

Presidential Documents

7455

Title 3—

The President

Memorandum of January 22, 1993

The Title X "Gag Rule"

Memorandum for the Secretary of Health and Human Services

Title X of the Public Health Services Act provides Federal funding for family planning clinics to provide services for low-income patients. The Act specifies that Title X funds may not be used for the performance of abortions, but places no restrictions on the ability of clinics that receive Title X funds to provide abortion counseling and referrals or to perform abortions using non-Title X funds. During the first 18 years of the program, medical professionals at Title X clinics provided complete, uncensored information, including nondirective abortion counseling. In February 1988, the Department of Health and Human Services adopted regulations, which have become known as the "Gag Rule," prohibiting Title X recipients from providing their patients with information, counseling, or referrals concerning abortion. Subsequent attempts by the Bush Administration to modify the Gag Rule and ensuing litigation have created confusion and uncertainty about the current legal status of the regulations.

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.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William Clinton

THE WHITE HOUSE,
Washington, January 22, 1993.

Editorial note: The Secretary of Health and Human Services is publishing documents relating to this memorandum in Part V of this issue. For the President's remarks on signing this memorandum, see p. 85 of the *Weekly Compilation of Presidential Documents*.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 59

Standards of Compliance for Abortion-Related Services in Family Planning Service Projects

AGENCY: Public Health Service, DHHS.

ACTION: Interim rule: suspension of effectiveness.

SUMMARY: This Interim rule suspends the rules issued in 1988 establishing standards for compliance by family planning services projects assisted under Title X of the Public Health Service Act with the statutory provision prohibiting abortion as a method of family planning in programs funded under that title. The rules, popularly known as the "Gag Rule", have been the focus of much litigation and controversy, and because the Secretary believes that the Rule inappropriately restricts grantees, she accordingly suspends them and, elsewhere in this issue of the *Federal Register*, proposes to return the program to the regulatory provisions and compliance standards operative prior to their issuance. This action is also consistent with a Memorandum issued by the President on January 22, 1993. During the pendency of the proposed rulemaking, the compliance standards that were in effect prior to the issuance of the Gag Rule will be used to administer the program.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Bennett, 202-690-8335.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services below suspends the rules issued on February 2, 1988, 53 FR 2922. Those rules, popularly known as the "Gag Rule," established standards for compliance by family planning services projects funded under Title X of the Public Health Service Act, 42 U.S.C. 300, et seq., with the statutory prohibition on the use of funds under that title "in programs where abortion is a method of family planning." 42 U.S.C. 300a-6. The prior history of the controversy surrounding sec. 300a-6 is fully described in the preamble to the 1988 rules.

Since their issuance, the February 2, 1988 rules have been the focus of much litigation and controversy. Although they were upheld by the Supreme Court in *Rust v. Sullivan*, 111 S.Ct. 1759 (1991), a subsequent interpretation of the rules by the Bush Administration,

under which physicians would have been permitted to counsel and refer Title X patients for abortion counseling and referral but other project employees would not have been permitted to do so, was recently held to be impermissible by the United States Court of Appeals for the District of Columbia Circuit, *National Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992). This recent decision, together with the change of Administrations, has left the current status of the 1988 Title X rules unclear.

On January 22, 1993, President Clinton sent to the Secretary a memorandum on this matter, which is published elsewhere in this issue.

The Secretary's action herein is based, in part, upon her conclusion that the "Gag Rule" is an inappropriate implementation of the Title X statute because it unduly restricts the information and other services provided to individuals under this program. Therefore, the Secretary suspends the 1988 rules and announces that, on an interim basis, the agency's nonregulatory compliance standards that existed prior to February 2, 1988, including those set out in the 1981 Family Planning Guidelines, will be used to administer the Family Planning Program.

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

As noted in the President's memorandum, these compliance standards were in effect for a considerable period of time prior to 1988, and the Department believes that they are generally well-understood within the Title X provider community.

Notice and comment and delay in effective date are waived for good cause and because delay would be impracticable and unnecessary and contrary to the public interest. The

issues involved in this matter are well known and have been extensively debated. Based on that record, it is the conclusion of the Secretary that: (1) Repeated attempts by the Bush and Reagan Administrations to enforce and modify the "Gag Rule" have created considerable confusion about the status of the regulations and the policy underlying them and, therefore, a substantial health risk to potential recipients of Title X program services; (2) suspension of the regulation, though tantamount to a statement of enforcement policy, is preferable because it provides clearer guidance and more certainty to the grantees and to women making family planning decisions; (3) the 1988 regulation would require many grantees to make extensive and expensive alterations in their physical facilities and organizational structures. To require those changes in the face of the proposed reversal of those rules is impracticable and contrary to the public interest; (4) evidence exists that the continued failure to provide women with complete and accurate medical information will result in significant health risks. The Notice of Proposed Rulemaking being contemporaneously published will give those with differing views on the matter an opportunity to rebut this conclusion. In the interim, the Secretary believes that it is important not to continue the embargo of important health information; (5) the original interpretation of section 1008, which prohibited the use of Title X funds in programs where abortion is a method of family planning, did not include a prohibition on non-directive counseling on abortion; moreover, Congress's repeated attempts—vetoed by President Bush—to amend Title X to eliminate the restrictions justify suspension of the Rule while the regulations are being revised to further the purposes of Title X, as required by statute. For all of these reasons, as well as the reasons set out in the President's Memorandum, this Interim Rule is effective upon publication. Regional officials are being informed of this action, and will notify all present Title X grantees of the suspension of the 1988 rules.

List of Subjects in 42 CFR Part 59

Family planning—birth control, Grant programs—health, Health facilities, Low-income families.

Acting Assistant Secretary for Health.

Approved: February 1, 1993.

Donna E. Shalala,
Secretary.

For the reasons set out in the preamble, the Secretary amends subpart A of 42 CFR part 59 as follows:

PART 58—[AMENDED]

1. The authority for subpart A of part 59 continues to read as follows:

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

#59.2 [Suspended]

2. The following definitions in § 59.2 are suspended: The definitions of "Family planning", "Grantee", "Prenatal care", "Program", "Project", "Title X", "Title X program", and "Title X project."

~~55~~ 59.7-59.10 [Suspended]

3. Sections 59.7 through 59.10 are suspended.

4. Additionally, the miscellaneous amendments to § 59.5 on 53 FR 2944.

paragraphs 3 and 4, and the miscellaneous amendments appearing on 53 FR 2946, paragraph 6, are suspended.

[FR Doc. 93-2732 Filed 2-3-93; 1:18 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 59

Standards of Compliance for Abortion-Related Services in Family Planning Service Projects

AGENCY: Public Health Service, DHHS.

ACTION: Proposed rule.

SUMMARY: This document proposes revocation of the rules issued in 1988 establishing standards for compliance by family planning services projects assisted under Title X of the Public Health Service Act with the statutory provision prohibiting abortion as a method of family planning in programs funded under that title. The rules, popularly known as the "Gag Rule", have been the focus of much litigation and controversy, and because the Secretary believes that the Rule inappropriately restricts grantees, she accordingly proposes below to revoke them and return the program to the compliance standards operative prior to their issuance. This action is also consistent with a memorandum issued by the President on January 22, 1993.

DATES: Comments must be received on or before April 6, 1993.

ADDRESSES: Comments must be in writing, and must be sent to: Mr. Gerald Bennett, Acting Deputy Assistant Secretary for Population Affairs, Department of Health and Human Services, P.O. Box 23783, Washington, DC 20026-3783.

Comments will be available for public inspection during normal business hours at this address. PHS will take appropriate steps, where necessary, to afford individuals with disabilities and equal opportunity to comment.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Bennett, 202-690-8335.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services proposes below rules revoking the rules issued on February 2, 1988, 53 FR 2922. Those rules, popularly known as the "Gag Rule," established standards for compliance by family planning services projects funded under Title X of the Public Health Service, 42 U.S.C. 300, et seq., with the statutory prohibition on the use of funds under that title "in programs where abortion is a method of family planning." 42 U.S.C. 300a-6. The prior history of the controversy surrounding sec. 300a-6 is fully described in the preamble to the 1988 rules.

Since their issuance, the February 2, 1988 rules have been the focus of much litigation and controversy. Although they were upheld by the Supreme Court in *Rust v. Sullivan*, 111 S.Ct. 1759 (1991), a subsequent interpretation of the rules by the Bush Administration, under which physicians would have been permitted to counsel and refer Title X patients for abortion counseling and referral but other project employees would not have been permitted to do so, was recently held to be impermissible by the United States Court of Appeals for the District of Columbia Circuit. *National Family Planning and Reproductive Health Ass'n. v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992). This recent decision, together with the change of Administrations, has left the current status of the Title X rules unclear.

On January 22, 1993, President Clinton sent to the Secretary a memorandum on this matter, which is published elsewhere in this issue.

The Secretary's action herein is based, in part, upon her conclusion that the "Gag Rule" is an inappropriate implementation of the Title X statute because it unduly restricts the information and other services provided to individuals under this program. Therefore, the Secretary proposes below to revoke the 1988 rules and to readopt the Title X rules as they existed prior to February 2, 1988. The Secretary believes that the prior rules provide an appropriate approach to implementing Title X. In addition, the Secretary intends to reinstate the compliance standards that existed prior to that date, including those set out in the 1981 Family Planning Guidelines and in individual policy interpretations. (These compliance standards are being used on an interim basis because of the suspension of the "Gag Rule" discussed below.) Under these compliance standards, Title X projects would be 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 would not be 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 would also be 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.

As noted in the President's memorandum, these regulations and compliance standards were in effect for a considerable period of time prior to 1988, and the Department believes that they are generally well-understood within the Title X provider community. The rules proposed below are thus the Title X rules as in effect on February 1, 1988. It is 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.

The Secretary solicits comment on the proposals described above and suggestions for alternatives that will be consistent with the statute while promoting the interests of public health. Due to the considerations outlined in the President's memorandum, the Secretary's determination that the 1988 rules do not represent good public health policy, and due to the confusion and hardship caused by the 1988 rules, the Secretary has also, for the duration of the rulemaking period, suspended the 1988 rules. This action is being implemented pursuant to an Interim Rule which has been published separately in the Federal Register. Regional officials are being informed of this action, and will notify all present Title X grantees of the suspension of the 1988 rules.

Regulatory Flexibility Act and Executive Order 12291

The proposed rules would generally lessen the existing procedural and reporting requirements for covered entities. The Department has determined that the impact would not approach the annual \$100 million threshold for major economic consequences as defined in E.O. 12291. Therefore, a regulatory impact analysis is not required.

Consistent with the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Secretary certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12612

E.O. 12612 requires that a Federalism Assessment be prepared in any cases in which proposed 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 rules proposed below as imposing

FAX



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Date: _____

Number of pages including cover sheet: 5

To: Heather Howard

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From: Cynthia

____ Original will not follow
____ Original will follow, via _____

MESSAGE:

~~referred~~

has been in preamble

never been in full

only advocate for doing so is Gary Bauer

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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Public Health Service

42 CFR Part 59

Standards of Compliance for Abortion-
Related Services in Family Planning
Service Projects

AGENCY: Public Health Service, DHHS.

ACTION: Interim rule; suspension of
effectiveness.

SUMMARY: This Interim rule suspends the rules issued in 1988 establishing standards for compliance by family planning services projects assisted under Title X of the Public Health Service Act with the statutory provision prohibiting abortion as a method of family planning in programs funded under that title. The rules, popularly known as the "Gag Rule", have been the focus of much litigation and controversy, and because the Secretary believes that the Rule inappropriately restricts grantees, she accordingly suspends them and, elsewhere in this issue of the Federal Register, proposes to return the program to the regulatory provisions and compliance standards operative prior to their issuance. This action is also consistent with a Memorandum issued by the President on January 22, 1993. During the pendency of the proposed rulemaking the compliance standards that were in effect prior to the issuance of the Gag Rule will be used to administer the program.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT:
Mr. Gerald Bennett, 202-690-8335.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services below suspends the rules issued on February 2, 1988, 53 FR 2922. Those rules, popularly known as the "Gag Rule," established standards for compliance by family planning services projects funded under Title X of the Public Health Service Act, 42 U.S.C. 300, et seq., with the statutory prohibition on the use of funds under that title "in programs where abortion is a method of family planning." 42 U.S.C. 300a-6. The prior history of the controversy surrounding sec. 300a-6 is fully described in the preamble to the 1988 rules.

Since their issuance, the February 2, 1988 rules have been the focus of much litigation and controversy. Although they were upheld by the Supreme Court in *Rust v. Sullivan*, 111 S.Ct. 1759 (1991), a subsequent interpretation of the rules by the Bush Administration,

under which physicians would have been permitted to counsel and refer Title X patients for abortion counseling and referral but other project employees would not have been permitted to do so, was recently held to be impermissible by the United States Court of Appeals for the District of Columbia Circuit, *National Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992). This recent decision, together with the change of Administrations, has left the current status of the 1988 Title X rules unclear.

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Under these compliance standards, Title X projects would be required, in the event of an unplanned pregnancy and where the patient requests such action, to provide nondirective counseling to the patient on options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects.

However, consistent with the prior long-standing Departmental interpretation of the statute, Title X projects would not be permitted to promote or encourage abortion as a method of family planning, such as engaging in pro-choice litigation or lobbying activities. Title X projects would also be required to maintain a separation (that is more than a mere exercise in bookkeeping) of their project activities from any activities in which they engage that promote or encourage abortion as a method of family planning.

As noted in the President's memorandum, these compliance standards were in effect for a considerable period of time prior to 1988, and the Department believes that they are generally well-understood within the Title X provider community.

Notice and comment and delay in effective date are waived for good cause and because delay would be impracticable and unnecessary and contrary to the public interest. The

issues involved in this matter are well known and have been extensively debated. Based on that record, it is the conclusion of the Secretary that: (1) Repeated attempts by the Bush and Reagan Administrations to enforce and modify the "Gag Rule" have created considerable confusion about the status of the regulations and the policy underlying them and, therefore, a substantial health risk to potential recipients of Title X program services; (2) suspension of the regulation, though tantamount to a statement of enforcement policy, is preferable because it provides clearer guidance and more certainty to the grantees and to women making family planning decisions; (3) the 1988 regulation would require many grantees to make extensive and expensive alterations in their physical facilities and organizational structures. To require those changes in the face of the proposed reversal of those rules is impracticable and contrary to the public interest; (4) evidence exists that the continued failure to provide women with complete and accurate medical information will result in significant health risks. The Notice of Proposed Rulemaking being contemporaneously published will give those with differing views on the matter an opportunity to rebut this conclusion. In the interim, the Secretary believes that it is important not to continue the embargo of important health information; (5) the original interpretation of section 1008, which prohibited the use of Title X funds in programs where abortion is a method of family planning, did not include a prohibition on non-directive counseling on abortion; moreover, Congress's repeated attempts—vetoed by President Bush—to amend Title X to eliminate the restrictions justify suspension of the Rule while the regulations are being revised to further the purposes of Title X, as required by statute. For all of these reasons, as well as the reasons set out in the President's Memorandum, this Interim Rule is effective upon publication. Regional officials are being informed of this action, and will notify all present Title X grantees of the suspension of the 1988 rules.

List of Subjects in 42 CFR Part 59

Family planning—birth control. Grant programs—health. Health facilities. Low-income families.

Dated: January 29, 1993.

Andrey F. Manley,

Acting Assistant Secretary for Health.

Approved: February 1, 1993.

Donna E. Shalala,
Secretary.

For the reasons set out in the
preamble, the Secretary amends subpart
A of 42 CFR part 59 as follows:

PART 59—[AMENDED]

1. The authority for subpart A of part
59 continues to read as follows:

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

§ 59.2 [Suspended]

2. The following definitions in § 59.2
are suspended: The definitions of
"Family planning", "Grantor",
"Prenatal care", "Program", "Project",
"Title X", "Title X program", and "Title
X project."

§§ 59.7-59.10 [Suspended]

3. Sections 59.7 through 59.10 are
suspended.

4. Additionally, the miscellaneous
amendments to § 59.5 on 53 FR 2944,

paragraphs 3 and 4, and the
miscellaneous amendments appearing
on 53 FR 2946, paragraph 6, are
suspended.

[FR Doc. 93-2732 Filed 2-3-93; 1:18 pm]
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7463

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Office of the Secretary

Actions Regarding Family Planning
Service Projects, Transplantation of
Human Fetal Tissue, and Importation
of the Drug Mifepristone

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In accordance with directives
of President Clinton dated January 22,
1993, I have today ordered that the
following actions be taken:

- (1) The Standard of Compliance for
Abortion-Related Services in Family
Planning Service Projects (the "Gag Rule") is
to be suspended, pending the publication of
regulations to formally rescind the rule.
 - (2) The temporary moratorium imposed
March 22, 1988, by the Assistant Secretary
for Health and continued by the previous
Secretary on November 2, 1989, prohibiting
Federal funding of research involving
transplantation of human fetal tissue from
induced abortions, is to be rescinded.
 - (3) Food and Drug Administration Import
Alert 66-47, importation of the drug
Mifepristone ("RU-486") is to be immediately
and thoroughly reviewed regarding the
health and safety implications of potential
import of the drug for personal use.
- FOR FURTHER INFORMATION CONTACT:

Audrey Manley, M.D., M.P.H., Acting
Assistant Secretary for Health, Public
Health, Public Health Service (202) 890-
7694.

SUPPLEMENTARY INFORMATION: The
Standard of Compliance for Abortion-
Related Services in Family Planning
Service Projects (the "Gag Rule")—In
documents printed elsewhere in this
issue of the Federal Register, the
amendments to 42 CFR part 59, subpart
A, published on February 2, 1988 (53 FR
2922)—commonly referred to as the
"Gag Rule"—are suspended and new
regulations are proposed to govern the
Family Planning program established
under Title X of the Public Health
Service Act.

**Federal Funding of Fetal Tissue
Transplantation Research**—This notice
advises the public that the PHS is
directed to rescind the moratorium
imposed on March 22, 1988 which
prohibits Federal funding of research
involving transplantation of human fetal
tissue from induced abortions. Such
funding may be provided, subject to the
procedures and protections which
govern Federal support of biomedical
research, and subject to guidelines as
recommended by a National Institutes
Health advisory committee. Interim
guidelines are to be prepared
immediately by the Director of the

National Institutes of Health, as
recommended by the committee, to
assure that Federal support of such
research does not encourage the choice
of induced abortion.

**FDA Alert 66-47 Excluding
Importation of the Drug Mifepristone
("RU-486")**—The FDA has been
directed to initiate immediate and
thorough review, directed at the health
and safety implications of potential
import of the drug for personal use.
Findings of the review are to be reported
promptly to the Secretary. If sufficient
evidence does not exist to warrant
exclusion of the RU-486 from the list of
drugs that qualify for the personal use
importation exemption, this import alert
shall be rescinded. At the same time,
FDA is directed to promptly assess
initiatives to promote testing of RU-486
or other antiprogestins in the United
States, and, as appropriate, licensing
and manufacturing in this country, and
report on options to the Assistant
Secretary for Health and the Secretary.

The President's memoranda are
published in Part IV of this Federal
Register issue.

Donna E. Shalala,
Secretary.

[FR Doc. 93-2738 Filed 2-3-93; 1:18 pm]
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