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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

RIN: 0940–AA00

Standards of Compliance for 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, with one revision, that applied to the program prior to February 2, 1988. Several technical changes to the regulation are also made to remove and/or update obsolete regulatory references. The effect of the revisions 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.

DATES: These rules are effective July 3, 2000.

FOR FURTHER INFORMATION CONTACT: Samuel S. Taylor, 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 and one substantive modification, 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 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 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 polices 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) Prohibited the provision to Title X clients of nondirective counseling on all pregnancy options and referral to abortion providers, (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. 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 not 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. Indeed, the rule itself, now requires the provision to pregnant women, on request, of neutral, factual information and non-directive counseling on each of three options. 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 she must justify each separate part of the Gag Rule being discarded, we do not agree. The pre-1988 interpretation of the statute represents a permissible exercise of administrative discretion. The crucial difference between this approach and the Gag Rule is one of experience. Because of ongoing litigation, the Gag Rule was never implemented on a nationwide 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 reflected in, 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 these policies and interpretations, 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.

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 and comment period. The Secretary has thus addressed the concern about notice of the content of the policies and interpretations expressed by these comments.

As is further discussed below, the Secretary has incorporated in the regulatory text the policies relating to nondirective counseling and referral of the 1981 Program Guidelines for Project Grants for Family Planning Services (1981 Guidelines). The comments urging that these Guidelines requirements be reflected in the regulations have thus been accepted. With respect to the longstanding program interpretations, however, the Secretary does not agree that the Department is required to set out those

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, the Secretary has decided not to do so. With respect to the areas that continue to be covered by guidance, the Secretary believes that incorporating the guidance into the regulations below would be inadvisable and unnecessary. 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 grantees have operated on the basis of the policies of the 1981 Guidelines and the interpretations summarized in the notice published elsewhere in this issue of the **Federal Register** for virtually the entire history of the program 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 31 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/HARD–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 believe that the notice will provide grantees with sufficient guidance to reduce or eliminate potential variations in grantee practice.

The Secretary views this final rule, the principal purposes of which are to revoke the Gag Rule and adopt the counseling and referral requirements noted, as separate and severable from the Notice. The interpretations set out in the Notice are being set out in order to clarify 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 interpretations reflected in the Notice rather than at the revision of the regulation itself. Were the policies set forth in the Notice to be challenged or invalidated, 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 project and from engaging in counseling and referral practices inconsistent with the regulatory requirements adopted in that section. Such an outcome would be consistent with a permissible interpretation of the statute.

C. Amend, or Adopt a More Restrictive Reading of, the Statute

Fifteen of the comments that stated support for 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 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 provisions 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 that 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 legislation 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 suggestions 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 requests:

- 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 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.

A number of comments argued that the regulatory text should reflect the requirement for nondirective counseling and referral. These comments recommended that the final regulations include specific language providing for options counseling as a necessary component of quality reproductive health care services. Some cited medical ethics and good medical care as requiring that patients receive full and complete information to enable them to make informed decisions. For example, a leading medical organization commented that all women, regardless of their income level, have a right to full and accurate information about all options for managing an unwanted pregnancy. The organization pointed out that it is essential that the program regulations contain specific language about the counseling and referral requirements, and recommended the incorporation of sections of the 1981 Title X program guidelines into the regulations so as to be absolutely clear that pregnancy counseling and referral must be provided to patients facing an unwanted pregnancy upon request. Congress has also repeatedly indicated that it considers this requirement to be an important one: the program's four most recent appropriations, Pub. L. 104–208 (110 Stat. 300–243), Pub. L. 105–78 (111 Stat. 1478), Pub. L. 105–277 (112 Stat. 2681), and Pub. L. 106–113 (113 Stat. 1501–225), required that pregnancy counseling in the Title X program be ''nondirective.'' Consequently, the Secretary has decided to reflect this fundamental program policy in the regulatory text. *See,* § 59.5(a)(5) below. The interpretive summary has also been revised to reflect this change to the regulation. However, in response to the apparent confusion as to the amount of counseling permitted to be provided under the pre-1988 interpretations, the interpretive summary 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. It should be noted, though, that the previous restriction as to the ''type'' of information that may be provided about abortion continues: Information and counseling provided by Title X projects on all options for pregnancy management, including pregnancy termination, must be nondirective. Thus, grantees may provide as much factual, neutral information about any option, including abortion, as they consider warranted by the circumstances, but may not steer or direct clients toward selecting any option, including abortion, in providing options counseling.

The Secretary is retaining the ''on request'' policy in the regulatory language adopted below, on the ground that it properly implements the requirement for nondirective counseling. If projects were to counsel on an option 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 a particular option. 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; indeed, such an offer is required under § 59.5(a)(5) below. However, if the client indicates that she does not want information and counseling on any particular option, that decision must be respected. The regulatory language below reflects this policy. Also, consistent with longstanding program practice and sound public health policy (see the discussion in the following paragraphs) and to avoid ambiguity in when the offer of pregnancy options counseling must be made, the rule has been clarified to require the offer of pregnancy options counseling to be made whenever a pregnant client presents, not just when the pregnancy is ''unintended.''

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'' and the regulatory language adopted below 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, totally omitting information on a legal option or removing an option from the client's consideration necessarily steers her toward the options presented and is a directive form of counseling. 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, 199–1997 ed. 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.). By contrast, the 1981 Guidelines required appropriate referral on request, while the pre-1988 interpretations 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 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 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.

Consistent with the incorporation of the requirement for nondirective counseling in the regulations, the regulations below also include the remaining requirement from the 1981 Guidelines, the requirement to provide a referral, if requested by the client. As referenced previously, a number of comments argued that the regulatory text should reflect the requirement for nondirective counseling and referral. One comment described the provision of factual information and referral as requested as both a necessary and significant component of the Title X program for many years. Another comment pointed out that the program guideline requirements regarding pregnancy options counseling and referral have been used for many years, are well understood and accepted in the Title X provider community, and should be required services in Title X family planning clinics. Since the services about which pregnancy options counseling is provided are not ones which a Title X project typically provides, the provision of a referral is the logical and appropriate outcome of the counseling process.

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 regulations and 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 space 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 regulatory language adopted below, the options of prenatal care and delivery and adoption are options that are required to be part of the options counseling process, so an

appropriate referral for one or the other option would be required, if the client chose one of those options and requested a referral. However, requiring a referral for prenatal care and delivery or adoption where the client rejected those options would seem coercive and inconsistent with the concerns underlying the ''nondirective'' counseling requirement. The Secretary also rejects the criticism that the provision requiring referral for abortion where medically indicated is undefined and confusing. 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. 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 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. However, the Department will continue to monitor the issue of self-referrals in the Title X program, to forestall the type of problem suggested by these commenters.

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 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-relation 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 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 parental 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 patent 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 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 abortions 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 the 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 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 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 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 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 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 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 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 issues 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 clarify the existing provisions or 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 of 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. § 59.11: The word ''documented'' has been inserted before the word ''consent'' in this section to clarify what was implicit in this section, that the consent for disclosure must be documented by the project.

7. § 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 adopted in the regulations below and the interpretations adopted in conjunction with them 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 the Regulatory Flexibility Act (5 U.S.C. 601–612), and certifies that this final rule will not have a significant impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act (the 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. This rule will not result in such an expenditure; consequently, it is not covered by Section 202 of the Act.

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. The Department does not intend or interpret this final rule as imposing additional costs or burdens on the States. The Department has evaluated the public comments. Public comments from State and local health departments indicate support for the Title X policies contained in the final rule and the interpretations to ensure the provision of quality medical care and patients' rights to comprehensive services. In the interest of consistent program operation and uniform understanding of the policy, the final rule codifies what has been longstanding program policy and is consistent with current program practice.

The Office of Management and Budget has reviewed this rule pursuant to Executive Order 12866.

List of Subjects in 42 CFR Part 59.

Family planning—birth control; Grant programs—health; Health facilities.

Dated: June 28, 2000.

David Satcher,

Assistant Secretary for Health and Surgeon General.

Approved: June 28, 2000.

Donna E. Shalala,

Secretary.

PART 59—GRANTS FOR FAMILY PLANNING

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:

Subpart A—Project Grants for Family Planning Services

Sec.

Subpart A—Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a–4.

§ 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. 3200) 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. Outlaying Islands (Midway, Wage, *et al.*), the Marshall Islands, the Federated State 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 participated 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 of religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or martial status.

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

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

(A) Prenatal care and delivery;

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

(C) Pregnancy termination.

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

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

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

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

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

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

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

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

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

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

[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.''

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 documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure orb protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

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