.
G Matching and Cost Sharing.
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

[38 FR 26199, Sept. 19, 1973]

PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

Sec.
59a.1 Programs to which these regulations apply.
59a.2 Definitions.
59a.3 Who is eligible for a grant?
59a.4 How are grant applications evaluated?
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59a.6 How may funds or materials be used?
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Subpart B—Establishment of Regional Medical Libraries

59a.11 Programs to which these regulations apply.
59a.12 Definitions.
59a.13 Who is eligible for a grant?
59a.14 How to apply.
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SOURCE: 56 FR 29189, June 26, 1991, unless otherwise noted.

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

AUTHORITY: 42 U.S.C. 286b-2, 286b-5.

§ 59a.1 Programs to which these regulations apply.

(a) The regulations of this subpart apply to grants of funds, materials, or both, for establishing, expanding, and improving basic medical library resources as authorized by section 474 of the Act (42 U.S.C. 286b-5).

(b) This subpart also applies to cooperative agreements awarded for this purpose. In these circumstances, references to "grant(s)" shall include "cooperative agreements(s)."

§ 59a.2 Definitions.

Undefined terms have the same meaning as provided in the Act. As used in this subpart:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Project period—See § 59a.5(c).

Related instrumentality means a public or private institution, organization, or agency, other than a medical library, whose primary function is the acquisition, preservation, dissemination, and/or processing of information relating to the health sciences.

Secretary means the Secretary of Health and Human Services and any other official of the Department of Health and Human Services to whom the authority involved is delegated.

examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(1) There is an immediate health hazard involved;

(2) There is an immediate need to protect Federal funds or equipment;

(3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

(4) It is probable that the alleged incident is going to be reported publicly.

(5) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

§ 50.105 Institutional compliance.

Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

Arrange for means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (1) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or (2) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for

purposes which include the ability to consent to sterilization.

Public Health Service means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

The *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

[43 FR 52165, Nov. 8, 1978, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of § 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and § 50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) Advice that the sterilization procedure is considered to be irreversible;

(4) A thorough explanation of the specific sterilization procedure to be performed;

(5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(6) A full description of the benefits or advantages that may be expected as a result of the sterilization; and

(7) Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in § 50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

(c) Suitable arrangements must be made to insure that the information specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 50.205 Consent form requirements.

(a) *Required consent form.* The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) *Required signatures.* The consent form must be signed and dated by:

(1) The individual to be sterilized; and

(2) The interpreter, if one is provided; and

(3) The person who obtains the consent; and

(4) The physician who will perform the sterilization procedure.

(c) *Required certifications.* (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter's knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

(i) The individual is already sterile at the time of the hysterectomy.

(ii) The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

(i) That the woman was already sterile, stating the cause of that sterility; or

(ii) That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance adminstered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and as applicable, either acknowledgments of receipt of hysterectomy information or certification of an exception for hysterectomies.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.210 Review of regulation.

The Secretary will request public comment on the operation of the provisions of this subpart not later than 3 years after their effective date.

APPENDIX TO SUBPART B OF PART 50—REQUIRED CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from _____ (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on ___ (day), ___ (month), ___ (year).

I, _____, hereby consent of my own free will to be sterilized by _____ by a method called _____. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature _____
Date: _____
(Month, day, year)

You are requested to supply the following information, but it is not required:

Race and ethnicity designation (please check)

Black (not of Hispanic origin) _____
Hispanic _____
Asian or Pacific Islander _____
American Indian or Alaskan native _____
White (not of Hispanic origin) _____

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter _____
Date _____

STATE OF PERSON OBTAINING CONSENT

Before _____ (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent _____
Date _____
Facility _____
Address _____

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon _____ (name of individual to be sterilized), on _____ (date of sterilization), _____ (operation), I explained to him/her the nature of the sterilization operation _____ (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

☐ Premature delivery
Individual's expected date of delivery: _____
☐ Emergency abdominal surgery:
(Describe circumstances): _____

Physician _____
Date _____

[43 FR 52165, Nov. 8, 1978, as amended at 58 FR 33343, June 17, 1993]

Subpart C—Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

AUTHORITY: Sec. 118, Pub. L. 96-86, Oct. 12, 1979, unless otherwise noted.

SOURCE: 43 FR 4570, Feb. 2, 1978, unless otherwise noted.

§ 50.301 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, appropriated to the Department of Health and Human Services and administered by the Public Health Service.

§ 50.302 Definitions.

As used in this subpart: (a) *Law enforcement agency* means an agency, or any part thereof, charged under applicable law with enforcement of the general penal statutes of the United States, or of any State or local jurisdiction.

(b) *Medical procedures performed upon a victim of rape or incest* means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

(c) *Physician* means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she practices.

(d) *Public health service* means: (1) An agency of the United States or of a State or local government, that provides health or medical services; and

(2) A *rural health clinic*, as defined under section 1(d)(aa)(2) of Pub. L. 95-210, 91 Stat. 1485; except that any agency or facility whose principal function is the performance of abortions is specifically excluded from this definition.

§ 50.303 General rule.

Federal financial participation is not available for the performance of an abortion in programs or projects to which this subpart applies except under circumstances described in § 50.304 or § 50.306.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.304 Life of the mother would be endangered.

Federal financial participation is available in expenditures for an abortion when a physician has found, and so certified in writing to the program or project, that on the basis of his/her professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

(Sec. 101, Pub. L. 95-205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978]

§ 50.305 [Reserved]

§ 50.306 Rape and incest.

Federal financial participation is available in expenditures for medical procedures performed upon a victim of rape or incest if the program or project has received signed documentation from a law enforcement agency or public health service stating:

(a) That the person upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;

(b) The date on which the incident occurred;

(c) The date on which the report was made, which must have been within 60 days of the date on which the incident occurred;

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Revised: 12/2002

Office of Population Affairs
Office of Family Planning
Regional Health Administrators

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Revised: 12/2002

Resource List for Title X Family Planning Programs

The following is a list of selected resources that provide additional guidance in specific areas. It is intended to assist programs in administering their Title X grant and in providing services to clients. The list is not intended to be exhaustive, nor does it imply endorsement of any of the non-governmental resources.

The Law, Regulations, and Guidelines

The Title X Family Planning statute (42 USC 300 et. seq.) and regulations can be obtained from :

- Office of Family Planning
  Office of Population Affairs
  Office of Public Health and Science
  U.S. Department of Health and Human Services
  4350 East West Highway, Suite 200
  Bethesda, MD 20817
  (301) 594-4008
  http://www.hhs.gov/opa/

- Office of Population Affairs Clearinghouse
  P.O. Box 30686
  Bethesda, MD 20824-0686
  301-654-6190
  E-mail: OPA@Tascon.com

Application, Grants Administration, and Legal Issues

- Grants Management
  Http://www.hhs.gov/grantsnet

- *Grants Process Policy Notices for Title X Family Planning Services*, rev. 1999
  (Available from Title X Grants Management Office. 1301 Young Street, Ste.766, Dallas, TX 75202; 214-767-3490)

Project Management and Reporting Requirements

- Annual Report for OPA Title X Family Planning Program Grantees Forms and Instructions (Available from the Regional Office).

- Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services. http://www.bphc.hrsa.gov/odpp/

Client Services

- Cultural Competence
  http://www.omhrc.gov/clas/index.htm

- Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency. Federal Register, Vol. 65, No. 169. 52762 – 52774. http://www.hhs.gov/ocr/lep/

- U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services*, 2nd Edition. Chapter 63 Counseling to Prevent Unintended Pregnancy. Washington, DC: U.S. Department of Health and Human Services, 1996.
  http://odphp.osophs.dhhs.gov/pubs/guideeps/

- Hatcher, Robert A., et. al. *Contraceptive Technology, Seventeenth Revised Edition*, Ardent Media, Inc. 1998.

- American College of Obstetricians and Gynecologists. *Emergency Oral Contraception. ACOG Practice Patterns.* Number 3. Washington, DC: The American College of Obstetrics and Gynecologists, December, 1996.

- *Your Contraceptive Choices for Now, for Later.* Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, Office of Population Affairs. Updated Spring 1998.

- Green M, Palfrey JS, eds. 2000 *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents.* Arlington, VA: National Center for Education in Maternal and Child Health. http://www.brightfutures.org./

- American Medical Association. ***Guidelines for Adolescent Preventive Services (GAPS)**: recommendations and rationale.* Chicago: American Medical Association. 1994

- *Primary and Preventive Health Care for Female Adolescents*, American College of Obstetricians and Gynecologists, November 1999.

- American College or Obstetricians and Gynecologists, *Guidelines for Women's Health Care*, 1996.

- Centers for Disease Control and Prevention. *1998 Guidelines for Treatment of Sexually Transmitted Diseases*. MMWR 1998: 47 (RR-1); 1-118. http://www.cdc.gov/nchstp/dstd/1998_STD_Guidlines/98m1633.pdf

- Centers for Disease Control and Prevention. *Revised Guidelines for HIV Counseling, Testing and Referral*. October 17, 2000. http://www.cdc.gov/hiv/frn.htm

Health Promotion/Disease Prevention

- U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. . Washington, DC: U.S. Government Printing Office, November, 2000. http://www.health.gov/healthypeople/

- *Guidelines for Health Education and Risk Reduction Activities* CDC, National Center for Prevention Services, Division of Sexually Transmitted Diseases/HIV Prevention Publication date: 04/01/1995 http://aepo-xdv-www.epo.cdc.gov/wonder/PrevGuid

- U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services*, 2nd Edition. Chapter 63 Counseling to Prevent Unintended Pregnancy. Washington, DC: U.S. Department of Health and Human Services (HHS), 1996. http://odphp.osophs.dhhs.gov/pubs/guidecps/

Appendix B

Minor's Consent Law

FP—Maryland Minors Consent Law

Maryland's Minor Consent Law (Article 20-102 of the Maryland Annotated Code)

This law permits minors to receive contraceptive services on a confidential basis. The law states that "a minor has the same capacity as an adult to consent to treatment for or advice about drug abuse, alcoholism, venereal disease, pregnancy, and contraception other than sterilization." This means minors can get the following services without parental knowledge or consent:

- Pregnancy testing
- Birth control
- Exams
- Testing and treatment of sexually transmitted infections (STIs)

Planned Parenthood encourages adolescents to communicate with their parents and guardians when seeking contraceptive health care, but does not require that they do so. According to a report in the *Journal of the American Medical Association* (JAMA), most adolescents already inform parents about their use of reproductive health services.

Definition of a Minor: In Maryland, a minor is anyone under the age of 18 years who is not married or the parent of a child.

Maryland's Parental Notification for Abortion Law (Article 20-103 of the Maryland Annotated Code)

Maryland law requires that one parent or guardian be notified before a minor has an abortion. The parent/guardian does not need to consent (agree) with the minor's choice, but does need to know the minor is planning to have an abortion. Maryland's parental notification law says specifically that no notification is required if, in the judgment of the doctor performing the abortion:

- The minor is mature and capable of giving her informed consent to the procedure, OR
- Notification would not be in the minor's best interest, OR
- Notice may lead to physical or emotional abuse of the minor, OR
- The minor patient does not live with her parent or guardian, OR
- A reasonable effort to give notice has been unsuccessful.

Our experience at Planned Parenthood of Maryland, and the scientific research done by the Alan Guttmacher Institute , show that the vast majority of adolescents (81 percent, according to the AGI study) already involve a parent or other adult in the abortion decision. The remaining young people usually do not turn to their parent because of difficult circumstances – they may not live with the parent, or they may be legitimately concerned about abuse or being thrown out of their homes. Maryland law provides the above exclusions to protect these young people.

Click **here** to view Planned Parenthood of Maryland's Parental Notification Form.

Article - Health - General

[Previous] [Next] [Another Article]

§ 20-102.

(a) A minor has the same capacity as an adult to consent to medical treatment if the minor:

(1) Is married; or

(2) Is the parent of a child.

(b) A minor has the same capacity as an adult to consent to medical treatment if, in the judgment of the attending physician, the life or health of the minor would be affected adversely by delaying treatment to obtain the consent of another individual.

(c) A minor has the same capacity as an adult to consent to:

(1) Treatment for or advice about drug abuse;

(2) Treatment for or advice about alcoholism;

(3) Treatment for or advice about venereal disease;

(4) Treatment for or advice about pregnancy;

(5) Treatment for or advice about contraception other than sterilization;

(6) Physical examination and treatment of injuries from an alleged rape or sexual offense;

(7) Physical examination to obtain evidence of an alleged rape or sexual offense; and

(8) Initial medical screening and physical examination on and after admission of the minor into a detention center.

(c-1) The capacity of a minor to consent to treatment for drug abuse or alcoholism under subsection (c)(1) or (2) of this section does not include the capacity to refuse treatment for drug abuse or alcoholism in an inpatient alcohol or drug abuse treatment program certified under Title 8 of this article for which a parent or guardian has given consent.

(d) A minor has the same capacity as an adult to consent to psychological treatment as specified under subsection (c)(1) and (2) of this section if, in the judgment of the attending physician or a psychologist, the life or health of the minor would be affected adversely by delaying treatment to obtain the consent of another individual.

(e) A physician, psychologist, or an individual under the direction of a physician or psychologist who treats a minor is not liable for civil damages or subject to any criminal or disciplinary penalty solely because the minor did not have capacity to consent under this section.

(f) Without the consent of or over the express objection of a minor, the attending physician, psychologist or, on advice or direction of the attending physician or psychologist, a member of the medical staff of a hospital or public clinic may, but need not, give a parent, guardian, or custodian of the minor or the spouse of the parent information about treatment needed by the minor or provided to the minor under this section, except information about an abortion.

[Previous] [Next] [Another Article]

Appendix C

Child Abuse and Neglect
Family Law §5-704

Article - Family Law

§ 5-704.

(a) Notwithstanding any other provision of law, including any law on privileged communications, each health practitioner, police officer, educator, or human service worker, acting in a professional capacity in this State:

(1) (i) who has reason to believe that a child has been subjected to abuse, shall notify the local department or the appropriate law enforcement agency; or

(ii) who has reason to believe that a child has been subjected to neglect, shall notify the local department; and

(2) if acting as a staff member of a hospital, public health agency, child care institution, juvenile detention center, school, or similar institution, shall immediately notify and give all information required by this section to the head of the institution or the designee of the head.

(b) (1) An individual who notifies the appropriate authorities under subsection (a) of this section shall make:

(i) an oral report, by telephone or direct communication, as soon as possible:

1. to the local department or appropriate law enforcement agency if the person has reason to believe that the child has been subjected to abuse; or

2. to the local department if the person has reason to believe that the child has been subjected to neglect; and

(ii) a written report:

1. to the local department not later than 48 hours after the contact, examination, attention, or treatment that caused the individual to believe that the child had been subjected to abuse or neglect; and

2. with a copy to the local State's Attorney if the individual has reason to believe that the child has been subjected to abuse.

(2) (i) An agency to which an oral report of suspected abuse is made under paragraph (1) of this subsection shall immediately notify the other agency.

(ii) This paragraph does not prohibit a local department and an appropriate law enforcement agency from agreeing to cooperative arrangements.

(c) Insofar as is reasonably possible, an individual who makes a report under this section shall include in the report the following information:

(1) the name, age, and home address of the child;

(2) the name and home address of the child's parent or other person who is responsible for the child's care;

(3) the whereabouts of the child;

(4) the nature and extent of the abuse or neglect of the child, including any evidence or information available to the reporter concerning possible previous instances of abuse or neglect; and

(5) any other information that would help to determine:

(i) the cause of the suspected abuse or neglect; and

(ii) the identity of any individual responsible for the abuse or neglect.

Appendix D

Health Education Forms

Center for Maternal and Child Health
Family Planning and Reproductive Health Program
Community Health Education
Annual Report Form

Family Planning Program Reporting: _____

Person Name & Title Completing Report: _____

Date of Report: _____

Instructions: This form is to be used to document all community health education activities conducted. What is considered a community health education activity? A community health education activity may consist of presentations conducted on specific health topic (e.g., contraceptive methods, nutrition, and relationships). The activity may take place locally or statewide (e.g., school, recreational center, college campus, religious center, community clinic, and community support centers).

Program Narrative: (Goal and Objectives including estimated number(s) to be performed for each category)

List Clinic Education Programs Conducted: (e.g., presentations, groups (adult, teenage)

List Community Education Programs Conducted: (e.g., church/Faith Based Centers, schools, community centers, Family Support Centers, local government agencies (WIC, DSS), colleges/universities, Libraries)

List Informational and Educational Reviews Conducted: (e.g., date, location, and representation of community)

List Health Fairs Attended or Sponsored: (e.g., date, facility name & address)

List Project Promotions Conducted: (e.g., community awareness and access to FP services (radio, television, local & state newspaper/newsletter)

Informational & Educational Material Review Evaluation Worksheet

Title of material: _____

Type of material:
- ❑ brochure
- ❑ fact sheet
- ❑ video
- ❑ other _____

This material is for:
- ❑ males
- ❑ females
- ❑ both

Target age group(s): *(check all that apply)*
- ❑ teen (13-18)
- ❑ young adult (19-24)
- ❑ adult (25 and up)

Is the material current? *(no more than 5 years old)*
- ❑ yes
- ❑ no
- ❑ unsure

Is the material available in other languages?
- ❑ yes *(list languages)* _____
- ❑ no

Please answer the following questions: (circle)	**Poor**		**Satisfactory**		**Excellent**
Is it eye-catching?	1	2	3	4	5
Is it easy to read?	1	2	3	4	5
Is the information accurate?	1	2	3	4	5
Is it from a reliable source?	1	2	3	4	5
Is it culturally sensitive?	1	2	3	4	5
Recommendation:	Do not recommend		Recommend		Strongly recommend

Other comments:

_____

_____

Reviewer's name: _____
School or organization: _____
Date: _____

Family Planning and Reproductive Health Program
Center for Maternal and Child Health, Maryland Department of Health & Mental Hygiene

Appendix E

Surveys

FAMILY PLANNING CLIENT SURVEY

We are interested in knowing how well we are providing services to you. Please answer the questions below. If you feel we have missed something that is important to you, please write it in the comment section. When you are finished, please ask a clinic staff member where to place your completed survey. **CIRCLE THE LETTERS TO THE RIGHT OF THE QUESTIONS WHICH BEST DESCRIBE YOUR FEELINGS.**

	Strongly Agree	**Agree**	**Neutral / No Opinion**	**Disagree**	**Strongly Disagree**
1. I had a problem getting transportation to the clinic.	SA	A	N	D	SD
2. The clinic hours are convenient.	SA	A	N	D	SD
3. I had an appointment and was seen at or close to my appointment time.	SA	A	N	D	SD
4. I did not have an appointment and waited 2 hours or more for services.	SA	A	N	D	SD
5. The information on birth control was understandable.	SA	A	N	D	SD
6. The information I received was understandable.	SA	A	N	D	SD
7. I received the service and/or information I came for.	SA	A	N	D	SD
8. The staff was caring and helpful.	SA	A	N	D	SD
9. I was satisfied with my family planning visit.	SA	A	N	D	SD
10. I would tell a friend to come here for family planning services.	SA	A	N	D	SD
11. I will come back to the clinic in the future	SA	A	N	D	SD

Comments: _____

_____

Date: _____ Name of Health Department : _____

Age: _____ Gender (Circle): Female/Male Race (Optional): _____

THANK YOU!

Rev. 3/3/2004
SYW / DP

TARJETA DE INFORME SOBRE PLANIFICACIÓN FAMILIAR

Nos gustaría conocer cuán efectivamente le estamos proporcionando los servicios. Por favor, conteste el siguiente formulario. Si considera que hemos omitido algo importante para usted, por favor escríbalo en la sección para comentarios. Cuando termine, pídale a un miembro del personal de la clínica dónde colocar la encuesta que ha llenado. **MARQUE CON UN CÍRCULO LAS RESPUESTAS QUE MEJOR DESCRIBAN SUS SENTIMIENTOS EN LAS SIGUIENTES PREGUNTAS.**

	Totalmente de acuerdo	**De acuerdo**	**Neutral / Ninguna opción**	**En desacuerdo**	**Totalmente en desacuerdo**
1. Tuve problemas para obtener transporte hasta la clínica.	TA	A	N	D	TD
2. El horario de atención de la clínica es conveniente.	TA	A	N	D	TD
3. Tenía una cita y fui atendido en el horario programado.	TA	A	N	D	TD
4. No tenía una cita programada y tuve que esperar 2 horas o más para recibir atención.	TA	A	N	D	TD
5. La información sobre los anticonceptivos fue comprensible.	TA	A	N	D	TD
6. La información que recibí fue comprensible.	TA	A	N	D	TD
7. Recibí el servicio y/o la información que necesitaba.	TA	A	N	D	TD
8. El personal fue atento y servicial.	TA	A	N	D	TD
9. Estuve satisfecho con mi visita de planificación familiar.	TA	A	N	D	TD
10. Yo, recomendaría este lugar a un amigo para que obtenga servicios de planificación familiar.	TA	A	N	D	TD
11. Volveré a la clínica en el futuro.	TA	A	N	D	TD

Comentarios: _____

Fecha: _____ Nombre del Departamento de Salud : _____

Edad: _____ Sexo (encerrar en un círculo): Femenino/Masculino Raza (Opcional): _____

¡GRACIAS!

SW/DP
March, 2004

Customer Satisfaction Survey

Thank you for participating in this customer satisfaction survey as a provider in the Maryland State Family Planning Program. At the Center for Maternal and Child Health, we are interested in continuously improving the quality of our service to you. This undertaking can only be successful with your feedback. Please take a few minutes to give us your candid evaluation of the services provided by central office staff during FY 2008 and any suggestions you may have for ways that we can serve you better. This is a confidential survey. Your answers and suggestions will be combined with those of all other respondents and will not be traced back to you. The survey should take 15-20 minutes to complete.

Clinical and Clinical Support Services

Central office clinicians regularly work in our clinic(s) __ Yes ___ No

(If no, please skip to question 4)

Clinical services are provided by the following central office staff:

___ Nurse Practitioner/Midwife
___ Physician
___ Nurse Practitioner/Midwife and Physician

Select the answer that best describes your satisfaction with the medical services provided by central office clinician(s) at your facility:

___ Very satisfied ___ Somewhat satisfied ___ Neutral

___ Somewhat dissatisfied ___ Dissatisfied

Comments:
_____
_____
_____

Select the answer that best describes your satisfaction with the medical/clinical education/training and information, consultation and support you receive from central office staff:

___ Very satisfied ___ Somewhat satisfied ___ Neutral

___ Somewhat dissatisfied ___ Dissatisfied

Comments:

_____

_____

_____

Administrative Support and Grant Monitoring Services

Select the answers that best describe your views, based on the following statements:

Central office staff are responsive, helpful and knowledgeable when it comes to programmatic and fiscal issues.

___ Strongly Agree ___ Agree ___ Neutral/Not sure

___ Disagree ___ Strongly Disagree

Comments:

_____

_____

_____

Central office staff are responsive, helpful and knowledgeable when it comes to support with Informational and Educational (I&E) Review, health education and client satisfaction survey requirements:

___ Strongly Agree ___ Agree ___ Neutral/Not sure

___ Disagree ___ Strongly Disagree

Comments:

_____

_____

_____

Central office staff are responsive, helpful and knowledgeable when it comes to support with contraceptive products and supplies.

___ Strongly Agree ___ Agree ___ Neutral/Not sure

___ Disagree ___ Strongly Disagree

Comments:

_____

_____

_____

Central office staff are responsive, helpful and knowledgeable when it comes to support with data and data system issues:

___ Strongly Agree ___ Agree ___ Neutral/Not sure

___ Disagree ___ Strongly Disagree

Comments:

_____
_____
_____

Region of the State where you work:_____

Suggestions:

_____
_____
_____
_____
_____
_____
_____

Thanks Again!

Appendix F

Limited English Proficiency

DHMH POLICY

http://www.dhmh.state.md.us/policies/inpolm.htm

OFFICE OF EQUAL OPPORTUNITY PROGRAMS (OEOP) - POLICY 02.06.07
Effective September 5, 2006

POLICY ON EQUAL ACCESS TO DHMH SERVICES BY INDIVIDUALS WITH LIMITED ENGLISH PROFICIENCY (LEP)

SHORT TITLE: LEP POLICY

I. EXECUTIVE SUMMARY

In accordance with applicable State and federal law, the Department of Health and Mental Hygiene (DHMH) seeks to make programs, services, and benefits accessible to eligible individuals who, as a result of national origin, are limited in their English proficiency. The Department's ongoing efforts to make these programs, services and benefits accessible to persons with limited English proficiency (LEP) is consistent with the obligations imposed under Title VI of the Civil Rights Act of 1964 and the Annotated Code of Maryland, State Government Article, §§ 10-1101--10-1104.

This policy applies to those programs operated or funded by DHMH that provide services or benefits directly to the public; to grant-in-aid programs; and providers of health services, contractors and sub-contractors that receive federal or State funds, which are collectively referred to as "covered entities" in this policy.

Each covered entity that provides services or benefits DIRECTLY to the public shall develop language assistance procedures for 1) assessing the language needs of the population served; 2) translating both oral and written communications and documentation; 3) training staff in the language assistance program requirements; and 4) monitoring to assure that LEP individuals are receiving equal access to services and are not treated in a discriminatory manner.

The Fair Practices Officer in the DHMH Office of Equal Opportunity Programs (OEOP) shall monitor the LEP Policy compliance efforts of covered entities, and will, with the assistance of program designees, enforce this policy.

II. BACKGROUND

Title VI of the Civil Rights Act of 1964 states that "No person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied benefits of, or be subjected to, discrimination under any program or activity receiving Federal financial assistance."

The federal government has promulgated policies prohibiting national origin discrimination against persons with limited English proficiency. See Presidential Executive Order 13166, issued August 11, 2000, and U.S. Department of Health and Human Services–Office of Civil Rights Policy Guidance published in the Federal Register on August 30, 2000 [pp. 52762-52774] and August 8, 2002 [pp. 47311 to 47323]. In essence, these policies require

federal fund recipients to take reasonable steps to create meaningful access to information and services provided at the State and local level. "What constitutes reasonable steps to ensure meaningful access will be contingent on a number of factors. Among the factors to be considered are the number or proportion of LEP persons in the eligible service population, the frequency with which LEP individuals come in contact with the program, the importance of the service provided by the program, and the resources available to the recipient." Department of Justice Policy Guidance dated August 11, 2000.

The Annotated Code of Maryland-State Government Article §§10-1101--10-1104 also mandates that State departments, agencies, and programs take reasonable steps to provide equal access to public services for individuals with limited English proficiency. The law also requires certain "vital documents" to be translated into any language spoken by a LEP group that constitutes 3% of the overall population within a specified geographic area under specified circumstances.

This version of the DHMH 020607 LEP Policy supersedes an earlier version dated December 1, 2003. The changes are administrative in nature, replacing the name of the Office of Community Relations (OCR) with the Office of Equal Opportunity Programs (OEOP).

III. POLICY STATEMENTS

A. DEFINITIONS

1. The definitions included in the Annotated Code of Maryland, State Government Article, §10-1102 are hereby included by reference in this policy. **http://mlis.state.md.us/cgi-win/web_statutes.exe?gsg&10-1102**

2. **"Appropriately trained"**- shall mean:
   - proficiency in both English and the language spoken by the LEP individual;
   - orientation or training that includes the ethics of interpreting; and,
   - fundamental knowledge in both languages of specialized terms and concepts used in the subject program.

3. **"Covered entities"** shall mean, to the extent that they provide services or benefits directly to the public:
   - all administrations and programs operated or funded by DHMH;
   - all grant-in-aid programs of DHMH;
   - all health service providers, contractors, or subcontractors of DHMH that receive Federal or State funds.

   "Covered entities" excludes any DHMH unit or other entity that does not provide services or benefits directly to the public including but not limited to the DHMH Office of Procurement and Support Services (OPASS), the Office of Human Resources (OHR), the Laboratories Administration, and the Health Occupation Boards.

4. **"Fair Practices Officer"** shall mean the Executive Director, OEOP, or his/her designee.

5. **"Limited English Proficiency (LEP)"** shall describe someone who, as a result of his/her national origin cannot adequately understand or express

oneself in a health care or social services setting using the spoken or written English language.

6. **"Vital Documents"** shall mean documents that individuals applying for services or benefits from a covered entity must understand, respond to or complete in order to access the services/benefits or continue to receive the services or benefits. Vital documents also include documents that inform the participant of his/her rights under each covered entity.

B. GENERAL POLICY STATEMENTS

It is the policy of DHMH that eligible applicants and recipients having limited English proficiency shall be provided with equal access to public services in accordance with State and Federal law. Through the adoption of this policy, DHMH seeks to enhance the quality and efficacy of the services provided to persons with limited English proficiency.

C. RESPONSIBILITES

1. The Office of Equal Opportunity Programs (OEOP) and the Office of the Inspector General (OIG) are responsible for monitoring the ongoing efforts of all DHMH units to comply with this policy.

2. The Chief Administrative Officer of each DHMH unit shall be responsible for implementing this policy, with respect to the programs operated by that unit.

3 The OEOP will provide technical assistance by cataloging translation and interpreter resources.

4. The OEOP will monitor the efforts of covered entities to implement this policy and offer recommendations to enhance the effectiveness of these programs.

5. Each principal DHMH unit and other covered entities identified by the Department will submit an annual report to the OEOP beginning July 30, 2004. Subsequent annual reports will be submitted by July 30th of each year. The report shall include the following information:
   a. A summary of efforts to fully implement and improve LEP services during the reporting period;
   b. An outline of possible initiatives to enhance LEP services that might be implemented during the forthcoming reporting period;
   c. A listing of vital documents translated in accordance with this LEP policy;
   d. A description of the number of individual translator services provided to LEP individuals and the process used to deliver such services;

D. LANGUAGE ASSISTANCE PROCEDURE

1. Language assistance procedures will be developed for each covered entity subject to this policy. These procedures will take into consideration:
   a. the number or proportion of LEP persons eligible to be served or likely to be encountered by the covered entity;

b. the frequency with which LEP individuals come in contact with the program;
c. Nature and importance of the program, activity or service provided by the program to people's lives; and
d. Resources available to the covered entity and costs.

2. Language assistance procedures shall be designed and implemented so that the covered entity has the affirmative capability to communicate with the LEP individual.

3. Covered entities shall take appropriate steps to make LEP individuals aware that they may request the services of an interpreter or have access to other appropriate communication aids. In accordance with legal mandates, these services shall be supplied by the program at no cost to the individual. Depending on the circumstances, notification may be given verbally by staff, posted at appropriate entry points throughout the facility, and/or printed on forms and brochures.

4. Program staff will be instructed not to require/request that LEP persons utilize family members, especially minor children or friends as foreign language interpreters. The emotional involvement of family or friends with an LEP person can jeopardize interpretation and translation of critical information. Additionally, family or friends may not be adequately versed in the specialized terminology required for communication between the LEP person and the service provider.

5. A person's own interpreter should only be used at the request of the LEP person, and when use of that interpreter would not compromise the effectiveness of services or violate the LEP individual's confidentiality. An LEP person's request to use his/her own interpreter will be noted in the individual's record.

6. Covered entities shall take appropriate steps to secure access to community or contractual interpreter resources. These resources may be utilized in the event that the program does not have sufficient and/or competent in-house interpreter resources or in the event that in-house interpreter resources are not available for a specific language or at a specific time. All costs incurred through the use of a contractual interpreter will be paid by the covered entity.

7. The procedures and information necessary for securing qualified foreign language interpreters, including contact information for both live interpreters and telephone service interpreters, shall be made available to employees, especially staff that are in direct contact with patients, family members, and program clients (e.g., physicians, nurses, aides, billing clerks, admissions personnel, etc).

8. If the program utilizes in-house staff interpreters, these staff members will be appropriately trained to provide needed services.

9. The covered entity shall maintain appropriate records of requests for communication assistance.

10. Vital documents will be translated into appropriate languages and made available to LEP individuals.

EXCEPTIONS: "Vital documents" does not include applications and examinations related to licensure, certification, or registration under the Annotated Code of Maryland: Health Occupation Article, Financial Institutions Article, and Business Regulation Article, within the jurisdiction of DHMH or DLLR.

11. Modifications to Language Assistance Procedures will be made whenever necessary to ensure that LEP individuals have meaningful access to DHMH program services.

E. COMPLIANCE

The Fair Practices Officer shall monitor the LEP Policy compliance efforts of each covered entity and will, with the assistance of program designees, enforce this policy. The Fair Practices Officer or designee shall investigate LEP complaints as it does other EEO complaints.

IV. REFERENCES

- Title VI, Civil Rights Act of 1964, as amended. **http://www.usdoj.gov/crt/cor/coord/titlevi.htm**
- *Lau v. Nichols*, 414 U.S. 563 (1974). **http://laws.findlaw.com/us/414/563.htm**
- Federal Executive Order No. 13166 signed on August 11, 2000. **http://www.usdoj.gov/crt/cor/13166.htm**
- U.S. Department of Health and Human Services-Office of Civil Rights Policy Guidance, Federal Register, August 30, 2000 [pp. 52762-52774]. **http://www.hhs.gov/the Equal Opportunity Programs/lep/the Equal Opportunity Programslepguidance.htm**
- U.S. Department of Health and Human Services-Office of Civil Rights Policy Guidance, Federal Register, August 8, 2002 [pp. 47311-47323]. **http://www.hhs.gov/the Equal Opportunity Programs/lep/the Equal Opportunity Programslepguidance.htm**
- Annotated Code of Maryland-State Government Article- §§10-1101--10-1104. **http://mlis.state.md.us/cgi-win/web_statutes.exe?gsg&10-1101**

APPROVED:

/S/ Signature on file

S. Anthony McCann, Secretary, DHMH

September 5, 2006
Effective Date

MARYLAND
DEPARTMENT OF
BUDGET & MANAGEMENT

MARTIN O'MALLEY
Governor

ANTHONY BROWN
Lieutenant Governor

T. ELOISE FOSTER
Secretary

On June 20, 2007, the Board of Public Works approved new contracts to provide foreign language interpretation services to commence on July 1, 2007 and terminate on June 30, 2012, as follows:

Lionbridge Global Solutions II, Inc.: **BPO #050B7800036**
PRIMARY CONTRACTOR: Onsite Interpretation Services

Schreiber Translations, Inc.: **BPO #050B7800035**
PRIMARY CONTRACTOR: Written Document Translation Services

CTS LanguageLink: **BPO #050B7800015**
PRIMARY CONTRACTOR: Telephonic Interpretation Services
SECONDARY CONTRACTOR: Onsite Interpretation Services; *and*
Written Document Translation Services

State agencies using this contract are required to reference the BPO #s listed above when entering purchase orders in ADPICS.

Each agency is responsible for establishing their account(s) and reimbursing CTS LanguageLink, Lionbridge Global Solutions II Inc., and Schreiber Translations, Inc. respectively for services rendered.

Please copy Jacqué Boock (jboock@dbm.state.md.us), Contract Administrator, on correspondence regarding issues that may arise while doing business with each vendor.

If you have any questions, please contact Andrea R. Lockett at 410-260-7374 or by email at alockett@dbm.state.md.us.

Although ALL interpreting services are available 24/7/365, please contact each company as follows to set up your account (User ID) and find out about user training:

Telephonic Interpretation:
Sarah Gamble / 1-877-963-7466 / sarahg@ctslanguagelink.com

Onsite Interpretation:
Susan Gryder / stateofmaryland@lionbridge.com / 1-800-423-6756, x 4046

Written Document Translation:
Andres Peterson / translation@schreibernet.com / 1-301-424-7737 x131

FOREIGN LANGUAGE INTERPRETATION CONTRACTS
RATES AND TERMINOLOGY

The following terms apply to ALL Service Categories:

Continuously Available – Provision of translation services on a 24-hours per day, 7 days per week, 365 days per year basis (366 days in a leap year).

Core Languages – A specified group of mandatory languages within each service category. Offerors shall be able to provide Continuously Available services for all mandatory languages within each service category being proposed.

Non-Core Languages –Languages not specified as Core Languages.

Non-Standard Hours – All hours not specified as Standard Hours.

Observed Holidays – The following are the Observed Holidays for this RFP. Each holiday will start at 12:00 a.m. and end at 11:59 p.m. on that day: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day.

Requesting Agency or Requesting Entity – The specific State government agency or non-State of Maryland government entity requesting telephonic, on-site and/or written document translation services.

Requesting Agency or Requesting Entity Representative – A Representative of the specific State government agency or non-State of Maryland government entity serving as the contact person for billing and all other purposes related to the request of telephonic, on-site and/or written document translation services. ***A Requesting Agency or Requesting Entity may designate more than one individual authorized to initiate requests.***

Standard Hours – Standard Hours are weekdays (Monday through Friday) from 8:00 a.m. to 8:00 p.m. Local Time, excluding Observed Holidays.

User ID – The identification code assigned by the Contractor to the Requesting Agency or Requesting Entity for billing and contact purposes for telephonic, on-site and/or written document translation services.

The State contract prices for the following services apply to all languages:

Telephonic Interpretation: - Primary Contractor – CTS LanguageLink

~Year 1 (7/1/2007 – 6/30/2008);
Standard and Non-Standard per minute rate - **$0.85** (billed in 1/10th of a minute increments after the first minute)

[Telephone interpretation under the previous contract was $1.73 per minute]

Onsite Interpretation: - Contractor – Primary Lionbridge Global Solutions II, Inc.

~Year 1 (7/1/2007 – 6/30/2008);

Standard and Non-Standard hourly rate –

$49.45 Routine core languages / **$52.75** Expedited core languages / **$56.05** Critical core languages
$59.34 Routine non-core languages / **$65.28** Expedited non-core languages / **$65.28** Critical non-core languages

Routine, Expedited and Critical Onsite Interpretation - two hour minimum; billing in 1/10th of an hour increments thereafter during both Standard and Non-Standard hours.

Mileage over thirty (30) miles, one way from interpreter's Base of Operations, reimbursable in accordance with State travel regulations.

Travel Time over thirty (30) miles, one way from interpreter's Base of Operations, reimbursable in 1/10th of an hour increments, at the rate of 1 minute of time for each ½ mile traveled. Travel distance shall be verified using the mapping distance listed on Mapquest.com.

Base of Operations – Location from which an interpreter will be traveling to reach a destination of onsite language translation; i.e. the interpreter's home address.

Critical On-Site – Requests for on-site interpretation that are sent by the Requesting Agency/Entity to the Contractor with less than six (6) hours notice.

Expedited On-site – Requests for on-site interpretation that are sent by the Requesting Agency/Entity to the Contractor with less than forty-eight (48) hours but greater than six (6) hours notice.

Long-term Onsite Assignments – Onsite assignments beyond eight (8) hours.

On-Site State Representative – An individual authorized by the State to validate the information contained in Section B of the On-site Interpreter Assignment Sheet attached as Attachment M.

"Point-To-Your-Language" Cards – A card (no smaller than 2" x 3" and no larger than 3" x 5") that is constructed of a lightweight, but durable material that contains the appropriate translation for "Do You Speak" in (at a minimum) all eleven (11) On-Site Core Languages on one side and Additional Languages and Dialects on the other side. These cards shall be made available by the Primary Contractor to on-site interpreters, Requesting Agency(s), Requesting Entity(s) and the Contract Administrator.

Primary Contractor For On-Site Interpretation Service – The Contractor that will be initially contacted for all occasions of need of on-site interpretation.

Repetitive Onsite Assignments - Onsite assignments that are repetitive or of the same nature.

Routine On-site – On-site interpretation requests that are sent by the Requesting Agency/Entity to the Primary Contractor with a minimum of forty-eight (48) hours notice.

Secondary Contractor For On-Site Interpretation Service – The Contractor that will be contacted if the Primary Contractor for On-Site Interpretation Service does not provide service in a timely manner.

~ 20% discount for advanced-notice scheduling of 1 interpreter for long-term and/or repetitive assignments over 8 and up to 16 hours (all languages)

~ 10% discount for non-advanced-notice scheduling of 1 interpreter for long-term and/or repetitive assignments over 8 and up to 16 hours (all languages)
~ 20% Surcharge for requesting interpreter with specific Knowledge, Skill-set or Certification; i.e. legal or medical terminology
~ Will receive 25 Point-To-Your-Language Cards to each Requesting Agency upon account set-up.

[Onsite interpretation under the previous contract was $70.00 per hour with one hour minimum/billing in half hour segments thereafter; no requirement to provide any specific number of Point-To-Your-Language Cards]

Written Documentation Translation: - Primary Contractor – Schreiber Translations, Inc.
~Year 1 (7/1/2007 – 6/30/2008);
Routine Written Documentation translation per word rate - **$0.185** (for continuously available core/non-core languages)
Routine Written Documentation translation per word rate - **$0.185** (for not continuously available non-core languages)
Expedited Written Documentation translation per word rate - **$0.19** (for continuously available core/non-core languages)
Expedited Written Documentation translation per word rate - **$0.195** (for not continuously available non-core languages)

~ 75% discount for repetitive text clearly identified by the Requesting Agency

Expedited Written – Requests for 10 or fewer pages of Target Language translation that shall be completed within one (1) day from the day the Requesting Agency or Entity sends the Source Language to the Contractor. One additional day shall be permitted for each additional 10 pages of Target Language translation.

Repetitive Text – For written translation services, language that is repeated within a document or from a previous document to a subsequent document in a single assignment or from a previous assignment to a subsequent assignment .

Routine Written – Requests for 20 or fewer pages of written document translation that shall be completed within one (1) week from the day the Requesting Agency/Entity sends the Contractor the Source Language. One additional day shall be permitted for each additional 10 pages of Target Language translation, or portion thereof, beyond the first 20 pages.

Source Language – For written translation services, the language in which existing documents are written.

Target Language – For written translation services, the language into which existing documents are to be translated.

[Written Documentation translation under the previous contract was $0.252 per word]

Appendix G

Fee Assessment Script

Fee Assessment Script

- Welcome to the Maryland County Health Department Family Planning clinic. The clinic is supported with State and federal funds. This allows us to offer services that are affordable for those most in need, especially people who do not have insurance.

- The clinic fee will cover the entire cost of your family planning visit, including any laboratory tests that we do and cost of whatever contraceptive you receive.

- The clinic fee is based on your ability to pay. For that reason I need to ask you a couple of questions.

- What is your/your family's yearly income?

- Did you have anything that shows that amount?

- In cases where people do not have documentation of their income, we ask them to tell us how much income they have and then to sign a form indicating what they have said and that it is a true statement.

- Based on the information you have provided, your clinic fee today is _____.

- Will you be able to pay all or part of the fee today?

- If you cannot pay your fee today, we will send you a bill. Is there any reason we should not mail a bill to you?

- Some people who do not have to pay a fee or whose fee is very low ask if they can make a donation to help cover the cost of the services. We are happy to accept donations but this will not affect your services any way.

- We may need to contact you to follow up with lab results other important information. May we contact you at home or by phone? If not, what is another way to contact you?

- Thank you for choosing our clinic for your family planning services. We want to help you to stay healthy and to plan your life and your family in a way that is best for you.

DRAFT 2/07

Appendix H

Quality Assurance Site Review Process

CENTER FOR MATERNAL AND CHILD HEALTH
MARYLAND STATE FAMILY PLANNING PROGRAM
CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

Introduction

The name of the Quality Assurance/Continuous Quality Improvement Process for the Family Planning and Reproductive Health Program is the **Center for Maternal and Child Health Maryland State Family Planning Program Clinical and Administrative Site Review Process.**

I. Purpose

The purpose of the quality assurance (QA) and continuous quality improvement (CQI) activities is to measure the effectiveness of the family planning program's mission and goals. Title X Program Guidelines Section 10.4 requires that "a quality assurance system must be in place that provides for ongoing evaluation of project personnel and services."

II. Principles

A Quality Assurance System, according to Title X Guidelines, should include:

A. An established set of clinical, administrative, and programmatic standards to maintain conformity (i.e. Maryland State Family Planning Program Administrative and Clinical Guidelines);
B. A tracking system for clients in need of follow-up and/or continuing care;
C. Ongoing audits to determine conformity with agency standards;
D. Medical review procedures to evaluate clinician performance, to provide feedback to health care providers, and to initiate any needed corrective action for areas needing improvement;
E. Periodic review of guidelines, protocols and procedures to insure maintenance of current standards;
F. A process to obtain consumer feedback;
G. A procedure to insure ongoing and systematic documentation of quality assurance/ continuous quality improvement activities.

III. Process

A. The Maryland State Family Planning Program within the Center for Maternal and Child Health (CMCH) will maintain a schedule of site reviews and medical record audits of all family planning program service sites (local health department programs and contracted vendors).

B. All sites will be reviewed on an annual basis either through a site visit by Maryland State Family Planning Program reviewers or through a self-review

system which provides for a written summary report to the Maryland State Family Planning Program. Forms will be developed and periodically revised by the Maryland State Family Planning Program to assess compliance with state and federal regulations and quality client care standards. Additional information on the content and structure of local health department/vendor quality assurance systems may be found in the most current edition of the "*Family Planning Program Administrative Guidelines."*

C. Local program files should include a description of local quality assurance plans, written documentation of local activities, trainings, and meetings, medical record review results, Information and Education Committee meeting minutes, client satisfaction survey results, and methods used to address problem areas.

D. Depending upon the nature of the family planning service site being reviewed, the annual site review process may include a Clinic Site Review, Chart Review, Observation of Client Visit, and Data Audit of reported visits (State reviews only). A Summary of Site Review form completed by the reviewer (State or local) and the Site Review Response Form written by the Site or Program Supervisor/Manager will be prepared for each site review and copies maintained in the CMCH Family Planning Program Site Review Process central files.

E. Participation in the Family Planning Site Review Process is a **Condition of Award** for all jurisdictions receiving family planning categorical grant funding through CMCH.

IV. Health Departments with a Single Site - Local Health Department Programs that have one site providing clinical services for Family Planning

A. A Full State Site Review by a Maryland State Family Planning Program Reviewer will be performed every two years. The reviewer may be the program consultant assigned to the local program, or may be an alternate designated Maryland State Family Planning Program Reviewer. A Full State Site Review includes completion of the Clinic Site Review, Observation of Client Visit, and Chart Review forms, and completion of the Family Planning Data Audit Worksheet. The reviewer completes all forms, follows a client through the clinic process, reviews charts, and inspects the site and local processes/policies. The local program will be expected to respond within 2 weeks of receipt to the Summary of Site Review findings, using the Site Review Response Form, which will be provided.

B. A Full State Site Review may be done by a single reviewer (the assigned program consultant or an alternate reviewer designated by the Site Review Process Planning Team) or a two person review team, with the review team dividing up the multiple tasks.

C. In the intervening year between Full State Site Reviews, the local program will conduct a Self-Review, to include a site inspection, an internal review of local

processes/policies, chart review, and client visit observation. Site Review tools – Clinic Site Review, Observation of Client Visit, and Chart Review forms, plus associated instructions forms - will be provided. A time frame for conducting the Self-Review will be provided to the local Family Planning Program Supervisor/Manager at the beginning of each calendar year's cycle by the CMCH program consultant. The local Program Supervisor/Manager will arrange the scheduling of Self-Reviews, and determine who will conduct the Self-Review. At the discretion of the Program Supervisor/Manager, different staff may be used for different portions of the Review, or a single staff person (or the Program Supervisor/Manager) may conduct the entire Self-Review. One day or multiple days may be used to complete all portions of the Review. As a result of the Self-Review the local program will identify any problems found and use the Summary of Site Review form to compile results. The local program will then develop a plan to address those problems, using the Site Review Response form.

D. Copies of the completed Summary of Site Review and Site Review Response forms are to be provided to the CMCH family planning contract monitor within 2 weeks of completion of the Self-Review for review and filing in the Central Office Site Review Process files. These forms may be returned by electronic copy (e-mail), FAX or mail.

E. All completed working forms must be kept as part of local program Quality Assurance files, and should be available for on-site review when requested by the Family Planning/Reproductive Health program consultant or designated State reviewer.

F. The Site Review Process Certification Form, developed by the Site Review Process Planning Team, will be used to document the actual completion of the Self-Review in the local programs. This Certification form is to be signed by the local program supervisor/manager/director (or other responsible designee), certifying that the Self-Review has been done according to the described process and the results are accurately reported. The signed form is to be returned by mail or FAX when the Summary form and Response form are returned. An **electronically scanned** copy of the signed form is acceptable for those sites preferring to use this technology. All forms should be directed to the CMCH family planning program consultant for filing in the Central Office Site Review Process files, with a copy kept with the local program Self-Review Quality Assurance files.

V. Health Departments With Multiple Full-Service Sites - Local Health Department Programs that have multiple full-service sites or satellites providing clinical services for Family Planning during all hours and days that the local health department is open

A. A Full State Site Review (see Section IV A-B) will be done on one site each year on a rotating basis, with no site remaining unreviewed by a State Reviewer for more than 3 years. In the case of local programs with more than

three full service sites, more than one review per year within that jurisdiction will be scheduled in order to insure a full State site review every three years for every site.

B. Self-Reviews (see previous description) will be done by the local program for each permanent site on an annual basis except for the site or sites that will be undergoing a Full State Site Review for the year. The schedule for State Site Reviews for multiple full service site programs will be provided at the beginning of each year's cycle for local planning purposes, along with the time frame for completing Self-Reviews. Review of programmatic/administrative processes and policies does not have to be repeated if the satellite site follows the same administrative guides and policies as the main site. This should be noted by the reviewer on the Site Review form "Comments" section for clarity.

C. All completed working forms for Self-Reviews must be kept as part of local program Quality Assurance files, and should be available for on-site review when requested by the Family Planning/Reproductive Health program consultant or designated State reviewer. Copies of the completed Summary of Site Review and Site Review Response Forms for Self-Reviews are to be provided to the CMCH family planning program consultant within 2 weeks of completion of the Self-Review for review and filing in the Central Office Site Review Process files. These forms may be returned by electronic copy (e-mail), FAX or mail

D. The Site Review Process Certification Form will be used to document the actual completion of Self- Reviews in the local programs. This Certification form is to be signed by the local program supervisor/manager/director (or other responsible designee), certifying that the Self-Review has been done according to the described process and the results are accurately reported. The signed form is to be returned by mail or FAX when the Summary form and Response form are returned. Electronically scanned copy is also acceptable. All forms should be directed to the CMCH family planning program consultant for filing in the Central Office Site Review Process files, with a copy kept with the local program Self-Review files. A separate signed Certification form is required for each site.

E. Local programs are to report the opening of any new sites or sites re-opening after major renovation to their assigned program consultant. A brief "Walk-Through" of any new or newly renovated sites should be performed by the program consultant or State Reviewer designee within 12 months of opening, at a clinic or non-clinic time convenient to both the local program and the consultant/reviewer. Pages 1-4 of the Clinic Site Review form should guide the Walk-Through assessment of the physical characteristics of the site. These the elements on these pages should be completed to the extent possible, and include brief narrative comments on the physical characteristics and location. A Summary Report and subsequent Response are not required **unless** serious compliance issues are noted on the Walk-Through. The Walk Through report should be placed in the Central Office Site Review Process

files. The site should also be placed on a future schedule for Full State, Self-, or Abbreviated Review as appropriate to the site characteristics.

VI. Health Departments with Non-Permanent Satellite Sites Local Health Department Programs that have a single main site but also operate non-permanent satellite clinic sites on a periodic basis (sites that are not open each day during regular health department hours, but are open only for limited hours/days/services)

A. The main site will be subject to the procedure as described for Single Site programs, including a Full State Site Review every two years and a Self-Review in the intervening year.

B. Non-Permanent Satellite sites will be subject to a brief physical facility site inspection "Walk-Through" visit by the program consultant or a designated State reviewer at least once every three years. Each satellite may be inspected on a separate visit day, or all satellites may be visited on a single day. These visits do not have to take place during the time of a scheduled clinic, since the client observation is not a required element of this inspection, but may be done at a time convenient to the local program and the program consultant/designated State reviewer. The Clinic Site Review form should be used to guide the inspection, and the State reviewer should complete Pages 1 through 4 to the greatest extent possible and add any narrative comments or observations. Chart Review, Client Observation, and programmatic/administrative procedures and policies will be evaluated through the main site's Full State Site Review or Self-Review. A Summary Report and subsequent Response are not required **unless** serious compliance issues are noted on the Walk-Through.

C. The local program will perform an Abbreviated Self-Review of the satellite sites on an annual basis. Items to be assessed will include Pages 1 through 5 of the Clinic Site Review form, and Observation of Client Visit form. If records are kept on a permanent basis at the satellite site, the Chart Review form should also be completed as part of the abbreviated Self-Review. If records are transported to and from the main site, the Chart Review will be performed as part of the main site's Full State or Self-Review. Review of programmatic/administrative processes and policies does not have to be done for non-permanent satellites, and is to be incorporated into the review of the local program's main site. As a result of the Abbreviated Self-Review, the local program will identify any problems found and use the Summary of Site Review form to compile results. The local program will then develop a plan to address those problems, using the Site Review Response form.

D. All completed working forms for Abbreviated Self-Reviews of non-permanent satellite sites must be kept as part of local program Quality Assurance files, and should be available for on-site review when requested by the Family Planning/Reproductive Health program consultant or designated State reviewer. Copies of the completed Summary of Site Review and Site Review

Response forms for each satellite site are to be provided by e-mail, FAX or mail to the contract monitor for review and filing in the Central Office Site Review Process files, with a copy of all documents kept in local program files.

E. The assigned CMCH family planning program consultant should be sent the signed Site Review Process Certification Form, with the signature of the local program supervisor/manager/director or designee, certifying the Abbreviated Self-Review has been done according to the described process and the results are accurately reported. This Certification Form will be kept in the Central Office Site Review Process files.

VII. Health Departments with Sub-Grantees/Contractors – Local or State health department programs that have delegated services to other agencies or contracted with sub-grantees to provide family planning services

A. Local Programs that have entered into contractual arrangements to provide family planning services are expected to review the performance of their subgrantees/contractors and visit contracted sites at least annually. These Self-Reviews of subgrantees are the responsibility of the local health department entering into the contractual arrangement. The local program may develop its own Site Review Process for its contracted sites, or may use and adapt the existing Site Review Process forms in use by the Maryland State Family Planning Program, CMCH. The procedure to be used should be discussed with the CMCH assigned program consultant for that local program, and the requirements for annual Site Review should be clearly stated in the contractual arrangements with the subgrantee/contractor. Subgrantees/contractors may NOT perform their own self-reviews for reporting as part of this Site Review Process if they are in a contractual arrangement with the local health department. Alternate Site Review Process procedures and forms must be submitted for approval to the Family Planning Program Site Review Process Planning Team and assigned Family Planning program consultant prior to use.

B. The local health department reviewer should share Self-Review results in writing with the sub-grantee/contractor and require a written response for any areas noted as needing improvement or not in compliance with their contract. All completed reports and working forms for contractual subgrantee/contractor sites must be kept in the local health department Quality Assurance files and be made available for on-site review by the CMCH Family Planning/Reproductive Health program consultant or designated State reviewer when requested. Copies of the completed Summary of Site Review and Site Review Response forms (or their local equivalents) for each contractual site are to be sent to the CMCH program consultant by e-mail, FAX or mail for review and filing in the Central Office Site Review Process files within 2 weeks of completion.

C. The CMCH program consultant/reviewer will check the results of the local program's review activities for each subgrantee/contractor, and work with the

local health department program to insure that any serious compliance problems are promptly addressed.

D. The local program supervisor, manager, director or other appropriate individual will be expected to certify in writing on a Site Review Process Certification Form as to the performance and accuracy of results for the local review activities for each contractual subgrantee/contractor. This signed Certification Form should be returned by mail or FAX or as scanned electronic copy to the assigned family planning program consultant when the Summary and Response forms are returned. All forms will be kept in the Central Office Site Review Process files.

E. Maryland State Family Planning Program contracts with private, non-profit providers will be monitored on an annual basis using a Full State Site Review process (see Section IV A-B). The Site Review Process Planning Team will identify site reviewers to apply the Site Review Process and tools to each contractual site providing Family Planning Services under an existing contract. In arrangements where local and state contracts overlap at the same sites, responsibility for conducting the Full Site Review may be shared between the Maryland State Family Planning Program and the local family planning program, if such an arrangement is agreeable to both State and local programs. Alternatively, State and local site reviews may be conducted independent of each other.

VIII. Sites with Identified Significant Compliance Issues – Sites that are identified as having one or more major compliance issues during a Full State Site Review or reported as part of a Self-Review

A. The Maryland State Family Planning Site Review Process Planning Team (see Section X) will meet on a periodic basis (at least quarterly) and as needed to discuss identified major site compliance problems requiring more intense follow-up. The Team will establish and monitor an appropriate follow up plan for these sites. The Team will recommend a course of action to the assigned CMCH program consultant for the local program with the compliance issue.

B. A problem-specific follow up contact by the CMCH Family Planning program consultant for that local program or a designated State reviewer should be made to any site that is identified as having a serious clinical or administrative compliance problem during the course of a Full State Site Review or identified through reported Self-Review results. All identified problems are expected to have a Plan of Action for correction listed in the Site Review Response Form, and the follow-up visit should occur within 3 - 12 months of the institution of corrective measures, depending on the severity and type of problem.

C. At the discretion of the assigned program consultant and with consultation from the Site Review Process Planning Team, follow-up may be done in person or via telephone or e-mail, with appropriate documentation provided to

the assigned program consultant for review and filing in the Central Office Site Review Process file. Also at the discretion of the program consultant and with Team consultation, more frequent Full State Site Reviews, follow-up site visits, or Self-Reviews may be required to insure continued monitoring of the identified problem.

IX. Special Topical Site Reviews – Site reviews for a specific or topical purpose at one or more local health department sites or subgrantee/contractor sites

A. From time to time, a site review may be scheduled to assess a particular clinical or administrative issue or procedure, or to review a specific clinic process in one or more local sites. These topical reviews will generally be limited in focus and activity, and be in addition to any regularly scheduled Full State Site Reviews or Self-Reviews.

B. Special Topical Site Reviews will be considered and arranged by the Site Review Process Planning Team in consultation with assigned CMCH Family Planning program consultants. Special Site Reviews may be requested, with justification, by CMCH administrative or clinical staff or by local health department program staff.

C. On determination of need of a special topical review, the Planning Team will then assign appropriate reviewers from the State Family Planning Program, or will determine if the review is best performed by local health department staff at the local program level.

X. Site Review Process Planning Team

A. A Maryland State Family Planning Program Site Review Process Planning Team will be established and will meet at least quarterly. This Team will be chaired by the Chief Nurse Consultant, Family Planning and Reproductive Health or her/his designee, and will consist of Family Planning/Reproductive Health program consultants and Family Planning/Reproductive Health Program site reviewers. CMCH administrative personnel may also request or be invited by the Team to take part in these meetings, depending on issues to be discussed.

B. The Site Review Process Planning Team will be responsible for establishing the annual schedule of Full State Review, Self-Review, and Abbreviated Review visits and insuring that the local family planning programs receive the schedule for local review planning purposes. The Planning Team will assign reviewers for all Full State Site Reviews, Abbreviated Reviews, and Walk-Through visits needed in local health departments and for contractual agencies, and for any special site reviews or follow-up reviews needed.

C. The Site Review Process Planning Team will address special situations, such as school-based clinics, community health centers, non-profit clinics or

hospital-based services on an as-needed basis. Modification of the Site Review Process to accommodate special situations will be determined by the Team.

D. The Site Review Process Planning Team will discuss issues related to the Site Review Process raised by program consultants, site reviewers, CMCH administrative personnel, or local health department personnel. The Team will periodically review the process and forms, and modify in response to issues and changing program needs.

E. The Site Review Process Planning Team will review and approve proposed alternate Site Review Process forms and procedures developed by local programs to meet their local Site Review or subgrantee/contractor requirements. The Planning Team will provide consultation and Technical Assistance to local programs as needed in developing local procedures and forms and conducting the local Self-Review Process and subgrantee/contractor reviews.

F. The Site Review Process Planning Team will discuss specific site review compliance issues and concerns presented by program consultants/site reviewers and local programs, and provide consultation on the appropriate follow-up and plan of action.

G. A member of the Site Review Process Planning Team will be designated to periodically review the Central Office Site Review Process file, update the Schedule Tracking form, and file individual documents into the appropriate local program/agency folder. All files will be kept in a locked file cabinet.

H. Maryland State Family Planning Program Site Review Process Planning Team members will be available to State program consultants and reviewers and to local programs for consultation and technical assistance purposes on site review issues between scheduled Team meetings.

I. Minutes will be kept of Planning Team Meetings and maintained in the Central Office Site Review Process files

XI. Additional Site Review Process Information

F. The CMCH Family Planning program consultant may be the State reviewer for her/his assigned programs, but other State reviewers may perform the State Site Review in her/his stead. However, the assigned Family Planning program consultant is responsible for insuring State and Self-Reviews have been carried out for those assigned local family planning programs, and that the corresponding reports and certification forms are present in the Central Office Site Review Process files. Program consultants should periodically review their assigned program files, the State Review results, Self-Reviews, and Subgrantee/contractor results.

G. A Central Office Site Review Process File will be maintained at CMCH with a folder for each local program/agency/subgrantee and site, to contain all official letters, forms, and formal and informal communications relating to that site. This will be a locked file cabinet for security.

H. A Schedule Tracking Form will be maintained in the Central Office Site Review Process File, to include information on the date of last visit performed and type of visit, next projected or scheduled visit and type, reviewer assignment, Summary form completion dates, receipt of Response form and Certification form dates, and any other pertinent comments.

I. Local Programs will be advised that Technical Assistance will be available from the Family Planning/Reproductive Health Program Site Review Process Planning Team regarding instituting Self-Review activities, using Continuous Quality Improvement techniques to solve identified problems, and understanding the Clinical and Administrative Site Review Process. Assigned CMCH program consultants should be contacted to discuss Technical Assistance needs.

XII. Future Expansion – Peer Review Component

A Clinician Peer Review component is under development as a future portion of the Maryland State Family Planning Program Clinical and Administrative Site Review Process.

A. The core of the Peer Review component will be a Clinician Chart Review form, based on the existing Chart Review but incorporating specific elements relating to clinician function and client management within family planning clinical programs at the State and local levels. This Clinician Chart Review form is currently in draft revision form and scheduled for further piloting in selected local health departments.

B. After final revision and validation of the usefulness and applicability of the form, recommendations regarding the process and procedure for Clinician Peer Review will be established. The Site Review Process Planning Team will take the lead in form and procedure development for the process, and then solicit input from local programs and clinicians in finalizing the system and its forms. It is anticipated that clinician peer review will become part of a total process of Clinical Competency Assessment in the future.

C. It will be recommended that all local health departments and contractual agencies document a peer review process for clinicians (nurse practitioners, nurse midwives, physician's assistants, and physicians) working in a clinical capacity in the family planning program, and the Clinician Peer Review component of the Site Review Process will be made available for that purpose.

D. A check of local clinician peer review activities will be incorporated into the Full State Site Review and Self-Review procedures as part of the overall examination of clinical competency assurance.

E. Tentative future plans for implementation of the Clinician Chart Review include the use of a panel of 2 to 3 clinicians participating on a rotating, volunteer basis and representing both State and local programs. This Peer Review Panel will visit a local health department program to review local or contractual clinicians or a site where State clinicians provide services, reviewing a pre-determined number of client records using the review form, and developing a consensus statement on the practice of the clinician(s) undergoing peer review.

CENTER FOR MATERNAL AND CHILD HEALTH
MARYLAND STATE FAMILY PLANNING PROGRAM
CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

PROCEDURE FOR CONDUCTING SITE REVIEW VISITS

Section I - Full State Site Review

Procedure for Center for Maternal and Child Health Family Planning Program Consultants/Reviewers conducting Local Health Department or Contractor site reviews ONLY

All permanent local health department family planning service sites will be subject to a Full State Site Review conducted by a Center for Maternal and Child Health (CMCH) Family Planning Program Reviewer every 2 to 3 years, depending on the number of sites that comprise the specific local health department program. In addition, private, nonprofit agencies/subgrantees contracted by the State to provide family planning services will undergo a Full State Site Review annually. The schedule of future site review visits will be determined by the Maryland State Family Planning Program Site Review Process Planning Team. The schedule of sites slated for Full State Site Reviews during an upcoming calendar year will be made available to local programs at the beginning of the calendar year. The Schedule Tracking System forms will be regularly updated to reflect upcoming visits and the status of completed visits. The Full State Site Review may be performed by the assigned CMCH program consultant for a given local family planning program, or an alternate designated State reviewer. The reviewer should determine who in each local program/agency should be contacted concerning the site visit arrangements. The procedure is as follows:

1. Call or e-mail the family planning supervisor (from the current master list) to discuss and schedule the proposed Full State Site Review Process visit. At least part of the visit needs to be scheduled during a clinic session. Explain the entire site visit procedure. Tell her/him that you will walk through the clinic site to observe clinic systems/operation and clinic environment. Explain that you will want to observe an annual or initial visit from the time the client signs in until the end of the visit. Explain that you will be doing a chart review and that you will select the charts to be pulled using the pap log (or alternatively any other mutually agreeable process that assures a random record selection) on the day of the site review. State that you plan to do a Data Audit as well (see Section 1-3). Tell her/him if you will be coming alone or if anyone else will be with you either as an observer or as a second reviewer. Explain that a site manager or supervisor needs to be available for questions and assistance during the review.

2. Ask your contact to inform her/his supervisor/ nursing director/health officer about the visit and extend an invitation to be present for all or part of the review. Remind your contact that this quality improvement activity allows us to work together to insure high quality family planning services and to assure that Title X and State guidelines are being consistently followed, and that we look at the Site Review Process as a learning experience and a line of communication.

3. An extra component of the Full State Site Review that is NOT required in Self-Reviews is a data audit done by using the Family Planning Data Audit Worksheet. This form will be used to verify the accuracy of the data submitted by the subgrantee/contractor or local health department. In performing this portion of the review, a computerized list of unduplicated clients who received services during a specified quarter will be generated through the State Family Planning Program's current data system and provided to the reviewer(s). Each client will be identified with an ID number, date of birth, and date of services rendered. Local programs may need lists that include client names for purposes of record location. During the site visit, the computerized list will be used to select a random sample (25-50 records, OR 5-10% of unduplicated clients seen in the quarter) of records to be pulled and reviewed using the Worksheet in order to validate reported client visits. Incorporating this portion of the review may necessitate a second day visit, or two people performing the review together on a single day, depending on the complexity and size of the program being reviewed, and the preferences of the reviewer and program.

4. Two to four weeks before the scheduled visit, send a confirmation letter or e-mail that summarizes what was previously arranged by phone or e-mail. If requested by the program to be reviewed, send the most recent version (hard copy or electronic version) of each of the tools that will be used during the visit:

    Clinic Site Review
    Chart Review
    Observation of Client Visit
    Family Planning Data Audit Worksheet

6. Prior to the day of the visit, assemble all needed forms and review recent past site review reports for any significant issues that have been identified.

7. Day of visit- arrive and conduct site review as planned. Complete all required forms according to form instructions. If all elements of the review are not completed in one day, confirm arrangements for the return visit to complete the review. At the discretion of the State reviewer, portions of the Site Review form relating to local program-wide policies and procedures may be eliminated in the case of local health departments with multiple full-service sites if the main site or another full-service site has undergone a Full State Review within the past 12 months. This should be noted on those sections of the Site Review form that are being eliminated.

8. At the conclusion of the review, conduct a brief exit interview that may be attended by any personnel that the local family planning supervisor invites. This exit interview should cover those items that will be discussed as "Strengths" and "Areas Needing Improvement" on the Summary of Site Review form.

9. Prepare the review report within 4 weeks. Send a set of completed forms to the family planning supervisor or identified site review contact. The following items should be sent:

Cover letter with the completed Chart Review, Client Observation, and Clinic Site Review working forms

The completed Summary of Site Visit Form (This contains the areas of strength and the areas needing improvement)

The Response Form (The form will be completed and returned by the family planning supervisor)

10. At the reviewer's discretion, other forms may be included with the report, such as sample lab or pap logs, inventory control sheets, copies of guidelines or policies, medication information sheets, etc. in an effort to assist the site in reaching identified improvement goals.

11. Remind the family planning supervisor that the Site Review Response form should be completed after receipt of the Summary and mailed back to the reviewer at the Center for Maternal and Child Health within 2-4 weeks.

12. **NOTE:** If preferred by both State reviewer and local program, Summary and Response forms may be completed electronically. However, a copy of the working forms used for the review should be maintained in the Central Office Site Review Process file and a hard copy of working forms provided to the local program for their files.

13. Place a copy of all forms and all correspondence in the "To Be Filed" Central Office Site Review Process file for filing in the appropriate local program folder.

14. If a Response form is not received within 4 weeks, follow up with a reminder phone call or e-mail to the family planning supervisor/contact to see if she/he has questions or needs assistance. Be sure to stress the importance of a response for documentation and for the proper monitoring of the quality of the family planning program. Document follow-up calls or e-mail in the Central Office Site Review Process file folder for that program. If no response is received within 2 weeks of the phone call or e-mail, complete and send a follow-up letter to the local contact emphasizing the importance of a timely response. Place a copy in the Central Office file in the "To Be Filed" folder to insure that the Planning Team will be looking for a final response.

15. Review returned Site Review Response forms and place them in the "To Be Filed" folder of the Central Office file. Do not file in the local program folder yourself, because the receipt of Response forms is part of the Schedule Tracking information that will be regularly updated by the assigned Team member. **Bring any major time-sensitive problems or serious compliance issues specifically to the attention of the program consultant for that local program, or to the Chief Nurse Consultant or Family Planning Program Chief.** Other reviews or issues that need a discussion of appropriate follow-up may be referred to the next meeting of the Site Review Process Planning Team.

16. It is the State reviewer's responsibility to check for return of responses on a regular basis for those Site Reviews recently conducted. It is the family planning

program consultant's responsibility to be familiar with the results of State and local site reviews in the assigned programs, to insure that reviews have been scheduled according to the Site Review Process and to work with reviewers on any additional follow-up issues.

17. Collect questions or comments (i.e. good ideas, systems problems) encountered so that they can be discussed at Site Review Process Planning Team meetings. Also collect questions of a legal nature so that we can request answers from a legal source.

Section 2 - Local Health Department Self-Review

Procedure for Local Health Department Staff conducting local self-reviews on permanent family planning sites ONLY

The schedule of future Local Health Department Self-Review sites will be determined by the Maryland State Family Planning Program Site Review Process Planning Team. The Schedule Tracking System forms will be regularly updated to indicate which sites are scheduled for a Self-Review during the upcoming calendar year review cycle. Local family planning programs will receive the annual schedule for all reviews prior to the upcoming annual Review Cycle. The schedule will identify a quarter (first, second, third or fourth quarter) of the upcoming calendar year during which a given site's Self-Review is to be completed. All programs with single sites and/or multiple (one or more) permanent full-time satellite sites are expected to perform annual Self-Reviews for those sites that are not undergoing Full State Site Review for the year. The procedure for conducting a Local Health Department Self-Review is as follows:

1. On receipt of the annual Schedule for Site Reviews, the local Family Planning Program Supervisor/Manager will determine the best time during the assigned quarter of the calendar year to schedule the performance of the Self- Review for her/his full-service site or sites. Supervisors are encouraged to plan for the optimum and least disruptive times to accomplish all review components during the assigned quarter. The local Self-Review may be performed by the local Family Planning Program Supervisor/Manager, or the supervisor's designated reviewer. The supervisor may choose to assign multiple professional staff to different portions of the review. The Self-Review may be done during a single day or over multiple days, but all components (Clinic Site Review Form, Observation of Client Visit Form, and Chart Review Form) must be completed for all sites. The Data Audit Worksheet (or comparable data verification form) is NOT required as part of Self-Reviews except in the case of local program review of subgrantees/contractors (see Section 2-Procedure introduction).

2. Inform all staff of the date or dates of the review(s). This should occur two to four weeks prior to the Self-Review, or at the discretion of the Supervisor. Forms and other Site Review Process materials may be shared with staff as needed. Other supervisors, Directors of Nursing, Medical Directors, and Health Officers should be informed of the Self-Review process and schedule. Everyone involved should be reminded that this process is a learning experience and a line of

communication to insure high quality family planning services that are in compliance with state and federal guidelines and principles of good client care.

3. Inform the CMCH Family Planning Program Consultant of the dates scheduled for the Self-Review. This information will be maintained on the Schedule Tracking System in the Central Office Site Review Process file.

4. Prior to the Self-Review, assemble all needed forms and go over any recent past site reviews (State or Self) for any previously identified areas needing improvement.

5. On the day(s) of the review, complete all forms according to form instructions. At the conclusion of the review, supervisors should consider reviewing all findings with the staff involved and with nursing directors and health officers, or as appropriate. This discussion should cover those items that will be included in the Summary of Site Review form to be submitted to the CMCH program consultant for family planning

6. After all components of the review have been completed according to form instructions, use the Summary of Site Review to summarize the results. In addition, complete the Site Review Response form to address correction plans and timeline for any "Areas Needing Improvement" identified on the Summary. These forms should be completed within 2 weeks of completing the Self-Review. In addition, at this time, the program supervisor/manager needs to sign the Site Review Process Certification form, indicating that the Self-Review has been conducted according to procedure and the results are as indicated. This needs to be provided to the assigned program consultant for filing in the Central Office files, and a copy kept at the local program level.

7. A copy of **all** completed working forms, Summary, Response, and Certification forms must be kept in the local health department Quality Assurance files, since they may be requested for review by the CMCH Family Planning Program Consultant or designated Maryland State Family Planning Program reviewer. The working forms **do not** need to be sent to CMCH.

8. On completion of the report, send the Summary of Site Review and the Site Review Response form (by e-mail, FAX or mail) to the assigned CMCH contract monitor. The signed Certification form should also be included (if mail or FAX) or sent under separate cover if e-mail is used for the other forms. A scanned electronic copy of the Certification Form that has the required signature is acceptable for those programs that wish to use this technology. The program consultant will review the results, consult with the Site Review Process Planning Team if necessary to establish any specialized follow-up, contact the local program directly with any questions or suggestions, and place the forms in the Central Office Site Review Process file "To Be Filed" folder. The program consultant will also bring serious issues or concerns to the attention of the Chief and administrative staff of the Family Planning Program.

9. The Site Review Process Planning Team will periodically review Central Office files and Schedule Tracking information and advise program consultants of any

reviews needing scheduling or missing Summaries, Responses, or Certifications. Program consultants will contact the local program supervisors with reminders as needed.

Section 3 – Local Health Department Abbreviated Self-Review

Procedure for Local Health Department Staff conducting local self-reviews on non-permanent satellite family planning sites ONLY

An Abbreviated Self-Review may be done by the local health department program for those satellite sites that are not open on a full time basis during regular health department hours, but are open only for limited hours/days/services. The schedule of future Local Health Department Abbreviated Self-Review sites will be determined by the Maryland State Family Planning Program Site Review Process Planning Team. At the start of the calendar year, local family planning programs will receive the upcoming annual schedule for all reviews, indicating the quarter within the calendar year that the review(s) should be performed, including those deemed appropriate for Abbreviated Self-Review. If a local health department program believes that a site is qualified for an Abbreviated Self-Review but it has not been so designated on the schedule, the assigned contract monitor should be contacted and the issue discussed. The procedure for an Abbreviated Self-Review is as follows:

1. The local Family Planning Program Supervisor/Manager will determine the best time within the assigned calendar year quarter to schedule the Abbreviated Self-Review for her/his non-permanent satellite(s) and determine who will conduct the review.

2. Inform staff of the date or dates of the review(s). Forms and other Site Review Process materials may be shared as needed. Health Officers, Directors of Nursing, and other appropriate personnel should be informed, as should the assigned CMCH Family Planning program consultant.

3. Assemble all needed forms prior to the review, and go over recent past reviews (Self or State) for any special issues that had been identified.

4. All required forms should be completed according to form instructions. For Abbreviated Reviews, the Observation of Client Visit form needs to be done, and Site Review form pages 1-4 completed. Also assess the presence of the Family Planning Clinical and Administrative Guidelines on site. The remainder of the form may be deferred to the review (Full State or Self) of the main site. The Chart Review is not required if records are not kept permanently at the site.

5. At the conclusion of the review, consider reviewing all findings with the staff involved, Findings should be shared with health officers and directors of nursing as appropriate.

6. The Summary of Site Review form and the Site Review Response form should be completed and sent to the local program's assigned program consultant either

by e-mail, FAX, or mail within 2 weeks of the review. The program supervisor/manager should also complete and sign the Certification of Site Review form and mail or FAX back to the contract monitor. A scanned copy of the Certification form with original signature is acceptable. Copies of all working forms should be kept in the local program quality assurance files, and copies of the Summary, Response, and Certification forms will be kept in the Central Office Site Review Process files at CMCH.

7. The program consultant will review results, and provide any necessary consultations or suggestions, as described in Section 2-8.

Section 4 – Local Health Department Subgrantee/Contractor Review

Procedure for Local Health Department staff conducting reviews of local contractor/subgrantee sites ONLY

Local programs with non-profit sub-grantees or contractors should perform all components of the Self-Review for their contracted agencies on an **annual** basis. Local programs are also responsible for the accuracy of data submitted by their subgrantees/contractors. Local health departments should use the Family Planning Data Audit Worksheet to verify the accuracy of the subgrantee/contracted agency's data, or an alternate local means of data verification may be used instead. Alternate procedures used by local programs for data verification of subgrantees/contractors should be submitted to the Site Review Process Planning Team for review prior to use.

1. Local programs should develop contracts that specify participation in the Maryland State Family Planning Clinical and Administrative Site Review Process or comparable local quality assurance/improvement system as a requirement of the contract.

2. Follow the procedure outlined for Local Health Department Self-Reviews – Section 2, 1-8.

3. In addition, verification of the accuracy of submitted data is needed. The procedure used in Full State Site Reviews (Section 1 - #3) using the Data Audit Worksheet may be used, or an alternate method that has been presented to the CMCH program consultant and reviewed by the Site Review Process Planning Team. Computer-generated lists of unduplicated client visits for a specified quarter may be requested through the assigned CMCH Program Consultant as needed.

Section 5 - State Walk-Through Visits

Procedure for Center for Maternal and Child Health Family Planning Program Consultants/Reviewers ONLY

State Walk-Through Visits are brief physical facility site inspections done by State CMCH reviewers or program consultants to assess the physical characteristics and location of local health department program non-permanent satellite sites. Local

programs perform Abbreviated Self-Reviews for these sites. These satellite sites are subject to a Walk-Through Visit by CMCH contract monitors/reviewers every two to three years. The same process will be applied to new sites being opened or sites being re-opened after major renovation. Newly opened sites or newly renovated sites should have a physical facility inspection using the State Walk-Through Visit procedure within 12 months of opening. The procedure for Walk-Through Visits is as follows:

1. The Site Review Process Planning Team will determine what sites are subject to a Walk-Through Visit for the upcoming annual review cycle. Program consultants, clinical or administrative personnel, or local program staff should inform the Planning Team of the opening of new sites at any time, and those sites will be added into the schedule to insure a visit within 12 months of opening. The Planning Team will assign a reviewer to perform the Walk-Through (assigned program consultant or alternate State reviewer).

2. Contact the local program supervisor/manager and arrange a mutually convenient time to conduct the State Walk-Through Visit. The program supervisor must assure access to the site and should arrange for herself/himself or an appropriate staff designee to guide the Walk-Through and answer any facility-specific questions.

3. Visits should be arranged at least 2 weeks in advance. The arrangements will be confirmed in writing (e-mail or confirmatory letter).

4. Each satellite within a given local health department program may be inspected on a separate visit day, or all satellites may be visited on a single day. These visits do not have to take place during the time of a scheduled clinic, since the Observation of the Client Visit is not a required element of this inspection, but may be done at a time convenient to the local program and the program consultant/designated State reviewer.

5. The Clinic Site Review form should be used to guide the inspection, and the State reviewer should complete Pages 1 through 4 to the greatest possible extent and add any narrative comments or observations. An overall impression of the site should be included. Chart Review, Client Observation, and Administrative procedures and policies will be evaluated through the main site's Full State Site Review or Self-Review and are **not** part of the Walk-Through Visit.

6. Within 2 weeks of completion of the State Walk-Through Visit, place a copy of the Clinic Site Review form in the "To Be Filed" folder of the Central Office files. If there are no serious facility compliance problems noted, a Summary of Site Review form does not need to be done. However, if the Walk-Through reveals significant problems, the Summary should be completed and sent to the local program supervisor, and the Response form requested in return. Minor questions or issues may be discussed informally via phone or e-mail, and communication documented in the Central Office files.

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CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

INSTRUCTIONS FOR FAMILY PLANNING DATA AUDIT WORKSHEET

Purpose of Data Audit: To verify the accuracy of clinical services data reported by family planning programs in local health departments and by family planning subgrantees/contractors. The Data Audit Worksheet is designed to be used primarily for Full State Site Reviews conducted by Center for Maternal and Child Health (CMCH) Family Planning Program reviewers. However, the Data Audit Worksheet should also be used by local health department programs to verify the accuracy of clinical services information provided by their locally contracted subgrantees/contractors.

SECTION I - Procedure for Verification of the Accuracy of Submitted Data – STATE (CMCH) REVIEWERS ONLY

1. Provide a list of upcoming local health department and subgrantee/contractor site visits to the Family Planning Program Data Management Information Specialist at CMCH. A list of reported unduplicated clients with identifier, date of birth, and visit date for the preceding quarter of the year will be generated at the Central Office prior to the site review. Arrange to pick up needed lists prior to the site reviews.

2. **BE CERTAIN TO REVIEW AND ASSESS IF THE CLIENT LIST IS A LIST OF UNDUPLICATED CLIENTS**, as the first audit issue. Please note directly on the audit form if the list is or is **not** of unduplicated clients.

3. Randomly choose a representative sample of 25-50 unduplicated client records from the CMCH generated list. Request the clinic site to pull the selected records.

4. Using the Data Audit Worksheet, fill in the first 3 columns, then verify the reported data by placing an “X” or checkmark in the “Visit Documented” column if a family planning visit is documented in the client record for the date indicated on the CMCH generated list.

5. Document the total number of records reviewed in the TOTAL RECORDS row. Document the total number of accurate records in the last column. Determine the accuracy, in percent, of the data presented for validation by dividing the number of accurately documented records by the total number of records reviewed. CMCH CLIENT LISTS MUST BE COMPLETELY DESTROYED IMMEDIATELY AFTER THE AUDIT IS COMPLETED.

6. Report findings in the Summary of Site Review. The findings may be reported as:

   Data Audit Worksheet:
   No Duplicated Listings (or Duplicated Listings are present)
   Accuracy of Reported Data: [%] Visits documented for dates reported

7. The goal is 100% accuracy of reported data. Describe any findings below 100% accuracy in the "Areas Needing Improvement" section of the Summary of Site Visit form, and request a response to the finding, including a plan for reaching the 100% accuracy goal.

8. Serious compliance problems (under 90% Accuracy) with the Data Audit should be brought to the attention of the Site Review Process Planning Team and the Chief or Chief Nurse Consultant of the Family Planning and Reproductive Health Program.

SECTION II - Procedure for Verification of the Accuracy of Submitted Data - LOCAL HEALTH DEPARTMENT REVIEWERS ONLY

1. Local health departments that have subgrantees/contractors providing all or part of the family planning clinical services must be able to document a process by which the data submitted by subgrantees/contractors is verified for accuracy on an annual basis. The local Family Planning Program supervisor/manager should determine the appropriate staff person to conduct a Data Audit for data verification.

2. The Data Audit Worksheet (DHMH 4645) should be used by local programs to complete data audits of subgrantees/contractors. If an alternate method is used, inform the Site Review Process Planning Team at CMCH of the proposed process and form(s) to be used. The Planning Team will approve the process and forms, or work with the local health department program to insure a workable and locally feasible method of data verification for subgrantees/contractors.

3. When using the Data Audit Worksheet, request a list of reported unduplicated clients with identifier, date of birth, and visit date for a preceding quarter of the year from your State Family Planning Program Consultant. Your Program Consultant will then request the list from the CMCH Family Planning Program Data Management Information Specialist and arrange to get the list to you. On receiving the reported data list, conduct the data audit. See Section I – 2 through 8 for a full description of the procedure to be followed.

4. Results should be shared with the subgrantee/contractor under review. Findings below 100% accuracy should be considered an area needing improvement, and a plan for achieving the accuracy goal and for further follow-up should be developed between subgrantee and local health department. Bring serious problems with data reporting accuracy (below 90% Accuracy) to the attention of the assigned State Family Planning program consultant. Maintain copies of completed Data Audit Worksheets in the local health department quality assurance files to be available for review by the assigned State program consultant or designated State reviewer.

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FAMILY PLANNING DATA AUDIT WORKSHEET

Clinic_____ **Local Health Dept. Site**_____ **Subgrantee/Contractor Site**_____

Date of Review_____ **Quarter Reviewed**_____ **Reviewer**_____

Unduplicated Client List : Yes_____ **No**_____ **ACCURACY of DATA:** _____ **%**

CLIENT IDENTIFIER	CLIENT'S DATE OF BIRTH	DATE OF VISIT	VISIT DOCUMENTED
TOTAL RECORDS:	**----**	**----**	**# Accurate Records:**

DHMH 4645
CMCH 8/2004 (REV. 2/2008)

CENTER FOR MATERNAL AND CHILD HEALTH
MARYLAND STATE FAMILY PLANNING PROGRAM
CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

INSTRUCTIONS, DEFINITIONS AND SUGGESTIONS FOR COMPLETION OF THE CHART REVIEW FORM

INSTRUCTIONS

1. The Chart Review form should be completed as part of each Full State Site Review, each local Self-Review, and each subgrantee/contractor annual review. Abbreviated Reviews do not need to include the Chart Review component unless records are actually kept at the non-permanent site.

2. Select a date to perform the Chart Review, and a reviewer to complete the form. This form may be completed on a clinic or non-clinic day. It may be completed by itself, or in combination with other elements of the Maryland State Family Planning Site Review Process. At the State level, either CMCH FP program consultants or designated State site reviewers may perform the review. At the local health department program level, the family planning program supervisor may elect to complete the form, or an alternate staff person may be designated.

3. Records for review should be randomly selected from the abnormal pap records in the local Pap Log, or alternatively by any other process that assures a random selection. Five to ten records should be reviewed as part of the Site Review Process, although additional records may be requested for review at the discretion of the reviewer. This Chart Review should be performed as part of the Site Review Process independent of the local chart reviews required of all programs as part of internal Quality Assessment/Improvement activities.

4. Criteria listed in the Chart Review form are to be applied to visits since the last review at the clinic site, in order to allow for changes that had been made as a result of previous site review recommendations.

5. Fill out all information at the top of the form. Do not use client names on the review form – use an alternate means of record identification. Complete each item on the form, scoring the item as “0” if it is not present or inadequate; “1” if the item is partially complete or partially documented or partially present, or “2” if the item is present and adequate to excellent. Items marked with at “0” or “1” should be clarified at the bottom of the form in the space provided, and improvements needed should be noted. This space may also be used for general comments/impressions.

6. After completion of the form, the Chart Review should be used along with the other elements of the Site Review Process to compile the Summary of Site Review form. For Full State Reviews, the working forms should be filed in the Central Office Site Review Process files. For local health department reviews, the working forms should be maintained in local Quality Assurance files. A copy of the Summary of Site Review will be kept in the Central Office Site Review Process files, and a copy should be kept in local program files.

DEFINITIONS AND SUGGESTIONS

Legibility/Medical-Legal Accuracy
Documentation is easy to read and in ink.
Signatures are easy to read and clearly titled and dated or signature verification forms with associated printed names are used.
Errors remain legible, but have been corrected, initialed and dated.
Line has been drawn through blank lines between notations.
Student records are all countersigned by preceptor.

Completeness
The clinician orders have been carried out and documented.
Name of client is on all sheets.
Blank spaces are completed or stricken through on flow sheet, initial or interval forms.
Exam forms are signed.
Nurses' and chaperones' signatures are present in designated areas as indicated.
Interpreter names are listed as indicated

Consents signed appropriately
All consent forms are appropriate and have been signed, witnessed and updated as required. A break in service of one year or greater requires a new consent. All consents should be updated at least every four years. New method/procedure consents signed with indicated.

Documentation for HIPAA Compliance
A copy of HIPAA disclosures signed by the client is present in the chart, or the record has been stamped/labeled with HIPAA compliance assurances.

Documentation of annual fee assessment
Documentation of annual fee assessment is present, or such documentation is accessible for verification if not included with the record.

Standardized DHMH forms used
Self-explanatory. Variations from standard forms must be discussed with/submitted to CMCH for review.

Record contents are tabbed and easy to locate
There are tabs or dividers clearly separating the sections of the chart.

Lab slips initialed, dated when received, secured
Lab slips have been initialed and dated when they were received - focus on lab slips received since last site visit.
All slips are secured in the record.
Also, it is recommended that all lab slips be in order with the most current on the top.
There should not be any marking of results with highlighters or ink.

Standard follow-up system for tracking abnormal pap, lab, and STD results used
This is an opportunity to check to see if the pap log or lab tracking system is operating

in an effective high quality manner. Check if the pap result has been recorded correctly and in a timely manner. Check if other lab results are recorded as indicated.
Follow-up or attempted follow-up should be clearly documented.
Written referrals given to the client should be clearly documented.
Responses to referrals should be obtained and noted in the chart and follow-up conducted.

Documentation of client education on FP
Documentation on flow sheet, continuation sheets or exam pages may include:
Methods of contraception discussed;
Video shown; Literature given.

Documentation of STD/HIV counseling and information
Documentation of STD/HIV counseling and information is on flow sheet, continuation sheet, or exam pages, and may include risk assessment/reduction, “safer sex” or A-B-C message.

Documentation of preconception counseling
Documentation of preconception health counseling (when indicated) is on flow sheet or continuation sheets.

Documentation of encouraging family involvement for minors
Documentation of encouraging family involvement for minors seeking family planning services is on flow sheet or continuation sheets.

Documentation of counseling to adolescents on avoidance of sexual coercion
Documentation of counseling to adolescents on recognizing and avoiding sexual coercion is on flow sheet or continuation sheets.

Documentation of screening for domestic violence/family and intimate partner violence
Documentation of screening for domestic violence/family and intimate partner violence on is flow sheet or continuation sheets and counseling/referral is done when indicated.

Documentation of reported child abuse/sexual abuse and the required mandatory reporting
Documentation of reported child abuse/child sexual abuse and the required mandatory reporting as per Maryland law is present.

Documentation of discussion regarding health promotion and disease prevention
Documentation of discussion about health promotion and disease prevention and referral for services as indicated (i.e. Smoking cessation, weight management, primary care, substance abuse/mental health services) is on flow or continuation sheets.

Other (Optional) – Specify
This section may be used to add a topical item for review at a particular site or sites at the discretion of the CMCH State Reviewer or local program. Specify item(s) that will be added.

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CHART REVIEW

Select records from the pap log of clients who have abnormal paps. Evaluate each record for each area of assessment. Score each area using the point system below. Complete 5-10 records as part of the Site Review Process.

Clinic_____ **Local Health Department Site**_____ **Subgrantee/Contractor Site**_____

Full State Site Review ____ **Self-Review (Local HD)**____ **Other(specify)**_____ **Reviewer**_____ **Date**_____

CHART IDENTIFIER					
AREA OF ASSESSMENT					
LEGIBILITY					
MEDICAL/LEGAL ACCURACY					
COMPLETENESS (INCLUDING SIGNATURES AS REQUIRED)					
CONSENTS SIGNED APPROPRIATELY					
DOCUMENTATION OF HIPAA COMPLIANCE					
DOCUMENTATION OF ANNUAL FEE ASSESSMENT					
STANDARDIZED DHMH FORMS USED					
RECORD CONTENTS ARE TABBED AND EASY TO LOCATE					
LAB SLIPS INITALED, DATED WHEN RECEIVED, SECURED					
STANDARD FOLLOW-UP SYSTEM FOR TRACKING ABNORMAL PAP, LAB AND STD RESULTS USED					

DOCUMENTATION OF CLIENT EDUCATION ON FAMILY PLANNING					
DOCUMENTATION OF STD/HIV COUNSELING AND INFORMATION					
DOCUMENTATION OF PRECONCEPTION COUNSELING					
DOCUMENTATION OF ENCOURAGING FAMILY INVOLVEMENT FOR MINORS					
DOCUMENTATION OF COUNSELING TO ADOLESCENTS ON AVOIDANCE OF SEXUAL COERCION					
DOCUMENTATION OF SCREENING FOR DOMESTIC VIOLENCE/FAMILY AND INTIMATE PARTNER VIOLENCE					
DOCUMENTATION OF CHILD ABUSE/SEXUAL ABUSE AND THE REQUIRED MANDATORY REPORTING					
DOCUMENTATION OF DISCUSSION REGARDING HEALTH PROMOTION AND DISEASE PREVENTION SERVICES (i.e. smoking cessation, weight management, substance abuse/mental health services, primary care)					
OTHER (OPTIONAL) – Specify					

POINTS **2 =** Present and Adequate to Excellent **1 =** Partially Documented or Present / indicate improvement needed in space below
0 = Not Present or Inadequate / indicate improvement needed in space below **NA =** Not Applicable to Chart Under Review

PROBLEMS NOTED/IMPROVEMENT NEEDED/Comments (List by Chart Identifier)

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INSTRUCTIONS FOR OBSERVATION OF CLIENT VISIT

NOTE: The Observation of Client Visit may be done on the same day as other components of the Site Review Process, or an alternate clinic day may be chosen. The reviewer should be a licensed health care professional employed by the Maryland Department of Health and Mental Hygiene or local health department who is familiar with family planning/reproductive health, medical/legal documentation, clinic flow, counseling, interviewing, and the components of a clinical visit.

1. Approach a client on arrival to the clinic. Introduce yourself. Describe the purpose of the observation: To assure quality reproductive health services and improve client care within the family planning program. Request the client's permission to follow her through the entire clinic process from sign-in to exit.

2. Complete the top portion of the Observation of Client Visit form except for the End Observation time.

3. Check off the appropriate column for each observation at each station. Use the "Comments" column to clarify an observation, provide added information, or note a particular related issue. Record the time spent at each station.

4. Record the name of the staff member providing services where requested on the observation form.

5. Record answers as honestly as possible according to what was observed. **This is a tool for system assessment/improvement and staff discussion** - not a method of judging individual staff performance – and combines both objective and subjective evaluations by the reviewer.

6. At the conclusion of the observation, record the "Time Observation Ended" on the first page of the observation form. Review the chart of the client with attention to the items listed under the "Overall Procedure and Record Review" section, and record observations in the appropriate column.

7. Document overall service time and gaps in service, and add any additional comments or impressions.

8. Use the results of the Observation of Client Visit in compiling the Summary of Site Visit form sections on Strengths and Areas Needing Improvement.

9. Maintain a copy of the working Observation form in the Central Office Site Review Process files (for Full State Site Reviews) or in the local health department Quality Assurance files (for local Self-Reviews, local subgrantee reviews, and local Abbreviated Reviews).

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OBSERVATION OF CLIENT VISIT

Clinic/LHD/Agency_____ Local HD Site ___ Subgrantee/Contractor Site___

Type of Review: Full State Site Review____ Self- Review (Local HD)____

Abbrev. Self-Review (Local HD)____ Other (specify)_____

Visit Type: Initial___ Annual____ Problem/Evaluation____ Reviewer_____

Date:_____ Time Observation Began:_____Time Ended:_____

STATION / TIME	***OBSERVATION***	***YES***	***NO***	***N.A.***	***COMMENTS***
Sign-In	Is privacy/confidentiality maintained for sign-in?				
	Are HIPAA requirements addressed (verbally or as evident record documentation from a previous visit)?				
	Is the time from sign-in to being called less than 15 minutes?				
Fiscal	Is a recent (within one year) fee assessment present in the chart (or otherwise accessible) OR documented during the interview?				
	Is a sliding fee scale used and used appropriately?				
	Is client verbal report of income accepted in establishing fees/waiver of fees?				
Laboratory Testing	Are Universal Precautions used?				
	Is confidentiality concerning testing and results respected?				
Pre-Interview Name of staff member:	Does the staff member introduce self?				
	Is the reason for the visit accurately assessed?				
	Is the client's perception of the reason for the visit assessed?				
	Are required informed consents adequately obtained and directly witnessed by staff?				
	Is counseling / education appropriate for this client?				

STATION / TIME	*OBSERVATION*	*YES*	*NO*	*N.A.*	*COMMENTS*
Clinician Name of Clinician:	Does the clinician introduce self?				
	Does the clinician verify the client's identity by name?				
	Is the reason for the visit addressed?				
	Does the clinician offer an explanation of the exam?				
	Is breast self exam encouraged?				
	Does the clinician encourage the client to ask questions?				
	Does the clinician offer an explanation of findings and recommendations?				
	Is the clinician sensitive to the client's needs and comfort?				
	Is a chaperone present for the entire exam while the client is in any state of undress?				
Post Interview / Exit Name of Staff Member:	Are counseling and teaching appropriate for the prescribed method?				
	Are counseling/ teaching/referral appropriate for the client's problems or issues?				
	Is the client encouraged to ask questions?				
	Is the client given names and telephone numbers to call for questions after the visit?				
	Are after hours emergency care instructions given?				
Specific Assess-ments (Time not required)	Is safer sex and/or ABC message addressed? **(specify** "safer sex " or "ABC" in Comments**)**				
	Was client privacy and confidentiality maintained throughout the visit?				
	Was all information given accurate and current?				
	Did the clinic process avoid unnecessary duplication of information or teaching?				
	Is Emergency Contraception availability and/or Advanced Placement addressed for appropriate clients?				

STATION / TIME	*OBSERVATION*	*YES*	*NO*	*N.A.*	*COMMENTS*
Overall Procedure and Record Review (Time not required)	Were "Initial Visit" services provided and properly documented in the medical record? These include Education, Counseling, Informed Consent, History, Examination, Laboratory Testing, Follow Up and Referrals, and Method Provision. Were "Return Visit" (Annual, Problem/Evaluation) services provided and properly documented in the medical record? These include History, Examination, Laboratory Testing, Follow-Up and Referrals, Assessment of Current Health Status and Complaints, and Method Evaluation. Were appropriate CPT/ICD codes used for this visit?				

Document the total length of time for the client visit and note major gaps in service time:

Additional Comments or Impressions:

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CLINIC SITE REVIEW FORM INSTRUCTIONS

Section 1 – General Instructions

1. The Clinic Site Review form is to be used in Full State Site Reviews, local Self-Reviews, Abbreviated Reviews, and Walk-Throughs. It should also be used by State and local programs as a part of the annual evaluation of delegate agencies or subgrantees/contractors, unless other arrangements have been made through the CMCH Family Planning Site Review Process Planning Team.

2. A date to perform the Clinic Site Review should be selected, and a reviewer designated to complete the form. This form may be completed on a clinic or non-clinic day. It may be completed by itself, or in combination with other elements of the Maryland State Family Planning Site Review Process. At the State level, program consultants may perform the review, or a designated State site reviewer may complete the form. At the local level, the family planning program supervisor/manager may elect to complete the form, or an alternate professional staff person may be designated.

3. As part of the form completion, a local program supervisor or knowledgeable designee should be available to provide answers to questions about the site, services, safety, policies, procedures, outreach, education, quality assurance, and current issues. In instances where the local supervisor or other administratively and programmatically knowledgeable person is performing a Self-Review, that person may be able to answer all questions without additional consultation.

Section 2 – Procedural Instructions for Completion of Clinic Site Review Form

1. Fill out the top portion of the form.

2. Walk through the clinic site in a systematic way, observing for the required Areas of Assessment. For each question in each Area of Assessment of the Clinic Site Review, check “Yes” or “No” as appropriate. Additional comments, clarifications, suggestions, information, or implementation plans may be recorded in the last column for “Comments/Implementation.” Complete questions relating to administrative and programmatic function with consultation from local program staff, as necessary.

3. For Full State Site Reviews and local Self –Reviews of main or full time satellite sites, the entire form should be completed. At the discretion of the reviewer, review of items addressing programmatic processes/policies does not have to be done for full-service full-time satellite sites if this information is obtained during a review of the main site, and all information is the same. Please note this in the “Comments”

section of the form. For Abbreviated Reviews of non-permanent satellite sites and for Walk-Throughs, Pages 1 through 4 of the form should be completed, and an assessment made as to whether Family Planning Program Administrative and Clinical Guidelines copies are kept at the site. "NA" (Not Applicable) written in the "Comments/Implementation" column may be used for any elements that are not addressable at the site, or are only answerable as part of the main site's review. The "Comments/Implementation" column may also be used for clarifications and additional information.

4. Additional space is available in the "Current Issues" area of the form (page 10) for the addition of additional individualized questions or assessment elements. These are optional, and may be written in as needed.

5. After completion, the Clinic Site Review form should be used along with the other elements of the Site Review Process to compile the Summary of Site Review. A copy of the Summary will be kept in the Central Office Site Review Process files. Local programs should keep the working copy of the Clinic Site Review and a copy of the Summary in their quality assurance files for review by their assigned family planning program consultant or a State reviewer at a future visit. The most recent Full State Site Review working copy will be maintained in the Central Office Site Review Process files.

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CLINIC SITE REVIEW

County/Agency _____ **Clinic Site**_____

Type of Site: Local Health Dept. Main Site_____ Local Health Dept. Satellite Site_____ Subgrantee/Contractor Site_____

Type of Review: Full State Site Review _____ Walk-Through (State)_____

Self-Review (Local)_____ Abbreviated Self-Review (Local)_____ Review of Subgrantee/Contractor_____

Date of Review_____ **Reviewer**_____ **Clinic Site Contact** _____

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Physical Facilities			
1. Is the site geographically accessible and clearly identified for the population being served?			
2. Is parking and/or mass transit available and adequate?			
3. Is exterior lighting adequate for evening clinics?			
4. Does the site meet ADA requirements for building accessibility to clients with handicaps?			
5. Are service hours and clinic hours posted?			
6. Does the facility appear clean, orderly, and pleasant?			
7. Are hand washing facilities available in exam rooms?			
8. Does the exam room have equipment listed as specified in the Family Planning Administrative Guidelines?			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Safety / Security / Emergency			
1. Are fire/disaster evacuation plans posted?			
2. Is there documentation of a fire drill in the past 12 months?			
3. Has the fire extinguisher been recharged within the past 12 months?			
4. Are exits clearly marked and free from barriers?			
5. Are hallways free of clutter and do they provide an easy exit from the building?			
6. Is there a record of the emergency tray being monitored each month?			
7. Are all Emergency Tray medications current and unexpired?			
8. Are there current written protocols for clinic emergencies (fire, vandalism, bomb/terrorism, evacuation, disaster)?			
9. Are there current written procedures for medical emergencies, including vaso-vagal reactions/fainting, anaphylaxis, cardiac/respiratory arrest or difficulties, shock/hemorrhage, EMS transport, after-hours emergencies?			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Lab, Equipment, and Supplies			
1. Is the refrigerator temperature between 34-42 F (2-8 C) degrees?			
2. Is there a lab tracking log or system to ensure the timely return of all lab results?			
3. Are the sharps container and gloves near the microscope and phlebotomy equipment?			
4. Are safety needles used for all bloodwork and injections?			
5. Are applicable CLIA licenses current and posted?			
6. Is there a record of maintenance for each piece of equipment (microscope, autoclave, BP cuffs)?			
7. Is there a method for tracking pharmaceuticals in case of manufacturer recall?			
8. Are there defined inventory control procedures for clinic supplies and pharmaceutical materials with a designated person responsible?			
9. Are security, supply, and record keeping of pharmaceuticals conducted in accordance with state pharmacy laws and professional practice regulations?			
10. Are Nurse Dispensing Regulations **FULLY** implemented? If "NO" describe current progress in your agency toward Implementation under "Comments" or on back of page.			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Confidentiality and Privacy			
1. Does the system allow for privacy and confidentiality of medical records, interviewing processes, counseling and consultation?			
2. Is the follow-up policy sensitive to client concerns for confidentiality and privacy?			
3. Are medical records secured and locked when not in use?			
4. Are computers with client information secured and protected from unauthorized use?			
5. Are clients provided with required written HIPAA information?			
6. Are there written procedures that are followed regarding release of information or records?			
7. Do client changing facilities insure complete privacy when undressing/dressing?			
8. Are procedures in place that insure confidential services are kept confidential (i.e. no bills, statements, charges for services sent to confidential clients/adolescents)?			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Client Services			
1. Is there a broad range of acceptable/effective medically approved methods **including fertility awareness methods** available on-site or by referral?			
2. Are abbreviated records kept for pregnancy testing clients?			
3. Are pregnancy testing clients entered into the State Family Planning Data System?			
4. Is pregnancy counseling provided consistent with Title X Regulations as neutral, factual, nondirective process on each of the pregnancy options (prenatal care, pregnancy termination, adoption?			
5. Are written policies in place for follow-up on abnormal lab/exam results and referrals?			
6. Are adolescents given appointments within two weeks or less of their request?			
7. Is eligibility for discounts for minors who receive confidential services based solely on the income of the minor?			
8. Is a Schedule of Discounts (sliding fee scale) in place for incomes between 101-250% of Federal Poverty Level?			
9. Is there a mechanism in place that insures the waiving of fees for individuals who, for good cause, are unable to pay?			
10. Are voluntary donations accepted?			
11. Are third party payments pursued?			
12. Is verbal report of income accepted for fee determination?			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Education / Health Promotion			
1. Are appropriate FP and related materials available in waiting areas or clinic area?			
2. Are there client instruction sheets for each medication that is given in the clinic?			
3. Is there a mechanism in place to document referral for primary care services for all MA FP card and MA clients?			
4. Is there a community resource list for clients? Is it updated annually? (ie. Emergency medical facilities, shelters, law enforcement, etc.)			
5. Is there an Information and Education committee (5-9 members broadly representative of the community served) in place to review client and educational materials? **If "No" has a waiver been obtained from the Regional Office?**			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Community Outreach and Information			
1. Has information about clinic services been distributed into the community?			
2. Has staff conducted community education related to reproductive health within the past 12 months?			
3. Is there an identifiable process of assessing the needs of the community with respect to reproductive health? (ie. Client Survey, county needs assessment, Community Networking, etc)			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Policies and Procedures			
1. Are the current CMCH FP Administrative and Clinical Guidelines available on site? Please note if the new staff have reviewed and signed the Guidelines as well as the staff familiar with family planning			
2. Are new updated guidelines inserted into the Administrative and/or Clinical manuals as they become available?			
3. Are local policies reviewed and updated periodically (i.e. at least within the past 3 years)?			
4. Is the Blood Borne Pathogen Exposure Plan locatable?			
5. Are there written procedures about infection control and infectious waste management?			
6. Is there a written procedure for orientation of new Family Planning staff?			
7. Is there a written training/inservice policy for staff?			
8. Is there a written plan for providing services to non-English speaking clients?			
9. Is there a written plan for serving special needs clients (i.e. hearing/visually impaired, physically/mentally challenged)?			
10. Are there written personnel policies regarding nondiscrimination in recruitment, selection, performance evaluation, discipline, promotion, and termination?			
11. Is there a process that insures confidentiality and privacy of personnel records?			

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Quality Assurance			
1. Has a client satisfaction survey been done in the past year?			**Date of Last Survey:**
2. Is there staff training documentation for Blood Borne Pathogen Exposures within the last year?			
3. Are records maintained for all staff training?			
4. Has all appropriate staff received CPR training within the last two years?			
5. Is there documentation that all appropriate staff received training in state laws regarding reporting of child abuse/molestation, sexual abuse, rape, or incest?			
6. Are there staff credentialing/licensing processes and Records that are maintained and updated annually?			
7. Are periodic staff meetings held and minutes maintained?			
8. Is there a formal process for Quality Assurance (QA)?			
9. Are QA activities documented in a QA notebook or file?			
10. Were at least 60 (or 10% of the unduplicated client base) medical record audits completed in the past 12 months?			
11. Is there an identified process for client complaint follow-up?			
12. Is there a formal process for clinical competency assurance for local clinician staff? **Please describe under "Comments" or on back of page.**			
13. Has CMCH been advised of research projects at the local health department/agency utilizing family planning clients?			**List existing research projects:**

AREA OF ASSESSMENT	YES	NO	COMMENTS / IMPLEMENTATION
Current Issues			(**Use Back of Form if Necessary)**
1. Does the program provide Emergency Contraceptive Pills to clients when a Family Planning Nurse is not on site?			
2. Does the program provide services to males? Explain.			
3. Does the program provide community outreach to males? Explain.			
4. Are there professional challenges faced by the program? Explain.			
5. Are other departments in the health department familiar with Reproductive Health Program services? Explain.			
6. Does the program provide/support health promotion activities and Resources (i.e. Smoking cessation, Healthy Heart, weight loss, nutrition, stress management)? Explain.			
7. Are prescriptions for contraceptives given to clients? Under what circumstances (please explain)?			
8. Are out of county and out of state clients seen for family planning services? Explain.			

ADDITIONAL NOTES:

CENTER FOR MATERNAL AND CHILD HEALTH
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CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

SITE REVIEW PROCESS CERTIFICATION FORM

I, _____ do hereby certify that the
(Print Name)

(check one) Self-Review____ Abbreviated Self-Review____ LHD Review of subgrantee____

of _____ was completed on _____
(Site Reviewed) **(Date)**

according to the established local health department review procedures of the Maryland State Family Planning Program Clinical and Administrative Site Review Process and the results are accurately reported to the Maryland State Family Planning Program.

_____
Signature Date

_____
Title/Position

_____
Local Health Department

CENTER FOR MATERNAL AND CHILD HEALTH
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CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

SUMMARY OF SITE REVIEW

County/Agency_____Clinic site_____

Local Health Dept. Main Site____ Local HD Satellite Site_____ Subgrantee/Contractor Site_____

Date of site review_____ Site Contact_____

Date of Summary_____ Reviewer_____

Summary Report of (Check One): Full State Site Review___ Satellite Walk-Through (State)___

Self Review(Local)___ Abbreviated Self-Review(Local)___ Review of Subgrantee/Contractor___

Areas of Commendation:

1.

2.

3.

4.

5.

Areas Needing Improvement:

1.

2.

3.

4.

5.

CENTER FOR MATERNAL AND CHILD HEALTH
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CLINICAL AND ADMINISTRATIVE SITE REVIEW PROCESS

SITE REVIEW RESPONSE FORM

County/Agency_____ Clinic site_____

Local Health Dept. Main Site_____ Local HD Satellite Site_____ Subgrantee/Contractor Site_____

Date of site review_____ Reviewer_____

Date of response_____ Site Respondent_____

Response to (Check One): Full State Site Review_____ Satellite Walk-Through (State)_____

Self-Review(Local)____ Abbreviated Self-Review(Local)____ Review of Subgrantee/Contractor____

Area Needing Improvement	Action	Projected Date of Completion
1.		
2.		
3.		
4.		
5.		

Appendix I

Family Planning Forms

INDIVIDUAL'S AUTHORIZATION

Purpose: This form is used to confirm the direction of an individual to authorize DHMH to request, to use, or to disclose the individual's health information.

Please type or print neatly; we are not able to process incomplete or illegible forms.

☐ **Check if this authorization is for psychotherapy notes.**

If this authorization is for psychotherapy notes, DHMH will not use it as an authorization for any other type of health information. If the individual seeks to authorize the use and disclosure of other health information as well, an additional form must be submitted.

SECTION A: Individual's Health Information authorized for Use and Disclosure.

Last Name:_____First Name:_____MI:___

Street Address:_____Apt #:_____

City:_____State:_____ Zip:_____

Phone: (home)_____(work)_____Date of Birth: / /

SECTION B: The Use and/or Disclosure being authorized
Provide a detailed description of the health information you are authorizing us to use and/or disclose.

The purpose of the disclosure (optional:)

Who is authorized to Disclose your health information:

DHMH PROGRAM NAME(S):_____ ADDRESS:_____

TELEPHONE NUMBER:_____

Who is authorized to Receive and Use your health information:

NAME(S):_____ ADDRESS:_____

TELEPHONE NUMBER:_____

If the information which the program has includes records or information from another entity, I ___ do or ____ do not wish to have that information released under this authorization.

SECTION C: Expiration and revocation. (IF THIS SECTION IS NOT COMPLETED, DHMH CANNOT ACCEPT THIS FORM.)
Expiration: This authorization will expire (complete one):

- ☐ On ____/____/____
- ☐ On occurrence of the following event (which must relate to the individual or to the purpose of the use and/or disclosure being authorized):
  _____

Right to Revoke: I understand that I may revoke this authorization at any time by giving written notice of my revocation to DHMH. In order to obtain a revocation form to revoke this authorization, I understand that I may contact _____. I understand that revocation of this authorization will not affect any action that DHMH or others named or unnamed took in reliance on this authorization before DHMH received my written notice of revocation.

SECTION D: Signature.
To the Individual – Please read the following.

I authorize the use and/or disclosure of my health information as described in Section B above. I understand this authorization is voluntary.

I understand that if the persons or organizations I authorize to receive and/or use my health information are not subject to the federal or state health information privacy laws, they might further disclose the health information, and it may no longer be protected by the health information privacy laws.

I have had full opportunity to read and consider the contents of this authorization, and I confirm that the contents are consistent with my intent.

Signature: _____ Date: _____

If a personal representative is making this request, please attach a copy of any document granting legal authority and complete the following:

Personal Representative's Name:_____

Relationship to Individual:_____

MARYLAND STATE FAMILY PLANNING PROGRAM VOLUNTARY PARTICIPATION POLICY ACKNOWLEDGEMENT FORM

To the Employee: This document contains the Maryland State Family Planning Program policy on Voluntary Participation and an acknowledgement that you have been informed of the policy. After you have read the policy and discussed it with your supervisor, please sign the signature block below. The original of this form is retained in your personnel file. Please keep a copy for your records.

VOLUNTARY PARTICIPATION

The participation of clients in any and all services offered through the Maryland State Family Planning Program must be solely on a voluntary basis. Individuals must not be subjected to coercion of any type regarding their use of family planning services or their decision to use or not to use any particular method of birth control. As stated in the federal Title X **Program Guidelines for Project Grants for Family Planning Services 2001,** which can be found in the **FAMILY PLANNING ADMINISTRATIVE GUIDELINES**, "Acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other service or assistance from or participation in any other programs. Project personnel…may be subject to prosecution under federal law if they coerce or endeavor to coerce any person to undergo an abortion or sterilization procedure." [**APPENDIX A**, I.5.1]

I hereby acknowledge that I have reviewed and understand this policy on Voluntary Participation and that I have received a copy of it.

Employee: _____ Date: _____

Name of Agency: _____

Address: _____

Unit:_____

Supervisor's Signature: _____ Date: _____

CHRONOLOGIC COLPOSCOPY FLOW RECORD

Name _____

List cytopathology, histopathology, colposcopy, surgery or other therapeutic procedures; diagnosis and treatment of infections and other conditions of the genital tract, especially vulva, vagina, and cervix which might affect cytopathology or histopathology reports; pregnancy, referral, and any personal item which would produce an interruption in the flow process.

Date	Test/ Procedure	Diagnosis	Treatment/ Management	Plan/ Follow-up/ Disposition	Date Next Appt

FAMILY PLANNING COLPOSCOPY RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
G ___ T ___ P ___ A ___ L ___ LNMP _____ UCG _____
Current Method of Contraception _____
Current Medications (prescription, OTC, vitamins, herbal) _____

_____

Initial colposcopy visit ☐ Follow-up colposcopy visit ☐
Reason(s) for Visit _____
Pertinent past GYN history, medical history, history of abnormal Pap(s) and/or HPV test(s), colposcopy, related treatment and/or procedures _____

_____

_____

_____

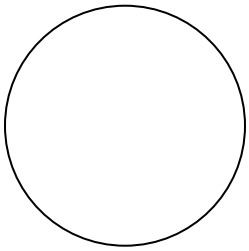
Date _____ **Interpreter Signature** _____

Date _____ **Staff Signature** _____

Colposcopy Findings:

Satisfactory ☐ yes ☐ no Pap ☐ HPV ☐ CT ☐ GC ☐ HSV ☐ Biopsy(s) ☐ ECC ☐

Wet Mount _____



Assessment _____
Plan(s) after Colposcopy _____

_____

Date _____ **Chaperone Signature** _____

Interpreter Signature _____ **Colposcopist Signature** _____

Summary of laboratory reports from this evaluation _____

_____

_____

Plan after reports _____

_____

Date _____ **Staff Signature** _____

Interpreter Signature _____ **Colposcopist Signature** _____

FAMILY PLANNING FLOW RECORD

Name _____ D.O.B _____

DATE				
Reason for visit				
Contraception used				
LNMP				
Last intercourse				
B/P				
Weight				
BMI				
Urine P/G				
Urine hCG				
PAP				
HPV				
Chlamydia				
GC				
STS				
HIV				
Hgb/Hct				
Abd pain				
Chest pains				
Headaches				
Eye problems				
Severe leg pain				
Irregular bleeding				
Smoking/amount				
Current medications				
Allergies				
CHN signature				
POST/CONF				
Contraception/amt				
Other medications				
RTC date				
Reason				
CHN signature				

FAMILY PLANNING DMPA INITIATION RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications _____
LNMP _____ Last sexual intercourse _____

History

Current known pregnancy or suspected pregnancy	□ yes	□ no
Currently breastfeeding	□ yes	□ no
Unexplained vaginal bleeding	□ yes	□ no
Headaches with focal neurological symptoms and/or aura	□ yes	□ no
Known or suspected breast cancer or history thereof	□ yes	□ no
Hypertension (>140/90 mm Hg) or history thereof	□ yes	□ no
Diabetes mellitus (vascular disease or >20 yrs duration)	□ yes	□ no
Current thromboembolic disease or history thereof	□ yes	□ no
Cerebrovascular or coronary artery disease or history thereof	□ yes	□ no
Hepatic disease (tumors, hepatitis, cirrhosis)	□ yes	□ no
Cancer of the endometrium (or estrogen dependent tumor)	□ yes	□ no

BP _____ **Urine Pregnancy Test** (if indicated) □ pos □ neg

Date _____ **Interpreter Name** _____

Staff Signature _____

****

Clinician Comments _____

_____

Assessment DMPA contraception candidate □ yes □ no

Contraception Plan

□ EC _____ □ offered □ given
□ Condoms □ offered □ given
□ DMPA (150 mg IM) □ offered □ given
□ DMPA (104 mg SQ) □ offered □ given
□ Other method of contraception initiated/continued/restarted _____

_____

Clinician Comments _____

Return Visit _____

Date _____ **Interpreter Name** _____

Clinician Signature _____

FAMILY PLANNING IMPLANON™
INSERTION RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications _____
LNMP _____ Day of client's cycle _____
Last sexual intercourse _____

History

Annual examination within 1 year	□ yes	□ no
Allergic or hypersensitivity to iodine	□ yes	□ no
Allergic or hypersensitivity to Lidocaine	□ yes	□ no
Allergic or hypersensitivity to any component of Implanon	□ yes	□ no
Current medications on Appendix D list	□ yes	□ no
Current known pregnancy or suspected pregnancy	□ yes	□ no
Currently breastfeeding (at least 4 weeks postpartum)	□ yes	□ no
Unexplained vaginal bleeding	□ yes	□ no
Current thromboembolic disease or history thereof	□ yes	□ no
Known or suspected breast cancer or history thereof	□ yes	□ no
Cerebrovascular or coronary artery disease or history thereof	□ yes	□ no
Hepatic disease (tumors, hepatitis, cirrhosis)	□ yes	□ no

Comments _____

BP _____

Urine Pregnancy Test (if indicated) □ pos □ neg

Date _____ **Interpreter Name** _____

Staff Signature _____

FAMILY PLANNING IMPLANON™
INSERTION RECORD Name _____

Clinician Comments _____

_____

_____

_____

Assessment Implanon candidate □ yes □ no

Consent signed □ yes □ no

Implanon Insertion

Insertion site □ left upper arm □ right upper arm
Antiseptic □ iodine □ alcohol
Anesthetic □ Lidocaine ____% ____ mL □ other _____

Implanon inserted according to protocol □ yes □ no
If no, explain _____
Implanon Lot # _____ Exp. Date _____

Confirm implant placement by palpation □ yes □ no
If no, what action planned or taken
□ Implant localization protocol initiated □ yes □ no
□ Referral for localization □ yes □ no
□ Backup contraception initiated _____

Complete USER CARD and give to client □ yes □no
Complete Patient Chart Label, affix to chart □ yes □ no

Difficulty with implant insertion □ yes □ no
If yes, specify _____

If Implanon not inserted:
□ Condoms □ offered □ given
□ Combined oral contraceptive initiated brand name _____
# of cycles _____ start date _____
□ Other method of contraception initiated/continued/restarted _____
_____

Return Visit _____

Date _____ **Interpreter Name** _____

Chaperone Signature _____

Clinician Signature _____

FAMILY PLANNING IMPLANON™
REMOVAL RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications _____
LNMP _____

Date of insertion _____ Insertion Record reviewed □ yes □ no

Reason(s) for removal
- □ 3 years since insertion
- □ Desire pregnancy
- □ Pregnancy occurred
- □ Irregular bleeding
- □ Other side effects _____
- □ Other _____

Implant palpable before removal □ yes □ no

If no, how was implant localized _____

Implant removed intact □ yes □ no

Difficulty with removal □ yes □ no

If yes, specify
- □ Significant fibrosis
- □ Implant broken or fractured
- □ Implant in fascia or muscle
- □ Incision needed to be enlarged
- □ Implant not found
- □ Referral for removal _____

After Implanon removed
- □ Condoms □ offered □ given
- □ Combined oral contraceptive initiated brand name _____
  # of cycles _____ start date _____
- □ Other method of contraception initiated _____

Return Visit _____

Date _____ **Interpreter Name** _____

Chaperone Signature _____

Clinician Signature _____

FAMILY PLANNING INITIAL RECORD

Name _____
Age _____ Race _____
Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications (prescription, OTC, vitamins, herbal) _____

Reason(s) for Visit _____

OBSTETRIC HISTORY

Total # Preg	Full Term	Premature	Induced Abs	Spon Abs	Ectopics	Multiple Births	Living

Date of last delivery _____ Breastfeeding now □ yes □ no
Cesarean # ___ Indication(s) _____
Pregnancy Complications _____
Planning pregnancy in the next 12 months □ yes □ no

GYNECOLOGIC HISTORY

1st day last menstrual period _____ 1st day prior menstrual period _____
Usual duration of flow _____ # days length of cycle _____
Pain with periods □ yes □ no DES exposure □ yes □ no
Prior contraception use □ OCs □ DMPA □ IUD □ Implant □ Condoms □ Other _____
Date of last Pap _____ Results _____
Colposcopy/Abnormal Pap(s)/Rx _____
GYN cancer/Surgery/Hospitalization _____

SEXUAL HISTORY

Ever had sexual intercourse □ yes □ no Age of 1st intercourse _____
Type of sex □ vaginal □ oral □ rectal # of lifetime sexual partners _____
Sexual partners □ men □ women □ both Sexually active now □ yes □ no
Date of last sexual activity _____ □ vaginal □ oral □ rectal
Length of time with current partner _____
Condom use □ always □ sometimes □ never
New sexual partner in the last 3 months □ yes □ no
2 or more sexual partners in the last year □ yes □ no
History of STD in the last year □ yes □ no (list in Infectious Disease History)
Any concern about a possible STD now □ yes □ no _____
Exchange of sex for drugs or money □ yes □ no
Illicit, street, or recreational drug use □ yes □ no
Sex partner: with STD in the last year □ yes □ no Name of STD _____
with IV drug use □ yes □ no
with exchange of sex for drugs or money □ yes □ no
with admittance to jail or other detention facility □ yes □ no
is male having sex with men □ yes □ no
with other high-risk behavior □ yes □ no _____

FAMILY PLANNING INITIAL RECORD

Name _____

INFECTIOUS DISEASE HISTORY

Chlamydia _____ HPV _____ Hepatitis _____
Gonorrhea _____ Herpes _____ HIV _____
Trichomoniasis _____ Syphilis _____ Other _____
TB exposure _____

SOCIAL HISTORY

Alcohol (# drinks/wk) _____ (age begun) _____
Smoking (# cig/day) _____ (age begun) _____
Illicit, street, or recreational drug use (type/frequency/age onset) _____
Sexual assault/domestic violence ☐ yes ☐ no _____
Sexual coercion ☐ yes ☐ no _____
Child abuse/neglect/sexual abuse ☐ yes ☐ no _____
Parental Involvement ☐ yes ☐ no ☐ encouraged _____

PAST MEDICAL HISTORY

Heart disease _____ Headaches/migraine _____
Hypertension _____ Seizures _____
Stroke _____ Kidney disease/UTI _____
Blood clots (lungs/legs) _____ Gastrointestinal _____
Anemia _____ Hepatitis/liver disease _____
Blood transfusions _____ Lung/TB/asthma _____
Diabetes _____ Thyroid _____
Breast Cancer _____ Eating disorders _____
Other Cancer _____ Injuries _____
Operations/other hospitalization _____
Immunodeficiency _____
Mental health _____
Other _____
Immunizations HBV _____ Rubella _____

FAMILY HISTORY

Heart disease _____ Breast cancer (with age onset) _____
Hypertension _____ GYN cancer _____
Stroke _____ Diabetes _____
Blood clots _____ Other _____

COMMENTS _____

_____
_____
_____
_____

Date _____ **Interpreter Name** _____

Staff Signature _____

FAMILY PLANNING INITIAL RECORD

Name _____

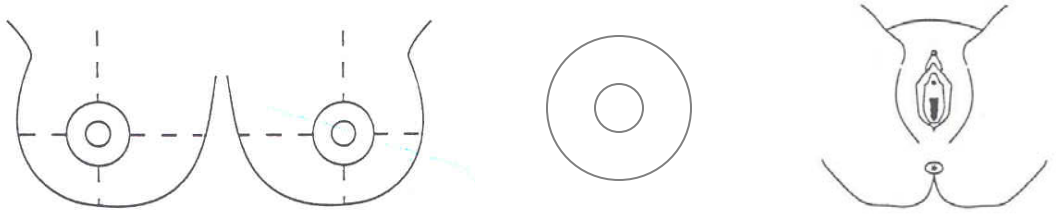
SUBJECTIVE _____

PHYSICAL EXAM BP _____ Wt _____ Ht _____ BMI _____ UCG _____

	NORMAL			NORMAL	
HEAD			VULVA		
NECK			VAGINA		
HEART			CERVIX		
LUNGS			UTERUS		
BREASTS			ADNEXA		
ABDOMEN			RECTAL		
EXTREMITES			OTHER		

PAP ☐ HPV ☐ CT ☐ GC ☐ HSV ☐ OTHER _____

WET MOUNT _____



COMMENTS _____

ASSESSMENT _____

PLAN _____

RETURN VISIT _____ **Chaperone Signature** _____

Date _____ **Interpreter Name** _____

Clinician Signature _____

FAMILY PLANNING ANNUAL/INTERVAL RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
G ___ T ___ P ___ A ___ L ___ LNMP _____ PMP _____
Current Method of Contraception _____
Current Medications (prescription, OTC, vitamins, herbal) _____

Reason(s) for Visit _____

INTERIM HISTORY (within the last 12 months or since the last exam or annual exam)
Date of last Pap _____ Results _____
Colposcopy/Abnormal Pap(s)/Rx _____
Changes in menstrual or bleeding pattern _____
Ever had sexual intercourse □ yes □ no Age of 1st intercourse _____
Type of sex □ vaginal □ oral □ rectal # of lifetime sexual partners _____
Sexual partners □ men □ women □ both Sexually active now □ yes □ no
Date of last sexual activity _____ □ vaginal □ oral □ rectal
Length of time with current partner _____
Condom use □ always □ sometimes □ never
New sexual partner in the last 3 months □ yes □ no
2 or more sexual partners in last year □ yes □ no
History of STD in the last year □ yes □ no Name of STD: _____
Any concern about a possible STD now □ yes □ no _____
Exchange of sex for drugs or money □ yes □ no
Illicit, street, or recreational drug use □ yes □ no
Sex partner: with STD in the last year □ yes □ no Name of STD _____
with IV drug use □ yes □ no
with exchange of sex for drugs or money □ yes □ no
with admittance to jail or other detention facility □ yes □ no
having sex with men □ yes □ no
with other high-risk behavior □ yes □ no
Smoking □ yes □ no (# cig/day) _____ Alcohol □ yes □ no (# drinks/wk) _____
Pregnant since last visit □ yes □ no _____
Breastfeeding □ yes □ no
Planning pregnancy in the next 12 months □ yes □ no
Sexual assault/domestic violence □ yes □ no _____
Sexual coercion □ yes □ no _____
Child abuse/neglect/sexual abuse □ yes □ no _____
Personal medical history update _____
Surgery/hospitalization update _____
Mental health update _____
Parental involvement □ yes □ no □ encouraged _____
Family history update (CV, BP, Stroke, Ca) _____

Date _____ **Interpreter Name** _____

Staff Signature _____

FAMILY PLANNING INTERVAL RECORD

Name _____

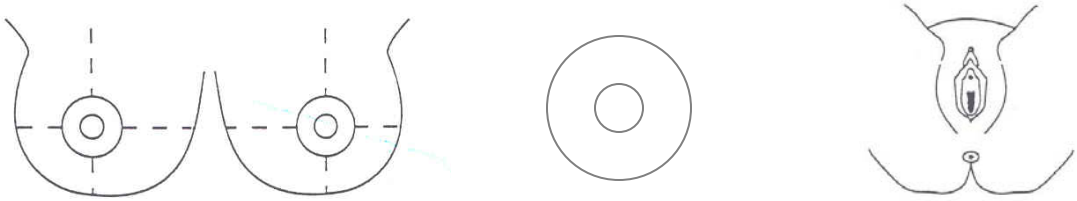
SUBJECTIVE _____

PHYSICAL EXAM BP _____ Wt _____ Ht _____ BMI _____ UCG _____

	NORMAL			NORMAL	
HEAD			VULVA		
NECK			VAGINA		
HEART			CERVIX		
LUNGS			UTERUS		
BREASTS			ADNEXA		
ABDOMEN			RECTAL		
EXTREMITIES			OTHER		

PAP ☐ HPV ☐ CT ☐ GC ☐ HSV ☐ OTHER _____

WET MOUNT _____



COMMENTS _____

ASSESSMENT _____

PLAN _____

RETURN VISIT _____ **Chaperone Signature** _____

Date _____ **Interpreter Name** _____

Clinician Signature _____

FAMILY PLANNING IUC
INSERTION RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
G ____ T ____ P ____ A ____ L ____
Current Method of Contraception _____
Current Medications _____
LNMP _____ Last sexual intercourse _____

History

Confirmed or suspected pregnancy	□ yes	□ no
Multiple sexual partners in the past 3 months	□ yes	□ no
Known or suspected cervical or uterine malignancy	□ yes	□ no
Acute cervicitis (current or within the past 3 months)	□ yes	□ no
Pelvic inflammatory disease (current or within the past 3 months)	□ yes	□ no
Sexually transmitted infection (current or within the past 3 months)	□ yes	□ no
Postpartum endometritis (current or within the past 3 months)	□ yes	□ no
Postabortion endometritis (current or within the past 3 months)	□ yes	□ no
Severe dysmenorrhea	□ yes	□ no
Hypermenorrhea	□ yes	□ no
Allergy or hypersensitivity to iodine	□ yes	□ no
Allergy or hypersensitivity to copper or history of Wilson's disease	□ yes	□ no
Undiagnosed abnormal vaginal bleeding	□ yes	□ no
History of Cesarean section(s)	□ yes	□ no
History of cervix treatment (cone, LEEP, cryo)	□ yes	□ no
Uterine fibroids that may interfere with IUC placement	□ yes	□ no
Uterine distortion (congenital or acquired)	□ yes	□ no
Current thromboembolic disease or history thereof	□ yes	□ no
Known or suspected breast cancer or history thereof	□ yes	□ no
Cerebrovascular or coronary artery disease or history thereof	□ yes	□ no
Hepatic disease (tumors, hepatitis, cirrhosis)	□ yes	□ no
Signs or symptoms of anemia	□ yes	□ no

If yes, hgb/hct _____

Comments _____

BP _____ **Urine Pregnancy Test** □ pos □ neg

Date _____ **Interpreter Name** _____

Staff Signature _____

FAMILY PLANNING IUC
INSERTION RECORD Name _____

Clinician Comments _____

_____

_____

Assessment IUC candidate □ yes □ no

Consent signed □ yes □ no

IUC Insertion

Pelvic examination
- Vulva □ normal _____
- Vagina □ normal _____
- Cervix □ normal _____
- Uterus □ normal _____
  - □ anteflexed □ axial □ retroflexed
- Adnexa □ normal _____

IUC name □ ParaGard® □ Mirena® Lot # _____ Exp. Date _____
Cervical prep antiseptic □ iodine □ none □ other _____
Anesthetic □ yes □ no
- If yes, describe _____

Tenaculum for cervical traction □ yes □ no
Uterus sounded ____ cm/inches
IUC inserted per product directions □ yes □ no
- If no, explain _____

Difficulty with IUC insertion □ yes □ no
- If yes, specify _____

IUC string cut to ____ cm/inches
Bleeding at tenaculum site □ yes □ no
- If yes, action taken
  - □ Pressure only
  - □ Silver nitrate applied
  - □ Monsel's solution applied
  - □ Other _____

If IUC not inserted:
- □ Condoms □ offered □ given
- □ Oral contraceptive initiated (brand name) _____
  # of cycles _____ start date _____
- □ Other method of contraception initiated/continued/restarted _____

_____

Return Visit _____ **Interpreter Name** _____

Date _____ **Chaperone Signature** _____

Clinician Signature _____

FAMILY PLANNING ORAL CONTRACEPTIVE INITIATION RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications _____
LNMP _____ Last sexual intercourse _____

History

Current known pregnancy or suspected pregnancy	□ yes	□ no
Currently breastfeeding	□ yes	□ no
Unexplained vaginal bleeding	□ yes	□ no
Cigarette smoker age 35 or older	□ yes	□ no
Headaches with focal neurological symptoms and/or aura	□ yes	□ no
Known or suspected breast cancer or history thereof	□ yes	□ no
Hypertension (>140/90 mm Hg) or history thereof	□ yes	□ no
Diabetes mellitus (vascular disease or >20 yrs duration)	□ yes	□ no
Current thromboembolic disease or history thereof	□ yes	□ no
Cerebrovascular or coronary artery disease or history thereof	□ yes	□ no
Hepatic disease (tumors, hepatitis, cirrhosis)	□ yes	□ no
Cancer of the endometrium (or estrogen dependent tumor)	□ yes	□ no

BP _____ **Urine Pregnancy Test** (if indicated) □ pos □ neg

Date _____ **Interpreter Name** _____

Staff Signature _____

****

Clinician Comments _____

_____

Assessment Combined oral contraception candidate □ yes □ no

Contraception Plan

- □ Plan B □ offered □ given
- □ Condoms □ offered □ given
- □ Combined oral contraceptive initiated brand name _____
  # of cycles _____ start date _____
- □ Other method of contraception initiated/continued/restarted _____

_____

Return Visit _____

Date _____ **Interpreter Name** _____

Clinician Signature _____

FAMILY PLANNING EMERGENCY CONTRACEPTIVE PILLS RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications _____
Last Normal Menstrual Period (LNMP) _____
Last bleeding episode, if not LNMP _____

Unprotected sexual intercourse
Reason for requesting ECPs _____
Date _____ Time _____ AM / PM
# of hours since last unprotected intercourse _____
Any other unprotected intercourse since LNMP or other bleeding episode □ yes □ no
If yes, # of episodes of unprotected intercourse ___
List dates and times of other unprotected intercourse _____
_____

History
Now pregnant □ yes □ no
Unexplained vaginal bleeding □ yes □ no
Allergy to any ingredient in ECPs □ yes □ no

Urine Pregnancy Test (if indicated) □ pos □ neg

Exam (if indicated) _____

Consent signed □

Rx (check medication given)
- □ Plan B, 2 tablets PO immediately
- □ Plan B One-Step, 1 tablet PO immediately
- □ Next Choice, 2 tablets PO immediately

Follow-up Appt/Plan _____

Contraception (initiated, continued, or restarted)
- □ Post-ECPs instructions discussed
- □ Condoms □ offered □ given
- □ Quick Start contraception initiated _____
- □ Established method of contraception continued/restarted _____
  _____

Comments _____

Date _____ **CHN Signature** _____

Interpreter Signature _____ **Clinician Signature** _____

PREGNANCY TESTING ENCOUNTER RECORD

Name _____
Age _____ Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications (prescription, OTC, vitamins, herbal)_____
_____
Last Normal Menstrual Period (LNMP) _____
Last bleeding episode, if not LNMP _____
Reason for requesting pregnancy test _____

□ **Positive** urine pregnancy test: (check all that apply) **EDC** (by LMP) _____

- □ Verification form given
- □ Options counseling
- □ Multivitamin with folic acid recommended
- □ Prenatal education
- □ Prenatal care recommended
- □ Refer for supportive services (WIC, MCHP, Healthy Start, DSS)

□ **Negative** urine pregnancy test: (check all that apply)

- □ Repeat pregnancy test recommended if no menses in 2 weeks
- □ Preconception counseling
- □ Family planning appointment given Date _____ Time _____
- □ Contraception education
- □ Emergency contraception □ offered □ given
- □ Condoms □ offered □ given
- □ Quick Start contraception initiated (name) _____
- □ Multivitamin with folic acid recommended

_____
_____
_____
_____
_____
_____

I understand that the pregnancy test is not always 100% accurate and that actual diagnosis of pregnancy or other condition depends on a clinical evaluation which should be performed in 2 weeks. I assume full responsibility for any decisions I make. I have been offered non-directive options counseling and state without reservation that I have not been influenced or advised by any member of the Health Department staff to accept any one particular option.

Date _____ **Client Signature** _____

Interpreter Signature _____**CHN Signature** _____

Appendix J

Family Planning Consent Forms

CONSENT FOR COLPOSCOPIC EXAMINATION

I, (print or type name) _____,
give my consent for colposcopy, cervical biopsy, and endocervical curettage. Colposcopy is a diagnostic examination that permits a clinician to examine the cervix, vagina, and vulva with a special microscope to determine the cause of abnormal findings from an examination or Pap smear. The colposcopic examination will assist the clinician in determining or finding an abnormal area that is visible. In order to establish the degree of abnormality and to assist in the type of treatment, one or more biopsies may be taken. A cervical biopsy is a small sample of tissue that is obtained from the surface of the cervix. An endocervical curettage yields a small sample of tissue removed from just inside the opening in the cervix. After analysis of tissue specimens, the laboratory provides a diagnosis for guidance in possible treatment.

I understand that a single colposcopic examination might not explain my problem, and that additional examinations and testing might be recommended.

I understand that during or after the procedure one or more of the following might occur:

- Dizziness
- Fainting
- Cramping
- Mild bleeding
- Vaginal discharge
- Infection

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Date: _____ Parent/Guardian Signature: _____

****

If translation of CONSENT FOR COLPOSCOPIC EXAMINATION was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR CRYOTHERAPY

I, (print or type name) _____, give my consent for cryotherapy. Cryotherapy is a form of treatment in which a freezing probe is applied to the cervix or other areas to accomplish the destruction of abnormal cells and the regrowth of normal tissue.

I acknowledge that no guarantees have been made or implied to me as to the result of this treatment. Follow-up evaluations for about two years should be anticipated.

I understand that during or after the procedure one or more of the following might occur:

- Dizziness
- Fainting
- Cramping
- Mild bleeding
- Vaginal discharge
- Infection

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Date: _____ Parent/Guardian Signature: _____

****

If translation of CONSENT FOR CRYOTHERAPY was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR DEPOT MEDROXYPROGESTERONE ACETATE (DMPA)

I, (print or type name) _____,
request the contraceptive injection of depot medroxyprogesterone acetate (also known as DMPA, Depo-Provera™, depo-subQ provera 104™, Depo, or "the Shot"), as my family planning method.

I have received a pamphlet (included with each injection) that has information about the benefits and risks of DMPA and how to use DMPA.

I understand that no birth control method is perfect and that some women have gotten pregnant while on DMPA (3 out of every 1000 women during the first year of use).

I understand DMPA will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with DMPA to decrease the effectiveness of DMPA. I know it is important to tell all my health care providers that I am on DMPA.

I understand that when using DMPA, the chances of developing health problems increase with certain conditions such as:

- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using DMPA:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with DMPA include:

- Weight gain
- Irregular bleeding or spotting
- Breast tenderness
- Hair loss
- Acne
- Depression

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I understand that there may be thinning of the bones with use of DMPA and that after stopping DMPA the bone structure might not return to normal. It is not known if use of DMPA as a teenager or young adult will increase the risk of fractures in the later years. DMPA should be used long-term (over 2 years) only if other forms of birth control are not satisfactory.

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR DEPOT MEDROXYPROGESTERONE ACETATE (DMPA) was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR EMERGENCY CONTRACEPTIVE PILLS

I, (print or type name) _____, request emergency contraceptive pills (ECPs) to minimize a possible pregnancy risk. I understand it is not a main method of birth control.

I have received package instructions that have information about the benefits and risks of the ECPs that I have been given.

I understand that taking ECPs does not prevent pregnancy 100% of the time. Some pregnancies do occur. In spite of this, I wish to try to prevent pregnancy at this time.

I understand that the risk of development of birth defects in the fetus is unknown and that if treatment fails, I must accept this risk should I decide to continue with this pregnancy. No known increased fetal risk of congenital anomalies has been detected so far.

I understand that possible side effects of ECPs may include:

- Nausea and vomiting
- Breast tenderness
- Headaches and dizziness
- Tiredness
- Irregular vaginal bleeding
- Abdominal pain
- Menstrual cycle disturbances
- Diarrhea

I understand that if I see a health care provider for any reason before I get my period, I should tell him/her that I have taken ECPs.

I understand that I should expect my period within 1-3 weeks and I agree to have a pregnancy test if it has not occurred within that time. I will inform a health care provider of any severe lower abdominal pain. It may be a sign of a more serious condition such as ectopic pregnancy (pregnancy outside the uterus).

I understand that ECPs will not protect me against pregnancy from unprotected sexual intercourse after I have taken ECPs.

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR EMERGENCY CONTRACEPTIVE PILLS was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR IMPLANON™ - SUBDERMAL CONTRACEPTIVE IMPLANT

I, (print or type name) _____,
request Implanon™- subdermal contraceptive implant as my family planning method.

I understand Implanon is good for 3 years and I have received a pamphlet that has information about the benefits, risks, and side effects of Implanon.

I understand that no birth control method is perfect and that some women have gotten pregnant while using Implanon (1 out of every 1000 women during the first year of use).

I understand Implanon will not protect me from HIV infection or other sexually transmitted infections and I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the Implanon to decrease the effectiveness of Implanon. I know it is important to tell all my health care providers that I am using Implanon for birth control.

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using Implanon:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that it is important to tell my health care provider if I have ever had any of the following conditions so my health care provider can explain problems that could happen if I use Implanon:

- Diabetes
- High cholesterol
- Headaches
- Seizures or epilepsy
- Gall bladder or kidney disease
- Depression
- High blood pressure

I understand that side effects sometimes associated with Implanon include:

- Changes in menstrual bleeding pattern, or even no periods
- Spotting or bleeding between periods
- Weight gain
- Headaches
- Acne
- Depression, mood swings, nervousness

I understand that certain problems can be related to the insertion or removal of Implanon:

- Pain, irritation, swelling, or bruising at the insertion/removal site on the arm
- Thick scar tissue around the Implanon making it difficult to remove
- Infection at the insertion/removal site
- Need for hospitalization to remove Implanon (the cost is your responsibility)

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR IMPLANON – SUBDERMAL CONTRACEPTIVE IMPLANT was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR PARAGARD® INTRAUTERINE DEVICE

I, (print or type name) _____, request ParaGard® T 380A Intrauterine Copper Contraceptive (IUD) as my family planning method.

I have received "Information for Patients" in the Patient Package Insert for the ParaGard IUD that has information about the benefits and risks of using this IUD.

I understand that no birth control method is perfect and that some women have gotten pregnant while using the IUD (less than 1 in 100 women during the first year of use).

I understand the IUD will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that the ParaGard IUD is good for 10 years of use.

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using the ParaGard IUD:

- Might be pregnant now
- Uterus with abnormal shape
- Previous surgery of the uterus
- Cancer of the uterus or cervix
- Unexplained vaginal bleeding
- An infection in the uterus after pregnancy or abortion in the last 3 months
- A pelvic infection called PID, an infection of the uterus, tubes, and ovaries
- An infection of the cervix
- A new sex partner in the last 3 months
- Multiple partners in the last year
- A partner who is having sex with other people
- Other high-risk behavior for sexually transmitted diseases
- Wilson's disease (a disorder in how the body handles copper)
- Allergy to copper

I understand that side effects sometimes associated with the ParaGard IUD include:

- Heavier or longer periods
- Spotting between periods
- Menstrual cramps
- Anemia
- Back pain
- Pain during sex
- Vaginal discharge
- Faintness
- Pain

I understand that rare but more serious side effects associated with the ParaGard IUD include:

- Pelvic inflammatory disease (PID), most likely to occur in the first 20 days after IUD insertion, or if you or your partner get a sexually transmitted disease
- Perforation of the uterus (the IUD goes through the uterus wall)
- Expulsion (the IUD may partially or completely fall out of the uterus)

I understand that I should contact a health care provider if I have any of the following:

- Miss a period or think that I might be pregnant
- Pelvic pain or pain during sex
- Unusual vaginal discharge
- Unexplained fever and/or chills
- Might be exposed to a sexually transmitted disease
- Can no longer feel the IUD string
- Severe or prolonged vaginal bleeding

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR PARAGARD® INTRAUTERINE DEVICE was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR REMOVAL OF NORPLANT®

I, (print or type name) _____,
request removal of Norplant® as my family planning method.

HOW NORPLANT® IS REMOVED:

As with insertions, the patient lies on her back on the examination table. After cleaning the removal site on the arm, a local anesthetic is injected. A small incision approximately ¼ inch is made with a scalpel. The Norplant® capsules are then separated from the surrounding tissue and removed. In some cases, removal of the capsules may be difficult. A second incision may be necessary to remove all of the Norplant® capsules. You may be asked to return in 4 to 6 weeks (after the site has healed) in order to remove the remaining capsules. With difficult removals, you may have to be referred to another provider (at your own expense) in order to have all of the capsules removed under anesthesia. Removals usually take about 20 to 30 minutes.

WARNING SIGNS OF POSSIBLE PROBLEMS:

- Redness, pus or bleeding at the removal site
- Swelling, bruising
- Fever
- Reaction to anesthesia

If you have any of the warning signs mentioned above or have any concerns about your care, you should contact your clinician. Within 24 hours after removal, most women return to their pre-insertion fertility rate; therefore, another method should be started immediately if you with to have birth control

****

I have reviewed this consent and discussed it with my clinician. My clinician has answered all my questions and has advised me of the risks involved. I have considered these factors and voluntarily choose to have the Norplant® capsules removed. It is my responsibility to seek another method of birth control if I so desire.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR NORPLANT® REMOVAL was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR NUVARING® - VAGINAL CONTRACEPTIVE RING

I, (print or type name) _____,
request the vaginal contraceptive ring as my family planning method.

I have received a pamphlet (included with each ring) that has information about the benefits and risks of the vaginal contraceptive ring and how to properly use the ring.

I understand that no birth control method is perfect and that some women have gotten pregnant while using the ring (3 out of every 1000 women during the first year of perfect use).

I understand the ring will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the ring to decrease the effectiveness of the ring. I know it is important to tell all my health care providers that I am on the ring.

I understand that when using the ring, the chances of developing health problems increase with certain conditions such as:

- Cigarette smoking
- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using the ring:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with the ring include:

- Nausea and vomiting
- Weight gain or loss
- Breast tenderness
- Spotting between periods
- Vaginal discharge

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR NUVARING – VAGINAL CONTRACEPTIVE RING was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS)

I, (print or type name) _____,
request birth control pills ("the Pill") as my family planning method.

I have received a pamphlet (included with each pack of pills) that has information about the benefits and risks of birth control pills and how to properly take birth control pills.

I understand that no birth control method is perfect and that some women have gotten pregnant while on the Pill (3 out of every 1000 women during the first year of perfect use).

I understand the Pill will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the Pill to decrease the effectiveness of the Pill. I know it is important to tell all my health care providers that I am on the Pill.

I understand that when taking the Pill, the chances of developing health problems increase with certain conditions such as:

- Cigarette smoking
- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before taking the Pill:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with the Pill include:

- Nausea and vomiting
- Weight gain or loss
- Breast tenderness
- Spotting between periods

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS) was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR ORTHO EVRA® - CONTRACEPTIVE PATCH

I, (print or type name) _____,
request the birth control patch as my family planning method.

I have received a pamphlet (included with each box of patches) that has information about the benefits and risks of the patch and how to properly apply the patch.

I understand that no birth control method is perfect and that some women have gotten pregnant while on the patch (1 out of every 100 women during the first year of use).

I understand the patch will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the patch to decrease the effectiveness of the patch. I know it is important to tell all my health care providers that I am on the patch.

I understand that when using the patch, the chances of developing health problems increase with certain conditions such as:

- Cigarette smoking
- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using the patch:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with the patch include:

- Nausea and vomiting
- Weight gain or loss
- Breast tenderness
- Spotting between periods
- Skin irritation

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I understand that by using the birth control patch I will have a higher overall level of estrogen in my body than if I had used the typical birth control pill. This higher estrogen level may increase my risk of side effects, including blood clots in the lungs or legs.

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR ORTHO EVRA – CONTRACEPTIVE PATCH was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR REPRODUCTIVE HEALTH SERVICES

I, (print or type name) _____, request family planning services from the _____ Health Department. I understand that I will give a medical history, have a physical examination, and may get several tests including but not limited to:

- Measurement of height, weight, and blood pressure
- Breast examination – for tumors and abnormalities
- Pelvic (vaginal) examination
- Pap test (Papanicolaou smear) – a screening test for cancer of the cervix and related conditions
- Male genital examination
- Tests for gonorrhea, chlamydia, and human papillomavirus (sexually transmitted infections)
- Urine test to check for diabetes and urine infection
- Urine and/or blood tests to check for pregnancy
- Blood tests to check for syphilis, anemia, and immunity to rubella
- Blood test for hemoglobin disorders
- Blood test for HIV (AIDS) infection
- Skin test for tuberculosis (TB)

I understand my health information is confidential. Confidential means that no one outside of the Health Department will be told about my visits or given information about my health care without my written permission. I understand that in certain cases (suspected child abuse/sexual abuse, child neglect) confidentiality cannot be kept because of Maryland law.

I request information about the different types of family planning methods which are available to me. I understand that these methods include, but are not limited to: fertility awareness methods, condoms, diaphragm, spermicide (vaginal film, foam, or gel), birth control pills, emergency contraception pills, intrauterine device (IUD), birth control "shot" (Depo-Provera), birth control skin patch (Ortho Evra), vaginal ring (NuvaRing) and skin implant (Implanon). With the help of my clinician I will decide on the family planning method which is best for me.

If it is found that I have a sexually transmitted infection, bladder infection, or other infection, I may request treatment for the infection.

If my test for gonorrhea, chlamydia, syphilis, or HIV is found to be positive, I understand that, by law, this result will be reported to the Division of Communicable Diseases of the Maryland State Department of Health and Mental Hygiene.

I understand that my health is my responsibility. I agree to call the family planning clinic for regular check-ups and to find out the results of my lab tests. I will tell the clinic if I change my address, phone number, or contact information. If I decide not to return to the clinic, I will seek care from another provider.

I understand that information in my health record may be disclosed in summary, statistical, or other forms without my consent when the information does not identify me by name.

I voluntarily agree to have family planning services. I understand that I may withdraw this consent at any time.

I understand and agree with the above statements.

Date: _____ Client Signature: _____

****

If translation of CONSENT FOR FAMILY PLANNING SERVICES was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use his/her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read this form or had it read to him/her by a translator or other person.
- The client states that he/she understands this information.
- The client has indicated that he/she has no further questions.

Date: _____ Staff Signature: _____

FAMILY PLANNING INDIVIDUALIZED CONTACT PLAN

I, (print or type name)_____, request the following plan to contact me regarding my family planning visits:

_____

_____

_____

_____

_____

_____

It is my responsibility to call the clinic for my test results in 10 to 14 days after each clinic visit. I may be asked to call again at a later date if all the test results are not ready.

It is my responsibility to let the clinic know if I change my address, phone number, or my contact information.

I will call for appointments so I can continue to receive good health care.

If I fail to call the clinic within 10 to 14 days of my visit or fail to respond to the above written plan, and if a serious health problem is found, I understand the Health Department staff may contact me by telephone, letter, or certified letter.

I understand and agree with the above statements.

Date: _____ Client Signature: _____

****

If translation of FAMILY PLANNING INDIVIDUALIZED CONTACT PLAN was required:

- A translator was offered to the client. □ yes □ no
- The client chose to use his/her own translator. □ yes □ no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
  (print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

****

- The client has read the form or had it read to him/her by a translator or other person.
- The client states that he/she understands this information.
- The client has indicated that he/she has no further questions.

Date: _____ Staff Signature: _____

Appendix K

Declaratory Ruling
Nurse Dispensing

Declaratory Ruling 01-1

RE: POLICY AND PROCEDURE FOR REGISTERED NURSES DISPENSING PRESCRIPTION AND OVER THE COUNTER DRUGS AND DEVICES IN PUBLIC HEALTH CLINICAL PRACTICE SETTINGS

INTRODUCTION

On April 28, 1999, Diane Matuszak, MD, MPH, Deputy Director, Office of Food Protection and Community Health Services petitioned the Board of Physician Quality Assurance to issue a declaratory ruling to allow physicians in public health clinics to delegate the authority to dispense medications to public health nurses.

On April 28, 1999, the Board of Physician Quality Assurance voted to proceed to issue a declaratory ruling for dispensing by public health nurses. The Board of Physician Quality Assurance delegated responsibility for consideration of the petition to the Practice of Medicine Committee to study the request and make a recommendation regarding registered nurses dispensing prescription and over the counter drugs and devices in public health clinical practice settings. The Practice of Medicine Committee considered the petition and made a recommendation that the Board of Physician Quality Assurance issue a declaratory ruling.

The Board of Physician Quality Assurance is authorized to issue a declaratory ruling pursuant to State Government Article §§ 10-301 et seq. and Code of Maryland Regulations 10.32.16 Petition for Declaratory Ruling.

RULING

The Board of Physician Quality Assurance ruled that a physician employed by the Department of Health and Mental Hygiene or a local health department may delegate dispensing authority to certain registered nurses who have received approved training to dispense drugs and devices in a safe and legal manner.

BACKGROUND

1.0 **PURPOSE**

To establish a uniform standard of practice to guide registered nurses in the delegated function of dispensing drugs in public health practice settings in local health departments throughout Maryland.

2.0 POLICY

Upon approval by the Board Physician of Quality Assurance, a physician employed by the Department of Health and Mental Hygiene or a local health department may delegate dispensing authority to certain registered nurses who have received approved training to dispense drugs and devices in a safe and legal manner.

3.0 DEFINITIONS

A. **“Adulterated Drug”** means a drug that:

1.Contains any “putrid, filthy or decomposed substance”;

2.Has been produced, packaged or held under unsanitary conditions where it might become contaminated;

3.Has been placed in a container that might render the contents injurious;

4.Does not have the identity, strength, quality or purity it is purported to possess;

5.Has been:

1.Mixed or packed in a way to reduce its quality or strength; or

1.Substituted in whole or in part; or

6.Does not otherwise meet the requirements of Health-General Article, §21-216, Annotated Code of Maryland.

7.**“Approved Formulary”** means a listing of the drugs or devices approved by the Committee on Nurse Dispensing and reviewed at least annually that a registered nurse may dispense in local health departments in accordance with this Policy and Procedure. Drugs will be dispensed to local health department patients in need of communicable disease, alcohol and drug abuse, and family planning and reproductive health services. A drug may be added to the approved formulary between reviews by filing a request for approval by the Committee on Nurse Dispensing. For a new or amended formulary to be approved by the Committee on Nurse Dispensing, it must include at least the following information on the drugs to be dispensed:

8.Drug name;

9.Vendor or manufacturer;

10.Dosage strength;

11. Quantity in a standard order; and

12. Specified, recommended, or suggested use.

The request for approval will be reviewed by the Committee on Nurse Dispensing. Registered nurses **may not** dispense controlled, dangerous substances except for methadone which may be dispensed to patients in a registered maintenance program.

C. **"Approved Training"** means initial and on-going training for registered nurses that must be approved by the Department of Health and Mental Hygiene, Board of Nursing, and Board of Pharmacy. The training will be designed to "train the trainer," thereby allowing registered nurses to receive standardized training so that they may return to their local health departments to train other registered nurses. The training curriculum must include instruction in accordance with this Policy and Procedure regarding the following:

13. Drugs and devices that a trained nurse may dispense according to this Policy and Procedure;

14. Steps in dispensing;

15. Local health department dispensing policies and procedure;

16. Storage, packaging, labeling and disposal of drugs and device;

17. Inventory;

18. Drug interaction management;

19. Patient consultation;

20. Record keeping;

21. Legal aspects of dispensing;

22. Procedures for minimizing general medication errors; and

1.Reviews of pharmacology, therapeutics, and side effects of drugs on the approved formulary.

D. **"Authorized Physician"** means a physician licensed in Maryland, employed by the Department of Health and Mental Hygiene or a local health department who has applied for and received authorization from the Board of Physician Quality Assurance to delegate dispensing authority to certain registered nurses who work in local health department clinical practice settings.

E. **"Board of Pharmacy"** means the Board established under Health Occupations Article, §12-201, Maryland Annotated Code, to regulate the licensure, continuing education, and practice of licensed pharmacists in Maryland.

F. **"Board of Physician Quality Assurance"** means the Board established under Health Occupations Article, §14-201, Maryland Annotated Code, to regulate the licensure, continuing education, and practice of licensed physicians in Maryland.

G. **"Board of Nursing"** means the Board established under Health Occupations Article, §8-201, Maryland Annotated Code, to regulate the licensure, continuing education, and practice of licensed registered nurses in Maryland.

23.**"Committee on Nurse Dispensing"** means a committee convened by the Department of Health and Mental Hygiene and composed of one representative designated by the Secretary and one representative from each of the Boards of Pharmacy, Nursing, and Physician Quality Assurance, a representative from the Maryland Council of Public Health Nurse Directors, and a volunteer pharmacist from the community as nominated by the Board of Pharmacy.

I. **"Department"** means the Department of Health and Mental Hygiene.

J. **"Designated Trainer"** means a health care professional licensed under the Health Occupations article of the Annotated Code of Maryland, which may include an authorized physician, a program physician, a pharmacist, a registered nurse, or any combination of these professionals, who has been approved by the Committee on Nurse Dispensing to provide training on dispensing drugs.

K. **"Device"** means an item used in the diagnosis, treatment, or prevention of disease. Devices may include prescription items such as diaphragms or non-prescription items such as spacers. Device does not include any:

1. Surgical or dental instrument;

2. Physical therapy equipment;

3. X-ray apparatus; or

4. Component part or accessory of any of these items.

L. **"Dispense"** means the procedure which results in the receipt of a prescription or non-prescription drug or device by a patient or patient's agent which includes:

24. Interpreting an authorized prescriber's prescription for a drug or device;

25. Selecting and labeling of the drug or device prescribed; and

26. Measuring and packaging of the drug or device in accordance with State and Federal laws.

M. **"Drug Inventory Log"** means an administrative form on which the following must be recorded:

1. Date received and quantity in each delivery to a local health department site of a particular drug;

2. Quantity of the drug that is dispensed with each prescription;

3. Quantity of the drug remaining in the clinic's stock; and

4. Prescription number and date that the drug is dispensed.

27. **"Drug References"** means up-to-date printed information on drug use, actions, adverse reactions, and interactions with other drugs.

28. **"Interpretation"** means:

1. Correctly identifying the drug prescribed; and

2. Preparing a label which accurately reflects the instructions for use given on the prescription, such as form, dosage, route, and frequency of dosing.

29. **"Misbranded drug"** means a drug whose:

1. Label is false or misleading in any way;

2. Label does not meet requirements for labeling under the State law;

3. Label does not carry the established name of the drug;

4. Label bears the name of a drug which is not what the container holds;

5. Packaging is in violation of the Federal Poison Prevention Packaging Act of 1970; or

6. Label does not otherwise meet the requirements of Health-General Article, §21-217, Annotated Code of Maryland.

30. **"Patient Profile"** means a computerized or hard copy format which lists the following information:

1. Patient's name, address, and date of birth;

2. Patient's allergies, medical problems, and medications;

3. Prescription number;

4. Name, strength, quantity, directions for administration, and manufacturer of drug; and

5. Date that the drug is dispensed.

31. **"Physician Delegation Documentation Log"** means an administrative form which certifies that the authorized physician has delegated dispensing authority to specified

registered nurses in compliance with this Policy and Procedure. The log must be signed and dated by an authorized physician annually.

S. **"Prescription Log"** means an administrative form on which each act of dispensing must be recorded in sequential order by prescription number. The information that must be recorded for each act of dispensing includes the following:

32. Prescription number, which should be sequential and without duplication;

1. Brand or generic name of the drug;

33. Name of the manufacturer or distributor of the drug;

34. Quantity dispensed;

35. Dosage strength;

36. Date of dispensing;

37. Lot or serial number assigned to drug dispensed;

38. Identification of the dispenser;

39. Records of refills, including date of refill and dispenser;

40. Name of the patient to whom the drug was dispensed; and

41. Expiration date.

42. **"Registered Nurse"** means an individual who is licensed by the Maryland Board of Nursing to practice registered nursing.

4.0 RESPONSIBILITIES

A. The authorized physician is responsible for:

43. Complying with the Board of Physician Quality Assurance requirements for delegation of dispensing authority;

44. Delegating dispensing authority only to registered nurses who have successfully completed a training program approved by the Committee on Nurse Dispensing created under this Policy and Procedure;

1.Signing the authorized Physician Delegation Documentation Log;

1.Assessing the potential for adverse effects if the prescribed medication is taken by a patient who is allergic to an ingredient in the prescribed medication or if the prescribed medication is taken concurrently with other medications being taken by the patient.

B. **The Health Officer or designee is responsible for:**

45.Assuring that authorized physicians and registered nurses who dispense drugs in local health department settings are aware of and in compliance with this Policy and Procedure;

46.Assuring competency of registered nurses who dispense drugs by providing continuing training relevant to dispensing and an annual review of the Approved Training curriculum;

47.Conducting an annual review of dispensing related activities of registered nurses who dispense drugs;

48.Obtaining the approval of the Committee on Nurse Dispensing for each local health department's formulary and any changes or additions to that formu lary;

49.Obtaining the approval of the Committee on Nurse Dispensing for each designated trainer used by the local health department;

50.Authorizing a registered nurse to dispense only after the registered nurse has successfully completed training and received the delegation of dispensing authority from an authorized physician;

51.Assuring that the Division of Drug Control is allowed to enter and inspect the premises at all reasonable hours;

52.Reviewing the training curriculum approved by the Committee on Nurse Dispensing;

53.Ensuring that written authorization or release of information is signed by the patient or the patient's authorized agent;

54.Ensuring that adequate safeguards are in place to maintain the confidentiality of patient's drug records;

55.Restricting access to the patient's drug records to only the following persons:

1.An adult patient for whom the prescription was written or the patient's legally appointed guardian;

2.An emancipated minor patient for whom the prescription was written;

(c) An unemancipated minor for whom the prescription was written, when the minor's consent was sufficient to authorize treatment for the minor's condition; 56. A parent or legally appointed guardian for an emancipated minor for whom the prescription was written, when the minor's consent is not sufficient to authorized treatment for the minor's condition;

57.The prescriber who issued the prescription;

58.The licensed practitioner who is treating the patient for whom the prescription was written;

59. A pharmacist who is providing pharmacy services for the patient for whom the prescription was written;

60.A person with signed authorization for release of the information from the patient or the patient's legally appointed guardian;

61.A person authorized by subpoena, court order, or statute;

62.A third party responsible for providing or paying for medical expenses for the patient for whom the prescription was written with the patient's written authorization;

63.A member or designated employee of the Board of Pharmacy or Maryland State Division of Drug Control;

64.The executor, or spouse or administrator of a deceased patient for whom the prescription was written;

65.Researchers as approved by the Department of Health and Mental Hygiene's Institutional Review Board;

66.Assuring that no additional fee is charged for dispensing drugs or devices;

67.Assuring that a licensed pharmacist is available for consultation; and

68.Assuring that up-to-date drug references are available to registered nurses who dispense medicines.

C. **The Board of Pharmacy is responsible for:**

(1) Selecting pharmacists with community health experience to assist with the development of the Approved Training Curriculum;

1.Selecting a licensed pharmacist with community health experience who may provide consultation; and

2.Reviewing and assuring, as needed, that this Policy and Procedure is in compliance with the Pharmacy Practice Act.

D. (1) **The registered nurse is responsible for**:

1.Successfully completing the approved training;

2.Complying with this Policy and Procedure;

3.Assuring that this delegated dispensing authority is **not** redelegated to other individuals;

4.Assuring that all drugs and devices dispensed pursuant to this Policy and Procedure are not adulterated drugs or misbranded drugs;

5.Maintaining medication related records and files in a manner that ensures the confidentiality of patient's drug records and is consistent with State and Federal laws and regulations;

1.Following the drug storage and inventory procedures in this Policy and Procedure;

6.Dispensing only to patients of the local health department;

7.Dispensing only at designated health department sites;

8.Maintaining access to suggested drug references;

9.Maintaining competency related to dispensing; and

10.Consulting with a licensed pharmacist, when appropriate, to answer questions that arise regarding drug or medication therapy.

69.**The registered nurse shall strictly adhere to the following steps** when dispensing a prescribed product:

1.Reading the prescription order. The registered nurse shall:

1.Verify that drug is on the approved formulary;

2.Verify that the prescription order includes at least the following information:

1.Date of issue;

2.Name and address of patient;

3.Name, address, and telephone of prescriber;

4.Name, strength, dosage form, and quantity of drug prescribed;

5.Stop date for refills, if authorized;

1.Route of administration, if applicable; and

6.Directions for use.

(iii) Verify that prescription or prescription orders are signed by the physician within four working days;

(iv) Check the patient profile for pertinent information, including information on allergies, concurrent prescription drugs, and over the counter medications; and

70. Determine that the prescription is not outdated and not to be filled if more than 120 days after issue, in accordance with Health Occupations Article, §12-503, Annotated Code of Maryland.

1.Selecting the medication. The registered nurse shall:

71.Select the appropriate drug or device in accordance with the prescription order;

(ii) Select the prescribed product in the correct dosage;

(iii) Inspect the prescribed product for defects;

(iv) Measure out appropriate quantity if unit of uses are not available;

72.Double check accuracy before returning drug to stock; and

73.Note in the patient chart and on the patient profile the brand, manufacturer or distributor of the product dispensed.

(c) Selecting the proper container. The registered nurse shall:

1.Package drugs and devices dispensed pursuant to this Policy and Procedure in suitable safety-closure containers unless the patient requests in writing that no safety container be used;

2.Select the appropriate container based on quantity, storage requirements, and need for child-resistant container;

3.Use a new container whenever refilling the prescription; and

4.Dispense relevant substances in safety packaging in accordance with the Poison Prevention Packaging Act of 1970.

74.Complying with other drug packaging requirements. The registered nurse shall act in conformity with the following provisions:

75.The prescriber or patient may request that non-safety closures be used. The patient may give a blanket waiver regarding all of the patient's prescriptions. This request must be in writing and signed by patient or authorized agent.

76.The prescriber may not give blanket authorization for the use of non-safety closures.

77.New packages must be used when refilling prescriptions. However, when glass containers are used, replacing the cap with a new one complies with the poison prevention packaging requirements.

(iv) The manufacturer's original package, with appropriate labeling, may be dispensed directly to the consumer if it carries a safety closure.

78.Labeling container. The registered nurse shall comply with the following provisions when dispensing both prescription and nonprescription drugs:

1.Drugs and devices dispensed pursuant to this Policy and Procedure shall be properly labeled (including necessary auxiliary labels) so as to provide information necessary for use and all other information required by state and federal law;

(ii) A drug dispensed by filling or refilling a written or oral

prescription of a legally authorized prescriber must bear a label with the following contents:

1.Local health department name, address and telephone number;

2. Patient name;

3.Clinic name and address;

4.Phrase “Dispensed by ....., R.N. and initials” with the name of the dispenser appearing in the blank;

5.Lot number and date of dispensing of the prescription;

6.Prescriber’s name;

7.Directions for use, including route of administration;

8.Name and strength of the drug, with the label showing the brand name of the drug, or in the absence of a brand name, the established generic name of the drug and the manufacturer or distributor of the drug;

9.Expiration date in accordance with Health-General Article, §12-505, Annotated Code of Maryland;

10.Any appropriate special handling instructions regarding proper storage of the drug or device;

11.Refills, if authorized; and

12.Prescription number.

(iii) Plastic containers or dispensers for oral contraceptives must be labeled with patient information leaflets attached; and

(iv) A medication supplied by the manufacturer with patient information leaflets must be dispensed with leaflet intact.

79.Giving medication to patient. The registered nurse shall:

1.Determine if the patient or patient's agent is to receive the medication;

2.Determine what information should be provided regarding correct use of the medication;

3.Determine the level of understanding of the patient or patient's agent for printed and verbal instructions;

4.Provide educational information about drugs in a format that the patient or patient's agent can comprehend;

5.Give the medication to the patient or patient's agent; and

6.Deliver the drug or device to the patient at home, only if necessary, following Federal, State and local laws and regulations.

80.Counseling patient on use. The registered nurse shall:

1.Explain the proper procedure for taking or administering the drug, based on the patient's or caregiver's ability to understand;

2.Describe to the patient or patient's agent any side effects of the dispensed drug and how to minimize them;

3.Explain the precautions regarding food or other drugs that might interact adversely with the drug being dispensed;

4.Explain the proper storage conditions for the drug;

5.Provide appropriate written information as necessary;

6.Explain the steps to be taken when a dose is missed; and

7.Explain any special considerations.

81.Retaining record of dispensing. The registered nurse shall retain prescriptions records for five years in accordance with Health Occupations Article, §12-403 (b)(13)(I), Annotated Code of Maryland. A prescription profile containing a record of each act of dispensing must be made in addition to the original prescription or chart order. Records shall include, but are not limited to, the following:

1.Name of the patient to whom the drug is dispensed;

2.Brand name, if any, or the established name and the manufacturer or distributor of the drug product that is dispensed;

1.Quantity dispensed;

3.Date of dispensing;

4.Lot or serial number assigned to the drug dispensed;

5.Identification of the dispenser (e.g., initials);

6.Records of refills, to date, including date of refill and the name of the dispenser; and

7.Prescription number.

E. **The designated trainers are responsible for**:

82.Developing and presenting the approved training curriculum in accordance with this Policy and Procedure and a self-instruction manual to registered nurses seeking dispensing authority; and

83.Conducting pre-training and post-training tests to registered nurses seeking dispensing authority.

F. **The Department of Health and Mental Hygiene is responsible for:**

(1) Convening a Committee on Nurse Dispensing to review and approve:

1.The formulary for each local health department where a physician delegates dispensing of drugs or devices to a registered nurse;

2.The training curriculum required for registered nurses to whom dispensing of drugs and devices has been delegated by a physician;

3.The designation of trainers requested by each local health department; and

4.The forms used to document required information and actions as stated in this Policy and Procedure.

1.Including representatives of the following as members of the Committee on Nurse Dispensing:

1.Board of Pharmacy;

2.Board of Nursing;

3.Board of Physician Quality Assurance;

4.Department of Health and Mental Hygiene;

5.Member of the Maryland Council of Public Health Nurse Directors; and

6.A volunteer pharmacist from the community.

5.0 **OTHER**

A. **Prescription Drug Storage and Inventory**

2.Receipt of Drug

1.Shipments of drugs received at the local health department must be handled in accordance with this Policy and Procedure. Staffs are required to:

1.Visually examine the package for identification and refuse acceptance of potentially adulterated prescription drugs or

prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents; and

(ii) Sign the packaging invoice confirming the quantity and date that the drugs were received.

84.Staff who receive drugs in the local health department are required to maintain inventories and records of all transactions regarding receipt and distribution of prescription drugs. A copy of the packaging invoice will be used to generate a Drug Inventory Log (sample attached) or similar local form, if desired.

(c) Upon receipt of drugs, staff shall:

1.Reject all shipments of drugs not listed on the approved formulary;

2.Complete sections 1 though 7 of the Drug Inventory Log upon acceptance of the drug shipment;

3.Immediately store drugs in an appropriate and secure dispensing area;

4.Complete sections 8, 9, and 10 of the Drug Inventory Log upon sending the drug to the clinic;

1.Complete section 11 of the Drug Inventory Log upon receipt of the drug; and

5.Make a photocopy of the Drug Inventory Log and maintain for initial inventory control.

85.Secured Drug Storage and Inventory

1.All drugs must be secured in a locked substantially constructed cabinet, storage closet, or refrigerator.

2.Only designated staff shall possess access to the locked storage closets and refrigerators.

3.The cabinet or storage closet must be at room temperature (68°- 77° F), in an area of adequate light, and maintained in a clean and orderly condition.

4.All drugs that require refrigeration must be stored at 2°-8°degrees C (35°-46° degrees F) to maintain biologic potency. All biologic storage refrigerators must be secured and have a 24 hour a day electronic monitoring alarm device to prevent biologic loss due to inappropriate storage or equipment failure. Refrigerators must be used only for the storage of biologicals and drugs.

5.Drugs must be stored according to manufacturer's recommendation and in a manner that ensures proper rotation of stock. Expired drugs or devices must be removed from stock each month. Documentation on the bottom of the Drug Inventory Log must reflect whether drugs were returned to the supplier or disposed. If disposed, the disposal process must meet requirements of State and Federal Laws.

6.In the event that drugs stocked at the Local Health Department become outdated (expired), the staff shall take the following actions:

1.Verification of the drug to be discarded must be established by comparing the expiration dates listed in the Drug Inventory Log with the actual date stamped on the drug container.

(ii) Expired drugs must be gathered, counted, and returned to the supplier or reverse distributor for partial credit, if possible, or properly disposed. This disposal must be witnessed and two licensed registered nurses must sign the

Drug Inventory Log attesting to having witnessed the disposal. The date, lot numbers, and reasons for disposal must also be noted. Controlled substances must be gathered, counted, and returned to the Drug Enforcement Agency (DEA) for disposal.

(iii) If a drug cannot be returned, the preferred method for disposal is incineration at an approved biomedical waste disposal site. For small quantities only, acceptable methods for drug disposal are double flushing or pouring of liquids down a drain.

(iv) Following disposal, the Drug Inventory Log related to the eliminated drugs must be removed from the active files, but retained for a minimum of five years.

86.Recalls

1.Drug recall notices must be reviewed by the Department and forwarded to the appropriate program manager at the local health departments. The program manager shall immediately arrange for removal of a recalled drug from distribution and return it to the manufacturer in accordance with the recall instructions. A copy of the recall letter must be returned to the Department with either:

1.Documentation that no such product is on site; or

2.Documentation that the product was returned to the supplier.

2.Notation of a recall must also be made on the Drug Inventory Log and retained for a minimum of five years.

3. In the event of a Class I (patient level) Recall, the program manager or designee must contact all patients that received the affected lot. The records documenting the contact with patients and returns shall be maintained on-site for at least two years following the recall.

CONCLUSION

The mission of the Board of Physician Quality Assurance is to protect the citizens of Maryland through the effective licensure and discipline of physicians and allied health practitioners under its jurisdiction. The Board of Physician Quality Assurance recognizes that the practice of medicine develops and evolves over time. The Board of Physician Quality Assurance reviews and considers developments in the practice of medicine within the context of its duty to protect the public. A physician employed by the Department of Health and Mental Hygiene or a local health department may delegate dispensing authority to certain registered nurses who have received approved training to dispense drugs and devices in a safe and legal manner.

_____

Samir R. Neimat, Chairman Date

EFFECTIVE DATE

The effective date of this Administrative Policy and Procedure is _____.

_____ _____

Date Department of Health and Mental Hygiene

_____ _____

Date Health Officer

_____ _____

Date Authorized Physician

_____ _____

Date Director of Nurses or Designee