DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington DC 20201

Date: March 1, 2011

To: Regional Health Administrators, Regions I-X
Title X Grantees

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 11-01: Title X Grantee Compliance with Grant Requirements and Applicable Federal and State Law, including State Reporting Laws

The Office of Population Affairs (OPA) is issuing this memorandum as a reminder to the regional offices, Title X grantees, and grantee subrecipients, about a number of longstanding Title X program requirements. Although the requirement that Title X services be provided confidentially has been a cornerstone of the Title X program since its inception, Title X providers are also required to comply with specific State reporting and notification laws. This requirement, which has been part of appropriations language since Fiscal Year 1999, was most recently included in section 210 of the Fiscal Year 2010 Consolidated Appropriations Act (Pub. L. No. 111-117), and which remains in effect, states as follows:

> *Notwithstanding any other provision of law, no provider of services under title X of the Public Health Service Act shall be exempt from any State law requiring notification, or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.*

OPA Program Instructions related to these requirements were issued previously, on January 12, 1999, and June 5, 2006, as OPA Program Instruction Series, OPA 99-1, "Compliance with State Reporting Laws" and OPA 06-01, and "Compliance with State Reporting Laws – Reminder Notification (Revised)." Both of these Program Instructions, OPA 99-1 and OPA 06-01, are attached to this memorandum and remain in effect. Title X grantees are reminded that they are responsible for ensuring that: (1) grantee clinics, subrecipients, and contract agencies, receive and are complying with the information included in this memorandum and OPA 99-1 and OPA 06-01; and (2) that written policies and procedures are in place to address notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, or any other form of domestic violence, as required by current applicable State law.

Title X grantees are also reminded that, as a condition of accepting Title X funds, they are required to comply with: 1) all assurances that were signed as part of the application for Federal funds (including Assurance # 18 of the SF 424B, which requires that applicants "comply with all applicable requirements of … Federal laws, executive orders, regulations and policies governing this program"); 2) all terms and conditions of the Notice of Grant Award; 3) all applicable Federal laws; 4) all Title X requirements set out in the Title X statute and regulation, as well as Title X policies set out in the Title X program guidelines and Program Instructions; and, 5) all applicable State laws.

As part of the requirement that grantees comply with all applicable Federal laws, grantees are reminded that they must comply with Federal anti-trafficking laws, including the Trafficking Victims Protection Act of 2000 (Pub. L. No.106-386), as amended, and 18 U.S.C. 1591. Noncompliance with these laws may result in the disallowance of Title X funds, or the suspension or termination of the Title X grant award.

As in the past, grantees also are responsible for ensuring compliance throughout their Title X projects with Section 1008 of Title X, which states that:

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

Grantees that have questions about the interpretation of section 1008 should refer to the July 3, 2000, Federal Register Notice entitled "Provision of Abortion-Related Services in Family Planning Services Projects," which is available at 65 Fed. Reg. 41281, on the Office of Population Affairs website, and which is attached hereto, as well as the July 3, 2000, final rule entitled "Standards of Compliance for Abortion- Related Services in Family Planning Services Projects," which is available at 65 Fed. Reg. 41270.

Regional Offices continue to be responsible for periodic reviews of Title X grantees to ensure compliance with all of these requirements, and should take immediate steps to address issues related to adherence to established policies and procedures, including, but not limited to immediate notification of the Office of Population Affairs. Title X grantees are responsible for conducting periodic reviews of sub-recipient agencies, and must undertake immediate steps to address issues related to lack of compliance with established policies and procedures. Grantees must maintain documentation of all reviews of their sub-recipient agencies, including outcomes and any corrective action steps necessary to address deficiencies. Regional Office reviews of grantees should include review of the documentation of grantee monitoring of all agencies within the grantee's Title X project to ensure that adequate monitoring is occurring, staff have received training, and that there are no apparent deficiencies in this area that have not been addressed. Regional Office monitoring specific to the content of this Program Instruction should occur during annual site visits to grantees, as well as during comprehensive Title X Program Reviews.

Title X providers must ensure that policies and procedures are current and reflective of applicable State laws. Failure of a Title X grantee or any grantee subrecipient to comply with applicable State laws addressing the notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, or any other form of domestic violence, as required by applicable State law may result in the disallowance of Title X funds, or the suspension or termination of the Title X grant award.

Regional Offices should ensure that Title X grantees, grantee subrecipients, and all other project staff receive training regarding the provisions of this Program Instruction within the next six months.

Questions relating to the requirements addressed in this memorandum should be addressed to the Office of Population Affairs.

Marilyn J. Keefe, MPH
Deputy Assistant Secretary for Population Affairs

Attachments:

OPA Program Instruction Series, OPA 99-1: Compliance with State Reporting Laws

OPA Program Instruction Series, OPA 06-01: Compliance with State Reporting Laws – Reminder Notification (Revised)

"Provision of Abortion-Related Services in Family Planning Services Projects," 65 Fed. Reg. 41281

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington DC 20201

October 9, 2009

TO: Regional Health Administrators, Regions I-X

FROM: Acting Director, Office of Population Affairs

SUBJECT: OPA Program Instruction Series, OPA 09-02:
Provision of 2009 H1N1 Vaccination in Title X Family Planning Projects

As you may be aware, on July 24, 2009, Secretary of Health and Human Services Kathleen Sebelius renewed the April 26, 2009, declaration by then Acting Secretary Charles E. Johnson that a public health emergency exists nationwide involving novel influenza A (H1N1) virus (which will be referred to throughout this Program Instruction as 2009 H1N1). The purpose of this Program Instruction is to provide guidance to Title X Family Planning service grantees regarding the provision of the 2009 H1N1 vaccination.

CDC's Advisory Committee on Immunization Practices (ACIP) has determined that certain groups of the population are at relatively higher risk, and should receive the 2009 H1N1 vaccine as soon as it becomes available. These target groups include pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months and 24 years old, and people ages 25 through 64 year of age who are at higher risk for 2009 H1N1 because of chronic health disorders or compromised immune systems. Vaccination efforts are designed to help reduce the impact and spread of 2009 H1N1.

Title X providers are encouraged, but not required, to make the 2009 H1N1 vaccine available to Title X healthcare personnel as well as to clients within Title X clinics, and may choose to provide the vaccine either as part of the Title X project, or outside of the Title X project. When the 2009 H1N1 vaccine is provided as part of the Title X project, all Title X regulations must be followed (e.g., confidentiality, schedule of discounts, nondiscrimination, etc.). In addition, grantees should be aware of other State and/or Federal requirements regarding provision of the vaccine.

Title X providers that provide the 2009 H1N1 vaccine, but not as part of the Title X project, must account for those services and the corresponding charges (e.g., staff time, etc.) separate and distinct from the Title X project.

Healthcare personnel within the Title X service system are at high risk for exposure to 2009 H1N1, and providing them with the vaccine will help to prevent the spread of H1N1 to uninfected co-workers and clinic patients. Also, among the target groups for the vaccine are pregnant women and persons between the ages of 6 months and 24 years. As documented on the

most recent Family Planning Annual Report (2007 FPAR), more than half (55%) of clients who receive services in Title X-funded family planning clinics are 24 years of age or younger. Pregnant women are a priority group for receiving the 2009 H1N1 vaccine, and although prenatal services are not within the scope of Title X, pregnancy testing and early pregnancy education and counseling are among the most commonly provided services in family planning clinics. Since it may be several weeks before the pregnant woman is seen for a first prenatal visit, pregnancy testing and diagnosis at a family planning clinic is an important opportunity to provide the 2009 H1N1 vaccine before a pregnant woman may be exposed to the virus.

In addition, Title X regulations at 42 CFR Part 59, Subpart A, § 59.5 (b)(2) ("What requirements must be met by a family planning project?") stipulate that projects must, unless the Secretary determines that the project has established good cause for its omission, "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*" (emphasis added). Provision of the 2009 H1N1 vaccine by Title X clinics may encourage more individuals to come to a clinic, where they could be provided with family planning services as well as the vaccine. However, note that only clients that meet the FPAR definition of a "family planning user" and receive a family planning service in addition to the 2009 H1N1 vaccine may be counted on the FPAR.

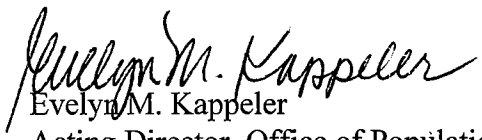
Grantees that are interested in providing the vaccine should visit the following CDC websites: http://www.cdc.gov/H1N1flu/vaccination/clinicians_qa.htm and http://www.cdc.gov/h1n1flu/vaccination/statelocal/. As explained in the CDC websites above, the Federal Government is the only source for the vaccine, and it is being allocated to states based on population size. The Federal Government is purchasing vaccine and supplies (syringes, alcohol swabs, sharps containers, and vaccine record cards) and distributing these at no cost to healthcare providers who make agreements with State and local public health authorities to provide the H1N1 vaccine. States are responsible for identifying providers who will participate in administration of the H1N1 vaccine, and State and local health departments are responsible for directing the flow of vaccine to providers within States. A number of States have already established registries for providers to request 2009 H1N1 vaccine allocations, and Family Planning service grantees are encouraged to work closely with their States to make their needs known and register with their State public health authorities to receive the vaccine. For more information, grantees should contact the State public health department website or the CDC 2009 H1N1 website at http://www.cdc.gov/H1N1flu/.

While the vaccine is free, providers are able to charge a fee for the administration of the vaccine, which is an allowable cost within the Title X program. Medicaid and the Children's Health Insurance Program (CHIP) will pay the administration fee for those clients that are eligible

under these programs. For additional information, grantees should be directed to http://www.cms.hhs.gov/smdl/downloads/SHO092409.pdf.

Grantees that are interested in providing the 2009 H1N1 vaccine should be aware of the Public Readiness and Emergency Preparedness (PREP) Act which provides broad liability protections, including protections associated with the administration of covered countermeasures, such as the 2009 H1N1 vaccine. Liability protections were put in place to ensure that an adequate supply of countermeasures was produced and made available in the U.S. by vaccine manufacturers. The PREP Act also provides a mechanism to compensate eligible individuals for covered injuries from a covered countermeasure. For an overview of these protections, see www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/medication-vaccine-qa.html.

For purposes of consistency, please direct all grantee questions regarding provision of the 2009 H1N1 vaccine to Central OPA.



Evelyn M. Kappeler
Acting Director, Office of Population Affairs

cc: Regional Program Consultants for Family Planning

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington, D.C. 20201

APR 2 8 2009

TO: Regional Health Administrators, Regions I-X

FROM: Acting Director, Office of Population Affairs

SUBJECT: OPA Program Instruction Series, OPA 09-01: Clinical Services in Title X Family Planning Clinics – Consistency with Current Practice Recommendations

The purpose of this Program Instruction is to provide guidance to Title X family planning services providers regarding the delivery of clinical services that are consistent with nationally recognized standards of care. A copy of this memorandum should be provided to all Title X grantees in your region.

The "Program Guidelines for Project Grants for Family Planning Services" (Title X Program Guidelines) were last revised and distributed to all Title X family planning services providers in January 2001. The purpose of the Title X Program Guidelines is to assist current and prospective grantees in understanding the family planning services grant program authorized by Title X of the Public Health Service Act (42 U.S.C. 300, et seq.), and to clarify the requirements of the program, as set out in the Title X family planning services regulations (42 CFR part 59, subpart A).

Since the issuance of the Title X Program Guidelines in 2001, based upon current, science-based evidence, there have been a number of changes or modifications to the recommendations or standards of practice for quality clinical services. Many of these changes impact clinical practice in Title X-funded service sites and, in certain areas, nationally recognized standards conflict with the recommendations set out in the Title X Program Guidelines. This Program Instruction is being issued to provide clarification and eliminate grantee confusion regarding any inconsistencies that may exist between current practice recommendations and the Title X Program Guidelines -- where there are inconsistencies, Title X providers should provide care that is consistent with current nationally recognized standards.

Therefore, in order for Title X grantees to continue to provide services that are of high quality and in compliance with Title X requirements, Title X providers, in consultation with agency medical directors, should develop written clinical protocols that are consistent with the most current nationally recognized standards of care. These protocols should be reviewed on a regular basis, and modified as needed. Agency protocols should include a reference to the specific nationally recognized standard(s) of care, recommendation(s), and/or practice standards, as well as the date of protocol review and modification. Clinical protocols should continue to

incorporate considerations of individual client characteristics, including the use of specific contraceptive methods, in addition to current standards for care.

Agency policies and procedures should indicate the frequency of protocol review. In addition, agencies should ensure that training be provided to clinical staff on nationally recognized practice standards and any changes to protocols along with quality improvement/quality assurance procedures. Clinical practice should adhere to written protocols based on identified national practice standards.

Clinical protocols should reflect the current recommendations for practice or standards of care established by health agencies or professional organizations, such as the following:

American Cancer Society: http://www.cancer.org
Agency for Health Care Policy and Research, U.S. Preventive Services Task Force: http://www.ahcpr.gov/clinic/uspstfix.htm
Centers for Disease Control and Prevention: http://www.cdc.gov
American College of Obstetricians and Gynecologists: http://www.acog.org
North American Society of Pediatric and Adolescent Gynecology: http://www.naspag.org
American Society for Colposcopy and Cervical Pathology: http://www.asccp.org
Agency for Healthcare Research and Quality: http://www.ahrq.gov/clinic/cpgsix.htm
Partners in Information Access for Public Health Resources (Department of Health and Human Services): http://phpartners.org/guide.html
AIDSinfo (Department of Health and Human Services): http://www.aidsinfo.nih.gov/
National Heart Lung and Blood Institute (Department of Health and Human Services): http://www.nhlbi.nih.gov/health/indexpro.htm.

Title X grantees are responsible for ensuring that all sub-recipient agencies maintain and use written clinical protocols that are consistent with nationally recognized practice standards. Regional offices should continue to review and monitor clinical protocols of Title X grantees, delegate agencies, and clinics, particularly during site visits and comprehensive program reviews.

If you have questions, please contact Susan Moskosky, Director, Office of Family Planning on (240) 453-2888.

Evelyn Kappeler
Acting Director, Office of Population Affairs

Cc: Regional Program Consultants for Family Planning

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington DC 20201

SEP 23 2008

TO: Regional Health Administrators, Regions I – X

FROM: Acting Director, Office of Population Affairs

SUBJ: OPA Program Instruction Series, OPA 08-1: Verification of Income for Title X Clients

The purpose of this Program Instruction is to provide guidance to Title X grantees regarding the extent of their discretion in verifying the family income of clients seeking services in Title X-funded clinics. Within the parameters set out by the Title X statute, regulations and Program Guidelines, Title X grantees have a large measure of discretion in determining the extent of income verification activity that they believe is appropriate for their client population. Written policies should be developed by grantees regarding verifying family income within the Title X project. Policies should be developed that embrace the mission and purpose of Title X, including that priority for services is to be given to persons from low-income families (as defined in the Title X regulations at 42 CFR 59.2), and that the inability to pay must not be a barrier to the receipt of services.

Grantee policies and procedures for documentation of family income will be reviewed by the Regional Health Administrator, and procedures for implementing will be monitored during site visits and comprehensive program reviews. In addition, policies and procedures for income verification should be reviewed and approved by the governing authority or board of the grantee organization.

Although not required to do so, grantees that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on client's self report.

This Program Instruction is being issued in response to recent questions for clarification regarding methods which may be applied to verify family income, and to ensure that Title X resources are properly directed. All requirements regarding fees and charges set out in the Title X statute and regulations, as well as all guidance regarding fees and charges provided in the Title X Program Guidelines and previously-issued Program Instructions remain in effect.

Evelyn M. Kappeler
Acting Director, Office of Population Affairs

cc: Regional Program Consultants, Regions I-X

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF PUBLIC HEALTH & SCIENCE
OFFICE OF POPULATION AFFAIRS

Memorandum

Date: June 5, 2006

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 06-01: Compliance with State Reporting Laws – Reminder Notification (Revised)

To: Regional Health Administrators, Regions I-X

This memorandum serves as a reminder notification regarding the following longstanding provision governing the use of Title X funds, which is included as section 213 of the Fiscal Year 2006 HHS appropriations act (Pub. L. No. 109-149):

> Notwithstanding any other provision of law, no provider of services under title X of the Public Health Service Act shall be exempt from any State law requiring notification, or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.

Previously, on January 12, 1999, the Office of Population Affairs (OPA) issued OPA Program Instruction Series, OPA 99-1, "Compliance with State Reporting Laws." OPA 99-1, which is attached to this memorandum, remains in effect. A copy of this memorandum, as well as the attached OPA 99-1, should be provided to all Title X grantees in your region. Title X grantees should be reminded that they are responsible for ensuring that all sub-recipients receive the information contained in this memorandum and OPA 99-1, and for ensuring that policies and procedures are in place to appropriately address notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, or any other form of domestic violence, as required by applicable State law.

Regional Offices are responsible for periodic review of Title X grantees to ensure compliance with the provisions of the appropriations language as they relate to applicable State law. The Regional Office must undertake immediate steps to address any issues related to adherence to established policies and procedures. Outcome of all Regional Office reviews, including any corrective action, must be included in the official grant file for the applicable Title X grantee. Title X grantees are responsible for conducting periodic reviews of sub-recipient agencies for compliance, and must undertake immediate steps to address issues related to adherence to established policies and procedures. Grantees must maintain documentation of reviews, including outcomes, and any corrective action steps necessary.

Title X providers are encouraged to work with appropriate local authorities to ensure that policies and procedures are compliant with applicable State laws. In addition, providers are encouraged to establish formal referral relationships and community collaborations with other local health care providers who may also have reporting obligations under State law, law enforcement officials, child protective services, social service experts and others in order to explore how to best address the issues involved.

Title X grantees are encouraged to ensure that periodic training regarding the provisions of this mandate is available to project staff.

Questions relating to the requirements addressed in this memorandum and/or OPA 99-1 should be addressed to the appropriate Office of Family Planning Regional Office, or the Office of Family Planning/Office of Population Affairs, as applicable.

Alma L. Golden, MD, FAAP

Attachment: OPA Program Instruction Series, OPA 99-1: Compliance with State Reporting Laws

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF PUBLIC HEALTH & SCIENCE
OFFICE OF POPULATION AFFAIRS

Memorandum

Date: October 17, 2005

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 05-03:
Full and Open Competition for Title X Funds;
Review of Applications for Title X Family Planning Grant Funds

To: Regional Health Administrators, Regions I-X

I. Full and Open Competition for Title X Funds

It is important that we ensure full and open competition for all available funds for Title X family planning grants. If, at any time, the Regional Office becomes aware of an area or population in need of family planning services, they are encouraged to make funds available for competition to serve the identified area or population. Federal family planning staff should provide appropriate technical assistance to potential applicants that includes explanation of program requirements as published in the program announcement. Appropriate input should be sought from the Office of Public Health and Science (OPHS) Office of Grants Management (OGM) staff regarding application and grants requirements.

II. Objective Review Policies

The Office of Public Health and Science follows the Awarding Agency Grants Administration Manual (AAGAM) and Grants Policy Directives (GPDs) as they apply to the objective review of grant applications. AAGAM Chapter 2.04.104.C Objective Review of Grants Applications governs the mechanism by which all applications must be reviewed, and should be referenced in organizing objective review procedures. These requirements are intended to ensure that the process for selecting applicants for funding is fair, equitable, "above board," and can withstand scrutiny; and that only those applications that offer the greatest potential for furthering the program purpose are selected for funding. Objective reviews will be based on this AAGAM chapter, and will adhere to, but not be limited to the following policies:

- Any circumstance that might introduce any conflict of interest, or appearance thereof, prejudices, biases, or predispositions into the process must be avoided. Independent reviewers are required to complete both a Conflict of Interest Statement and a Confidentiality Statement;
- Applications must undergo objective review by a minimum of three qualified independent reviewers (termed the Objective Review Committee or ORC). Documentation of the review outcome must be signed by all reviewers;

- Independent reviewers should be selected from a roster of individuals with knowledge in the field under review, and must be rotated on a regular basis. The reviewer roster must document the date the reviewer was placed on the roster, and dates of participation in reviews. No reviewer shall participate as a reviewer for the same program office for more than three consecutive years;

- Each application will be ranked based on predetermined ranking criteria using only the criteria published in the program announcement and available to all potential applicants;

- The ORC will rank all applications in order by score. The approving official, as noted in the program announcement, is responsible for reviewing the application ranking document and determining which applications will be approved for funding. The approving official may consider additional, objective information (e.g., published program priorities, published preference of special consideration, reviews of the Grants Management Office and Program Official) in determining approval for funding of a particular application. Should the application's position in the list of applications approved for funding be different than its position in the ranking list, a statement of the reasons for the difference that influenced the judgement of the approving official must be provided. This should include a justification for funding of the particular application.

III. Award of Supplemental Funds to Existing Grantees

Supplemental funds must be distributed to existing grantees based on a competitive process. Regional Offices should develop and publish an announcement of availability of supplemental funds that includes eligible entities, total funds available, total number of awards anticipated, amount or range of individual awards, purpose of supplemental awards, and criteria for review of applications.

In addition to review by the awarding Regional Office family planning program staff, competing supplemental requests should be reviewed by a party or parties outside the awarding Regional Office family planning program and decision-making authority. Documentation of review results, including reviewer signatures, must be compiled and forwarded to the OPHS Office of Grants Management for inclusion in the official grant file.

Alma L. Golden, MD, FAAP
Deputy Assistant Secretary
for Population Affairs

Attachment:

1) "Objective Review Process Policy," (April 28, 2005, memorandum from John Jarman, OPHS Executive Officer).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF PUBLIC HEALTH & SCIENCE
OFFICE OF POPULATION AFFAIRS

Memorandum

Date: October 17, 2005

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 05-02: Administrative Policies

To: Regional Health Administrators, Regions I-X

This memorandum serves as official notification of current administrative policies of the Office of Family Planning, Office of Population Affairs. The intent of these policies is to maintain effective program management and documentation of program activities as they relate to program responsibilities in administration of project grants.

I. Recision of Grants Process Policy Notices (GPPNs)

In March 2005, the Office of Public Health and Science officially rescinded the GPPNs previously used to guide administration of family planning grants. The official references for grants management operations are the Awarding Agency Grants Administration Manual (AAGAM) and the Grants Policy Directives (GPDs). Information pertaining to the AAGAM Chapters, transmittals, and GPDs can be found at http://intranet.grantsinfo.hhs.gov. (See Attachment #1)

II. Official Grant File

All official grantee actions must be included in the official grant file maintained in the Office of Public Health and Science (OPHS) Office of Grants Management (OGM). This includes but is not limited to: site visit reports; program review reports; corrective action plans; grantee technical assistance and/or training reports; and any correspondence between Federal family planning staff and the grantee agency. In addition, all oral communication with grantees about pertinent issues surrounding grant activities must be documented. This record should include the following:

Date of Initiating Communication
Date of Response or Continuing Communication
Regional Office
Program Staff Person(s)
Grantee Name
Grant Number
Grantee Staff Person(s) Involved
Topic or Issue
Type of contact (telephone conversation; in person discussion, meeting, etc.)

Summary of the Discussion

A recommended form for documenting this information is attached. Family planning program staff should respond to telephone calls, emails, and other inquiries within 48 business hours.

It is incumbent on Federal family planning program staff to forward the information mentioned in the paragraph above to the OPHS OGM at least quarterly for inclusion in the Official Grant File. (See Attachment #2)

III. Response to Request Grantee Requests Requiring Prior Approval

Requests for grantee-initiated requests requiring prior approval must be submitted either electronically or in writing to the OPHS Office of Grants Management. After concurrence with the family planning program office (as appropriate), the OPHS Office of Grants Management will respond to requests that result in the issuance of a Notice of Grant Award or official correspondence within 30 days from the date the request was received. In the event that the request is still under consideration, the grantee shall be informed of the delay within the 30 day time frame. Examples of applicable requests include, but are not limited to, budget revisions, removal of special conditions, and program plan revisions. Grantees are expected to obtain advance approval before incurring costs or undertaking activities that require awarding office prior approval. All requests and responses must be included in the official grant file. (See Attachment #3)

IV. Financial Status Reports

Reviewing Financial Status reports is the responsibility of the OPHS Office of Grants Management. Financial Status Reports (FSR) must be submitted by grantees to the OPHS Office of Grants Management within 90 days of the end of the grantee budget period. The OPHS Office of Grants Management will notify grantees in writing within 30 days of the time the FSR becomes delinquent that failure to submit the required FSR within 30 days from the date of the letter may result in draw down restrictions or denial of future funding. (See Attachment #4)

Alma L. Golden, MD, FAAP
Deputy Assistant Secretary
for Population Affairs

Attachments:

1) "Notice to Formally Rescind Grant Process Policy Notices," (April 28, 2005, memorandum from John Jarman, OPHS Executive Officer).

2) OPHS Contact Report (sample).

3) "Compliance to GPD Part 3.05 (D)2 Process Requirements," (April 28, 2005, memorandum from John Jarman, OPHS Executive Officer).

4) "Compliance to GPD Part 1.04.104-3 (C)2q Grants Management Officer Responsibilities, Review of Financial Status Reports," (March 4, 2005, memorandum from Karen Campbell, Director, OPHS Office of Grants Management).

Assistant Secretary for Health
Office of Public Health and Science
Washington, DC 20201

Date: February 10, 2005

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 05-01:
Updated Safety Information for Depo-Provera Contraceptive Injection
(medroxyprogesterone acetate injectable suspension)

To: Regional Health Administrators, Regions I-X

On November 17, 2004, the U.S. Food and Drug Administration (FDA) announced that a "black box" warning would be added to the labeling of Depo-Provera Contraceptive Injection. This warning highlights that prolonged use of Depo-Provera may result in significant loss of bone density. The loss of bone density is greater the longer the drug is administered and may not be completely reversible after discontinuation of the drug. The "black box" warning indicates that Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than two years) only if all other methods are inadequate. In addition, the warning states that it is unknown if the use of Depo-Provera Contraceptive Injection during adolescence or early adulthood will reduce peak bone mass and increase the risk of osteoporotic fracture in later life. On November 18, 2004, U.S. Pharmaceuticals, Pfizer Inc., the pharmaceutical company that manufactures Depo-Provera, issued letters to Healthcare Professionals and Healthcare Organization Leaders, informing them of the new "black box" warning, as well as other updated safety information included in the drug's labeling (copies of these letters are attached).

Although the FDA has indicated that Depo-Provera remains a safe and effective contraceptive (see attached "FDA Talk Paper"), the "black box" warning was added to the drug's labeling to "ensure that physicians and patients have access to this important information." The addition of the "black box" warning came as a result of the FDA's and Pfizer's analysis of data from two separate studies that showed Depo-Provera's effect on bone density during prolonged use. One study began in 1994 and enrolled 540 women ages 25 to 38. The other study--which started in 1997 and will continue through 2006--enrolled approximately 400 girls ages 12 to 18 who were taking the drug and is examining ways to reverse bone mineral density loss. References for these two studies are attached.

Depo-Provera has been authorized for use in Title X-funded projects since October 29, 1992, when the FDA announced approval of Depo-Provera for the prevention of pregnancy. Among females who received services in Title X-funded clinics during calendar year 2003, the Family Planning Annual Report (FPAR) reflected that 16 percent relied on Depo-Provera as their primary method of contraception.

As with other prescriptive contraceptive methods, Title X providers should ensure that medical protocols are developed and followed in accordance with the most current evidence-based information, accepted standards of care, and current recommendations for use. Title X providers should ensure that their medical protocols, informed consent and practice related to the use of Depo-Provera Contraceptive Injection are consistent with the November 17, 2004, "black box" warning added to the Depo-Provera package insert. Special consideration should be given to the potential impact of long term use in adolescence and early adulthood. It is incumbent on grantee agencies to ensure that delegate agencies and clinics have and use protocols that reflect this updated safety information.

If you have any questions, please contact Susan Moskosky, Director of the Office of Family Planning, on 301-594-4008.

Alma L. Golden, M.D., F.A.A.P.

Attachments:

1) Depo-Provera Contraceptive Injection package insert, Revised November 2004.

2) "Dear Healthcare Professional Letter" and "Dear Healthcare Organization Leader Letter" from U.S. Pharmaceuticals Pfizer Inc, dated November 18, 2004.

3) FDA Talk Paper, November 17, 2004.

4) Requested Medical Information from Pfizer Inc., December 09, 2004. This information contains a summary of 29 studies and a review of 2 unpublished studies (includes references for the two studies cited in the Program Instruction).

cc: Regional Program Consultants
Regions I-X

Assistant Secretary for Health
Office of Public Health and Science
Washington, DC 20201

TO: Regional Health Administrators, Regions I-X

FROM: Deputy Assistant Secretary for Population Affairs

SUBJECT: OPA Program Instruction Series, OPA 03-01: Screening for Cervical and Colorectal Cancer and Sexually Transmitted Diseases (STD)

In January 2001, *"Program Guidelines for Project Grants for Family Planning Services"* (Title X Program Guidelines) were revised and distributed to all Title X providers. The purpose of the Title X Program Guidelines is 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.

Currently, Title X Program Guidelines, Section 8.3, specify that the initial physical examination for females must include a Pap smear. In that same section, the Guidelines specify that colorectal cancer screening must be provided for individuals over the age of forty, both males and females.

Since 2001, a number of professional organizations that establish national standards of care have published revised recommendations for cervical and colorectal cancer screening based on current evidence. In particular, the American College of Obstetricians and Gynecologists (ACOG), the American Cancer Society (ACS), and the U.S. Preventive Services Task Force (USPSTF) are recognized groups that have established revised recommendations for standards of care in one or both of these areas.

With the concurrence of agency medical directors, Title X providers should ensure that their medical protocols and practice related to cervical cancer and colorectal cancer screening correspond with current recommendations issued by the formerly mentioned professional groups (ACOG, ACS, USPSTF). Individual agency protocols should note the specific standard of care being utilized in the development of said protocols, as well as the date the protocols were revised. Specifics regarding initiating screening and screening intervals for cervical and colorectal cancer should be noted in the protocol. Clinical protocols should continue to take into account individual client risks, use of specific methods of contraception, as well as current national standards of care.

It is incumbent on grantee agencies to ensure that delegate agencies and clinics have and use protocols that meet these standards. Clinical protocols of Title X grantees, delegates, and

clinics will continue to be monitored by the regional office, particularly during site visits and comprehensive program reviews

Sexually transmitted diseases (STD) continue to be of concern for clients served in Title X service projects. For example, each year, young, sexually active females have the highest reported rates of chlamydia and gonorrhea, and other STDs are common. All clients served in Title X clinics should have a thorough history and physical assessment performed that includes screening for risk of STDs.

Regardless of whether or not an annual Pap test is conducted, clinicians should screen young, sexually active women (ages 15 - 24) at least annually for chlamydia. In high prevalence areas, gonorrhea screening should also be part of the routine annual STD screening tests for young, sexually active women. Clients who are symptomatic of other STDs should be screened according to the current Centers for Disease Control and Prevention STD Treatment Guidelines (http://www.cdc.gov/std/treatment). In addition to these screening tests, providers should inquire about sexual behaviors, assess ongoing risk for STDs, and counsel about risk avoidance and risk reduction.

If you have questions, please contact Susan Moskosky, Director of the Office of Family Planning on (301) 594-4008.

Sincerely,

Alma L. Golden, M.D., F.A.A.P.
Deputy Assistant Secretary
for Population Affairs

References:

1) American Cancer Society: **Guideline for the Early Detection of Cervical Neoplasia and Cancer**, Saslow et al.*; CA A Cancer Journal for Clinicians,* Vol. 52:6, November/December 2002.

2) ACOG Practice Bulletin Number 45, **Cervical Cytology Screening**, August 2003.

3) U.S. Preventive Services Task Force (USPSTF-January 2003): **Cervical Cancer - Screening.**

4) U.S. Preventive Services Task Force (USPSTF- July 2002): **Colorectal Cancer - Screening**.

cc: Regional Program Consultants, Regions I - X

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington, D.C. 20201

Date: January 12, 1999

From: Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 99-1: Compliance with State Reporting Laws

To: Regional Health Administrators, Regions I-X

The Fiscal Year 1999 Omnibus Appropriations bill (P.L. 105-277) contains new language governing the use of Title X funds. Specifically section 219 states,

> *Notwithstanding any other provision of law, no provider of services under title X of the Public Health Service Act shall be exempt from any State law requiring notification, or reporting of child abuse, child molestation, sexual abuse, rape, or incest.*

This memorandum is intended to serve as a formal notice to the regional offices, as well as Title X grantees, concerning compliance with State reporting laws. A copy of this memorandum should be provided to all Title X grantees in your region, and Title X providers should refer to this memorandum as needed, if questions in this area arise.

The language of section 219 means that Title X providers must report such incidents to the appropriate State authority in accordance with requirements imposed by State laws. The reporting and notification requirements referenced in section 219 concern State laws; the authority to enforce compliance with such laws lies with the States. It is therefore important that grantees review and be familiar with the relevant reporting requirements in their individual State. Because State laws vary, it is not possible for this office to provide more specific guidance as to the requirements of particular States' laws; grantees are urged to consult with their own attorneys for specific guidance.

Identified instances of child abuse, child molestation, sexual abuse, rape, or incest present serious medical and psychological situations for patients and their families. Findings of such instances coming within the applicable State law should be documented in the medical record and reported as required by the applicable State requirements. The Office of Population Affairs encourages efforts to augment existing training programs for Title X providers to ensure optimal medical assistance in such situations. Grantees should fully understand their obligations under State law related to reporting when such acts or actions are disclosed, and they should review current protocols for responding to such reports. We

also encourage enhanced counseling and education efforts targeted to the unique needs of adolescents. Title X providers are encouraged to continue to work at the local level in an interdisciplinary manner with other local health care providers who may also have reporting obligations under State law, law enforcement officials, child protective services, social service experts and others in order to explore how best to respond to these situations. To accomplish this, regional offices and Title X grantees are encouraged to utilize resources available through the regional training centers and the technical assistance contractor, as well as other available resources.

We appreciate your continued cooperation in assuring that grantees are aware of their obligations and hope this memorandum provides clarification on this matter.

/s/
Denese Shervington, M.D., M.P.H.

cc: Regional Program Consultants, Regions I-X

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington, D.C. 20201

Date: February 24, 1998

From: Acting Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 98-1: Certifications for Encouraging Family Participation and Counseling to Minors on How to Resist Coercive Attempts to Engage In Sexual Activities

To: Regional Health Administrators, Regions I-X

The fiscal year 1998 appropriations bill for the Departments of Labor/HHS and Education (P.L. 105-78) contains language governing the use of Title X funds. Specifically, the language states:

> "None of the funds appropriated in the Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities."

To implement this requirement, each Title X grantee is required to have on file with the Office of Grants Management, an updated Title X Certification of Compliance certifying that the grantee: (1) encourages family participation in the decision of minors to seek family planning services, and (2) provides counseling to minors on how to resist coercive attempts to engage in sexual activities. Attached for your information is a copy of the revised certification. The Office of Grants Management will contact each Title X grantee to obtain the necessary signatures. Compliance with the signed certification will continue to be an item reviewed by regional office staff as part of ongoing program oversight activities and during periodic on-site program reviews.

Clinic staff should be made aware of the new certification requirement. Toward that end, we encourage sharing of this memorandum with delegate agencies and service providers. We would also like to take this opportunity to encourage grantees to review existing policies to assure that service, counseling and outreach provisions reflect the concerns contained in the appropriations language. As is always the case, it is important that client records include documentation of all counseling and information provided. We also encourage grantees to assure that appropriate training is available, including utilization of training available through the Title X training grantees, as need be.

If you have any questions, please contact Sam Taylor, Acting Director of the Office of Family Planning at (301) 594-4008.

/s/
Thomas C. Kring
Acting Deputy Assistant Secretary
for Population Affairs

Attachment

cc: Regional Program Consultants
Regions I-X

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date: April 23, 1997

From: Acting Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 97-2: Emergency Contraception

To: Regional Health Administrators
Regions I-X

On February 25, 1997, the Food and Drug Administration (FDA) issued a notice in the Federal Register announcing that certain regimens of combined oral contraceptives are safe and effective for postcoital emergency contraception when initiated within 72 hours after unprotected intercourse. This action is based on the FDA's review of the published literature concerning postcoital use of currently available oral contraceptives, knowledge of the safety of oral contraceptives as currently labeled, and on the unanimous conclusion of the FDA Advisory Committee on Reproductive Health Drugs, which met on June 28, 1996, to consider the safety and efficacy of this contraceptive option.

According to Section 1001(a) of the Title X statute and Section 59.5(a)(1) of the Title X regulations, family planning projects must offer a broad range of acceptable and effective family planning methods. In considering the range of methods that will be offered in a special family planning project, Title X grantees should consider the availability of emergency contraception the same as any other method which has been established as safe and effective.

As with all other prescriptive contraceptive methods, emergency contraception must be prescribed in accordance with medically accepted protocol, and in accordance with a sliding fee scale that is based on the actual cost of providing the service. Resources attached may be helpful in developing protocols for providing emergency contraception.

/s/
Thomas Kring

Attachments (3)

(1) ACOG Practice Patterns on Emergency Oral Contraception, Number 2, October 1996.

(2) Federal Register, Vol. 62, No. 37, Tuesday, February 25, 1997, "Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception."

(3) Gynetics Announcement of Intent to Market "Yuzpe Method" of Emergency Contraception in 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date: April 24, 1997

From: Acting Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 97-1: Fees and Charges to Title X Low-Income Clients and Teenagers (Revised)

To: Regional Health Administrators, Regions I-X

This memorandum superseded OPA Program Instruction Series OPA 86-5, "Fees and Charges to Title X Low-Income Clients and Teenagers."

In response to recent questions, this memorandum provides guidance on Title X policy regarding fees for services, in particular the process for charging fees to low income clients and unemancipated minors. Applicable regulations and guidelines remain unchanged.

Projects should be aware that Title X regulations require them to :

- not charge fees to clients from low-income families;
- make all reasonable efforts to obtain third party reimbursement for services; charge fees for services to all other clients, with a schedule of discounts based on ability to pay;
- design fee schedules to recover the reasonable cost of providing service; and
- not refuse services because of users' inability to pay.

It is important to note that in providing services, Title X projects must assure that priority is given to persons from low-income families. Low income families are those whose annual income is not above 100 percent of the Poverty Income Guidelines issued by the Department. Clients from low-income families may not be charged for service, including the provision of contraceptives or related medical services.

Clients from families with annual incomes between 100 and 250 percent of the Income Poverty Guidelines must be charged for services. Charges for services must be in accordance with a fee schedule, which has discounts based on ability to pay. In addition, clients from families with incomes above 250 percent of the Income Poverty Guidelines must be charged a full fee to recover the reasonable cost of providing services.

When a client is unable to pay, for good cause (as determined by the project director), for family planning services the fee may be waived. The project must determine, as accurately as possible, the client's ability to pay based upon family income. This determination and notice of any applicable waiver should be made prior to the delivery of services and must be conducted each

time a client requests services.

When considering charges to minors for services, several conditions must be taken into account. If the minor is unemancipated and confidentiality of services is not a concern, the family's income must be considered in determining the charge for the services. When a minor requests confidential services, without the involvement of a principal family member, charges for services must be based on the minor's income.

Income actually available to the minor, such as wages from part-time employment, stipends and allowances paid directly to the minor, should be considered in determining the minor's ability to pay for services. Those services normally provided by parents/guardians, e.g., food, shelter, transportation, tuition, etc., should not be included in determining a minor's income.

Under certain circumstances where confidentiality is restricted to limited members of the family, e.g., one parent is aware of the minor seeking services but the other is not because of disagreement regarding the minor's right to receive family planning services, the charges shall be based on the minor's income if the minor's confidentiality would be breached in seeking the full charge.

It is not allowable to have a general policy of no fee or flat fees for the provision of services to minors. Nor is it allowable to have a schedule of fees fro minors that is different from other populations receiving family planning services.

Projects must seek payment from third parties who are authorized or legally obligated to pay for services unless, in doing so, patient confidentiality would be compromised. Also, since discounts or waivers are only applicable to individual clients, billing statements to third parties should show total charges without any applicable discount or waiver.

I appreciate your continued cooperation in assuring that grantees are in compliance with Title X requirements, and I hope this memorandum provides additional clarification on this matter.

/s/
Thomas C. Kring

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date: June 25, 1993

From: Acting Deputy Assistant Secretary for Population Affairs

Subject: OPA Program Instruction Series, OPA 93-1: Deferred Physical Examinations for Title X Clients

To: Regional Health Administrators
Regions I-X

The issue of deferral of physical examination for clients beginning oral contraceptives was recently addressed by the Food and Drug Administration's (FDA) Fertility and Maternal Health Drugs Advisory Committee. Current FDA labeling criteria for oral contraceptives require a complete medical history and physical examination prior to initiation or r6commencement of oral contraceptives. The Committee recommended to the FDA that oral contraceptive labeling be revised to permit the provision of oral contraceptives prior to a physical examination, and it is likely that this will be approved by FDA in the near future.

Title X has traditionally taken the position that grantees should conform to current FDA policy as expressed in its labeling standards for contraceptives. OPA continues to be of the view that this policy is appropriate and is, as a general practice, reluctant to waive Guideline criteria which involve conformance with requirements under FDA labeling instructions.

However, it is highly probable that prescription of oral contraceptives prior to physical examination will be regularly allowable in Title X projects in the near future, as it appears likely that the FDA will change its labeling instructions in this regard. The evolution of standards of practice in this area, and the strong support of the FDA Advisory Committee and national reproductive health organizations during the discussion of this issue point to the resultant probability that FDA will indeed change its requirements.

Therefore, until FDA makes a final decision on this issue, the Office of Population Affairs is providing authorization to Regional Health Administrators to waive current policy on the requirement for a physical examination on a case-by-case basis. To ensure patient safety, no request for waiver of current standards should be approved unless the following requirements are met:

- Physical examination and any blood work should not be delayed for more than 3 months after the initial visit. Substantial justification is warranted for projects that propose as a general practice to defer the examination beyond the 3-month period. In no case may deferral of the physical examination be extended beyond a maximum of 6 months.

- Counseling regarding contraceptive choice, STD protection and the need for a physical examination (after deferral) must be provided to each client at the initial visit.

- Written informed consent and medical protocols for delayed examinations must be developed and approved by the project's medical committee.

  Informed Consent: Clients must sign an informed consent form describing the special process for the delayed examination and explaining the patient package insert information accompanying oral contraceptives.

  Medical Protocols must:

  -- Outline what medical, educational and counseling services will be provided at each point leading up to the examination (i.e., initial visit, follow-up counseling, telephone follow-up, visit for physical examination and blood work).

  -- Provide for verification through a highly sensitive pregnancy test that the client is not pregnant.

  -- Provide that the project will obtain at the initial visit a comprehensive medical history (including menstrual history, pregnancy history, contraceptive history, and sexual history) which demonstrates that the client is healthy and has no contraindications for oral contraceptives.

  -- Provide that the project will ensure that clients have no symptoms or reported contact with sexually transmitted diseases (STDs); are provided with information on oral contraceptives and condoms for STD prevention; and have a negative breast examination for women over age 30.

  -- Provide that the project will ensure that any medical problems associated with the delayed examinations must be documented.

If you have any questions, please contact me or Dr. Barbara Tausey, OPA Chief Medical Officer.

/s/
Jerry Bennett