EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

FAX TRANSMITTAL

TO:	Ruby Shamir	65696	62878
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PAGES: 12 (including cover sheet)

FROM: **Amy Squires**
Office of Information and Regulatory Affairs
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MESSAGE:

Ruby, you had asked for some background about our meeting @ 2pm today with women's groups on the HHS rule regarding the gag order.

I'm sending a 2 pager with background, for use only within the EOP.

I'm also sending along the Executive Order that governs this type of meeting. John Spotila of OMB/OIRA will host. Call if questions. Thanks! Amy

not address the fundamental issue of whether certain interpretations and policies should be expressed in the rule rather than agency guidance.

Issue II: Improved Preamble Response to Comments

HHS has not responded to public comments on a variety of issues. These include incorporation of the program guidance into the rule, conflict of interest concerns with self-referrals, policies regarding dues payments to advocacy groups, and whether the rule addresses the Family Executive Order. OMB staff believe these issues will receive significant public attention and

E.O. 12866

58 FR 51735: Monday, October 4, 1993

EXECUTIVE ORDER #12866: REGULATORY PLANNING AND REVIEW
September 30, 1993

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs

impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential

Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Assistant to the President for Science and Technology; (7) the Assistant to the President for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Deputy Assistant to the President and Director of the White House Office on Environmental Policy; and (12) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" or "rule" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations or rules that are limited to agency organization, management, or personnel matters; or

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that

minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) The Regulatory Plan. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;

(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) Conferences. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as

in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

WILLIAM J. CLINTON

THE WHITE HOUSE,
September 30, 1993.

HHS "Gag Rule"

Background

On December 28, 1999, HHS submitted for OMB review a final rule revoking the 1988 "gag rule" along with revised guidance for Title X clinics.

The final 1988 "gag rule" interpreted the existing Title X statute as prohibiting Title X clinics from providing abortion counseling and referrals. The 1988 rule was never implemented due to court challenges. On January 22, 1993, President Clinton issued an Executive Memorandum directing HHS to issue a new interim final rule suspending the 1988 "gag rule." The HHS final rule currently under review would revoke, rather than simply suspend, the 1988 "gag rule."

The HHS rule is substantively identical to the rule in place prior to the 1988 "gag rule." It is very general (clinics must provide "a broad range of acceptable and effective medically approved family methods"), but is further clarified in accompanying program guidance that allows for disclosure of abortion-related information *upon request* and in a *nondirective* manner. The rule permits clinics to provide referrals for abortion services, but prohibits additional action to secure abortion services for a patient.

Status of OMB Review

OMB staff have identified two issues with the final rule and guidelines:

Issue I: Incorporation of Guidance Policy Into Rule

A large number of comments on both sides (including the American Civil Liberties Union (ACLU), the American College of Obstetricians and Gynecologists, legal and public policy research firms specializing in reproductive rights, and numerous Planned Parenthood Clinics) recommended that HHS incorporate legislative and/or program guidance language into the rule. Commenters argued that reliance on program guidance leads to less clear and effective policy. For example, the Center for Reproductive Law and Policy argued that reissuing the pre-1988 rule would leave behind "a legacy of uncertainty and distrust for both providers and their clients." In its preamble discussion, HHS states that it resolved many of these issues by publishing the program guidance for comment on June 23, 1993. Publication of this guidance, however, does not address the fundamental issue of whether certain interpretations and policies should be expressed in the rule rather than agency guidance.

Issue II: Improved Preamble Response to Comments

HHS has not responded to public comments on a variety of issues. These include incorporation of the program guidance into the rule, conflict of interest concerns with self-referrals, policies regarding dues payments to advocacy groups, and whether the rule addresses the Family Executive Order. OMB staff believe these issues will receive significant public attention and

have argued that comments on incorporation of guidance and self-referrals particularly deserve thoughtful consideration and discussion.

HHS Response

HHS staff have responded that they desire flexibility in the future and are concerned that it would be difficult to defend incorporating into the rule certain guidance provisions over others. Since they believe that reliance on guidance before 1988 worked well, they are not inclined to make changes that may create new problems. They are also concerned that much time has elapsed since the proposed rule. Accordingly, they advise us that they believe that the legal risk of inadequately treating comments may be less than the risks of making substantive policy changes this late in the rulemaking process.

Next Steps

We continue to work with HHS staff on the above concerns. We also anticipate an E.O. 12866 meeting with advocacy groups in the near future.

FACSIMILE

From the Immediate Office of the Secretary
Executive Secretariat

To what pro
Definitions.
Who is eligibl
How does or
What requir

To: Allison Eydt

Fax#: 395-6974 395-5167

Re: Draft language for discussion at tomorrow's mtg. on the GAG Rule page 6

Date:

Pages: including this cover sheet ____

From the desk of:

- [X] LaVarne Burton
- [ ] Sandy Bart
- [ ] Kimberly Harold
- [ ] Christy Quigley
- [ ] Mirtha Beadle
- [ ] Scott Boule
- [ ] LaJuana Caldwell
- [ ] Carlos Cano
- [ ] Sean Donohue
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- [ ] Lorraine Fishback
- [ ] Johnathan Friebert
- [ ] Jackie White
- [ ] John Gallivan
- [ ] Carlos McCormick
- [ ] Martina Varnado
- [ ] Ann White
- [ ] Melvin Whitfield
- [ ] Other ____

Comments:

U.S. Department of Health and Human Services
Immediate Office of the Secretary- Executive Secretariat

200 Independence Avenue SW
Washington, DC 20201
Fax: 205-8870 or 205-2135

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is hereby revised to read as follows:

PART 59 - Grants for Family Planning Services

Subpart A - Project Grants for Family Planning Services

Sec.

Subpart B - [Reserved]

Subpart C - Grants for Family Planning Service Training

AUTHORITY: 42 U.S.C. 300a-4.

Subpart A - Project Grants for Family Planning Services

Sec.

§ 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.

§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 States of Micronesia and the Republic of Palau.

§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;

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closehold

handicapping condition, age, sex, number of pregnancies, or marital status.

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

(i) Offer pregnant women the opportunity to be provided information and counseling regarding: (A) Prenatal care and delivery;

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

(C) Pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling, and appropriate referral on request, on each of the options, except for any options that the pregnant woman indicates that she does not wish to receive information and counseling about.

(ii) Ensure that project funds are not used for, and project activities are separate and distinct from, any non-title X activities of the grantee that provide or promote or encourage abortion as method of family planning.

(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

Close hold

(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,

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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."

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 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 regional

(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.

§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 non-federal 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 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.

DRAFT

new language

handicapping condition, age, sex, number of pregnancies, or marital status.

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

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

(A) Prenatal care and delivery;

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

(C) Pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling, and appropriate referral on request, on each of the options, except for any options that the pregnant woman indicates that she does not wish to receive information and counseling about.

(ii) Ensure that project funds are not used for, and project activities are separate and distinct from, any non-title X activities of the grantee that provide or promote or encourage abortion as method of family planning.

(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

in

EXECUTIVE ORDER 12866 SUBMISSION

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1. Agency/Subagency originating request
Office of Population Affairs, OSOPHS
US.Department of Health and Human Services

2. Regulation Identifier Number (RIN)
0940-AA00 0940-A001

3. Title Standards of Compliance for Abortion-Related Services in Family Planning Projects

4. Stage of Development
___ Prerule
___ Proposed Rule
___ Interim Final Rule
_X_ Final Rule
___ Final Rule - No material change
___ Notice
___ Other

Description of Other

5. Legal Deadline for this submission
a) ☐ Yes ☒ No
b) Date ____/____/____ (DD / MM / YYYY)
c) ☐ Statutory ☐ Judicial

6. Designations
a) Economically Significant (E.O. 12866)
☐ Yes ☒ No
b) Unfunded Mandate (2 U.S.C. 1532)
☐ Yes ☒ No
If either of the above is "Yes," submit four (4) complete packages to OIRA

7. Agency Contact (person who can best answer questions regarding the content of this submission)
Evelyn Kappeler
Phone (301) 594-7608

Certification for Executive Order 12866 Submissions

The authorized regulatory contact and the program official certify that the agency has complied with the requirements of E. O. 12866 and any applicable policy directives.

Signature of Program Official	Date
Evelyn Kappeler	1-3-2000
Signature of Authorized Regulatory Contact	**Date**
Lorraine Fishbach	1-3-2000

OMB 83-R Revision: 12/97 (Previous versions obsolete)

EXECUTIVE ORDER 12866 SUBMISSION

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1. Agency/Subagency originating request
U.S. Department of Health and Human Services

2. Regulation Identifier Number (RIN)
RIN:0937-AA00

3. Title
Provision of Abortion-Related Services in Family Planning Projects

4. Stage of Development
____ Prerule
____ Proposed Rule
____ Interim Final Rule
__X__ Final Rule
____ Final Rule - No material change
____ Notice
____ Other

Description of Other

5. Legal Deadline for this submission
a) ☐ Yes ☒ No
b) Date ____/____/____ (DD / MM / YYYY)
c) ☐ Statutory ☐ Judicial

6. Designations
a) Economically Significant (E.O. 12866)
☐ Yes ☒ No
b) Unfunded Mandate (2 U.S.C. 1532)
☐ Yes ☒ No
If either of the above is "Yes," submit four (4) complete packages to OIRA

7. Agency Contact (person who can best answer questions regarding the content of this submission)
Evelyn Kappeler
Office of Population Affairs/OPHS/OS
Phone (301) 594-7608

Certification for Executive Order 12866 Submissions

The authorized regulatory contact and the program official certify that the agency has complied with the requirements of E. O. 12866 and any applicable policy directives.

Signature of Program Official	Date
Evelyn Kappeler — for E. Kappeler	12/23/99
Signature of Authorized Regulatory Contact	**Date**
Lorraine Fishback — Lorraine Fishback	12/23/99

Billing Code: 4160-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science

42 CFR Part 59

RIN: 0937-AA00

Provision of Abortion-Related Services in Family Planning Services Projects

AGENCY: Office of Population Affairs, OPHS, DHHS.

ACTION: Final rules.

SUMMARY: The rules issued below revise the regulations that apply to grantees under the federal family planning program by readopting the regulations that applied to the program prior to February 2, 1988. Several technical changes to the regulations are also made to remove and/or update obsolete regulatory references. The effect of the revision made by the rules below is to revoke the compliance standards, promulgated in 1988 and popularly known as the "Gag Rule," that restricted family planning grantees from providing abortion-related information in their grant-funded projects.

DATE: These rules are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Denese O. Shervington, Office of Population Affairs, (301) 594-4001

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services issues below regulations establishing requirements for recipients of family planning services grants under section 1001 of the Public Health Service Act, 42 U.S.C. 300. The rules below adopt, with minor technical amendments, the regulations proposed for public comment on February 5, 1993,

at 58 FR 7464. They accordingly revoke the compliance standards, known as the "Gag Rule," promulgated on February 2, 1988.

By notice published elsewhere in this issue of the Federal Register, the Department is separately acting to reinstitute, with minor changes, the policies and interpretations of the statute relating to the provision of abortion-related information and services that applied to grantees prior to the issuance of the Gag Rule. The Secretary had previously proposed reinstituting these policies and interpretations in the notice of February 5, 1993 and requested public comment on this proposed action; the public comment period was subsequently reopened by notice of June 23, 1993, 58 FR 34024.

I. Background. In 1988, the Secretary of Health and Human Services issued rules, widely known as the "Gag Rule," which substantially revised the longstanding policies and interpretations defining what abortion-related activities were permissible under Title X's statutory limitation on abortion services. That statutory limitation, section 1008 (42 U.S.C. 300a-6), provides that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." The rules issued on February 2, 1988 (53 FR 2922) set out detailed requirements that (1) restricted the provision to Title X clients of nondirective counseling on all pregnancy options and referral to abortion providers on request, (2) required physical and financial separation of abortion-related activities from Title X project activities, and (3) prohibited Title X projects from engaging in activities that encourage, promote, or advocate abortion. These requirements are presently codified principally at 42 CFR §§ 59.7 - 59.10.

The February 2, 1988 "Gag Rule" was extremely controversial: the proposed rules

generated approximately 75,000 public comments, many of which were negative. 53 FR 2922. The rules were subsequently challenged in several district courts by a variety of providers, provider organizations, and others. Although the requirements embodied in the Gag Rule were upheld by the Supreme Court in 1991 as a permissible construction of section 1008, the rules continued to be a source of controversy, with the provider and medical communities litigating after 1991 to prevent enforcement of the rules. Following his inauguration in 1993, President Clinton ordered the Secretary to suspend the rules and initiate a new rulemaking:

> The Gag Rule endangers women's lives and health by preventing them from receiving complete and accurate medical information and interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients. Furthermore, the Gag Rule contravenes the clear intent of a majority of the members of both the United States Senate and House of Representatives, which twice passed legislation to block the Gag Rule's enforcement but failed to override Presidential vetoes.
>
> For these reasons, you have informed me that you will suspend the Gag Rule pending the promulgation of new regulations in accordance with the "notice and comment" procedures of the Administrative Procedure Act. I hereby direct you to take that action as soon as possible. I further direct that, within 30 days, you publish in the Federal Register new proposed regulations for public comment.

Presidential Memorandum of January 22, 1993, published at 58 FR 7455 (February 5, 1993). The Secretary subsequently suspended the 1988 rules on February 5, 1993 (58 FR 7462) and issued proposed rules for public comment (58 FR 7464).

The notice of proposed rulemaking proposed to revise the program regulations by readopting the program regulations as they existed prior to the adoption of the Gag Rule, which would have the effect of revoking the Gag Rule. It also proposed that the policies and interpretations in effect prior to the issuance of the Gag Rule be reinstated, both in substance and in form. As noted in the proposed rules, these policies and interpretations, which had been in

effect for a considerable time prior to 1988, were set out largely "in the 1981 Family Planning Guidelines and in individual policy interpretations." 58 FR 7464. The pre-1988 interpretations had been developed during the 1970's and early 1980's in response to questions arising out of the Department's initial interpretation that section 1008 not only prohibited Title X projects from performing or providing abortions, but also prohibited actions by Title X projects that "promoted or encouraged" abortion as a method of family planning. Over time, questions were raised, and answered in a series of legal opinions, as to whether particular actions would violate the statute by promoting or encouraging abortion as a method of family planning. As summarized in the proposed rules, the answers that were developed were generally as follows:

> Title X projects [are] required, in the event of an unplanned pregnancy and where the patient requests such action, to provide nondirective counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects. However, consistent with the long-standing Departmental interpretation of the statute, Title X projects [are] not ... permitted to promote or encourage abortion as a method of family planning, such as by engaging in pro-choice litigation or lobbying activities. Title X projects [are] also ... required to maintain a separation (that is more than a mere exercise in bookkeeping) of their project activities from any activities that promote or encourage abortion as a method of family planning.

Id. By notice dated June 23, 1993 (58 FR 34024), the Secretary made available for public comment a detailed exposition of the prior policies and interpretations.

In the public comment periods, the Secretary received 146 comments, virtually all of which concerned the proposed policies and interpretations rather than the proposed regulations themselves. Approximately one-third of these opposed the proposed policies and interpretations on various grounds; most of these comments were from individuals who, in general, were opposed to any change to the Gag Rule. The remainder of the public comments, most of which were from providers and other health organizations, generally supported the reinstatement of the

prior policies and interpretations, although a number of these comments suggested that they be modified in various respects. The public comments and the Secretary's response thereto are summarized below.

II. Public comment and Departmental response. The public comment generally focused on a few issues raised by the rulemaking. As noted above, these comments generally pertained to the proposed policies and interpretations rather than to the proposed regulatory language itself. The policies and interpretations are not (and were never proposed to be) part of the regulations themselves, and are seen by the Department as essentially separate and severable from the revisions to the Title X regulation, the purpose of which is to revoke the Gag Rule. However, the necessity to respond to the public comment dictates that we address the concerns raised by the public comment in this document. Accordingly, the comments on the issues raised in the rulemaking are summarized below, and the Secretary's response thereto is provided.

A. Lack of a rational basis to revoke the Gag Rule; necessity for continuation of the Gag Rule. Most of the comments in opposition to the proposed rules came from individuals, and most objected to the proposed revocation of the Gag Rule on the ground that abortion is wrong or that tax dollars should not be used to provide abortion services of any kind. Several comments also objected that the Secretary had no rational basis for revoking the Gag Rule, as it had never gone into operation. For example, a comment signed by fifteen members of Congress argued that --

> HHS intends to discard the February 2, 1988 regulations in their entirety ... regardless of whether any particular portion was the subject of court challenge or legislative action. * * * We believe the rejection of the 1988 rule is precipitous and that each portion of the 1988 regulations must be reviewed on its merits and justification provided in any final regulations as to why the 1988 clarifications were or were not maintained in a new rule.

With respect to the comments objecting to the revocation of the Gag Rule or the use of tax dollars for abortion on moral grounds, the Secretary notes that, under the interpretations adopted in conjunction with the regulations below, the funding of abortion or activities that promote or encourage abortion with Title X funds has been and will continue to be prohibited. Rather, what changes under the interpretations reinstated in conjunction with the regulations below is which activities are considered to "promote or encourage" abortion. In contrast to the position taken under the Gag Rule, under the present view (which was also the Department's view of the statute prior to 1988), the provision of neutral and factual information about abortion is not considered to promote or encourage abortion as a method of family planning. Thus, the basic statutory interpretation underlying both the Gag Rule and the specific policies that governed the Title X program prior to 1988 -- that section 1008 prohibits activities that promote or encourage abortion as a method of family planning -- remains unchanged.

With respect to the contentions that the Secretary lacks a rational basis for revoking the Gag Rule and that it must justify each separate part of the Gag Rule that it is discarding, we do not agree that either contention is sound. Both the pre-1988 interpretations of the statute and the revised interpretation of the statute embodied in the Gag Rule are legally supportable; they represent different points on the spectrum of what is legal and, thus, both represent a permissible exercise of administrative discretion. The crucial difference between the two options is one of experience. Because of ongoing litigation, the Gag Rule was never implemented on a nation-wide basis, so that its proponents can point to no evidence that it can and will work operationally on a national basis in the Title X program. The policies and interpretations reinstituted in conjunction with the regulations below, on the other hand, have been used by the program for

virtually its entire history; indeed, they have been in effect during the pendency of this rulemaking. Both the program managers and the Title X grantee community are well-versed in the policies that are reinstituted in connection with this rulemaking, and the grantees have in the past generally been able to operate in compliance with them. Further, as evidenced by the public comment received, the reinstituted policies and interpretations are generally acceptable to the grantee community, in contrast to the compliance standards in the Gag Rule, which were generally unacceptable to the grantee community. This factor likewise favors their adoption, as it suggests a far greater likelihood of voluntary compliance by grantees. Finally, the suggestion that the Gag Rule provisions should be accepted or rejected separately is rejected as unsound. The provisions of the Gag Rule were an interrelated set of requirements that depended on several underlying assumptions about how the Title X program should work; moreover, they depended in part on several definitions that applied to all the major provisions of the Gag Rule. See, in this regard, 53 FR 2923, 2925; see also, the discussion of definitions at 53 FR 2926-2927. The suggestion that the Gag Rule policies be considered and accepted or rejected seriatim is thus impractical and is rejected.

B. Failure to comply with the Administrative Procedure Act; vagueness of standards. A number of comments, from both proponents of and opponents to the proposed rules, objected to the failure to publish the actual policies and interpretations as part of the proposed rule on the ground that this violated the public comment requirements of the Administrative Procedure Act (APA); several comments argued that it was impossible to comment on policies that had never been published. A related criticism was that several of the interpretations described in the preamble to the notice of proposed rulemaking, particularly the interpretation relating to physical

separation, were too vague.

The Secretary agreed that the provision of further information on the specific details of the pre-1988 policies and interpretations would promote more helpful public comment. Accordingly, by notice dated June 23, 1993 (58 FR 34024), the Department made available on request a summary of the policies and interpretations in existence prior to 1988. The June notice also extended the public comment period for 45 days, to permit further substantive comment on the prior policies and interpretations. Over a third of the public comments, including the majority of the comments from individuals, were received during the re-opened comment period. The Secretary has thus addressed the basic concern about notice of the content of the interpretations expressed by these comments.

The Secretary views this final rule, which revokes the Gag Rule, as separate and severable from the Notice, which summarizes the Department's interpretations of section 1008 of the Public Health Service Act, also being published in this edition of the Federal Register. The primary purpose of this rulemaking is to revoke the Gag Rule. This has been done by publishing, after notice and comment, a revision of the Title X regulations that excludes the provisions added by the Gag Rule. The policies and interpretations set out in the Notice are being sent out in order to clarify for the affected public the Department's view of the statute and its operation in practical terms, and because so much of the public comment received was directed at the policies and interpretations rather than at the revision of the regulation itself. They are, however, not central to the rulemaking action being taken, which is the revocation of the Gag Rule. Indeed, were the policies set forth in the Notice to be challenged and to be struck down, it is our view that the Title X program could still be administered under the rules below in compliance with the

statute, in that grantees would be prohibited by § 59.5(a)(5) below from providing abortions as part of the Title X family planning project. Such an outcome would be consistent with a permissible, if not the best, interpretation of the statute.

The Secretary does not agree that the Department is required to set out the policies and interpretations in the regulations promulgated below and accordingly has not accepted the comments suggesting that it do so. As noted above, the interpretations themselves were developed in the classic way in which statutory interpretations are done: that is, they have generally been developed in legal opinions written to answer questions about how the statutory prohibition, as initially interpreted by the Department, applied to particular situations. This is not an unusual approach within the program as a whole: interpretive guidance has been provided on a number of issues (e.g., fee schedules, use of certain methods) over the years, as particular questions have arisen in the course of the program. While the program could incorporate those interpretations in the legislative rules below, it has decided not to do so. The Secretary believes that incorporating the existing interpretive guidance into the regulations below would be inadvisable and unnecessary. None of the other interpretive guidances that have been issued from time to time to guide grantee operations have been set forth in the regulations, and the Secretary does not see the need to do so in this area. The Secretary has thus chosen to preserve the program's flexibility to address new issues that may arise in this area.

Moreover, the Title X program has operated on the basis of policies developed by interpretation for virtually its entire history and in general compliance with them. As the comment of one State agency grantee stated with regard to this issue:

The [State] Family Planning Program has been a participant in the nation's Title X

program since the early 1970's. The rules and 1981 Family Planning Guidelines in place prior to the "Gag Rule" were adequate guidance to the state for program operation and for compliance with the statutory prohibition related to abortions. These guidelines and directives have been used successfully for many years in providing quality medical care, education and counseling to clients in the program.

The audits of 14 Title X grantees conducted by the GAO and of 32 Title X grantees conducted by the Department's Office of the Inspector General in the 1980's showed only minor compliance problems. Indeed, the principal recommendation of both audit reports was that the Department provide more specific guidance to its grantees than that previously available in the program guidelines and prior legal opinions, not that the Department undertake major disallowances, require major corrective actions, or develop new interpretations of the law such as that embodied in the Gag Rule. See, e.g., Comp. Gen. Rep. No. GAO/HRD-82-106 (1982), at 14-15. The Secretary is addressing this recommendation through the specific guidance in the notice published elsewhere in this edition of the Federal Register and believes that the notice will provide grantees with sufficient guidance to reduce or eliminate potential variations in grantee practice.

C. Amend, or adopt a more restrictive reading of, the statute. Fifteen of the comments that ostensibly supported the proposed policies and interpretations suggested, however, that the prior limitations in the policies and interpretations with respect to what abortion-related activities a Title X project could engage in be eliminated. A few of these comments suggested that the statutory prohibition of section 1008 be repealed outright. Most of the comments, however, suggested in essence that the statute be read strictly to prohibit only the use of funds for abortions, thereby permitting Title X projects to engage in a number of abortion-related activities that would not be permitted under the pre-1988 interpretations.

With respect to the suggestion that section 1008 be repealed, such an action is obviously outside the scope of what can be accomplished through rulemaking and thus cannot be accepted in this context. With respect to the remaining comments, while the Secretary agrees that the statute could on its face be read only to proscribe the use of Title X funds for the provision of abortion, this is not considered to be the better reading of the statutory language. Rather, the legislative history of section 1008 indicates that that section was intended to restrict the permissible scope of abortion-related services provided under Title X. Conf. Rep. No. 1667, 97th Cong., 2d Sess. 8-9 (1970). The floor statements by the section's principal sponsor, Rep. Dingell, indicated that the section's restrictions on the "use" of Title X funds should be read as having a broader scope than is urged by these comments:

> Mr. Speaker, I support the legislation before this body. I set forth in my extended remarks the reasons why I offered to the amendment which prohibited abortion as a method of family planning * * *. With the "prohibition of abortion" the committee members clearly intended that abortion is not to be encouraged or promoted in any way through this legislation. Programs which include abortion as a method of family planning are not eligible for funds allocated through this Act.

116 Cong. Rec. 37375 (1970). The Department has consistently, since 1972, read section 1008 as incorporating this limitation on activities that "promote or encourage" abortion as a method of family planning. This interpretation is well-known to Congress, which has not, to date, amended section 1008. Thus, there is legal support for this longstanding interpretation of the statute. Moreover, there is nothing in the rulemaking record that suggests that this fundamental reading of the statute, as it was administered before the Gag Rule, presented major operational problems for Title X projects. Accordingly, the Secretary has not accepted the suggestion made by this group of comments that section 1008 be read only to prohibit the provision of, or payment for,

abortions.

D. Abortion information and counseling. The Gag Rule prohibited the provision of information other than information directed at protecting maternal and fetal health to women determined to be pregnant; thus, it prohibited what is generally known as "options counseling", i.e., the provision to pregnant women in a nondirective fashion of neutral, factual information about all options for the management of a pregnancy, including abortion. See, 42 CFR 59.8 (1989 ed.). The pre-1988 policies, in contrast, required options counseling, if requested. As stated in the 1981 "Title X Guidelines" :

> Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon request:
>
> - Prenatal care and delivery
> - Infant care, foster care, or adoption
> - Pregnancy termination.

The June, 1993 summary of the pre-1988 interpretations also stated that Title X projects were not permitted to provide options counseling that promoted abortion or encouraged patients to obtain abortion, but could advise patients of all medical options and accompanying risks.

Most of those comments supporting adoption of the proposed rules appeared to agree with the pre-1988 policies and interpretations. However, there appeared to be some confusion among those who agreed with the pre-1988 requirement for options counseling as to how much information and counseling could be provided. Several of these comments also suggested that that the "on request" limitation be deleted, particularly where State law requires the provision of information about abortion to women considering that option.

Several comments opposing adoption of the proposed rules and revocation of the Gag Rule also specifically addressed the issue of counseling. Several of these comments suggested that counseling on "all options" include the option of keeping the baby, and two comments suggested that the rules should contain an exception for grantees or individuals who object to providing such information and counseling on moral grounds.

In response to the apparent confusion as to the amount of counseling permitted to be provided under the pre-1988 interpretations, the interpretive summary published in the notices section of the Federal Register clarifies that Title X grantees are not restricted as to the completeness of the factual information they may provide relating to all options, including the option of pregnancy termination. However, the previous restriction as to the "kind" of information that may be provided about abortion continues: in keeping with the decision to adhere to the longstanding interpretation of the statute that projects may not "promote or encourage" abortion as a method of family planning, information and counseling provided by Title X projects on all options for pregnancy management, including pregnancy termination, must be nondirective. This interpretation, it should be noted, is also consistent with the requirement in the program's three most recent appropriations, Pub. L. 104-208 (110 Stat. 3009-243), Pub. L. 105-78 (111 Stat. 1478) and Pub. L. 105-277 (112 Stat. 2681), that pregnancy counseling in the Title X program be "nondirective." Thus, grantees may provide as much factual, neutral information about abortion as they consider warranted by the circumstances, but may not steer or direct clients toward selecting the option of abortion, or any other option, in providing options counseling.

The Secretary is retaining the "on request" policy in the interpretive summary published

in the notices section, on the ground that it properly implements the statute's prohibition of activities that promote or encourage abortion as a method of family planning. If projects were to counsel on the option of abortion even where a client indicated that she did not want to consider that option, there would be a real question as to whether the counseling was truly nondirective or whether the client was being steered to choose the option of abortion. We note that under the "on request" policy a Title X grantee is not prohibited from offering to a pregnant client information and counseling on all options for pregnancy management, including pregnancy termination; however, if the client indicates that she does not want information and counseling on any particular option, that decision must be respected.

With respect to the suggestion that counseling on "keeping the baby" be provided, the Secretary views that suggestion as co-extensive with the requirement for the provision of counseling on prenatal care and delivery, as the remaining counseling option set out in the 1981 "Title X Guidelines" relates to foster care and adoption. If a more directive form of counseling is meant by this suggestion, it is rejected as inconsistent with the underlying interpretation, recently reinforced by Congress, that counseling on pregnancy options should be nondirective.

Finally, the Secretary rejects the suggestion that an exception to the requirement for options counseling be carved out for those organizations that object to providing such counseling on religious or moral grounds. First, it is difficult to imagine a more directive form of counseling than totally omitting information on a legal option, as removing an option from the client's consideration necessarily steers her toward the options presented. Second, the Secretary is unaware of any current grantees that object to the requirement for nondirective options counseling, so this suggestion appears to be based on more of a hypothetical than an actual

concern. Third, the requirement for nondirective options counseling has existed in the Title X program for many years, and, with the exception of the period 1988-1992, it has always been considered to be a necessary and basic health service of Title X projects. Indeed, pregnancy testing is a common and frequent reason for women coming to visit a Title X clinic: in 1995, an estimated 1.1 million women obtained pregnancy tests in Title X clinics. (National Survey of Family Growth, 1995 cycle, special table.) Clearly, a significant number of Title X clients have a need for information and counseling relating to pregnancy. Fourth, this policy is also consistent with the prevailing medical standards recommended by national medical groups such as the American College of Obstetricians and Gynecologists and the American Medical Association. "Guidelines for Women's Health Care," American College of Obstetricians and Gynecologists, 1996 ed., at 65; "Pregnancy Choices: Raising the Baby, Adoption, and Abortion," American College of Obstetricians and Gynecologists, September, 1993, reviewed December, 1995; "Code of Medical Ethics: Current Opinions with Annotations," American Medical Association, 1996-1997 ed. In these circumstances, it is not reasonable (even if it were legally permissible) to subordinate appropriate public health policy considerations to the varying moral or religious beliefs of individual organizations which are, after all, free not to participate in the program if they find its policies objectionable. Accordingly, the Secretary has not accepted this suggestion.

The corollary suggestion, that the requirement to provide options counseling should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds, is likewise rejected. In addition to the foregoing considerations, such a requirement is not necessary: under 42 U.S.C. 300a-7(d), grantees may not require individual employees who

have such objections to provide such counseling. However, in such cases the grantees must make other arrangements to ensure that the service is available to Title X clients who desire it.

E. Referral for abortion. The Gag Rule specifically prohibited referral for abortion as a method of family planning and required grantees to give women determined to be pregnant a list of providers of prenatal care, which list could not include providers "whose principal business is the provision of abortion." 42 CFR 59.8(a) (1989 ed.). The Gag Rule permitted referral to an abortion provider only where there was a medical emergency. 42 CFR 59.8(a)(2) (1989 ed.). The pre-1988 policies and interpretations, in contrast, permitted Title X projects to make what was known as a "mere referral" for abortion; a "mere referral" was considered to be the provision to the client of the name and address and/or telephone number of an abortion provider. Affirmative actions, such as obtaining a consent for the abortion, arranging for transportation, negotiating a reduction in the fee for an abortion or arranging for or scheduling the procedure, were considered to promote abortion as a method of family planning and thus to be prohibited by section 1008. The pre-1988 rules (§ 59.5(b)(1)) were interpreted by the agency to require referral for abortion where medically indicated. See, Valley Family Planning v. State of North Dakota, 489 F.Supp. 238 (D.N.D. 1980), aff'd., 661 F.2d 99 (8th Cir. 1981).

A number of comments, mostly from individuals and organizations supporting revocation of the Gag Rule, suggested modifications of the proposed referral policies and interpretations. Most of these comments suggested that the content limitations on referrals be broadened, with Title X grantees being permitted to provide other relevant information, such as comparative charges, stage of pregnancy up to which referral providers may under State law or will provide abortion, the number of weeks of estimated gestation, etc. These comments argued

that the provision of such factual information does not "promote or encourage" abortion any more than does the provision of the abortion providers' names and addresses and/or telephone numbers. One comment also suggested that the restriction on negotiating fees for clients referred for abortion conflicts with the requirement to refer for abortion where medically indicated.

Several comments opposing revocation of the Gag Rule also expressed problems with the proposed referral policies and interpretations. A few comments urged that referrals to agencies that can assist clients who choose the "keeping the baby" or adoption options should be required. Another comment criticized the requirement for referral where "medically indicated" as confusing. Revisions suggested were that "self-referrals" for abortion be specifically prohibited, to reduce commercialization and profiteering by Title X grantees who are also abortion providers and that grantees who objected to abortion on moral or religious grounds be permitted not to make abortion referrals.

The Secretary agrees with the comments advocating expanding the content of what information may be provided in the course of an abortion referral. The content (as opposed to action) restrictions of the "mere referral" policy proceeded from an assumption that the provision of information other than the name and address and/or telephone number of an abortion provider might encourage or promote abortion as a method of family planning. The Secretary now agrees, based on experience and the comments of several providers on this point, that the provision of the types of additional neutral, factual information about particular providers described above is likely to do little, if anything, to encourage or promote the selection of abortion as a method of family planning over and above the provision of the information previously considered permissible; at most, such information would seem likely to assist clients in making a rational

selection among abortion providers, if abortion is being considered. Moreover, it does not seem rational to restrict the provision of factual information in the referral context, when no similar restriction applies in the counseling context. Accordingly, the Secretary has revised the policies and interpretations summarized in the notice section to clarify that grantees are not restricted from providing neutral, factual information about abortion providers in the course of providing an abortion referral, when one is requested by a pregnant Title X client.

The Secretary is not accepting the remainder of the comments on this issue, as they either proceed from a misunderstanding of, or do not raise valid objections to, the proposed policies and interpretations. The comment arguing that the restriction on negotiating fees conflicts with the requirement to refer for abortion where medically indicated is based on a misunderstanding of that requirement: in such circumstances, the referral is not for abortion "as a method of family planning" (i.e., to determine the number and/or spacing of one's children) but is rather for the treatment of a medical condition; thus, the statutory prohibition does not apply, so there is no restriction on negotiating fees and similar actions. The suggestion that referrals to agencies that can assist clients who choose the options of "keeping the baby" or adoption be required is likewise rejected as unnecessary. Under the policy set out in the 1981 "Title X Guidelines" provision set out in the preceding section, the options of prenatal care and delivery and adoption are options that are required to be part of the options counseling and referral process; thus, referral to providers who can assist a client with one of these options is already required, where that option is selected by the client. The Secretary also rejects the criticism that the provision requiring referral for abortion where medically indicated is undefined and confusing. It is noted that this comment came from a law school, not a health care provider. The meaning of the

regulatory requirement for referrals where medically indicated (which applies to all medical services not provided by the project, not just abortion services) has not in the past been a source of confusion for providers, and the Secretary believes that Title X medical personnel are able to make the medical judgments this requirement calls for. The Secretary likewise rejects the suggestion that "self-referrals" for abortion be banned as both unneeded and unwise. Very few current Title X providers are also abortion providers: it is estimated that, over the past decade, the percentage of Title X providers located with or near abortion providers has been at or below five percent, with approximately half of these providers consisting of hospitals. Thus, the issue this comment raises is irrelevant to the vast majority of Title X grantees and the program as a whole. Moreover, with respect to those few grantees that are also abortion providers, some may be the only or one of only a few abortion providers in their service area, making "self-referrals" a necessity in such situations. The Department has no evidence whatsoever that commercialization and profiteering are occurring in these circumstances; absent such evidence, the Secretary sees no reason to limit or cut off a legal service option for those Title X clients who freely select it. Finally, the Secretary rejects the suggestion that the referral requirement not apply to providers that object to it on moral or religious grounds for the same reasons it objected to the same suggestion with respect to counseling.

F. Physical and financial separation. The Gag Rule required Title X projects to be organized so as to have a physical and financial separation from prohibited abortion activities, determined by whether there was "objective integrity and independence [of the Title X project] from prohibited activities." 42 CFR 59.9 (1989 ed.). This determination was to be based on a case-by-case review of facts and circumstances. Factors relevant to this determination included,

but were not limited to, the existence of separate accounting records, the degree of separation from facilities (such as treatment, consultation, examination, and waiting room) in which prohibited activities occurred and the extent of such prohibited activities, the existence of separate personnel, and the extent of the presence of evidence of identification of the Title X project and the absence of identification of material promoting abortion. Id.

The pre-1988 policies and interpretations required Title X grantees to maintain physical and financial separation between the Title X project and any abortion-related activities they conducted, in that a Title X grantee was required to ensure that the Title X-supported project was separate and distinguishable from those activities. This requirement was held to go beyond a requirement for the technical allocation of funds between Title X project activities and impermissible abortion activities. However, it was considered permissible for a hospital grantee to provide abortions, as long as "sufficient separation" was maintained, and common waiting rooms were also permissible, as long as no impermissible materials were present. Common staff and unitary filing systems were also permissible, so long as costs were properly allocated and, with respect to staff members, their abortion-related activities were performed in a program that was itself separate from the Title X project. The test, as articulated in the summary made available for comment by the June 23, 1993 notice, was "whether the abortion element in a program of family planning services bulks so large and is so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost."

These policies and interpretations received by far the most specific and extensive public comment. The vast majority of this public comment was from providers and provider

organizations and was negative. Although it was generally agreed that the financial separation of Title X project activities from abortion-related activities was required by statute and, in the words of one comment, "absolutely necessary," many of these comments objected that requiring additional types of separation would be unnecessary, costly, and medically unwise. The argument was made that the requirement for physical separation is unnecessary, as it is not required by the statute which, on its face, requires financial separation only. Further, it was argued that since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary. With respect to the issue of cost, it was generally objected that requiring separation of staff and facilities would be inefficient and cost ineffective. For example, one comment argued that --

> The wastefulness and inefficiency of the separation requirements is ... illustrated by the policy which allows common waiting rooms, but disallows "impermissible materials" in them. This puts grantees in the position of having to continuously monitor health information for undefined "permissibility" or to build a separate waiting room just to be able to utilize those materials....

It was argued that these concerns were particularly important for small and rural clinics "that may be the only accessible Title X family planning and/or abortion providers for a large population of low-income women." Of particular concern for such clinics was the duplication of costs inherent in the separation requirements, as they --

> cannot afford to operate separate facilities or to employ separate staff for these services without substantially increasing the prices of ... services. Nor can they offer different services on different days of the week because so many of their patients ... are only able to travel to the clinic on one day.

Many providers also pointed out that requiring complete physical separation of services would be

inconsistent with public health principles, which recommend integrated health care, and would impact negatively on continuity of care. As one comment stated, "women's reproductive health needs are not artificially separated between services: a woman who needs an abortion may also need contraceptive services, and may at another time require prenatal care." Several providers objected in particular that such a separation would, in the words of one comment, "remove ... one of the most opportune time[s] to facilitate the entry of the abortion patient into family planning counseling, which is at the post-abortion check-up." It was also pointed out that separation of services would burden women, by making them "make multiple appointments or trips to visit different staff or facilities." Finally, the separation policy was objected to by several of the comments that otherwise generally supported the proposed rule as unnecessarily broad, ambiguous, and vague.

Several of the comments opposing the revocation of the Gag Rule and the adoption of the proposed rules likewise objected specifically to the separation requirements, generally on the ground that the pre-1988 policies were vague and unenforceable. Two comments also argued that, if the pre-1988 requirement of physical separation was to be reinstituted, it made no sense to revoke § 59.9 of the Gag Rule in its entirety, as that section of the Gag Rule contained specific standards to implement this requirement; alternatively, it was argued that if the Secretary is going to use different standards to determine whether the requisite physical separation existed, those should be published for public comment.

The Secretary agrees that the comments on both sides of this issue have identified substantial concerns with the pre-1988 policies and interpretations with respect to the issue of how much physical separation should be required between a grantee's Title X project activities

and abortion-related activities. The Secretary agrees with the comments that the pre-1988 interpretation that some physical separation was required was unenforceable. Indeed, since the pre-1988 interpretations had held that it was permissible to provide abortions on a Title X clinic site and to have common waiting areas, records, and staff (subject largely to proper allocation of costs), it was difficult to tell just what degree and kind of physical separation were prohibited. As a consequence, the agency attempted to enforce this requirement on only a few occasions prior to 1988. The Secretary does not agree with opponents of the proposed rules, however, who argued that the "physical separation" requirements in § 59.9 of the Gag Rule should be retained on the ground that they provide a necessary clarification of this issue. Although § 59.9 provided ostensibly more specific standards, the fundamental measure of compliance under that section remained ambiguous: "the degree of separation from facilities [in which prohibited activities occurred] and the extent of such prohibited activities," and "[t]he extent to which" certain materials were present or absent. Furthermore, since under § 59.9 compliance was to be determined on a "facts and circumstances" basis, this section of the Gag Rule provided grantees with less specific advance notice of the compliance standards than did the pre-1988 policies and interpretations. Moreover, the change in policy from the more concrete policies proposed during the Gag Rule rulemaking to the less concrete "facts and circumstances" standard ultimately adopted in the final Gag Rule as a result of the public comment suggests the practical difficulties of line-drawing in this area. In fact, since the Gag Rule was never implemented on a national basis, the precise contours of the compliance standards of § 59.9 were never determined. The Secretary has accordingly not accepted the suggestion from several opponents of the proposed rule that the policies of § 59.9 be retained.

As noted by many of the comments from groups that generally supported the revocation of the Gag Rule, the statute does not on its face require physical separation; rather, by its terms it is addressed to the use of "funds." While the interpretation of the statute by agency counsel on which the requirement for physical separation is based was reasonable, it is not the only possible reading of the statute. Rather, the fundamental question under the statute is, as the agency sees it, whether Title X funds are used by Title X grantees to promote or encourage abortion as a method of family planning in the Title X-assisted project. The Department has traditionally viewed a grant project as consisting of an identified set of activities supported in whole or in part by grant funds. If a Title X grantee can demonstrate by its financial records, counseling and service protocols, administrative procedures, and other means that -- within the identified set of Title X-supported activities -- promotion or encouragement of abortion as a method of family planning does not occur, then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for "physical" separation. Indeed, in light of the enforcement history noted above, it is not unreasonable to say that the standard of "physical" separation has, as a practical matter, had little relevance or applicability in the Title X program to date. Moreover, the practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the Gag Rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services. Accordingly, the Secretary has accepted the suggestion of a number of the comments that the requirement for physical separation be dropped; the policies and interpretations summarized in the notice published in the notices section of this edition of the Federal Register are revised accordingly. This decision makes it unnecessary to

respond to the remaining comments on the issue.

G. Advocacy restrictions. The Gag Rule, at 42 CFR 59.10 (1989 ed.), prohibited Title X projects from encouraging, promoting, or advocating abortion as a method of family planning. This section prohibited Title X projects from engaging in actions to "assist women to obtain abortions or increase the availability or accessibility of abortion for family planning purposes," including actions such as lobbying for the passage of legislation to increase the availability of abortion as a method of family planning, providing speakers to promote the use of abortion as a method of family planning, paying dues to any group that as a significant part of its activities advocated abortion as a method of family planning, using legal action to make abortion available as a method of family planning, and developing or disseminating materials advocating abortion as a method of family planning. The pre-1988 policies and interpretations likewise prohibited the promotion or encouragement of abortion as a method of family planning through advocacy activities such as providing speakers, bringing legal action to liberalize statutes relating to abortion, and producing and/or showing films that tend to encourage or promote abortion as a method of family planning. However, under those prior policies and interpretations, it was considered permissible for Title X grantees to be dues-paying members of abortion advocacy groups, so long as there were other legitimate program-related reasons for the affiliation.

Very few comments were received concerning these proposed policies and interpretations. Those received from persons and entities that generally supported the proposed rules generally argued against the restriction on showing films advocating abortion, on the ground that it was possible to violate this restriction by showing a film that was purely factual and detailed relative risks. The few comments on this part of the policies and interpretations

received from those who generally opposed revoking the Gag Rule pointed out the similarity between the advocacy policies articulated in the proposed policies and interpretations and § 59.10 of the Gag Rule and argued that § 59.10 should accordingly be reinstated.

As set out above, the Secretary is of the view that the Gag Rule cannot and should not be adopted piecemeal, as recommended by these comments. Moreover, the Secretary is of the view that the prohibition against dues paying contained in § 59.10 is not required by the statute and does not represent sound public policy. Accordingly, the suggestion that § 59.10 be reinstated has not been adopted. With respect to the criticism of the prohibition against Title X grantees showing films advocating abortion as a method of family planning, it is recognized that the prohibition should not encompass the kind of neutral, factual information that grantees are permitted to provide in the counseling context; the policies and interpretations have been clarified accordingly. To the extent that these comments seek to further liberalize the advocacy restrictions, however, they are rejected as inconsistent with the Secretary's basic interpretation of section 1008.

H. Miscellaneous. A number of comments were received on miscellaneous issues. Those comments, and the Secretary's responses thereto, are summarized below.

1. Changes outside the scope of the rulemaking. Several comments were received advocating changes to other sections of the regulations on issues other than the issue of compliance with section 1008. These comments included the following suggestions: that the regulations be revised to permit natural family planning providers to be Title X grantees; that the regulations be revised to prohibit single method providers from participating in Title X projects; that the footnote in the regulation addressing Pub. L. 94-63 be revised to state that the law also

forbids coercion to carry a pregnancy to term; that the regulations be revised to deal with recent medical developments, such as HIV or Norplant. All of these suggestions are rejected on the ground that they exceed the scope of the rulemaking because these issues were not the subject of the Notice of Proposed Rulemaking.

2. Audit standards. Several providers urged that the OMB audit standards for Title X projects be revised to reflect the change in the regulations. While this comment is likewise outside the scope of the rulemaking, the Department intends to work with the Office of Management and Budget to revise the program audit standards to reflect the regulations below and the policies and interpretations also being reinstituted.

3. Separation of powers. Two comments, including one from four members of Congress, argued that the suspension of the Gag Rule violated the separation of powers insofar as it misspent federal tax dollars without amendment to the statute or compliance with the APA. The Secretary disagrees that suspension of the Gag Rule violated either the statute or the APA. The Gag Rule was, in the Secretary's view, a permissible interpretation of the statute, but not the only permissible interpretation of the statute; thus, suspension of those rules (and reinstitution of the Department's longstanding policies and interpretations of the statute) is not inconsistent with the statute. Nor was the suspension action inconsistent with the APA, as the findings which the APA requires be made in such circumstances were made. Finally, the Secretary notes that this issue is now moot, with the publication of the regulations below.

I. Technical amendments. Because the proposed rules proposed the reissuance of the program regulations that were issued in 1980, it was recognized that --

some of the other regulations cross-referenced in the rules below may no longer be

operative or citations may need to be updated. However, such housekeeping details will be addressed in the final rules.

58 FR 7464. Further review of the proposed regulations has established that this is indeed the case. Accordingly, a number of technical amendments have been made to the regulations, to delete obsolete statutory or regulatory references or to incorporate new regulatory or other references made relevant by subsequent changes in the law. A summary of the technical amendments, and the reasons therefor, follows:

1. § 59.2 (definition of "low income family"): the reference to "Community Services Administration Income Poverty Guidelines (45 CFR 1060.2)" is changed to "Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2)." This change reflects a change in the law, effected by Pub. L. 97-35, § 673.

2. § 59.2 (definition of "State"): the definition of this term is changed to reflect statutory changes regarding the Trust Territories of the Pacific Islands effected by Pub. L. 99-239 (relating to the Federated States of Micronesia, the Marshall Islands, and the Republic of Palau).

3. § 59.5(a)(8): the reference to the "CSA Income Poverty Guidelines" is changed, consistent with and for the reason set out above with respect to § 59.2 (definition of "low income family").

4. § 59.9: the reference to "Subpart Q" of 45 CFR Part 74 has been deleted, as that subpart has been revoked. A reference to 45 CFR Part 92 has been added, to reflect the requirements at that part that apply by their terms to State and local governments.

5. § 59.10: the references to 42 CFR Part 122 and 45 CFR Part 19 have been deleted, as those parts have been revoked. A reference to 37 CFR Part 401, which applies by its terms, has

been added, reflecting a change in the law. The description of 45 CFR Part 74 has been changed, to reflect accurately the current title of that part. A reference to 45 CFR Part 92 has been added, to reflect the requirements at that part that apply by their terms to State and local governments.

6. § 59.12 (proposed): the proposed section (which was the prior section relating to inventions and discoveries) has been deleted, as it has been superseded by the government-wide regulations at 37 CFR Part 401, a reference to which has been added to § 59.10. This change has also occasioned the renumbering of the proposed § 59.13.

The above changes are all technical in nature and simply bring the regulations issued below into conformity with current law. They are thus essentially housekeeping in nature, as noted in the proposed rules. Accordingly, and for the reasons set out above, the Secretary finds that public comment on these changes would be impracticable, unnecessary, and contrary to the public interest and that good cause therefore exists for omitting public comment thereon.

III. Effective date. These regulations are adopted effective upon publication, as they meet the conditions for exception from the requirement for a 30-day delay in effective date under 5 U.S.C. 553(d). First, by revoking the Gag Rule, the regulations below relieve the restrictions imposed on grantees' conduct of their Title X projects by the Gag Rule. Second, the policies and interpretations adopted in conjunction with the regulations below are already largely in effect, by virtue of the suspension of the Gag Rule and the reinstitution of the pre-1988 policies and interpretations effected by the interim rules of February 5, 1993. To the extent this status quo is changed by the revision of the policies and interpretations in question, the effect of those revisions is to clarify and simplify certain of the present restrictions, which should make complying with the policies and interpretations easier for grantees than is presently the case.

Thus, no useful purpose would be served by delaying the effective date of these regulations, and the Secretary accordingly finds that good cause exists for making them effective upon publication.

IV. Analysis of impacts.

The Secretary has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601-612), and under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts and equity). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize such impact. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted for inflation) in any year. Because this rule is expected to reduce costs on private and public sector entities, preparation of such a cost-benefit analysis is not required.

The Secretary has determined that this final rule is consistent with or does not invoke the requirements of Executive Order 12866 or the Unfunded Mandates Act, because these regulations would not have a significant economic effect equaling or exceeding $100 million per year. This final rule implements the provisions that were proposed in the February 5, 1993 Notice of Proposed Rulemaking with no material changes. Because the final rule does not

materially alter the provisions of the proposed rule, it does not impose new economic benefits or costs that were not discussed in either the Notice of Proposed Rulemaking or the interim rule, also published on February 5, 1993. The Secretary, therefore, certifies that this final rule will not have a significant impact on a substantial number of small entities.

Executive Order 13132 requires that a Federalism Assessment be prepared in any cases in which policies have significant federalism implications as defined in the Executive Order. Among the types of actions which can have such implications are federal regulatory actions which preempt State law. The Department does not intend or interpret the this final rule as imposing additional costs or burdens on the States or preempting State laws, nor are the rules inconsistent with any of the principles, criteria or requirements established by the Executive Order. In fact, it is anticipated the rule will lessen present reporting and other burdens and costs. Therefore, this final rule complies with the Executive Order.

The final rule has been assessed in conformance with the criteria in Section 654 of the Treasury and General Appropriations Act of 1999. The final rule would get Title X clinics out of the middle of the abortion decision, returning it to the decision-making processes of the Title X clients and their families and enable them to act in what they have determined to be their own best interests. It would thus promote the stability of the family, support parental influence, reduce governmental intrusion on family activities, enhance the role and autonomy of the family in decision-making, and require less Federal involvement in monitoring activities than would the present rules. The rules below also support the message to young people that they should engage in responsible decision-making about their reproductive heath and choices. The Secretary certifies that the impact of the final rule on the well-being of families has been assessed in

accordance with the requirements of the Treasury and General Appropriations Act of 1999.

V. Paperwork Reduction Act of 1995. This final rule contains no provisions imposing any new burden of information collection which is not already subject to review and approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.).

VI. List of subjects in 42 CFR Part 59. The subjects in 42 CFR Part 59 Subpart A are: Family planning - birth control; Grant programs - health; Health facilities.

DATED: NOV 24 1999

David Satcher, M.D., Ph.D.
Assistant Secretary for Health and
Surgeon General

APPROVED: DEC 16 1999

Donna E. Shalala
Secretary

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is hereby revised to read as follows:

PART 59 - Grants for Family Planning Services

Subpart A - Project Grants for Family Planning Services

Sec.

Subpart B - [Reserved]

Subpart C - Grants for Family Planning Service Training

AUTHORITY: 42 U.S.C. 300a-4.

Subpart A - Project Grants for Family Planning Services

Sec.

§ 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.

§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 States of Micronesia and the Republic of Palau.

§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/

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

(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 abortions as a method of family planning.

(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

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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."

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 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.

§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 non-federal 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 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.

BILLING CODE: 4160-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science

Provision of Abortion-Related Services in Family Planning Services Projects

AGENCY: Office of Population Affairs, OPHS, DHHS.

ACTION: Notice.

SUMMARY: This notice informs the public of the policies and interpretations relating to the statutory requirement that no funds appropriated under Title X of the Public Health Service Act be used in programs in which abortion is a method of family planning.

FOR FURTHER INFORMATION CONTACT: Denese O. Shervington, Office of Population Affairs, (301) 594-4001.

SUPPLEMENTARY INFORMATION: On February 5, 1993, the Department of Health and Human Services published in the Federal Register a notice of proposed rulemaking that proposed to revise the regulations at 42 CFR Part 59, Subpart A. Subpart A of Part 59 sets forth the program requirements applicable to grantees under section 1001 of the Public Health Service (PHS) Act, 42 U.S.C. 300, et seq. The notice of proposed rulemaking proposed to revise that subpart by readopting the program regulations as they existed prior to February 2, 1988. This action would have the effect of revoking the regulations published on February 2, 1988, commonly known as the "Gag Rule," which set forth standards for the compliance by such grantees with section 1008 of that Act, 42 U.S.C. 300a-6.

The February 5, 1993 notice of proposed rulemaking also proposed to reinstitute the pre-1988 policies and interpretations regarding compliance with section 1008. 58 FR 7464. As explained in the notice of proposed rulemaking, those policies and interpretations derived from previous opinions of the Department concerning section 1008. To promote more useful public comment in the rulemaking process, the Department subsequently made available a more detailed summary of the policies and interpretations and reopened the public comment period. 58 FR 34042 (June 23, 1993).

A number of public comments on the prior policies and interpretations were obtained during the reopened comment period, and the public comments received during both comment periods were generally focused on the prior policies and interpretations rather than on the proposed regulatory language. The Department has modified its prior interpretations in several particulars based in part on the public comment received. These modifications, and the grounds therefor, are described in the preamble to the final rules published on this date in the rules section of the Federal Register. The policies and interpretations, as so modified, are set out in the summary statement below. The summary below is also reorganized from the summary statement made available for public comment, for purposes of clarification.

Accordingly, to provide guidance to grantees in order to promote uniform administration of the program and facilitate grantee compliance with the policies and interpretations that are being reinstituted in conjunction with the final regulations adopted on this date, provided below is a summary of the program policies and interpretations that relate to section 1008 of the PHS Act.

Program Policies Regarding the Title X National Family Planning Program and the Section 1008 Abortion Prohibition

Section 1008 of the Title X statute, 42 U.S.C. 300a-6, states: "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." This prohibition applies not only to the performance of abortion by a Title X project, but also to the conduct of certain abortion-related activities by the project. However, the prohibition does not apply to all the activities of a Title X grantee, but only to those within the Title X project. This statement summarizes the Department policies and interpretations in existence prior to the imposition of the 1988 "Gag Rule" with regard to implementation of section 1008, as modified following the rulemaking of 1993.

1. General principles. In general, section 1008 prohibits Title X programs from engaging in activities which promote or encourage abortion as a method of family planning. However, section 1008 does not prohibit the funding under Title X of activities which have only a possibility of encouraging or promoting abortion; rather, a more direct nexus is required. The general test is whether the immediate effect of the activity in question is to promote or encourage the use of abortion as a method of family planning. If the immediate effect of the activity in question is essentially neutral, then it is not prohibited by the statute. Thus, a Title X project may not provide services that directly facilitate the use of abortion as a method of family planning, such as providing transportation for an abortion, explaining and obtaining signed abortion consent forms from clients interested in abortions, negotiating a reduction in fees for an abortion, and scheduling or arranging for the performance of an abortion, promoting or

advocating abortion within Title X program activities, or failing to preserve sufficient separation between Title X program activities and abortion-related activities.

2. Abortion counseling and referral. According to the 1981 Title X Guidelines:

> Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon request:
>
> - o Prenatal care and delivery
> - o Infant care, foster care, or adoption
> - o Pregnancy termination.

There are limitations on what abortion counseling and referral is permissible under the statute: (a) a Title X project may not provide pregnancy counseling which promotes abortion or encourages persons to obtain abortion, although the project may provide patients with complete factual information about all medical options and the accompanying risks and benefits; (b) a Title X project may provide a referral for abortion. A referral may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider. The project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient; and (c) where a referral to another provider who might perform an abortion is medically indicated because of the patient's condition or the condition of the fetus (such as where the woman's life would be endangered), such a referral by a Title X project is not prohibited by section 1008 and is required by 42 CFR 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications.

3. Advocacy activities. A Title X project may not promote or encourage the use of abortion as a method of family planning through advocacy activities such as providing speakers to debate in opposition to anti-abortion speakers, bringing legal action to liberalize statutes relating to abortion, or producing and/or showing films that encourage or promote a favorable attitude toward abortion as a method of family planning. Films that present only neutral, factual information about abortion are permissible. A Title X project may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project). A Title X project may also discuss abortion as a backup method of family planning in a discussion of relative risks of various methods of contraception.

4. Separation. Non-Title X abortion activities must be separate and distinct from Title X project activities. Where a grantee conducts abortion activities that are not part of the Title X project and would not be permissible if they were, the grantee must ensure that the Title X-supported project is separate and distinguishable from those other activities. What must be looked at is whether the abortion element in a program of family planning services bulks so large and is so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost.

The Title X project is the set of activities the grantee agreed to perform in the relevant grant documents as a condition of receiving Title X funds. A grant applicant may include both project and nonproject activities in its grant application, and, so long as these are properly distinguished from each other and prohibited activities are not reflected in the amount of the total approved budget, no problem is created. Separation of Title X from abortion activities does not

require separate grantees or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008.

Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities: (a) a common waiting room is permissible, as long as the costs are properly pro-rated; (b) common staff is permissible, so long as salaries are properly allocated and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project; a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project; and (d) maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated.

Whether a violation of section 1008 has occurred is determined by whether the prohibited activity is part of the funded project, not by whether it has been paid for by federal or non-federal funds. A grantee may demonstrate that prohibited abortion-related activities are not part of the Title X project by various means, including counseling and service protocols, intake and referral procedures, material review procedures, and other administrative procedures.

Dated: Nov 22, 1999

Denese O. Shervington
Deputy Assistant Secretary for Population Affairs

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HHS "Gag Rule"

Background

On December 28, 1999, HHS submitted for OMB review a final rule revoking the 1988 "gag rule" along with revised guidance for Title X clinics.

The final 1988 "gag rule" interpreted the existing Title X statute as prohibiting Title X clinics from providing abortion counseling and referrals. The 1988 rule was never implemented due to court challenges. On January 22, 1993, President Clinton issued an Executive Memorandum directing HHS to issue a new interim final rule suspending the 1988 "gag rule." The HHS final rule currently under review would revoke, rather than simply suspend, the 1988 "gag rule."

The HHS rule is substantively identical to the rule in place prior to the 1988 "gag rule." It is very general (clinics must provide "a broad range of acceptable and effective medically approved family methods"), but is further clarified in accompanying program guidance that allows for disclosure of abortion-related information *upon request* and in a *nondirective* manner. The rule permits clinics to provide referrals for abortion services, but prohibits additional action to secure abortion services for a patient.

Status of OMB Review

OMB staff have identified two issues with the final rule and guidelines:

Issue I: Incorporation of Guidance Policy Into Rule

A large number of comments on both sides (including the American Civil Liberties Union (ACLU), the American College of Obstetricians and Gynecologists, legal and public policy research firms specializing in reproductive rights, and numerous Planned Parenthood Clinics) recommended that HHS incorporate legislative and/or program guidance language into the rule. Commenters argued that reliance on program guidance leads to less clear and effective policy. For example, the Center for Reproductive Law and Policy argued that reissuing the pre-1988 rule would leave behind "a legacy of uncertainty and distrust for both providers and their clients." In its preamble discussion, HHS states that it resolved many of these issues by publishing the program guidance for comment on June 23, 1993. Publication of this guidance, however, does not address the fundamental issue of whether certain interpretations and policies should be expressed in the rule rather than agency guidance.

Issue II: Improved Preamble Response to Comments

HHS has not responded to public comments on a variety of issues. These include incorporation of the program guidance into the rule, conflict of interest concerns with self-referrals, policies regarding dues payments to advocacy groups, and whether the rule addresses the Family Executive Order. OMB staff believe these issues will receive significant public attention and

E.O. 12866

58 FR 51735: Monday, October 4, 1993

EXECUTIVE ORDER #12866: REGULATORY PLANNING AND REVIEW
September 30, 1993

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles. (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs

impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential

Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Assistant to the President for Science and Technology; (7) the Assistant to the President for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Deputy Assistant to the President and Director of the White House Office on Environmental Policy; and (12) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" or "rule" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations or rules that are limited to agency organization, management, or personnel matters; or

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that

minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) The Regulatory Plan. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;

(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) Conferences. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as

in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

WILLIAM J. CLINTON

THE WHITE HOUSE,
September 30, 1993.

NARAL
Promoting Reproductive Choices
Publications

NARAL FACTSHEETS

TITLE X:

THE NATION'S CORNERSTONE FEDERAL FAMILY PLANNING PROGRAM

Enacted in 1970 with broad bipartisan support, Title X of the Public Health Service Act is the only federal program exclusively dedicated to family planning and reproductive health services. Title X has been the nation's cornerstone family planning program for more than 25 years, providing millions of women with services ranging from contraception to pap smears and breast cancer screening. For many women, Title X clinics provide the only basic health care that they receive. Publicly funded family planning services have helped reduce the rates of unintended pregnancies, unintended births, and abortions. In addition, they have been responsible for improving the quality of women's health and lives.[1] Yet, despite the importance of federally funded family planning services to American women and the nation as a whole, anti-choice lawmakers have attacked the program consistently. Since gaining a Congressional majority in the 1994 elections, anti-choice lawmakers in Congress have repeatedly attempted to defund the program and restrict minors' access.[2] Moreover, Congress has failed to provide adequate funding levels for Title X. **Title X funding must be increased without restrictions upon confidentiality in order to enhance women's access to contraceptive and family planning services and to give women real choices over their reproductive lives.**

I. TITLE X FAMILY PLANNING FUNDS PROVIDE WOMEN WITH ESSENTIAL SERVICES.

The Title X program funds medical services crucial to women's health, especially for women who have no other access to such care. For many women, Title X clinics may be their first point of entry into the health care system, thereby serving as a bridge to other services.*

A. Title X Assists Millions of Women.

Title X funds provide millions of women -- regardless of age, income or marital status -- with family planning services each year. In 1994, Title X provided some funding for 60 percent of all family planning agencies.[3] Each year, approximately 4.5 million women obtain services in more than 4400 clinics receiving Title X funds.[4]

Most of the women obtaining Title X services are young and poor and have never given birth. Approximately 80 percent of all clients served by publicly funded providers are under age 30 and 57 percent have family income levels under the federal poverty level. For over eight in ten women receiving family planning services, a Title X clinic is their sole source of services.[5]

Title X is particularly important in providing family planning services to low-income women who fail to qualify for Medicaid. Whereas Medicaid generally limits eligibility to very poor women who are single, have a child (or are pregnant) and meet other stringent

requirements,[6] Title X provides more women with access to services. Under Title X, women with incomes not exceeding 100 percent of the poverty level must receive entirely subsidized services; women with incomes 101-250 percent of poverty must be charged on a sliding scale; and women with incomes over 250 percent of poverty must be charged full fees. In addition, eligibility for a minor seeking confidential services is based on her own income, not that of her parents.[7]

B. Title X Provides Essential Services.

The Title X statutes and corresponding regulations prescribe a minimum standard of care for reproductive health care. The statutes define qualifying family planning projects broadly, as including "a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."[8] The regulations further explain that these family planning 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."[9] **The law prohibits Title X funds to be used for abortion.**[10] Furthermore, Title X funds support practitioner training programs and research designed to enhance the quality of the family planning services provided.[11] Finally, the law mandates that acceptance of services must be voluntary and not coerced.[12]

Title X guidelines promote women's health as well. Under the guidelines, Title X clinics must provide the following services: (1) pelvic exams and pap smear tests; (2) breast exams and education regarding self-examination; (3) screening and treatment for sexually transmitted diseases (STDs); (4) infertility screening; and (5) referrals to specialists. In addition, the guidelines recommend that Title X-funded agencies should offer other health promotion/disease prevention services such as screening, immunization, nutrition services, and general health education and counseling.[13]

Title X clinics also provide teens with educational services, giving teens the tools they need to make responsible choices about their sexual and reproductive lives. At Title X clinics, teens receive counseling and information concerning both abstinence and contraceptive methods.[14]

C. Title X Ensures Confidential Services.

Under Title X, all patients -- regardless of age -- must be ensured confidentiality.[15] Although the law requires entities receiving Title X funds to encourage family participation in teens' reproductive health decisions,[16] family involvement can not be mandated. Citing legislative intent and the clear statutory language encouraging -- not mandating -- parental involvement, two federal courts of appeal in 1983 prohibited enforcement of a regulatory attempt -- dubbed the "squeal rule" -- to require Title X clinics to notify parents when they prescribed contraceptives to minors.[17]

Title X clinics have therefore served as an invaluable source of confidential services for teens. In fact, three in ten individuals receiving contraceptive services from publicly funded family planning providers are under 20 years old.[18]

A bedrock principle of medical ethics, confidentiality is crucial to ensuring women's reproductive health. Empirical studies confirm that when parental consent or notice is mandated by law, thus breaching confidentiality, adolescents are likely to delay or avoid seeking needed care, particularly in the area of family planning. For example, 58 percent of high school students surveyed in three public schools in central Massachusetts reported having health concerns they would like to keep from their parents. Approximately 25 percent of the students said they would forgo seeking certain types of medical treatment if there were a possibility of disclosure to parents by physicians.[19] Another study of

adolescents found that if confidential treatment for sexually transmitted diseases were available, 50 percent of the adolescents would seek care. Only 15 percent reported that they would seek medical treatment if parental consent or notice were required.[20]

Recognizing this link between confidential services and receipt of reproductive health care, courts have acknowledged the importance of confidential services for teenagers. In *Planned Parenthood Affiliates of California v. Van De Kamp*, the California Court of Appeal found that if "minors are unable to obtain reproductive health care on a confidential basis, without their sexual conduct being reported to law enforcement for investigation, they will be deterred from seeking such care." Additionally, the court noted that "[i]t is nearly impossible to establish a professional, therapeutic relationship without a promise of confidentiality which the professional can keep."[21] A United States District Court, in *Planned Parenthood Association of Utah v. Matheson*, prohibited a "blanket parental notification requirement" for minors seeking contraceptives. In doing so, the court recognized that "minors seek contraceptives after becoming sexually active, not before [and] . . . that a significant percentage of sexually active minors would not cease their sexual activity if access to contraceptives is conditioned on parental notification. Instead, those minors would terminate their use of contraceptives. Thus, . . . [the law] would expose sexually active minors to the health risks of early pregnancy and venereal disease."[22]

Organized medicine in the United States has reached a remarkable consensus that contraceptive services should be available to adolescents on a confidential basis. In July 1998, the **American Academy of Family Physicians (AAFP)**, the **American Academy of Pediatrics (AAP)**, the **American College of Obstetricians and Gynecologists (ACOG)**, the **American Medical Women's Association (AMWA)**, the **American Society for Reproductive Medicine (ASRM)**, and the **Society for Adolescent Medicine** wrote a joint letter to members of Congress opposing attempts to require parental notification or consent for adolescents to receive contraceptive services in clinics funded by Title X. The letter states "[w]hile we applaud efforts to ensure that parents are involved in minor's health care decisions, we believe that such involvement is best achieved by the efforts of physicians and their patients in a manner which respects the adolescent's right to confidential health care. Forced parental involvement, in our view, will have a negative impact on the physician-patient relationship, as well as have the unintended consequence of deterring adolescents from seeking important health care services."[23]

Joining the consensus of the United Nations International Conference on Population and Development (ICPD) and the Fourth World Conference on Women (FWCW), the United States recognized adolescents' rights to confidential sexual and reproductive health information and services.[24] Specifically, the ICPD Programme of Action states that sexual and reproductive health services "must safeguard the rights of adolescents to privacy, confidentiality, respect and informed consent, respecting cultural values and religious beliefs. In this context, countries should, where appropriate, remove legal, regulatory and social barriers to reproductive health information and care for adolescents. . . ."[25] Similarly, the FWCW Platform for Action directs countries to "[p]repare and disseminate accessible information . . . designed to ensure that women and men, particularly young people, can acquire knowledge about their health, especially information on sexuality and reproduction, taking into account the rights of the child to access to information, privacy, confidentiality, respect and informed consent."[26] Thus, if the United States required parental involvement in Title X family planning services, it would violate these international accords.

Moreover, virtually every state in the U.S. has enacted legislation to permit minors to obtain care for sexually transmitted diseases without parental consent and many have legal provisions ensuring confidential access to contraceptives. As of September 1997, 49 states and the District of Columbia authorize minors to consent to the diagnosis and treatment of sexually transmitted diseases, and legislatures in 23 states and the District of Columbia have given minors the authority to consent to contraceptive services.[27] Any attempt to

eradicate Title X's guarantee of confidentiality would therefore trammel upon these individual state confidentiality protections.

II. PUBLICLY FUNDED FAMILY PLANNING SERVICES IMPROVE WOMEN'S LIVES.

A. Access to Contraceptive Services Enhances the Quality of Life for Women and their Families.

Access to contraceptive services is central to improving women's overall health and reducing unintended pregnancy. The ability to determine whether and when to have children is a key measure of women's autonomy. Moreover, as the U.S. Supreme Court recognized in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives."[29] Reducing the rate of unintended pregnancy and enhancing reproductive health and rights therefore are essential to promoting women's self-determination and ability to participate fully in society.

Nearly 50 percent of all pregnancies in the U.S. are unintended.[30] An estimated 31 million women, or one-half of all women in the U.S. of reproductive age, are at risk for unintended pregnancy. By decreasing the unintended pregnancy rate, access to contraceptive services also improves the quality of life for both parents and their children.[31]

- Negative health outcomes are strongly associated with unintended pregnancy. These outcomes include: delayed or inadequate prenatal care; increased fetal exposure to tobacco and alcohol; increased likelihood of low birth weight and death in the first year of life; and higher risk of abuse and failure to receive sufficient resources for healthy development.[32]

- Unintended pregnancy is also linked to negative social outcomes for parents and families, such as increased risk of the mother being physically abused, the dissolution of the parents' relationship, economic hardship, and a reduced likelihood that parents will achieve their educational and career goals.[33]

Participation in publicly funded family planning services also positively affects women's lives and helps ensure healthier babies.

- A national study found that family planning funds for 1982-1988 were linked to 20,000 fewer low birth weight births, 6,500 fewer infant deaths, and 5,500 fewer neonatal deaths.[34]

- Receipt of publicly funded family planning services increases the likelihood that a woman will receive adequate prenatal care if she does become pregnant. In one study, family planning funding from 1982-1988 was associated with 106,900 fewer births with no or late prenatal care. Meanwhile, a North Carolina study found that women were more likely to initiate prenatal care early, to receive sufficient care throughout pregnancy, and to participate in a food supplement program and other maternity-care services if they had used family planning services in the first two years prior to becoming pregnant.[35]

- Title X funds are also vital to STD screening and treatment. Each year 15.3 million new cases of STDs occur in the U.S., including approximately four million new cases among teenagers.[36] In 1990, 40 percent of all visits to an individual Title X grantee involved STD screening or treatment -- as compared to 10 percent of visits in 1980.[37]

B. Publicly Funded Family Planning Services Are Effective in Reducing Unintended Pregnancies, Unintended Births, and Abortions.

- Publicly funded contraceptive services annually prevent 1.3 million unintended pregnancies, which would result in 533,800 births and 632,300 abortions. Without such services, the number of abortions performed each year in the U.S. therefore would be approximately 40 percent higher.[38]

- Publicly funded contraceptive services have a particularly profound impact on adolescents. Without such publicly funded services, 385,800 additional teens would become pregnant annually. The result would be 154,700 more births and 183,300 more abortions, increasing the yearly total of teen births by about 25 percent and the number of abortions by about 58 percent.[39]

C. Publicly Funded Contraceptive Services are Cost-Effective.

- Compared to no contraceptive use, use of contraceptives is extremely cost-effective. Annually, 100 women having sexual intercourse without contraception will have 85 pregnancies.[40]

- Of the approximately 534,000 additional women who would give birth in the absence of publicly funded services, approximately 338,000 additional women would be eligible for pregnancy-related Medicaid coverage. About 80 percent of these women would be eligible solely because of their pregnancy. Through state and federal expenditures, the nation would spend an additional $1.2 billion for Medicaid each year. Every government dollar spent on contraceptive services thus saves the public approximately $3.00 in funds that otherwise would have been spent on pregnancy-related and newborn care through Medicaid.[41]

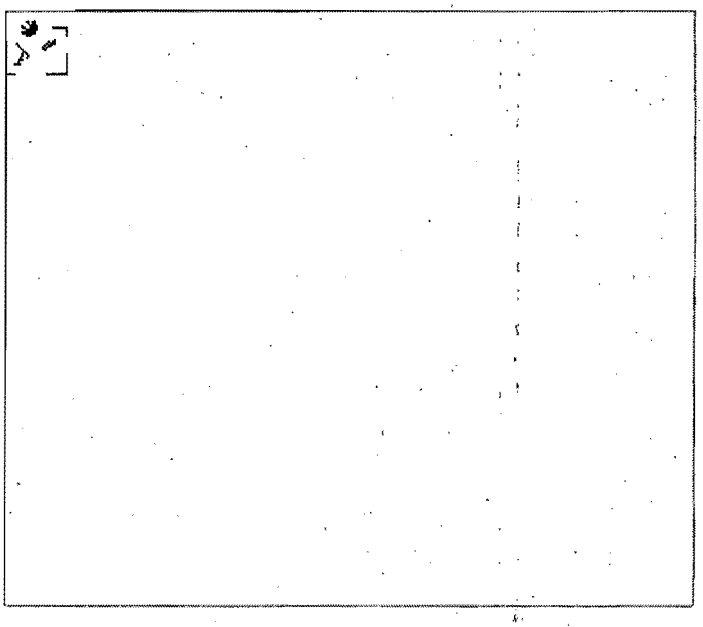
III. THE CURRENT FUNDING LEVELS FOR TITLE X ARE INADEQUATE.

A. In Constant Dollars, Title X Funding Has Decreased Over Time.

If Title X funding had increased at the rate of inflation from its FY 1980 funding level of $162 million, it presently would be funded at approximately $500 million. Yet, Title X's funding level for FY 1999 is less than half that amount -- $215 million. In fact, taking inflation into account, Title X funding for contraceptive services in constant dollars decreased by 61 percent between 1980 and 1998.[43]

B. Title X Clinics Face Increasing Costs.

While the level of public funding for family planning clinics declined, the number of patients they served rose -- overburdening the system.[44] Less than 30 percent of all women potentially eligible for services in 1994 were served by Title X clinics.[45] Moreover, while funding for Title X has decreased, the costs of providing certain services has risen, as has the number of patients needing certain services.[46]



Source: Frost, "Family Planning Clinic Services in the United States," 99.[47]

The notion that women should be able to choose freely from a broad range of contraceptive choices is inherent in the Title X regulations.[48] However, the increasing demand for long-lasting contraceptive technologies such as Depo-Provera has made it difficult for Title X clinics to accomplish this task. This contraceptive method is extremely effective, but has very high up-front costs as compared to oral contraceptives.[49] For example, 17 percent of Title X patients now use Depo-Provera, a drug whose increased use is credited as one of the factors responsible for the decreased teen pregnancy rate. Yet, providing one woman with Depo-Provera for a year is more expensive than providing three women with an annual supply of oral contraceptives. Thus, clinics are hard-pressed to come up with the financial resources to accommodate new Depo-Provera patients. This financial burden has made it difficult for providers to offer their clients the full range of contraceptive services. The rising costs of Pap smears and improved STD screening and detection techniques have aggravated this burden, hindering clinics' ability to make routine, effective diagnostic technologies available to all patients.[50]

C. The Proposed Increase in Title X Funding is Necessary but Not Sufficient.

Recognizing the importance of increased funding for Title X, President Clinton's FY 2000 budget proposal requests $25 million for Title X over the current level.[51] As First Lady Hillary Rodham Clinton remarked at NARAL's 26th anniversary of *Roe v. Wade* luncheon, "I think we can all agree that it is a tragedy when four in 10 pregnancies worldwide are unplanned -- and half of them end in abortion. Now if we want, really, to reduce those numbers, we know we cannot achieve that goal by making abortion harder to get. We must do it by standing up for family planning here and around the world. And I am pleased to announce that the President's budget request for FY 2000 does just that. He is asking for an increase of $25 million in Title X Family Planning grants -- the largest increase in 15 years . . ."[52] However, even if the extra $25 million is appropriated, that level of funding still would not be enough to meet all of the administration's objectives, including targeting hard-to-reach populations such as males, substance abusers, and the homeless.[53]

IV. CONCLUSION.

Title X funding for family planning services has assisted millions of women in obtaining essential care. Research has proven Title X's effectiveness in reducing the number of unintended pregnancies, unintended births, and abortions. Only through adequate levels of

funding, without restrictions on minors' access to confidential services, can Title X's benefits to women's lives and health continue and expand.

* Although Title X clinics primarily serve women, they provide services to male clients as well.

July 12, 1999

Notes:

1. 42 U.S.C. " 300 to 300a-8 (West through P.L. 105-394); Lisa Kaeser, Rachel Benson Gold and Cory L. Richards, *Title X at 25: Balancing National Family Planning Needs with State Flexibility* (New York and Washington, DC: The Alan Guttmacher Institute (AGI), 1996), 6-9. top

2. The NARAL Foundation/NARAL, *Who Decides? A State-by-State Review of Abortion and Reproductive Rights*, 5th edition (Washington, DC: The NARAL Foundation/NARAL, 1995), i; see amendments to FY 1996, FY 1997, FY 1998, and FY 1999 Labor, Health and Human Services, and Education & Related Agencies Appropriations bills. top

3. Jennifer Frost and Michele Bolzan, "The Provision of Public-Sector Services By Family Planning Agencies in 1995," *Family Planning Perspectives*, vol. 29, no. 1 (Jan./Feb. 1997): 12. top

4. Cynthia Dailard, "Title X Family Planning Clinics Confront Escalating Costs, Increasing Needs," *The Guttmacher Report on Public Policy* (Apr. 1999): 1; National Family Planning and Reproductive Health Association (NFPRHA), "Facts About the National Family Planning Program: Title X (ten) of the Public Health Service Act," 1999 (factsheet). top

5. Kaeser, Gold and Richards, *Title X at 25, 7, citing* "Effects of Implementing the Gag Rule," memorandum, 1991; Frost and Bolzan, "The Provision of Public-Sector Services," 8; AGI, "Title X and the U.S. Family Planning Effort," *Issues in Brief* (Feb. 1997): 2. top

6. Kaeser, Gold and Richards, *Title X at 25*, 8. top

7. AGI, "Title X and the U.S. Family Planning Effort," 2, 4; 42 U.S.C. § 300a-4 (West through P.L. 105-394); Fed. Reg. vol. 45, no. 108 (1980) (codified at 42 C.F.R. § 59.5(7), (8), § 59.2). top

8. 42 U.S.C. § 300(a) (West through P.L. 105-394). top

9. Fed. Reg. vol. 45, no. 108 (1980) (codified at 42 C.F.R. § 59.1). top

10. 42 U.S.C. § 300a-6 (West through P.L. 105-394). top

11. 42 U.S.C. § 300a-1 to -2 (West through P.L. 105-394). top

12. 42 U.S.C. § 300a-5 (West through P.L. 105-394). top

13. Bureau of Community Health Services (BCHS), U.S. Department of Health and Human Services (HHS), *Program Guidelines for Project Grants for Family Planning Services* (1981), 9-15. top

14. Stanley Henshaw and Aida Torres, "Family Planning Agencies: Services, Policies and Funding," *Family Planning Perspectives*, vol. 26, no. 2 (Mar./Apr. 1994): 56. top

15. Fed. Reg. vol. 45, no. 108 (1980) (codified at 42 C.F.R. § 59.11). top

16. 42 U.S.C. § 300 (West through P.L. 105-394). top

17. *Planned Parenthood Federation of America, Inc. v. Heckler*, 712 F.2d 650 (D.C. Cir. 1983); *State of New York v. Heckler*, 719 F.2d 1191 (2d Cir. (N.Y.) 1983); AGI, "Title X and the U.S. Family Planning Effort," 5; Kaeser, Gold and Richards, *Title X at 25*, 9. top

18. Frost and Bolzan, "The Provision of Public-Sector Services," 8; AGI, "Title X and the U.S. Family Planning Effort," 2. top

19. D. Hollander, "Some Teenagers Say They Might Not Seek Health Care if They Could Not Be Assured of Confidentiality," *Family Planning Perspectives*, vol. 25, no. 4 (Jul./Aug. 1993): 187, *citing* T.L. Cheng et al., "Confidentiality in Health Care: A Survey of Knowledge, Perceptions, and Attitudes Among High School Students," *Journal of the American Medical Association*, vol. 269 (1993): 1404-1407. top

20. Andrea Marks et al., "Assessment of Health Needs and Willingness to Utilize Health Care Resources of Adolescents in a Suburban Population," *The Journal of Pediatrics*, vol. 102, no. 3 (Mar. 1983): 459. top

21. *Planned Parenthood Affiliates of California v. Van De Kamp*, 181 Cal. App. 3d 245, 268-69 (Ct. App. 1986). top

22. *Planned Parenthood Association of Utah v. Matheson*, 582 F. Supp. 1001, 1009 (D. Utah 1983). top

23. Letter from American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologists (ACOG), American Medical Women's Association (AMWA), American Society for Reproductive Medicine (ASRM), and Society for Adolescent Medicine to each member of the U.S. House of Representatives (July 31, 1998) (on file with NARAL). top

24. United Nations, *Report of the International Conference on Population and Development* (Oct. 18, 1994) (5/21/99); United Nations, *Report of the Fourth World Conference on Women* (Oct. 17, 1995) (5/21/99). top

25. United Nations, *Report of the International Conference on Population and Development*, para. 7.45. top

26. United Nations, *Report of the Fourth World Conference on Women*, para. 107e. top

27. AGI, "Teenagers' Right to Consent To Reproductive Health Care," *Issues in Brief* (Oct. 1997): 3. top

28. Committee on Unintended Pregnancy, Institute of Medicine, *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families*, Sarah Brown and Leon Eisenberg, eds. (Washington, DC: National Academy Press, 1995), 11. top

29. *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 856 (1992). top

30. Stanley Henshaw, "Unintended Pregnancy in the United States," *Family Planning Perspectives*, vol. 30, no. 1 (Jan./Feb. 1998): 26. top

31. Committee on Unintended Pregnancy, *Best Intentions*, 28, 81, 259-62. top

32. Committee on Unintended Pregnancy, *Best Intentions*, 81. top

33. Committee on Unintended Pregnancy, *Best Intentions*, 81. top

34. Kenneth Meier and Deborah McFarlane, "State Family Planning and Abortion Expenditures: Their Effect on Public Health," *American Journal of Public Health*, vol. 84, no. 9 (Sept. 1994): 1468, 1471; AGI, "Title X and the U.S. Family Planning Effort," 3. top

35. Meier and McFarlane, "State Family Planning," 1468, 1471; Denise Jamieson and Paul Buescher, "The Effect of Family Planning Participation on Prenatal Care Use and Low Birth Weight," *Family Planning Perspectives*, vol. 24, no. 5 (Sept./Oct. 1992): 214, 216; AGI, "Title X and the U.S. Family Planning Effort," 3. top

36. The Henry J. Kaiser Family Foundation (KFF) and the American Social Health Association (ASHA), *Sexually Transmitted Diseases in America: How Many Cases and at What Cost?* (Menlo Park, CA: KFF and ASHA, 1998), 4, 8; KFF, MTV and TeenPeople, "What Teens Don't Know About STDs Puts Them at Risk: A National Survey Finds Few Sexually Experienced 15-17 Year Olds Get Tested for STDs, And Most Underestimate Their Risk," Mar. 8, 1999 (news release), 1. top

37. AGI, "Title X and the U.S. Family Planning Effort," 5. top

38. Jacqueline Darroch Forrest and Renee Samara, "Impact of Publicly Funded Contraceptive Services On Unintended Pregnancies and Implications For Medicaid Expenditures," *Family Planning Perspectives*, vol. 28, no. 5 (Sept./Oct. 1996): 192-93, *citing* S.K. Henshaw and J. Van Vort, "Abortion Services in the United States, 1991 and 1992, *Family Planning Perspectives*, vol. 26, no. 3 (May/June 1994): 100-106; AGI, "Title X and the U.S. Family Planning Effort," 3. top

39. Forrest and Samara, "Impact of Publicly Funded Contraceptive Services," 193; AGI, "Title X and the U.S. Family Planning Effort," 3. top

40. "Editorial: Failing to Prevent Unintended Pregnancy is Costly," *American Journal of Public Health*,

vol. 85, no. 4 (Apr. 1995): 479. top

41. Forrest and Samara, "Impact of Publicly Funded Contraceptive Services," 193-94; AGI, "Title X and the U.S. Family Planning Effort," 3. top

42. NFPRHA, "Facts About the National Family Planning Program," 3; FY 1999 Omnibus Appropriations Act, Pub. L. No. 105-277, Department of Health and Human Services Appropriations section, Tit. II. top

43. Dailard, "Title X Family Planning Clinics Confront Escalating Costs," 1. top

44. Committee on Unintended Pregnancy, *Best Intentions*, 142-43. top

45. Jennifer Frost, "Family Planning Clinic Services in the United States, 1994," *Family Planning Perspectives*, vol. 28, no. 3 (May/June 1996): 98. top

46. AGI, "Title X and the U.S. Family Planning Effort," 5. top

47. "Eligible women" refers to "women aged 20-44 who are at risk of an unintended pregnancy and whose income is less than 250% of the federal poverty level, plus all women younger than 20 who are at risk of an unintended pregnancy." The population of women served includes more than just eligible women; thus, the actual ratio of women served to eligible women is lower than shown here. top

48. Fed. Reg. vol. 45, no. 108 (1980) (codified at 42 C.F.R. § 59.5). top

49. Dailard, "Title X Family Planning Clinics Confront Escalating Costs," 1-2. top

50. Dailard, "Title X Family Planning Clinics Confront Escalating Costs," 2. top

51. Executive Office of the President of the United States, Office of Management and Budget, *Budget of the United States Government, Fiscal Year 2000* (Washington, DC: U.S. Government Printing Office, 1999), 92. top

52. First Lady Hillary Rodham Clinton, Remarks at NARAL's 26th Anniversary of *Roe v. Wade* Luncheon (Jan. 22, 1999) (transcript on file with NARAL). top

53. Dailard, ATitle X Family Planning Clinics Confront Escalating Costs,@ 1, 14; U.S. Department of Health and Human Services, *Fiscal Year 2000 Budget* (Washington, DC, 1999), 21. top

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THE GAG RULE

The Republican "Contract With America" calls for a federal gag rule that would endanger women's health and interfere with the doctor-patient relationship. The Personal Responsibility Act would provide state block grants to be used for pregnancy prevention programs and would impose a gag rule preventing participating women from obtaining medical advice, counseling and information about abortion. The gag rule would endanger women's health by denying them the complete and accurate information about their reproductive choices that is routinely available to those who can afford private care. It would also interfere with the doctor-patient relationship by requiring physicians to compromise their best medical judgment as to what information or treatment is in the best interest of their patient.

- Leading medical groups concerned with women's reproductive health, including The American Medical Association and the American College of Obstetricians and Gynecologists, oppose gag rules.

The new gag rule is strikingly similar to a counseling ban instituted during the Reagan/Bush era, but never fully implemented, that would have prohibited medical professionals at Title X clinics from counseling, advising or providing information about abortion and from referring women to health care facilities that offered abortion counseling or services. Health care providers would have been required to tell women who requested information about abortion that "abortion is not an appropriate method of family planning," even when the pregnancy threatened the woman's life.

- In 1991, a Harris poll found that 78 percent of Americans thought that Congress should pass a law to overturn the gag rule.

- Significant bi-partisan majorities in both houses of Congress approved legislation to overturn the gag rule, and twice these votes were vetoed by President Bush. President Clinton revoked the gag rule by executive order on January 22, 1993.

Women need access to family planning services and information about all the options available in order to make responsible decisions about their health. Reinstating a dangerous "gag rule" policy would undermine women's health and censor the information health care professionals may provide.

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EXECUTIVE ORDERS

On January 22, 1993 President Clinton issued five Executive Orders overturning anti-choice initiatives of the two previous administrations. After the 1994 elections, several anti-choice members of the new Congressional leadership stated their intent to pass legislation nullifying these Executive Orders as soon as possible.[1] Reversal of these policies in the 104th Congress would be a serious setback for women's reproductive health, and would inhibit important scientific research that has the potential to save lives.

The "Gag Rule"

Title X of the Public Health Service Act is the centerpiece of federal family planning efforts and since its inception in 1970 has specified that no federal funds appropriated for the program could be used for the performance of abortions. The act placed no restrictions on the ability of Title X clinics to provide abortion counseling or referrals. In 1988, President Reagan's Department of Health and Human Services (HHS) issued the "gag rule" prohibiting health care professionals at Title X clinics from counseling, advising or providing information about abortion. The regulations prohibited Title X service providers from referring women for abortion services, even when such information was specifically requested.

The "gag rule" was never fully implemented due to a series of legal challenges. President Bush vetoed congressional attempts to overturn the "gag rule" in 1991 and 1992. His 1992 veto was overridden in the Senate, but was sustained by a small margin in the House. President Clinton overturned the "gag rule" by executive order during his first month in office.

The "gag rule" resurfaced in the Republican "Contract With America." The Personal Responsibility Act included in the Contract would create state block grants to be used for pregnancy prevention programs and would prevent women participating in such programs from obtaining medical advice, counseling and information about abortion. Like its predecessor, this "gag rule" is dangerous for women, and also met with tremendous public opposition.

- Enforcement of the "gag rule" would endanger women's health by denying them complete and accurate medical information from their health care providers.
- The "gag rule" would interfere with the doctor/patient relationship, and is opposed by mainstream medical groups including the American Medical Association and the American College of Obstetricians and Gynecologists.

RU 486 - Mifepristone

RU 486 (also known as mifepristone) is an effective non-surgical method of early abortion. The drug was approved for use in France, England and Sweden following clinical trials documenting its safety and effectiveness, and has been used by approximately 150,000 women in Europe. RU 486 also has potential value in the treatment of breast cancer, AIDS,

brain tumors, Cushing's disease, diabetes and others.

Recognizing that mifepristone would expand women's choices and make it more difficult to target abortion clinics for violence and harassment, anti-choice forces have worked to deny American women access to RU 486. In 1989, the Bush Administration's FDA issued an "import alert" which helped ensure the drug would be unavailable in the U.S. for research or any other purposes. A United States District Court that examined a challenge to this import alert concluded that, "the decision to ban the drug was based not from any bona fide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety. [2]

In January of 1993, President Clinton signed an Executive Order directing the Department of Health and Human Services to assess initiatives to promote the testing and licensing of mifepristone. In May of 1994, the French pharmaceutical company, Roussel Uclaff donated the patent for mifepristone to the Population Council and cleared the way for clinical testing in the U.S. From October 1994 to September 1995, the Population Council conducted clinical trials involving 2,100 volunteers at 17 sites to collect data in support of an application for FDA approval of RU 486. The application was filed in March 1996. [3]

Fetal Tissue Research

In March of 1988, the Reagan Administration imposed a temporary moratorium on federal funding of fetal tissue transplantation research, pending the outcome of an exhaustive study by the Human Fetal Tissue Transplantation Research Panel on ethical, legal and scientific research. After reviewing this report, the Advisory Committee to the Director of the National Institute of Health recommended that the moratorium be lifted. Despite the panel's recommendation that the government resume funding, in November, 1989 the Secretary of the Department of Health and Human Services extended the moratorium indefinitely. The ban on federal funding for fetal tissue transplantation research severely restricted research that showed enormous promise for developing treatments for men and women suffering from a wide variety of medical conditions. Millions who suffer life-threatening diseases including: Parkinson's disease;[4] Alzheimer's disease;[5] Huntington's disease;[6] AIDS;[7] strokes [8] and; spinal cord injuries[9] may benefit directly from research involving fetal tissue transplantation.

President Clinton overturned the funding ban on fetal tissue research by Executive Order in January of 1993.

Ban on the Performance of Privately Funded Abortions at Military Hospitals

In 1988, the Reagan Administration's Department of Defense (DOD) announced a new policy prohibiting the performance of abortions at military facilities, even if paid for by the patient and even if abortion services were not otherwise available where a woman or her husband were stationed. Abortion would be permitted only when the life of the woman would be endangered by carrying the pregnancy to term. Prior to the new policy, a woman in the military or a military dependent could obtain an abortion at a military facility if she paid the costs of the procedure.

The Military Health Care Initiatives Act of 1992 which would have entitled military personnel stationed outside the United States to obtain reproductive health services including abortion in military hospitals provided they paid the full cost reached final passage in the House in October of 1992. It was pocket vetoed by President Bush on October 31, 1992.

President Clinton lifted the ban in January of 1993, permitting abortion services to be provided at U.S. military hospitals if paid for with non-DOD funds. This Executive Order

was overturned when HR 2126, the Defense Department's appropriations bill, was passed by Congress and became law on December 4, 1995 without President Clinton's signature. The bill imposes a ban on privately funded abortions at U.S. military facilities overseas except when the woman becomes pregnant as a result of rape or incest. On February 10, 1996, President Clinton signed a DOD Authorization bill that also includes a provision that bans privately funded abortions at overseas U.S. military facilities except in cases of rape or incest.

AID Family Planning Grants/Mexico City Policy

In 1985, the Reagan Administration announced its new policy on the U.S. international family planning program funded through the Agency for International Development. In exchange for family planning aid, foreign nongovernmental organizations were prohibited from providing - with their non-U.S. funds - any information or services relating to abortion even in countries where abortion was legal. This became known as the "Mexico City" policy, named for the 1984 United Nations Conference on Population at which the Reagan administration first announced it." This "international gag rule" seriously undermined efforts to promote safe and effective family planning programs in foreign nations and greatly limited the extent to which the U.S. could support international family planning programs. President Clinton overturned the Mexico City Policy by Executive Order in January of 1993.

Anti-choice legislators in the 104th Congress have repeatedly attempted to pass legislation that would impose restrictive family planning policies similar to the Mexico City policy. Although they have not succeeded, they were able to insert provisions in a continuing budget resolution that had the effect of cutting spending on international family planning programs by 85 percent. President Clinton signed this bill into law on January 26, 1996. On March 19, 1996, the Senate passed an omnibus appropriations bill that would allow the President to restore most international family planning funds.

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1. Spencer Rich, "Congress's Antiabortion Blocs Gain: Interest Groups Count at Least 39 More House Votes, 5 in Senate," *Washington Post*, Dec. 5, 1994, A1.
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NARAL FACTSHEETS

EXECUTIVE ORDERS

On January 22, 1993 President Clinton issued five Executive Orders overturning anti-choice initiatives of the two previous administrations. After the 1994 elections, several anti-choice members of the new Congressional leadership stated their intent to pass legislation nullifying these Executive Orders as soon as possible.[1] Reversal of these policies in the 104th Congress would be a serious setback for women's reproductive health, and would inhibit important scientific research that has the potential to save lives.

The "Gag Rule"

Title X of the Public Health Service Act is the centerpiece of federal family planning efforts and since its inception in 1970 has specified that no federal funds appropriated for the program could be used for the performance of abortions. The act placed no restrictions on the ability of Title X clinics to provide abortion counseling or referrals. In 1988, President Reagan's Department of Health and Human Services (HHS) issued the "gag rule" prohibiting health care professionals at Title X clinics from counseling, advising or providing information about abortion. The regulations prohibited Title X service providers from referring women for abortion services, even when such information was specifically requested.

The "gag rule" was never fully implemented due to a series of legal challenges. President Bush vetoed congressional attempts to overturn the "gag rule" in 1991 and 1992. His 1992 veto was overridden in the Senate, but was sustained by a small margin in the House. President Clinton overturned the "gag rule" by executive order during his first month in office.

The "gag rule" resurfaced in the Republican "Contract With America." The Personal Responsibility Act included in the Contract would create state block grants to be used for pregnancy prevention programs and would prevent women participating in such programs from obtaining medical advice, counseling and information about abortion. Like its predecessor, this "gag rule" is dangerous for women, and also met with tremendous public opposition.

- Enforcement of the "gag rule" would endanger women's health by denying them complete and accurate medical information from their health care providers.
- The "gag rule" would interfere with the doctor/patient relationship, and is opposed by mainstream medical groups including the American Medical Association and the American College of Obstetricians and Gynecologists.

RU 486 - Mifepristone

RU 486 (also known as mifepristone) is an effective non-surgical method of early abortion. The drug was approved for use in France, England and Sweden following clinical trials documenting its safety and effectiveness, and has been used by approximately 150,000 women in Europe. RU 486 also has potential value in the treatment of breast cancer, AIDS,

brain tumors, Cushing's disease, diabetes and others.

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THE GUTTMACHER REPORT ON PUBLIC POLICY
Volume 2, No. 5, October 1999

Issues & Implications

Family Planning and Adoption Promotion: New Proposals, Long-Standing Issues

By Cynthia Dailard

Within the last few months, a spate of bills has been introduced by long-standing opponents of family planning programs with the aim of promoting adoption in Title X family planning clinics and other federally funded health centers. Not surprisingly, these proposals are the source of significant concern within the family planning community. Individually, and especially taken together, they raise fundamental questions about the nature of adoption counseling that appropriately should be provided to pregnant women in government-funded programs and about the extent to which the nation's family planning program should assume functions historically performed by adoption agencies. At a time of severe budget constraints, they also raise a serious question about the extent to which family planning funds should be diverted for that purpose.

Of more immediate concern, however, is the fact that two of the proposed measures are directly aimed at denying women facing crisis pregnancies full information about their options--apparently on the basis of the notion that the best way to promote adoption is to prevent family planning providers from discussing abortion. One would revive the abortion "gag rule" imposed by the Reagan and Bush administrations; the other would go a step further to set up a program of direct federal subsidy to counseling organizations *on the condition* that the pregnancy-options information they provide is incomplete.

The Ethics of Informed Consent

Established in 1970, Title X of the Public Health Service Act is the only federal program devoted solely to the provision of family planning services to low-income women, teenagers and others in need of care. As part of its mission to help low-income women avoid unintended pregnancy through high-quality contraceptive care, Title X supports a wide range of reproductive health services, including pelvic and breast examinations, Pap smears and screening and treatment for sexually transmitted diseases, as well as pregnancy tests. Indeed, each year Title X clinics provide pregnancy tests to almost 1.3 million American women (almost 30% of Title X clients), or one in eight women obtaining a pregnancy test from a health care provider. With half of all pregnancies in this country unintended, many of the pregnancies detected at Title X clinics are unplanned.

Program guidelines that have been in place for almost two decades dictate that when a woman at a Title X clinic faces an unintended pregnancy and requests information about her options, she must receive information about *all* her options in a nonjudgmental manner. While by law Title X funds may not be used for abortion, the guidelines specify that a woman who requests information about her options must receive "nondirective counseling" on "prenatal care and delivery; infant care, foster care, or adoption; *and pregnancy termination"* (emphasis added). Once she decides how to proceed, the counselor will refer her for the services requested, which may include additional counseling if so desired.

Pregnancy counseling does not--and should not--involve advocacy of any one option. Rather, counselors who work in family planning clinics are trained to provide short-term counseling designed to convey basic, factual information about all of the alternatives, so that women can explore all of their options and decide for themselves which is best for them, given their life circumstances, values and desires. According to the Title X guidelines, nondirective counseling should "help clients resolve uncertainty, ambivalence, and anxiety in relation to reproductive health and to enhance their capacity to arrive at a decision that reflects their considered self-interest." Indeed, access to full information and freedom from coercion are cornerstones of the Title X program and fundamental to any notion of voluntarism.

The Title X standards for nondirective counseling are consistent with those promulgated by major medical organizations such as the American College of Obstetricians and Gynecologists. They also are consistent with a fundamental principle of modern medical ethics known as "informed consent"--that people can make an informed decision about medical care only after they have been given full information about their condition, the risks and benefits of proposed treatment and all possible alternatives. Moreover, a health care provider who does not obtain informed consent from a patient may be liable for medical malpractice.

Reviving the Antiabortion Gag

Abortion opponents, however, have long sought to prevent Title X providers from discussing abortion. Indeed, the Reagan administration in 1987 promulgated regulations, quickly dubbed the "gag rule," that specifically barred counselors in Title X clinics from discussing abortion as one of the alternatives available to women facing an unplanned pregnancy and from referring women to a provider of abortion services--even when such information or referrals were directly requested. At the same time, counselors were required to give *all* patients referrals for prenatal care and delivery services.

The gag rule was opposed by 78 national organizations, including the American Medical Association and the American College of Obstetricians and Gynecologists, as well as 36 state health departments, on the basis that it violated Title X providers' First Amendment right to free speech and interfered with the doctor-patient relationship. The U.S. Supreme Court, however, rejected these arguments in 1991, when it voted 5-4 in *Rust* v. *Sullivan* to uphold the regulations as a permissible exercise of executive power. When Congress passed legislation the following year to repeal the regulations, it fell 10 votes short of the two-thirds vote necessary to override President Bush's veto. It was not until the Clinton administration suspended the regulations in January 1993 that Title X providers were once again free to provide women with full information about all of their options.

While the Reagan administration took an overt approach to gagging Title X providers, some family planning opponents are now proposing a different--albeit more stealthy--approach to achieve the same end. The Adoption Awareness Act--introduced in July by Reps. Jim DeMint (R-SC) and Tom Bliley (R-VA), chairman of the House committee charged with oversight of Title X--would redefine nondirective counseling in a way that undermines the very meaning of the term. Instead of requiring family planning providers to disclose all options available to family planning clients facing an unintended pregnancy, the legislation explicitly limits nondirective counseling to information about "prenatal care and delivery; infant care; foster care; and adoption"--a list that echoes word-for-word the definition of nondirective counseling contained in the Title X guidelines, *minus* any mention of abortion.

The Women and Children's Resources Act, introduced in September by Rep. Joseph Pitts (R-PA)--known for his unsuccessful attempts two years running to entirely defund U.S. international family planning assistance--and Sen. Rick Santorum (R-PA), goes a step further. The bill would provide $85 million to the states for grants to pregnancy counseling centers as long as they do not provide any counseling about or referrals for abortions. Moreover, funds for any services related to *contraception* would be expressly prohibited under this "alternatives to abortion" program.

Title X and Adoption

The Reagan gag rule was motivated by the belief--still shared by many antiabortion, anti-family planning advocates--that Title X clinics "promote" abortion by encouraging women to terminate unplanned pregnancies and by either not providing any counseling about adoption or not portraying that option in a sufficiently positive light. In response, the Adoption Awareness Act, even as it reimposes the

gag rule, would provide $7 million in federal funds to a national adoption organization for the purpose of training Title X and other federally supported health care providers in how to better "promote" adoption.

The extent to which counselors in Title X clinics need additional training in counseling around adoption--and what the nature of that training should be--is questionable. Family planning providers already are required to discuss adoption in the course of routine nondirective counseling. Still, Frank Bonati, president and chief executive officer of the Family Health Council of Western Pennsylvania, the only Title X grantee in the nation that also is a licensed adoption agency, suggests that family planning counselors could benefit from training in adoption counseling. "Is there a need for family planning providers to be better versed in adoption? Certainly there is room, just as there is room for some family planning providers to have a greater appreciation of the nuances involved in delivering prenatal care and abortion. Knowledge of adoption should certainly be part of a counselor's routine tool bag." But Bonati rejects the notion that adoption should be emphasized any more than other options. "Should we be training family planning providers in adoption any more than other options? No."

Moreover, experts in the field of adoption distinguish between what is appropriate for a family planning provider to discuss in the course of nondirective counseling of a woman who has just had a positive pregnancy test and the counseling about adoption that should be provided to a woman who has decided to carry a pregnancy to term and is contemplating whether or not to choose adoption (see box). "An options counselor must provide the woman with enough information for her to make a rational, informed decision about how to proceed with a pregnancy," explains Bonati. "Once she has made that choice, family planning providers shouldn't be required to discuss adoption in any greater depth than if the woman had selected abortion or prenatal care with the intention of keeping the baby." All of these cases require referrals, Bonati asserts, to appropriate specialists who can discuss a potential course of action in far greater detail.

The Federal Adoption Services Act, introduced in July by Reps. Sue Myrick (R-NC) and Cliff Stearns (R-FL), offers a much more direct approach to adoption promotion under Title X--and in doing so, it raises the notion that family planning clinics ought to be providing fewer services related to contraception and more services related to adoption. Authorizing no new funds for the program, it specifically authorizes Title X funds to be diverted from the program's core historic mission of providing high-quality contraceptive services to low-income Americans to the provision of adoption services. This is proposed at a time when Title X providers face tremendous financial difficulties just in meeting existing demand for contraceptives among those in need of subsidized services (*TGR* Vol. 2, No. 2, April 1999).

The immediate prospects for these bills are uncertain, but it is clear that they constitute a serious threat to the future viability of federally funded family planning programs. Key principles should guide the family planning community's response. First and foremost, adoption should not be promoted at the cost of gagging doctors and violating principles of informed consent. Second, family planning providers do, indeed, have a clear and vitally important role to play in providing high-quality counseling, including counseling about adoption, to women facing unintended pregnancies--and they should be trained accordingly. At the same time, any effort to require Title X providers to become experts on adoption and to provide larger scale adoption services, at a minimum, would require a substantial infusion of additional funding and resources, in order to ensure that the program's ability to fulfill its responsibilities to the millions of low-income Americans in need of contraceptive care not be compromised. The latter point is critical because, ultimately, the provision of high-quality family planning services must remain a centerpiece of any serious national effort to reduce rates of unintended pregnancy and abortion.

An Adoption Professional Talks About Counseling

In August, I spoke with Susan Badeau, a Kennedy Public Policy Fellow in the office of Sen. Jay Rockefeller (D-WV). An adoption advocate and child welfare professional for 20 years, and an adoptive parent herself, Badeau has worked extensively with birth families, foster families and adoptive families as a counselor, trainer and program supervisor.--CD

CD: There seems to be confusion over what exactly adoption counseling entails, as well as who should

provide it and when. So, first, is there a difference for you between the counseling around adoption that should be provided to a woman in the context of pregnancy-options counseling and the counseling that would be appropriate for a woman after she has decided to carry a pregnancy to term?

SB: There are important differences in both the amount and type of counseling that should be provided. There are three basic, early messages that a woman should receive about adoption when she has just found out that she is pregnant and asks for information about her options. First, she needs to know that adoption is an option for her--but that she doesn't need to make a final decision until after the baby is born. Second, she needs to know that there are a range of adoption options--that she could opt for an open adoption and be involved in the process of selecting and meeting the parents, and even maintain contact with the child, or she could opt for a closed adoption and have less-intimate, or even minimal, involvement. Third, she must be told that the biological father will need to be identified, notified or involved in the adoption process--the specifics will vary depending on state law.

CD:. Should the counselor give her much information beyond that?

SB: The counselor should be able to answer basic questions, but beyond that, the client should be referred to an adoption agency. Remember, the point of talking about adoption at this point is so the woman can factor that possibility into her decision about whether or not to carry her pregnancy to term. You don't want to overload her with too much information, because she needs time to process the fact that she's pregnant.

CD: What about the kind of counseling that should be provided once a woman has decided to carry her pregnancy to term and is contemplating adoption?

SB: It should be far more sophisticated and in-depth than anything offered when a woman first discovers she is pregnant. In fact, a good adoption counselor should provide a woman considering adoption with at least four lengthy counseling sessions--often more.

First, the counselor must ensure that her client is well-informed about both her rights and her responsibilities as a birth parent, as well as explore a variety of emotional and practical issues such as how the client handles loss and grief and the extent of her support system.

The counselor should also help her client understand that there will be times when adoption-related emotions are intensely felt and other times when they are more in the background--and that as she reaches other milestones in her life, some of the feelings and issues associated with the adoption may surface in new ways.

The counselor also needs to help the client explore what she plans to do in her own life after the adoption. And finally, the counselor and client need to explore how the adoption might affect her relationship to others, such as the child's biological father or grandparents, her other children or her friends.

CD: What do you think is the appropriate role of family planning clinic personnel in the provision of adoption services, and what kind of training do they need?

SB: Obviously, pregnancy-options counselors in family planning clinics must be equipped to provide high-quality, nondirective counseling to women facing an unintended pregnancy. That means they must be sufficiently knowledgeable about adoption to provide the kind of information I described earlier, but they also must have enough training to be comfortable speaking *positively* about that option--something they must do in all conversations about adoption they have. As for the more extensive counseling that's appropriate for women who have decided to carry their pregnancies to term, that to my mind should be handled by very highly trained personnel in a licensed adoption agency. And while there's no reason in theory that a family planning clinic couldn't equip itself to provide full adoption services, the resources required would be considerable. We're talking about a very different and specialized service set--not just a simple add-on.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science

Provision of Abortion-Related Services in Family Planning Services Projects

AGENCY: Office of Population Affairs, OPHS, DHHS.

ACTION: Notice.

SUMMARY: This notice informs the public of the policies and interpretations relating to the statutory requirement that no funds appropriated under Title X of the Public Health Service Act be used in programs in which abortion is a method of family planning.

FOR FURTHER INFORMATION CONTACT: Denese O. Shervington, Office of Population Affairs, (301) 594-4001.

SUPPLEMENTARY INFORMATION: On February 5, 1993, the Department of Health and Human Services published in the Federal Register a notice of proposed rulemaking that proposed to revise the regulations at 42 CFR Part 59, Subpart A. Subpart A of Part 59 sets forth the program requirements applicable to grantees under section 1001 of the Public Health Service (PHS) Act, 42 U.S.C. 300, et seq. The notice of proposed rulemaking proposed to revise that subpart by readopting the program regulations as they existed prior to February 2, 1988. This action would have the effect of revoking the regulations published on February 2, 1988, commonly known as the "Gag Rule," which set forth standards for the compliance by such grantees with section 1008 of that Act, 42 U.S.C. 300a-6.

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The February 5, 1993 notice of proposed rulemaking also proposed to reinstitute the pre-1988 policies and interpretations regarding compliance with section 1008. 58 FR 7464. As explained in the notice of proposed rulemaking, those policies and interpretations derived from previous opinions of the Department concerning section 1008. To promote more useful public comment in the rulemaking process, the Department subsequently made available a more detailed summary of the policies and interpretations and reopened the public comment period. 58 FR 34042 (June 23, 1993).

A number of public comments on the prior policies and interpretations were obtained during the reopened comment period, and the public comments received during both comment periods were generally focused on the prior policies and interpretations rather than on the proposed regulatory language. The Department has modified its prior interpretations in several particulars based in part on the public comment received. These modifications, and the grounds therefor, are described in the preamble to the final rules published on this date in the rules section of the Federal Register. The policies and interpretations, as so modified, are set out in the summary statement below. The summary below is also reorganized from the summary statement made available for public comment, for purposes of clarification.

Accordingly, to provide guidance to grantees in order to promote uniform administration of the program and facilitate grantee compliance with the policies and interpretations that are being reinstituted in conjunction with the final regulations adopted on this date, provided below is a summary of the program policies and interpretations that relate to section 1008 of the PHS Act.

Program Policies Regarding the Title X National Family Planning Program and the Section 1008 Abortion Prohibition

Section 1008 of the Title X statute, 42 U.S.C. 300a-6, states: "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." This prohibition applies not only to the performance of abortion by a Title X project, but also to the conduct of certain abortion-related activities by the project. However, the prohibition does not apply to all the activities of a Title X grantee, but only to those within the Title X project. This statement summarizes the Department policies and interpretations in existence prior to the imposition of the 1988 "Gag Rule" with regard to implementation of section 1008, as modified following the rulemaking of 1993.

1. General principles. In general, section 1008 prohibits Title X programs from engaging in activities which promote or encourage abortion as a method of family planning. However, section 1008 does not prohibit the funding under Title X of activities which have only a possibility of encouraging or promoting abortion; rather, a more direct nexus is required. The general test is whether the immediate effect of the activity in question is to promote or encourage the use of abortion as a method of family planning. If the immediate effect of the activity in question is essentially neutral, then it is not prohibited by the statute. Thus, a Title X project may not provide services that directly facilitate the use of abortion as a method of family planning, such as providing transportation for an abortion, explaining and obtaining signed abortion consent forms from clients interested in abortions, negotiating a reduction in fees for an abortion, and scheduling or arranging for the performance of an abortion, promoting or

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advocating abortion within Title X program activities, or failing to preserve sufficient separation between Title X program activities and abortion-related activities.

2. Abortion counseling and referral. According to the 1981 Title X Guidelines:

> Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon request:
>
> - Prenatal care and delivery
> - Infant care, foster care, or adoption
> - Pregnancy termination.

There are limitations on what abortion counseling and referral is permissible under the statute: (a) a Title X project may not provide pregnancy counseling which promotes abortion or encourages persons to obtain abortion, although the project may provide patients with complete factual information about all medical options and the accompanying risks and benefits; (b) a Title X project may provide a referral for abortion. A referral may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider. The project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient; and (c) where a referral to another provider who might perform an abortion is medically indicated because of the patient's condition or the condition of the fetus (such as where the woman's life would be endangered), such a referral by a Title X project is not prohibited by section 1008 and is required by 42 CFR 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications.

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3. Advocacy activities. A Title X project may not promote or encourage the use of abortion as a method of family planning through advocacy activities such as providing speakers to debate in opposition to anti-abortion speakers, bringing legal action to liberalize statutes relating to abortion, or producing and/or showing films that encourage or promote a favorable attitude toward abortion as a method of family planning. Films that present only neutral, factual information about abortion are permissible. A Title X project may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project). A Title X project may also discuss abortion as a backup method of family planning in a discussion of relative risks of various methods of contraception.

4. Separation. Non-Title X abortion activities must be separate and distinct from Title X project activities. Where a grantee conducts abortion activities that are not part of the Title X project and would not be permissible if they were, the grantee must ensure that the Title X-supported project is separate and distinguishable from those other activities. What must be looked at is whether the abortion element in a program of family planning services bulks so large and is so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost.

The Title X project is the set of activities the grantee agreed to perform in the relevant grant documents as a condition of receiving Title X funds. A grant applicant may include both project and nonproject activities in its grant application, and, so long as these are properly distinguished from each other and prohibited activities are not reflected in the amount of the total approved budget, no problem is created. Separation of Title X from abortion activities does not

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require separate grantees or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008.

Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities: (a) a common waiting room is permissible, as long as the costs are properly pro-rated; (b) common staff is permissible, so long as salaries are properly allocated and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project; a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project; and (d) maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated.

Whether a violation of section 1008 has occurred is determined by whether the prohibited activity is part of the funded project, not by whether it has been paid for by federal or non-federal funds. A grantee may demonstrate that prohibited abortion-related activities are not part of the Title X project by various means, including counseling and service protocols, intake and referral procedures, material review procedures, and other administrative procedures.

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3/4/2000 "Dog Rule" mtg.

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