Shorter version

The Department's Response

In responding to these comments the following issues are addressed:

Constitutional Issues

- Argument -- The regulations violate minor's right to unrestricted access to contraceptives and constitutional right to privacy (Eisenstadt, Carey, Danforth).
- Response -- These cases are not pertinent because they deal with attempts by government to regulate access to family planning services. The regulations do not prohibit access to contraceptive services. The regulations implement a Federal assistance program (Title X) according to the conditions Congress has established for provision of the assistance.
- Argument -- The regulations unconstitutionally discriminate on the basis of gender since they apply only to prescription contraceptives which are used only by females.
- Response -- The regulations are a gender-neutral distincion focusing on health risks. If contraceptives for male use become available, the regulations would apply.

Legislative Intent

- Argument -- The regulations conflict with the legislative history and language of Title X:

- Response -- These arguments interpret individual parts of Title X and its history without considering the course of statutory development. Congress ultimately did amend section 1001(a) in 1981 to include requirement that projects encourage family participation.

- Argument -- The regulations conflict with legislative intent of the 1981 amendment to encourage family participation but not to mandate family involvement.

- Response -- The regulations do not mandate family involvement. They simply provide opportunity for family involvement. The regulations strike a desirable balance between requirement that adolescents receive services and requirement that family participation be encouraged to the extent practical.

Rights of Minors

- Argument -- Teenagers should have the right to obtain family planning services in complete confidentiality and that their interest should outweigh interest of their parents in notification.

  The regulations will constitute a breach of confidentiality of the doctor-patient relationship.

- Response -- The regulations require that projects advise minors of the notification requirement before providing services. By accepting services, minors will, in effect, be consenting to notification.

Low Income Discrimination

- Argument -- The regulations discriminate against minors on the basis of income.

- Response -- The amendment to the low income definition simply removes the requirement that projects consider minor's income and not the family resources. This amendment puts minors on the same footing as all other applicants for services.

Rights of Parents

- Argument -- The regulations should be revised to require parental notification prior to services.
- Response -- Piror notification could unduly delay or otherwise restrict access to services for adolescents contrary to statute.

- Argument -- Regulations should require parental consent.
- Response -- Consent would not maintain the proper balance between competing concerns of the statute that services be provided to adolescents and family participation be encouraged.

Effects on Society

- Argument -- The regulations will impose major societal costs because of an increase in adolescent pregnancies with costs for prenatal care, post-delivery support, and the lost human potential associated with teenage motherhood.

- Response -- This argument is based on the assumption that the regulations will increase adolescent pregnancies which we reject as highly conjectural. The predictions based on this assumption are equally speculative.

Family Participation

- Argument -- The regulations will negatively affect family relationships by causing anger and refusal to communicate.

- Response -- While there may be various possible outcomes, we conclude that the benefits of the regulations outweigh potential disadvantages and that the regulations are reasonably designed to implement the statutory mandate that family participation be encouraged.

- Argument -- The regulations are unnecessary because data indicate that over half of adolescents already tell their parents and that most clinics have programs to involve parents.

- Response -- We are encouraged that many family planning clinics recognize the value of parental involvement. That some parents are already involved should minimize adjustments clinics need to make to comply with the regulations but does not lessen the improtance of notifying all parents when their minor receives prescription contraceptives.

Effects on Family Planning Projects

- Argument -- Procedural costs of notification and verification will impose severe hardships and detract from ability to deliver services to eligible patients.

- Response -- While the regulations will impose some additional costs and administrative burdens, we believe certified mail (with restricted delivery and return receipt requested) ensures notification and verification at minimal expense and effectuates family involvement policies. Record-keeping is necessary to monitor project compliance. Counseling about notification, indirect expenses, and handling exemptions will not impose substantial costs on projects.

Effects of Notification on Minors

- Argument -- The regulations will result in large upswing in numbers of teenage pregnancies and abortions and an overall deterioration of adolescent health, particularly because of greater risks associated with pregnancy.

- Response -- This argument is misguided. Estimates of the numbers of additional pregnancies likely to result have been misguided. Parental notification is justifiable on health grounds. Prescription contraceptive practices of teenagers may improve as a result of parental involvement.(See Ayer, 1982) Some teens may be persuaded by parents to abstain from sexual activity.

- Argument -- The degree of health risk incurred by teenagers who use prescription contraceptives does not justify the regulations.

- Response -- We recognize difference of opinion between medical experts about the kinds and degrees of risk for teens using prescription contraceptives. However, clearly some measure of health risk does exist for prescription contraceptives and parental notification is necessary to protect the health of the child.

Comments on Specific Provisions of the Rules

Notification Requirement

- Argument -- The rule would require repeated notification.

- Response -- Notification applies only to "initial" provision of prescription contraceptive and when notification has been verified, no further notice is required for subsequent services.

Limitation to Prescription Drugs and Devices

- Argument -- Health risks of prescription contraceptives are relatively small compared to the risks of pregnancy.

- Response -- We do not agree with projections made as to the increase of teenage pregnancy likely to result from requiring notification of prescription methods. If an adolescent objects to notification, a project can provide non-prescription contraceptives and education.

- Argument -- The diaphragm should not be included because it poses no appreciable health risk.

- Response -- Prescription classification has not been changed to exclude diaphragms. We believe it is reasonable to defer to medical judgments made at the State and Federal levels concerning the safety and health criteria for the prescription classification.

Exception for Adverse Physical Harm

- Argument -- The exception should be broadened to include harm of a mental or emotional nature.

- Response -- The difficulty of determination and ambiguity of the concept would create administrative problems and could so expand the exception as to vitiate the rule.

- Argument -- The exception should be expanded to include other potential victims, such as a boyfriend who may be harmed by the minor's father, and other potential abusers, such as a sibling unhappy because of resulting parental restrictions on behavior.

- Response -- Such expansion would create practical difficulties in determining the likelihood of harm. We believe such cases of related abuse will be exceedingly rare.

- Argument -- The exception covers threatened pregnancy as substantial physical harm if notification would inhibit a minor's use of contraceptives.

- Response -- Exception applies to harm by a parent or guardian. Except in cases of incest, a threat of pregnancy would not qualify under the exception.

- Argument -- Exception imposes costly investigation and documentation requirements.

- Response -- Projects are required to describe factual basis underlying determinations that the exceptions applies but are not required to investigate medical and court records. Projects are expected to base determinations on reasonable professional judgment.

Definition of "Unemancipated Minor"

- Argument -- The regulations inconsistently defer to State laws that are more restrictive than the proposed definition while overriding the legislative judgment of 30 States which permit minors to consent to receiving birth control services.

- Response -- Definition does not override legislative judgment of 30 States Minors in those States continue to be able to consent to receipt of prescription services. State laws generally do not deal with the issue of notification. Case law establishes that it is reasonable to set a Federal age standard to accomplish a Federal statutory purpose.

- Argument -- The regulations are subject to fraud because minors will lie about their age or use bogus identification cards.

- Response -- Projects should follow their established procedures for determining when a minor is emancipated.

Exception for Venereal Disease

- Argument -- The public health risk of pregnancy is equivalent to that of STD.

- Response -- This argument does not consider the relevant risk in its entirety: the public health risk is not limited to females who forego contraception while engaging in sexual activity but rather extends to the entire sexually active adolescent population.

- Argument -- The same considerations apply to the treatment of STD that apply to prescription contraceptives.

- Response -- Materially different considerations are involved since there is no reasonable alternative to treatment of STD while a number of alternatives exist for the prescription contraceptive decision.

Definition of Low Income Family

- Argument -- The change is unfair to poor and minority adolescents.
- Response -- We continue to believe that it is inappropriate to target increasingly scarce Title X dollars to minors who, because of family circumstances, can pay all or a portion of the cost of the services. The change will be an improvement over the present definition that diverts Federal monies from those who most need financial assistance.
- Argument -- The change would present additional administrative problems for the projects.
- Response -- Currently, projects are required to make income determinations to decide whether patients are low income. We assume projects will continue to use procedures they have already developed.

DRAFT

PARENTAL NOTIFICATION REGULATIONS

SUMMARY

The Department of Health and Human Services announced (date) a notice of final rulemaking for federally funded family planning centers. The rules require these projects to notify the parent or guardian of unemancipated minors seeking family planning services when prescription drugs or devices are provided.

The rules implement a 1981 amendment to Title X of the Public Health Service Act which calls for projects supported by Title X funds to encourage family participation in the provision of family planning services.

In addition, where State law requires parental notification or consent to the provision of family planning services to minors, projects must comply with such a law. The rules also remove from existing regulations a provision requiring projects to disregard family income when determining fees to be charged for services to certain minors.

These rules are effective 30 days following the date of publication in the Federal Register.

BACKGROUND

On February 22, 1982, the Secretary of Health and Human Services proposed rules implementing the Title X amendment effected by Public Law 97-35 (Omnibus Budget Reconciliation Act of 1981) and clarifying the obligation of grantees to comply with certain applicable State laws (47 F.R. 7699).

The Secretary's request for public comment on the proposed rules elicited an overwhelming response. Over 120,000 individuals and organizations contributed to the public comment by writing letters, signing petiitions or sending form cards or letters, and these comments were duly considered.

The issues raised by the public reflect this broad base of interest and are, accordingly, extremely diverse. In addition to comments from thousands of teenagers and parents, approximately 1,200 letters were received from a broad spectrum of organizations, including family planning clinics, State and local governmental agencies, national and local professional groups, and church groups. Moreover, approximately 250 form letters, containing about 7,000 signatures, were received and about 50 different types of form postcards were sent in by some 10-20,000 individuals. Approximately 400 petitions were submitted, many containing thousands of signatures.

Proposed rules.

Under the proposed rules, Title X projects would be required to notify the parents or guardian of an unemancipated minor when prescription drugs or devices are provided to such minor. A Federal definition of the term "unemancipated minor" was proposed for purposes of this requirement. This definition treats minors age 17 or under as unemancipated

generally, but otherwise looks to State law to determine what specific acts, such as marriage or parenthood, constitute acts of emancipation. Projects would also be required to inform the minor, prior to the provision of the service, about the notification requirement. Projects would be required to notify the minor's parents or guardian within 10 working days following the initial provision of services by the project, except when the project director determines that notification would result in physical harm to the minor by the parents or guardian. Projects would be required to keep records of the number of such exceptions, as well as reasons for the determination. Where notification is provided, projects will be required to verify that it was received and to keep records of the notification and verification.

Projects would also be required to comply with any State law requiring that notification be provided to or consent obtained from the parents or guardian of unemancipated minors regarding the provision of family planning services to such minors. Finally, the definition of "low income family" in the current regulations would be changed by eliminating the requirement that projects consider adolescents on the basis of their own resources (rather than their families' resources) for purposes of charging for services.

Public Comment

The numbers and the nature of many of the comments make a precise count of the comment "for" and "against" the proposed rules impossible. For example, while many comments opposed the proposed rules as ~~inquiring~~ requiring too much intervention in the family planning decisions of minors, others opposed them on the ground that they did not require enough. In general, however, the public comment disclosed both a wide base of support

for, as well as opposition to, the policies of the proposed rules. The Department has carefully considered the specific issues raised by the comments, and they are discussed below. However, the Department's ultimate concern is with the merits of the points made in the comments rather than the number of times they were made. Therefore, ~~we do not~~ there is no discussion except in general terms, about the extent of support for particular points made by the public comment.

The public comment submitted was generally of two types. On the one hand, the majority the public comment either criticized or commended the proposed rule on the basis of issues the underlie the rule as a whole and supported their positions by: citing personal experiences; arguing moral, philosophical or religious grounds; utilizing medical reports and social science date; or presenting legal arguments. For example, numerous comments contained projections on the proposed rule's probable effect on teenage pregnancy, abortion, sexual behavior, welfare dependency and so on. Similarly, a number of comments raised legal issues about the overall approach of the proposed rules, such as the right of privacy of minors, custodial rights of parents, and the confidentiality of the doctor-patient relationship. A minority of the comments, on the other hand, addressed issues raised by specific provisions of the proposed rules. For example, a number of particular concerns were raised about the verification provision, including problems of ambiguity, cost and potential for fraud.

The Department's Response

In responding to these comments the following issues are addressed:

Constitutional Issues

- Argument -- The regulations violate minor's right to unrestricted access to contraceptives and constitutional right to privacy (Eisenstadt, Carey, Danforth).
- Response -- These cases are not pertinent because they deal with attempts by government to regulate access to family planning services. The regulations do not prohibit access to contraceptive services. The regulations implement a Federal assistance program (Title X) according to the conditions Congress has established for provision of the assistance.

- Argument -- The regulations unconstitutionally discriminate on the basis of gender since they apply only to prescription contraceptives which are used only by females.

- Response -- The regulations are a gender-neutral distincion focusing on health risks. If contraceptives for male use become available, the regulations would apply.

Legislative Intent

- Argument -- The regulations conflict with the legislative history and language of Title X:
  - -- basic authorizing legislation provides that projects shall offer a broad range of services without limitation;
  - -- 1978 amendment expressly requires services for adolescents and has no language which would support regulations;
  - -- Congress has perviously rejected attempts to require notification or consent.

- Response -- These arguments interpret individual parts of Title X and its history without considering the course of statutory development. Congress ultimately did amend section 1001(a) in 1981 to include requirement that projects encourage family participation.

- Argument -- The regulations conflict with legislative intent of the 1981 amendment to encourage family participation but not to mandate family involvement.

- Response -- The regulations do not mandate family involvement. They simply provide opportunity for family involvement. The regulations strike a desirable balance between requirement that adolescents receive services and requirement that family participation be encouraged to the extent practical.

Rights of Minors

- Argument -- Teenagers should have the right to obtain family planning services in complete confidentiality and that their interest should outweigh interest of their parents in notification.

  The regulations will constitute a breach of confidentiality of the doctor-patient relationship.

- Response -- The regulations require that projects advise minors of the notification requirement before providing services. By accepting services, minors will, in effect, be consenting to notification.

Discrimination

Gender -- see constitutional arguments

Age Discrimination

- Argument -- The regulations require discrimiantion on the basis of age in a manner that violates the Age Discrimination Act of 1975 and the Department's implementing regulations.

- Response -- The Act and implementing regulations create an exception where age is used as a measure of some other characteristic which is sought to be ascertained in order to achieve legitimate program purpose and can not be ascertained individually. These regulations use age as a measure of a minor's ability to make important decisions about prescription contraceptives in order to encourage family participation as required by statute and given the nature of the program and the large number of minors served, the ability to make these decisions cannot be ascertained on an individual basis.

Low Income Discrimination

- Argument -- The regulations discriminate against minors on the basis of income.

- Response -- The amendment to the low income definition simply removes the requirement that projects consider minor's income and not the family resources. This amendment puts minors on the same footing as all other applicants for services.

Rights of Parents

- Argument -- The regulations should be revised to require parental notification prior to services.
- Response -- Piror notification could unduly delay or otherwise restrict access to services for adolescents contrary to statute.

- Argument -- Regulations should require parental consent.
- Response -- Consent would not maintain the proper balance between competing concerns of the statute that services be provided to adolescents and family participation be encouraged.

Family Participation

- Argument -- The regulations will negatively affect family relationships by causing anger and refusal to communicate.

- Response -- While there may be various possible outcomes, we conclude that the benefits of the regulations outweigh potential disadvantages and that the regulations are reasonably designed to implement the statutory mandate that family participation be encouraged.

- Argument -- The regulations are unnecessary because data indicate that over half of adolescents already tell their parents and that most clinics have programs to involve parents.

- Response -- We are encouraged that many family planning clinics recognize the value of parental involvement. That some parents are already involved should minimize adjustments clinics need to make to comply with the regulations but does not lessen the improtance of notifying all parents when their minor receives prescription contraceptives.

Effects of Notification on Minors

- Argument -- A 1982 study by Furstenberg et al shows that parental awareness and involvement do not increase consistency in contraceptive use.

- Response -- This 1982 study is limited and does not comport with findings reached in several other studies (Fox, 1981) and therefore we are unpersuaded by its conclusions.

- Argument -- Assurance of confidentiality is one of the major factors, if not the major factor, in decisions of minors to seek family planning services.

- Response -- We do not believe sufficient data has been developed to support this contention. (See Zabin and Clark, "Why they Delay . . . 1981)

- Argument -- The regulations will result in large upswing in numbers of teenage pregnancies and abortions and an overall deterioration of adolescent health, particularly because of greater risks associated with pregnancy.

- Response -- This argument is misguided. Estimates of the numbers of additional pregnancies likely to result have been misguided. Parental notification is justifiable on health grounds. Prescription contraceptive practices of teenagers may improve as a result of parental involvement.(See Ayer, 1982) Some teens may be persuaded by parents to abstain from sexual activity.

Effects of Notification of Minors (cont'd)

- Argument -- The degree of health risk incurred by teenagers who use prescription contraceptives does not justify the regulations.

- Response -- We recognize difference of opinion between medical experts about the kinds and degrees of risk for teens using prescription contraceptives. However, clearly some measure of health risk does exist for prescription contraceptives and parental notification is necessary to protect the health of the child.

  We intend to monitor closely the effects of the regulations' implementation and to reconsider its appropriateness in light of any reliable data that are developed regarding its effects.

Effects on Family Planning Projects

- Argument -- Procedural costs of notification and verification will impose severe hardships and detract from ability to deliver services to eligible patients.

- Response -- While the regulations will impose some additional costs and administrative burdens, we believe certified mail (with restricted delivery and return receipt requested) ensures notification and verification at minimal expense and effectuates family involvement policies. Record-keeping is necessary to monitor project compliance. Counseling about notification, indirect expenses, and handling exemptions will not impose substantial costs on projects.

- Argument -- Regulations will impose signficant costs on non-Title X projects because of increased numbers of adolescent patients who willnot go to Title X clinics.

- Response -- These concerns are highly speculative. We are not persuaded that the regulations will lead to a large shift of minors to non-Title X clinics.

Effects on Society

- Argument -- The regulations will impose major societal costs because of an increase in adolescent pregnancies with costs for prenatal care, post-delivery support, and the lost human potential associated with teenage motherhood.

- Response -- This argument is based on the assumption that the regulations will increase adolescent pregnancies which we reject as highly conjectural. The predictions based on this assumption are equally speculative.

  The Department will, of course, consider any reliable data developed with respect to these concerns.

Comments on Specific Provisions of the Rules

Notification Requirement

- Argument -- Parental notification should occur prior to provision of services to enable parents to discuss contraceptive use with the minor before it is prescribed.

- Response -- Pre-service notification is inconsistent with the statute's goal of providing access to services. The 10-day rule will assure parents can be involved on a timely basis and should serve to provide most of the benefits sought by those who supported pre-service notification.

- Argument -- The rule would require repeated notification.

- Response -- Notification applies only to "initial" provision of prescription contraceptive and when notification has been verified, no further notice is required for subsequent services.

- Argument -- Potential problems and costly logistical difficulties arise if both parents must be notified such as when children live with only one or neither parent.

- Response -- To meet thse concerns, the phrase has been changed from "parens or guardian" to "parent or guardian which has been defined as "a parent or guardian residing with the minor or otherwise exercising ordinary parental functions with respect to the minor."

Notification Requirement (cont'd)

- Argument -- Class of persons to whom notification may be provided should be expanded to include siblings or other relatives selected by the minor.

- Response -- While we recognize other relatives may have a quasi-parental influence on the minor, we do not believe it would be appropriate to allow involvement of these relatives to supersedethe parent's or guardian's interest in and responsibility for the minor. Minors can still seek advice of such relatives.

- Argument -- The regulations are too vague about the method of notification and present mechanical problems and significant costs depending on the type of notification required.

- Response -- The regulations have been modified to require that notification be accomplished by certified mail (with restricted delivery and return receipt requested) or similar evidence of notification. This will result in minimal expense while still effectuating the statutory intent.

- Argument -- Notification will require health professionals to violate State statutes and Department regulations requiring that family planning services be provided confidentially.

- Response -- No notification is undertaken until the minor is advised of notification and consents to services knowing that notification will occur. Therefore, the regulations do not violate State statutes or Departmental regulations.

Verification

- Argument -- The regulations are too vague about the method of verification and too susceptibe to fraud.

- Response -- The regulations now specify that documentary verification is required. Where certified mail is used, it must be on a restricted delivery, return receipt basis. If any other method is used, the clinic must obtain a "similar form of documentation." The documentation should be reasonably designed to assure that it was signed by the parent or guardian.

- Argument -- The regulations fail to specify how parental refusal to acknowledge notification should be handled.

- Response -- The regulations make clear that failure to obtain requisite documentation means that additional prescription services may not be provided. We leave to the judgment of the project personnel how much effort should be made to obtain verification.

- Argument -- Clinics will face liability in responding either positively or negatively to a continued request for prescription contraceptives from a minor if parents object to such services after notification.

- Response -- The question of liability of a project which receives verification but parent objects to continuance of services is dependent on State law and is a judgment routinely made by projects providing services to minors.

Limitation to Prescription Drugs and Devices

- Argument -- Parents have a right to know of all contraceptives, prescription or non-prescription, given to their children.

- Response -- While recognizing that parents have a legitimate concern in being informed of all contraceptive use by their children, we must weigh the two competing statutory concerns of providing adolescents with family planning services and of encouraging family involvement. Health risks generally associated with prescription contraceptives necessitate promotion of family involvement.

- Argument -- Health risks of prescription contraceptives are relatively small compared to the risks of pregnancy.

- Response -- We do not agree with projections made as to the increase of teenage pregnancy likely to result from requiring notification of prescription methods. If an adolescent objects to notification, a project can provide non-prescription contraceptives and education.

- Argument -- The diaphragm should not be included because it poses no appreciable health risk.

- Response -- Prescription classification has not been changed to exclude diaphragms. We believe it is reasonable to defer to medical judgments made at the State and Federal levels concerning the safety and health criteria for the prescription classification.

Limitation to Prescription Drugs and Devices (cont'd)

- Argument -- The prescription classification discriminates against women because it precludes all effective methods of female contraception without parental notification but does not preclude analogous male methods.

- Response -- Prescription classification does not affect all women, just those choosing prescription methods. If a male prescription method becomes available, the regulations would apply.

Exception for Adverse Physical Harm

- Argument -- The exception should be broadened to include harm of a mental or emotional nature.

- Response -- The difficulty of determination and ambiguity of the concept would create administrative problems and could so expand the exception as to vitiate the rule.

- Argument -- The exception should be expanded to include other potential victims, such as a boyfriend who may be harmed by the minor's father, and other potential abusers, such as a sibling unhappy because of resulting parental restrictions on behavior.

- Response -- Such expansion would create practical difficulties in determining the likelihood of harm. We believe such cases of related abuse will be exceedingly rare.

- Argument -- The exception is administratively unworkable by limiting the waiver authority to the project director.

- Response -- The exception is revised to provide that a project director may delegate authority to make such determinations to clinic directors.

Exception for Adverse Physical Harm (cont'd)

- Argument -- Exception fails to define the type and degree of physical harm.
- Response -- The exception does not need further clarification but is intended to cover cases where substantial harm is probable. To further define the exception would limit the flexibility of health professionals who routinely make judgments about whether substantial harm has occurred and is likely to recur.

- Argument -- The exception covers threatened pregnancy as substantial physical harm if notification would inhibit a minor's use of contraceptives.
- Response -- Exception applies to harm by a parent or guardian. Except in cases of incest, a threat of pregnancy would not qualify under the exception.

- Argument -- Exception imposes costly investigation and documentation requirements.
- Response -- Projects are required to describe factual basis underlying determinations that the exceptions applies but are not required to investigate medical and court records. Projects are expected to base determinations on reasonable professional judgment.

Exception for Adverse Physical Harm (cont'd)

- Argument -- Exception will expose project director to legal liability if minor is abused as a result of notification or if a parent was not notified because he/she was labelled as a child abuser.
- Response -- The decisions which the regulations require project personnel to make are not significantly different from many decisions which they make every day. Family planning clinics, in many areas, require notification or consent and we are unaware of significant liability problems.

Definition of "Unemancipated Minor"

- Argument -- The regulations inconsistently defer to State laws that are more restrictive than the proposed definition while overriding the legislative judgment of 30 States which permit minors to consent to receiving birth control services.

- Response -- Definition does not override legislative judgment of 30 States Minors in those States continue to be able to consent to receipt of prescription services. State laws generally do not deal with the issue of notification. Case law establishes that it is reasonable to set a Federal age standard to accomplish a Federal statutory purpose.

- Argument -- The regulations are subject to fraud because minors will lie about their age or use bogus identification cards.

- Response -- Projects should follow their established procedures for determining when a minor is emancipated.

- Argument -- Definition is unconstitutional because it does not provide an exception for mature minors.

- Response -- Court cases making the mature/immature distinction arose from governmental attempts to limit access to services and do not apply when government chooses to impose conditions on financial assistance.

Exception for Venereal Disease

- Argument -- "Venereal disease" should be replaced with "sexually transmitted diseases" (STD).

- Response -- "Sexually transmitted diseases" replace "venereal disease."

- Argument -- The public health risk of pregnancy is equivalent to that of STD.

- Response -- This argument does not consider the relevant risk in its entirety: the public health risk is not limited to females who forego contraception while engaging in sexual activity but rather extends to the entire sexually active adolescent population.

- Argument -- The same considerations apply to the treatment of STD that apply to prescription contraceptives.

- Response -- Materially different considerations are involved since there is no reasonable alternative to treatment of STD while a number of alternatives exist for the prescription contraceptive decision.

Requirement of Compliance with State Law

- Argument -- The regulations selectively defer to more restrictive State laws while overriding many less restrictive State laws providing for confidential family planning services to adolescents.

- Response -- The reulations are not inconsistent with State laws. While conflicts may exist to the extent States enact laws prohibiting notification, failure to defer to such laws is not indicative of a lack of consistency in the rule as a whole. We believe notification best accomplishes statutory intent. Thus, it would be inconsistent to defer to contrary State laws.

Definition of Low Income Family

- Argument -- The change in the definition of low income family will render family planning services unaffordable by adolescents (Chamie, 1982).
- Response -- Because of its methodology, we do not believe that the Chaimie study clearly establishes that lessening or eliminating the present subsidy will make services unaffordable.
- Argument -- The change will deter many adolescents, particularly from the middle class, from using family planning services.
- Response -- We do not agree that children of middle class families will foregoservices because of the change. Where a project is concerned about the possible effect of the change, it has some flexibility in pricing its services. In the few cases where parents who are able to help pay but refuse, clinics, in accordance with existing language of current regulations, will be able to adjust fees.
- Argument -- The change is unfair to poor and minority adolescents.
- Response -- We continue to believe that it is inappropriate to target increasingly scarce Title X dollars to minors who, because of family circumstances, can pay all or a portion of the cost of the services. The change will be an improvement over the present definition that diverts Federal monies from those who most need financial assistance.

Definition of Low Income Family (cont'd)

- Argument -- The change violates Title X because it presents an economic deterence for minors seeking services.
- Response -- The change does not violate Title X because it will not constitute an economic deterence. In section 1006(c) of Title X, it is the income of the family, not of the person, that is relevant. Also the legislative history makes clear that the focus is on "medically indigent families."

- Argument -- The change would present additional administrative problems for the projects.
- Response -- Currently, projects are required to make income determinations to decide whether patients are low income. We assume projects will continue to use procedures they have already developed.

Executive Order 12291

- Argument -- The Department must comply with the requirements of Executive Order 12291.
- Response -- These regulations are not major rules because they will not have an effect on the economy of $100 million or more. Also, we found that we have adequate information concerning the need for and consequences of the requirements imposed by the regulations, the potential costs, regulations maximize the net benefits to society, and among the alternatives available, these regulations involve the least net costs to society.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Monday, January 10, 1983

Claire del Real - (202) 245-6343

Health and Human Services Secretary Richard S. Schweiker announced today his intention to publish final rules implementing a 1981 Omnibus Budget Reconciliation Act provision which calls for encouragement of family participation in the use of federally-funded family planning services.

The rules would require that family planning projects and clinics receiving federal funds under Title X of the Public Health Service Act notify a parent or guardian of unemancipated minors aged 17 or younger within ten days after they give the minor a prescription contraceptive drug or device. Clinics would advise minors of this notification requirement prior to providing services.

"This department has a deep responsibility to protect the health and safety of minor adolescents who are given prescription birth control drugs or devices paid for with taxpayer dollars," said Secretary Schweiker.

"As Congress recognized in its 1981 legislation, when Title X-funded clinics provide prescription contraceptives to minors, family involvement is an important protection for our children.

"While this rule does not mandate family participation, its great benefit is that it will provide an opportunity for family involvement where parents were previously kept in the dark. This will help remove a barrier between parents and adolescents, thereby encouraging more communication in many families. The new rule strikes a reasonable balance between the need to make federally-funded family planning services available to adolescents and the rights of parents in matters involving the health of their children."

(More)

A proposed rule on parental notification was published for public comment on February 22, 1982. Over 120,000 individuals and organizations commented on the proposal.

"We carefully considered all the issues raised by the public comments, and carefully weighed the merits of each before deciding on the final rule," said Schweiker. He noted that publication of the rule in the Federal Register will be accompanied by specific responses to issues raised in the public comments.

The parental notification requirement would not apply to the giving of birth control information, counseling or nonprescription contraceptives to minors, nor would it apply to the dispensing of drugs to treat sexually transmitted diseases.

Exceptions to parental notification will be allowed if the head of the clinic finds that notifying the parent would result in physical harm to the child.

One change made as a result of the public comments was to define "parent or guardian" as being one such person who lives with the minor or exercises ordinary parental functions. Another change from the original proposed rule clarifies how notification is to be handled--it will be done by certified mail or other similar form of documentation.

The rules now go to the Office of Management and Budget for review before publication in the Federal Register.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 59

Parental Notification Requirements Applicable to Projects for Family Planning Services

AGENCY: Public Health Service, HHS.

ACTION: Final rule.

SUMMARY: The rules below amend the regulations governing the program for family planning services funded under Title X of the Public Health Service Act. The rules implement a 1981 amendment to Title X which requires projects supported by Title X to encourage, to the extent practical, family participation in the provision of project services. The rules require that projects notify the parent or guardian of unemancipated minors seeking family planning services when prescription drugs or devices are provided. In addition, where State law requires parental notification or consent to the provision of family planning services to minors, projects must comply with such law. The rules also remove from existing regulations a provision requiring projects to disregard family income when determining fees to be charged for services to certain minors.

DATE: The rules are effective February 25, 1983.

FOR FURTHER INFORMATION CONTACT: Marjory E. Mecklenburg, Deputy Assistant Secretary for Population Affairs, Room 725H, 200 Independence Avenue, SW., Washington, D.C. 20201. (202) 472-9093.

SUPPLEMENTARY INFORMATION: On February 22, 1982, the Secretary of Health and Human Services proposed rules implementing an amendment to Title X effected by Pub. L. 97-35 and clarifying the obligation of grantees to comply with certain applicable State laws. 47 FR 7699. The Secretary's request for public comment on the proposed rules elicited overwhelming response: Over 120,000 individuals and organizations contributed to the public comment by writing letters, signing petitions or sending form cards or letters, and these comments were duly considered. The issues raised by the public reflect this broad base of interest and are, accordingly, extremely diverse. The numerous issues raised are set out below, along with the Department's responses thereto. Also set out, as background, is a brief discussion of the statutory and regulatory framework of the rule, the provisions of the proposed rule, and a general description of the comments submitted on the proposed rule.

I. Background

Statutory and Regulatory Framework

Title X of the Public Health Service Act (42 U.S.C. 300 *et seq.*) establishes a program of Federal financial assistance to public and private nonprofit entities for the provision of voluntary family planning services. Under section 1001(a) of that title, the Secretary may make grants to such entities for projects which will provide a "broad range of acceptable and effective family planning services." Under a 1978 amendment to section 1001(a), projects are required to provide "services to adolescents." The regulations implementing this section provide, among other things, that family planning services will be made available without regard to age or marital status. 42 CFR 59.5(a)(4). They also provide that personal information obtained by the project will be kept confidential except where disclosure is made with the patient's consent, is necessary to provide service to the

patient, or is required by law. 42 CFR 59.11.

On August 13, 1981, Congress amended section 1001(a). Section 931(b)(1) of Pub. L. 97–35 added to section 1001(a) the following provision:

> To the extent practical, entities which receive grants or contracts under this subsection shall encourage family (sic) participation in projects assisted under this subsection.

The Conference Report on Pub. L. 97–35 explains section 931(b)(1) as follows:

> The conferees believe that, while family involvement is not mandated, it is important that families participate in the activities authorized by this title as much as possible. It is the intent of the conferees that grantees will encourage participants in Title X programs to include their families in counseling and involve them in decisions about services. House Rep. No. 97–208, at 799.

The rules below implement this statutory requirement.

Proposed Rules

Under the proposed rules, Title X projects would be required to notify the parents or guardian of an unemancipated minor when prescription drugs or devices are provided to such minor. A Federal definition of the term "unemancipated minor" was proposed for purposes of this requirement. This defintion treats minor age 17 or under as unemancipated generally, but otherwise looks to State law to determine what specific acts, such as marriage or parenthood, constitute acts of emancipation. Projects would also be required to inform the minor, prior to the provision of the service, about the notification requirement. Projects would be required to notify the minor's parents or guardian within 10 working days following the initial provision of services by the project, except when the project director determines that notification would result in physical harm to the minor by the parent or guardian. Projects would be required to keep records of the number of such exceptions, as well as reasons for the determination. Where notification is provided, projects would be required to verify that it was received and to keep records of the notification and verification.

Projects would also be required to comply with any State law requiring that notification be provided to or consent obtained from the parents or guardian of unemancipated minors regarding the provision of family planning services to such minors. Finally, the definition of "low income family" in the current regulations would be changed by eliminating the requirement that projects consider adolescents on the basis of their own resources (rather than their families' resources) for purposes of charging for services.

Public Comment

The publication of the proposed rule was followed by intense public interest in and debate about its provisions. In the months following publication, approximately 60,000 comments were received from individuals, including thousands of teenagers and parents. In addition, approximately 1,200 letters were received from a broad spectrum or organizations, including family planning clinics, State and local governmental agencies, national and local professional groups, church groups and so on. Moreover, approximately 250 forms letters, containing about 7,000 signatures, were received on the regulations, and about 50 different types of form postcards were sent in by some 10–20,000 individuals. Finally, approximately 400 petitions were submitted, many containing thousands of signatures.

The numbers and the nature of many of the comments make a precise count of the comment "for" and "against" the proposed rule impossible. For example, while many comments opposed the proposed rules as requiring too much intervention in the family planning decisions of minors, others opposed them on the ground that they did not require enough. In general, however, the public comment disclosed both a wide base of support for, as well as opposition to, the policies of the proposed rules. The Department has carefully considered the specific issues raised by the comments, and they are discussed below. However, the Department's ultimate concern is with the merits of the points made in the comments rather than the number of times they were made. Therefore, we do not discuss, except in general terms, the extent of support for particular points made by the public comment.

The public comment submitted was generally of two types. On the one hand, the majority of the public commenters either criticized or commended the proposed rule on the basis of issues that underlie the rule as a whole and supported their positions by: citing personal experiences; arguing on moral, philosophical or religious grounds; utilizing medical reports and social science data; or presenting legal arguments. For example, numerous comments contained projections on the proposed rule's probable effect on teenage pregnancy, abortion, sexual behavior, and welfare dependency. Similarly, a number of comments raised legal issues about the overall approach of the proposed rules, such as the right of privacy of minors, custodial rights of parents, and the confidentiality of the doctor-patient relationship. A minority of the commenters, on the other hand, addressed issues raised by specific provisions of the proposed rules. For example, a number of particular concerns were raised about the verification provision, including problems of ambiguity, cost and potential for fraud. The discussion below initially examines and responds to the general comments that apply to the rules as a whole. We then examine and respond to the more specific concerns voiced with respect to particular provisions of the proposed rules. However, because of the vast number of issues raised and the permutations and combinations of these issues, we have not attempted to address every issue specifically. Instead, where possible, we have grouped together similar issues and addressed what we believe to be the central questions they raise.

II. Comments on the Rule as a Whole

Constitutional Issues

A great number of commenters challenged the constitutional basis of the notification provisions of the proposed regulations. These commenters contended that a notification requirement would violate a minor's right to unrestricted access to contraceptives and constitutional right to privacy. The commenters cited, in support of their challenge, cases such as *Eisenstadt* v. *Baird*, 405 U.S. 438 (1972), *Carey* v. *Population Services International*, 431 U.S. 678 (1977), and *Planned Parenthood of Central Missouri* v. *Danforth*, 428 U.S. 52 (1976). Many commenters also challenged the constitutionality of the regulations because they assertedly failed to distinguish between "mature" and "immature" minors, citing principally the case of *H.L.* v. *Matheson*, 450 U.S. 398 (1981).

It is the conclusion of the Department that these cases are inapposite, since they all deal with attempts by governmental entities to regulate *access* to family planning services. Two Supreme Court cases have distinguished between situations in which government sought to prohibit or regulate access to family planning services and those in which government was making choices as to the kinds of behavior it would actively assist, concluding that in the latter situations the "compelling interest" test enunciated in the former

cases was inapplicable. *Maher* v. *Roe*, 432 U.S. 464 (1977), *Harris* v. *McRae*, 448 U.S. 297 (1980). The Supreme Court in *Harris*, in upholding the right of the Federal Government to limit funding for abortion services, said:

> It cannot be that because government may not prohibit contraceptives * * * government therefore has an affirmative constitutional obligation to ensure that all persons have the financial resources to obtain contraceptives. To translate the limitations on governmental power implicit in the Due Process Clause into an affirmative funding obligation would require Congress to subsidize the medically necessary abortion of an indigent woman even if Congress has not enacted * * * Medicaid * * *. Nothing in the Due Process Clause supports such an extraordinary result. Whether freedom of choice that is constitutionally protected warrants federal subsidization *is a question for Congress to answer, not a matter of constitutional entitlement.* (Emphasis added).

The instant regulation does not prohibit access to contraceptive services. Rather, it implements a Federal assistance program, *i.e.*, Title X of the Public Health Service Act, 42 U.S.C. 300(a), by giving specific meaning to the conditions Congress has established for provision of the assistance. As such, the constitutional issue involved here is indistinguishable from the primary issue in the *Harris* case. Thus, the Department need establish only that there is a rational basis for the "notification" requirements of the proposed regulation. Governmental concern with the health of the minor patient and concern for the proper role of the family in the provision of certain family planning services constitute a clear and rational basis for the regulation. Further, even in the context of the Federal assistance program, the regulation would not act as a bar to funded services. The parental notification requirement would apply only to requests for prescription drugs or devices, and even these would be available immediately, with parental notification being required only in the 10 days following the provision of services.

The proposed regulation was also frequently challenged as discriminating unconstitutionally on the basis of gender. Many commenters observed that the notification requirement applied only to prescription drugs and devices which, at this time, are used only by women. A few commenters who made this point cited *Craig* v. *Boren*, 429 U.S. 190 (1976). The Department does not consider the distinction made in the notification provisions of the regulation, *i.e.*, prescription drugs or devices, to be gender-based discrimination, which would fall within the Supreme Court's analysis in *Craig* v. *Boren*. In that case, the Court struck down as violating the equal protection clause of the Constitution a State statute setting a higher minimum age for the sale of beer to males than the age applicable to females. The Court found that this explicit gender-based distinction could not stand. The notification requirement, on the other hand, is a gender-neutral distinction focusing on health risks. As such, the regulation falls well within the test established in the case *Geduldig* v. *Aiello*, 417 U.S. 484 (1974), in which the Supreme Court upheld a State disability insurance law which excluded benefits for certain pregnancy related services. In upholding the law, the Court said:

> While it is true that only women can become pregnant, it does not follow that every legislative classification concerning pregnancy is a sex-based classification * * *. Absent a showing that distinction involving pregnancy are mere pretexts designed to effect an invidious discrimination against the members of one sex or the other, lawmakers are constitutionally free to include or exclude pregnancy from the coverage of legislation such as this on any reasonable basis, just as with respect to any other physical condition. *Geduldig* at 496, footnote 20.

The reasoning in *Geduldig* clearly applies to the proposed notification provisions: the "prescription" classification applies equally to men and women; there is (and can be) no evidence produced to establish that the classification is a pretext to effect an invidious discrimination; and the underlying considerations, *i.e.*, the health and safety of minors and concern for family involvement, establish clear and rational basis for the classification. Furthermore, as has already been noted, non-prescription contraceptive services are available to minor women without notification, and, unlike the total exclusion of benefits in *Geduldig*, prescription services will still be provided, subject only to a subsequent parental notification.

Legislative Intent

A great many commenters asserted that both the notification provisions in § 59.5(a)(12)(i) and the provisions requiring adherence to applicable State law in § 59.5(a)(12)(ii) are inconsistent with Title X. These commenters make the following points:

1. The basic authorizing legislation provides that projects shall offer a broad range of services without limitation.

2. The authorizing legislation was amended in 1978 expressly to require that services be provided to adolescents, and there is no qualifying language which would support the attachment of notification or consent requirements.

3. Congress has previously rejected attempts to amend the authorizing legislation by attaching to it parental notification or consent requirements. Commenters cite in particular the "Volkmer Amendment" which was proposed but not enacted in 1978.

4. Although section 1001(a) of the Public Health Service Act was amended in 1981 to add the requirement that "(t)o the extent practical, entities * * * shall encourage family participation in projects * * *", the amendment was not intended to mandate family involvement but merely to encourage such involvement.

The problem with the first three of these comments is that they seek to interpret individual parts of the statute or individual bits of legislative history without consideration of the course of statutory development. It is true that section 1001(a) requires projects to provide a broad range of services and requires that services be provided to adolescents. It is also true that Congress did not act favorably on previous proposals to add parental notification requirements to section 1001 (a). However, the simple fact is that Congress ultimately did amend section 1001(a) in 1981 to include a requirement that projects encourage family participation to the extent practical and in so doing signaled a change in direction. It is on the basis of this amendment that the notification provisions of the regulation have been proposed and it is in the light of this amendment and its legislative history that one must judge the propriety of the notification provisions, not the legislative history surrounding defeated legislative proposals or interpretations of the statute prior to the 1981 amendment. The significant legislative history to the 1981 amendment is contained in the Conference Committee report, which provides:

> The conferees believe that while family involvement is not mandated, it is important that families participate in the activity authorized by this title as much as possible. It is the intent of the Congress that grantees will encourage participants in Title X programs to include their families in counseling and involve them in discussions about services. H.R. Rep. No. 97-208, 97th Cong. 1st Sess. 799 (1981).

The Department feels that the notification provisions in the proposed regulation strike a desirable balance between the requirement that adolescents receive services and the requirement that family participation be encouraged to the extent practical. Unlike the Volkmer Amendment, the Congressional disapproval of which was cited by some commenters, these provisions do not require parental

notification before services may be provided. Nor do they *mandate* family involvement. They do no more than provide an opportunity for family involvement by having projects advise parents that their children have received prescription drugs or devices. Furthermore, by limiting the applicability to prescription drugs and devices, notification is required in an area in which the relevant health considerations make parental involvement particularly appropriate. Accordingly, it is the conclusion of the Department that the notification requirements are consistent with the provisions of section 1001(a) as amended and the relevant legislative history.

Many commenters also challenged the provision of proposed § 59.5(a)(12)(ii) as being inconsistent with the 1981 amendment and in particular the legislative history contained in the conference report. Those commenters misperceive the principal purpose of § 59.5(a)(12)(ii). That section was intended to rationalize an increasingly confusing situation created by, on the one hand § 59.5(a)(4), which prohibits projects from discrimination on the basis of age, and on the other hand, the eventuality of States enacting laws imposing parental consent or notification requirements. The Department has been called on to make complex distinctions to recognize the constraints imposed by § 59.5(a)(4) while at the same time paying deference to State laws in the area of consent to certain health and medical services, an area traditionally within the jurisdiction of the States. Section 59.5(a)(12)(ii) will resolve that tension by providing that notwithstanding the provisions of § 59.5(a)(4), projects must comply with State laws regarding parental consent and notification. It is the opinion of the Department that there is nothing in the statute or legislative history which would require the program to be operated in such a way as to preempt or supersede otherwise valid State law, particularly with regard to a matter so traditionally a State concern. Nor does the above-quoted conference report language lead one to a different conclusion. To the extent that the language is relevant in interpreting the statute, it is a constraint upon the imposition of a mandate *by the Federal government.* It does not evince any view on whether the Federal government may, in its implementation of Title X, recognize otherwise applicable State law in this area. To conclude otherwise would be to require the Federal government to supersede or preempt State law in order to implement the Title X program, a result which certainly is not compelled by the statute and legislative history.

Rights of Minors

A large number of commenters argued that the parental notification rule would unfairly infringe upon the minor's right of privacy. (For a discussion of comments arguing that this would be an unconstitutional infringement, see the section above on constitutional issues.) The argument advanced by these commenters, among whom were many teenagers, is that they should have the right to obtain family planning services in complete confidentiality and that their interest in doing so should outweigh the interest of parents in being notified of their receipt of these services.

Many commenters objected to the rule on the grounds that parental notification would constitute a breach of the confidentiality of the doctor-patient relationship. Several argued that the rule would conflict with State and Federal confidentiality requirements. Others argued that it would require physicians to breach applicable codes of ethics (e.g., the Hippocratic oath) and accepted medical practice. Several argued that the requirement that projects make the required records on parental notification available to the Secretary for inspection would be a further violation of the patient's right of confidentiality.

In response to these concerns, we call attention to the requirement that the project advise the minor of the notification requirement before providing services. The minor will then be able to decide whether to accept services subject to subsequent parental notification. By accepting the services, the minor will be in effect consenting to the notification (assuming that the exception for physical harm to the minor does not apply). In light of this consent by the minor, we conclude that the regulation does not improperly infringe on the minor's right to privacy, the confidentiality of the minor's records, or the doctor-patient relationship. Nor, for this reason, would the rule cause the physician to breach ethical code or accepted medical practice standards. As to the Department's right to inspect records, we would seek only sufficient information to determine that the regulatory requirements are being followed. This Department must retain the right to inspect records for all of its grantees providing health services, so that we can determine whether the grantees are complying with applicable requirements. This point is clearly made in existing regulations, see 45 CFR Part 74, Subpart J.

A number of commenters claimed that the proposed rule on notification would conflict with the laws of many States under which minors, including unemancipated minors, may consent on their own behalf to the receipt of family planning services. We do not see this conflict. Projects must comply with State law regarding parental consent, but where State law does not require that a parent consent, the regulation does not do so either.

Discrimination

The proposed rule was challenged by many commenters as leading to discrimination against minors on a number of grounds: gender, age, and income. Many commenters opposing the regulation argued that the regulation discriminates against women, since only females use prescription contraception. Several commenters cited the legislative history of Title X to argue that Congress never intended such alleged gender discrimination. They also quoted the Department's regulations implementing Title X, which stipulate that clinics must "provide services without regard to religion, creed, age, *sex,* parity or marital status" 42 CFR 59.5(a)(4). (Emphasis added). (As to the argument of some commenters that this alleged gender discrimination is unconstitutional, see the discussion above of constitutional issues.) Finally, with respect to gender discrimination, several commenters remarked that exemption of treatment for sexually transmitted diseases (STD) from parental notification essentially allows Title X monies to protect young men from adverse consequences of sexual activity without parental notification while protecting young women from only one of the adverse consequences of sexual activity without parental notification.

The Department is not persuaded that the regulations will constitute improper discrimination on the basis of sex. The rule on its face is gender-neutral in that its operation is triggered only by the provision of prescription drugs and devices without regard to gender. The notification requirement applies only with respect to drugs and devices that may be obtained only with a prescription. If contraceptives for male use become available that would require prescriptions, they too would fall within the scope of the rule.

We also believe that the notification requirement does not conflict with the requirement of § 59.5(a)(4) that services be provided without regard to sex. First, the notification requirement does not result in the denial of requested services

in any case. Second, it does not make distinctions on the basis of sex. Third, even if it were viewed as doing so, as a regulatory requirement applicable to specific situations, it must be complied with even if a separate, general regulatory provision may be viewed as supporting a contrary approach in situations not covered by the specific requirement.

With respect to the exception for treatment of STD, we find the argument even less convincing. This exception applies to males and females alike and thus demonstrates that the regulation is not based on gender distinctions. The exception, like the general rule, was developed on the basis of factors wholly apart from the issue of gender, *i.e.*, public health considerations.

A number of commenters noted that, in practice, the notification requirement will affect only females and argued that the regulation should therefore be broadened to include non-prescription contraceptives as well. They maintained that the goal of family involvement would be better served if parents were notified of their sons' sexual activity as well as that of their daughters. While we agree that family involvement is to be encouraged in all cases, we have concluded that the distinctions based on the use of prescriptions reaches the situations where the parental involvement is likely to be of the most significant value.

Several commenters alleged that the regulation would require discrimination on the basis of age in a manner that violates the Age Discrimination Act of 1975, 42 U.S.C. 6101, *et seq.*, and the government-wide implementing regulations published by the Department, 45 CFR Part 90. That Act and its implementing regulations create an exception for cases where age is used as a measure of some other characteristic which is sought to be ascertained in order to achieve a legitimate program purpose and which cannot practically be ascertained on an individual basis. In this regulation, the Department is using age as a measure of an unemancipated minor's ability to make important decisions with respect to prescription drugs whose health consequences are potentially significant, in order to encourage family participation, as mandated by statute, in those decisions about family planning services which we have concluded will most benefit from parental involvement. Given the nature of the program and the large number of minors served, we conclude that determinations of their ability to make these decisions cannot practically be made on an individual basis.

Some commenters claimed that the proposed amendment to the definition of "low income family" would result in discrimination against minors on the basis of income. We address this issue more fully below, but note here that the amendment simply removes a requirement that projects consider only a minor's income and not consider family resources. This simply puts minors on the same footing as all other applicants for services.

The Rights of Parents

Of those supporting the regulation, many commenters argued that the custodial rights and responsibilities of parents outweigh minors' interests in confidential family planning services. These commenters believed that the proposed regulations are at least a beginning step toward re-establishing legitimate parental control over their children's health care. Many of these commenters pointed out that parents are the ones who are morally, legally, and financially responsible for their minor children, and that these parental responsibilities should not be undermined by federally-funded programs which ignore parental rights.

Of those supporting the regulation as a means of reasserting parental rights, a small number of commenters developed constitutional and legal arguments. While acknowledging that minors have constitutionally protected rights, they cited case law for the proposition that parents also have constitutionally guaranteed and protected rights which establish their broad authority over their minor children. These commenters argued that parental notification will aid in re-establishing these parental rights. Further, some commenters argued that while minors enjoy a constitutional right to privacy just as adults do, the proposed regulations would not violate the minor's right to privacy. As with every other constitutional right, the right to privacy protects an individual against government intrusion into his or her private affairs. According to these commenters, a right of a dependent minor to keep his or her affairs private from parents does not exist.

Some commenters requested that the regulation be revised to require parental notification prior to the provision of service rather than within 10 days following the provision of prescription contraceptives. This change in timing of notification would make it possible for the parents to discuss the decision regarding contraceptive use with the minor before it occured, opening up the possibility that the parents might be able to dissuade the minor from being sexually active. In addition, the commenters asserted, by talking to the minor in advance, parents would have the opportunity to relate relevant family medical information that should be brought to the attention of the medical personnel dispensing prescription contraceptives. A few commenters questioned whether parental notification procedures were to be followed by the project at any subsequent clinic visits by minor after the initial visit.

As we noted in the preamble to the proposed rule, to require prior notification could unduly delay or otherwise restrict access to services for adolescents, contrary to the statute's policy. Thus, we have not adopted the prior notification requirement. We believe that the family participation that may follow the notification that is required will permit parents to accomplish the goals described by the commenters. As to the question about subsequent clinic visits, the regulation explicitly prohibits the project from dispensing additional prescription drugs or devices if it cannot verify that notification of the first prescription service was received. Conversely, where the project can so verify, no further notification is required.

Some commenters, including a number of parents, requested that the regulation be revised to require parental consent to the provision of prescription drugs and devices. We conclude that such a requirement would not maintain the proper Federal balance between the competing concerns of the statute that (1) services be provided to adolescents, and (2) family participation be encouraged. Accordingly, we have not adopted this proposal.

Family Participation

There was a wide divergence of views among the comments received regarding the choice of the parental notification requirement as the mechanism for encouraging family participation. Those who favored the regulation claimed that family relationships would improve. They maintained that parents and teenagers would communicate more freely because notification would make them aware of how important it is to discuss these matters in the home. This awareness, they argued, would lead in turn to more responsible behavior on the part of the parents as well as the adolescent. Teenagers may realize that parents can be sources of information, support and guidance, and the guilt caused by the minor's secrecy over obtaining contraceptives may be eliminated. Some felt family

relationships would improve because authority and responsibility would return to the parents.

Many opposed to the regulation claimed that notification would negatively affect family relationships. Parents may feel hurt that the child did not confide in them. Parents, upset about adolescent sexuality, may think the government has reprimanded them. A variety of commenters thought parents may be quite angry when they learn that their child is sexually active. They may restrict or punish the child verbally or physically, or deny the child food and shelter. They may also direct hostility toward their child's sex partner.

Some letters also speculated that the teenager would shut off all communication with parents. Teenagers who are frightened by the initial outburst of parents may do something rash, such as run away. Other siblings, whose movement may also be restricted by parents as a result of notification, may be upset with the teenager who went to the family planning clinic.

The Department recognizes that this diversity of opinion may well reflect the different possible outcomes of the parental notification requirement. Nevertheless, the Department has a responsibility to ensure that projects take specific steps to implement the statutory mandate that family participation be encouraged, and we have concluded that the approach set forth in the regulation is reasonably designed to achieve that end. That in some cases the notification may lead to some of the adverse consequences predicted by commenters does not alter the fact that the encouragement of family participation has been mandated by Congress, nor is it inconsistent with our conclusion that the benefits of the rule outweigh these potential disadvantages.

Many of the letters opposed to the regulations also acknowledged the need for parental involvement but viewed the proposal as unnecessary or counter-productive. Comments from health care providers said that local and national survey data indicated that over half of the adolescent patients already tell their parents of their use of clinic services. A few comments cited surveys saying that most of clinics have programs to involve parents.

The Department is encouraged by the reports of these comments that many family planning clinics recognize the value of parental involvement. The fact that some parents are already involved should minimize the adjustments clinics will need to make to comply with the regulations, but does not lessen the importance of notifying parents when their unemancipated minor children receive prescription contraceptives. Comments that concluded the regulation is unnecessary because over half of the minor girls already tell their parents fail to recognize the benefits that the notification will bring to those families in which the parents are not involved.

Effects of Notification on Minors

The issue most frequently raised regarding parental notification was the effect that notification would have on the minor. The different effects predicted range from decreased sexual activity to increases in pregnancy and abortion rates, from more consistent use of contraceptives to the use of less effective contraceptives or none at all. Various studies and publications were cited to support different predictions. Some commenters extrapolated from their predictions of individual behavior to develop predicted societal costs of the notification requirement. We summarize below the various predictions made by the commenters.

Adolescent sexual activity was a pervasive theme of the public comment. Of those supporting the regulation, many predicted that sexual activity will decrease. Some said that the notification would lead to communication between parents and the adolescent, and, as a result, the adolescent would decide to abstain. Others speculated that the fear of notification alone will cause the teenagers to abstain.

A few commenters predicted, on the other hand, that adolescent sexual activity will increase as a result of the regulation. Some writers thought that fear of punishment will lead to less communication with both parents and family planning counselors, and claimed that the resulting lack of information will lead to increased adolescent sexual activity. A few thought sexual activity will increase because the regulation "penalizes" the adolescent who takes responsibility for her actions, making it more likely that the adolescent will behave irresponsibly.

Many of the commenters felt that the regulation will *not* affect adolescent sexual activity. Some writers thought teenagers will go to private physicians or clinics that do not receive Title X funds so that they can continue to have prescription contraceptives and remain sexually active. Others maintained that the sexually active teenager will rely on non-prescription contraceptives that can be obtained without parental notification. Quite a few of the commenters speculated that adolescents will simply find other means of getting prescription contraceptives, such as the black market or the use of bogus identification. Writers frequently speculated that adolescents will be sexually active without using contraception.

The most common criticism leveled against the regulation was that it will cause an increase in adolescent pregnancies and abortions. These letters assumed that parental notification constitutes a barrier to adolescents receiving contraceptive services. Some mention that, for example, low-income girls who are dependent on federally-funded family planning services will not seek birth control information because the services are not confidential, and that pregnancy among these girls will increase because they will turn to less effective birth control methods or use none at all.

Many of these commenters based these views on Torres, *et al.*, "Telling Parents: Clinic Policies and Adolescents' Use of Family Planning and Abortion Services," in *Family Planning Perspectives* (1980). This study of unmarried female teenagers served by family planning clinics claimed that 54 percent thought their parents knew of their visit to the clinic and another 5 percent were not sure. The study claimed that if parental notification were required, 77 percent of the total would continue to use the clinic and 23 percent would not. This latter class was comprised of 15 percent who would continue sexual activity but use a non-prescription contraceptive method, 4 percent who would do so with no contraceptive method, 2 percent who would abstain, and 2 percent undecided. The study then predicted that 33,000 additional pregnancies per year would result from a parental notification requirement, and that 14,000 of these pregnancies would end in induced abortions. A few commenters based their predictions regarding increases in pregnancies on local clinic data or personal observations.

Building on these and similar assumptions, many commenters claimed that the affected unemancipated minors will face adverse health consequences. Comments frequently cited the health risks of pregnancy and childbirth as substantially exceeding those of using oral contraceptives. Other commenters speculated that many adolescents will forgo visiting family planning clinics because of the notification requirement, and that as a result health problems such as sexually transmitted diseases, pelvic inflammatory disease, and cervical abnormalities will go undetected. Still other commenters claimed that the psychological health of adolescents will be adversely affected

by the projected increase in pregnancies and that this will be manifested in part by increased suicide attempts.

A large number of commenters who supported the regulation endorsed the view stated by the Department in the preamble to the proposed rules that the health considerations involved the minors' decisions regarding sexual activity and use of prescription drugs and devices justify the imposition of the notification requirement. Many of these writers stated that Federal policy should recognize parental responsibility in an area of their children's lives which has significant health implications. They noted that, while the pill and IUD have been shown to be safe for most women, studies have cautioned against an array of harmful side effects of these methods for some women. Increased risks of ectopic pregnancy, infection of the ovaries and fallopian tubes, and infertility after discontinuance were cited as side effects of IUD use. Such side effects of bloodclotting and stroke in connection with oral contraceptive use also were of concern to these commenters.

The commenters in favor of parental notification argued that informing parents of their children's use of contraceptive drugs or devices would enable them to monitor for any possible occurrence of these side effects. The minor would have the benefit of counsel from a concerned adult who might have even greater familiarity with the minor's medical history than would the minor. Furthermore, if the minor followed a common pattern and failed to return to the family planning clinic after the initial visit (as much as 50 percent of the time, according to the HHS Inspector General's Service Delivery Assessment (SDA) of Family Planning Services Teenagers Report of 1978 which was cited by several commenters), the benefit of professional surveillance would be lost as well. These writers thought that if parents were involved from the beginning, the minor would receive help in evaluating any health effects that might occur from using prescription contraceptives and support for seeking medical attention when needed. These commenters contended that it would be less likely that the adolescent would discontinue contraception at the first sign of complications or be inconsistent in the ongoing use of prescription contraceptives, because an interested person, who would support the minor in acting prudently, would be available for guidance.

On the other hand, many writers questioned whether the parental notification regulations are justified on health grounds and urged an examination of the comparative risks to life and health from use of the IUD or pill and from pregnancy. For example, some cited information from the FDA oral contraceptive patient labeling insert to the effect that the risk of death associated with pregnancy and childbirth among teenagers is significantly higher than the risk of death associated with the use of the oral contraceptives. Others maintained that the risks associated with pregnancy and childbirth also exceed those associated with the use of other contraceptive methods.

A few writers pointed to the existence of studies indicating that the most common medical problems associated with the use of oral contraceptives are not problems of teenage pill users. A few other writers stated that there are health benefits for teenagers associated with oral contraceptive use. These writers also argued that current departmental guidelines for projects already provide adequate medical protection for minors receiving prescription contraceptives.

Some of the commenters who objected to the proposed rule claimed that parental involvement does not increase consistency in contraceptive use. To support these claims, some of these commenters cited a study by Herceg-Baron and Furstenberg, "Adolescent Contraceptive Use: The Impact of Family Support Systems," in *The Childbearing Decision: Fertility Attitudes and Behavior*, G.L. Fox, ed. (1982), of adolescents treated by family planning clinics.

We have carefully considered the assorted arguments raised regarding the effects on minors of the parental notification requirement. We are not convinced that these effects can reasonably be predicted at this time. The local clinic data and personal observations included in the comment were usually unsystematic and incomplete. Accordingly, the 1980 study by Torres, *et. al.*, continues to be the sole analytical basis for an estimated increase of adolescent pregnancies. We have serious concerns about the applicability and validity of this study. This is the study cited for the proposition that pregnancies, abortions, and births will increase substantially because of the regulation. These projections were relied upon by many as support for their arguments that minors will suffer adverse health effects. We believe that the methodology used in this study was severely flawed. Among our many objections are the following: (1) The analysis fails to account for minors who will go to a private physician or other non-Title X provider to obtain prescription contraceptives; (2) the study includes teenagers who would be considered emancipated under the rule and who would therefore not be subject to parental notification (the study did exclude married teenagers, but did not attempt to address other indicia of emancipation), and (3) the analysis incorrectly estimated rates of contraceptive failures among teenagers which overstated the negative impact of a notification requirement.

We are also unpersuaded by the conclusions advanced by many commenters that parental awareness and involvement do not increase consistency in contraceptive use. The 1982 study by Herceg-Baron and Furstenberg, in particular, is limited and does not comport with the findings reached in several other studies (e.g., G.L. Fox, "The Family's Role in Adolescent Sexual Behavior," in *Teenage Pregnancy in a Family Context: Implications and Policy*, (1981)). Further, in contrast to the author's conclusion, data presented in that 1982 study may very well support the conclusion that mother-daughter communication about sexual activity does lead to more effective use. We also do not believe that sufficient data have been developed to support the contention of some commenters that an assurance of confidentially is one of the major factors, if not *the* major factor, in the decisions of most minors to seek family planning services (see, for example, Zabin and Clark, "Why They Delay: A Study of Teenage Family Planning Clinic Patients," in *Family Planning Perspectives* (1981)).

We also believe that parental notification is justifiable on health grounds. The contention that the regulations will result in a large upswing in the number of teenage pregnancies and an overall deterioration of adolescent health because of the greater risks associated with pregnancy is misguided. As indicated above, we believe estimates of the number of additional pregnancies likely to result have been exaggerated. The contraceptive practices of teenagers may also improve as the result of parental involvement, with teenagers paying greater attention to the health consequences of the various available methods of contraception. New evidence indicates that teenagers who discontinue pill use largely do so because of experienced or feared side effects. (J.W. Ager *et al*, "Method Discontinuance in Teenage Women:

Implications for Teen Contraceptive Programs," 1982)). Also, some teenagers may be persuaded through conversations with their parents to abstain from sexual activity, removing all health risks associated with such activity. Given these various considerations, the Department does not see a sufficient basis for the claims of commenters that the notification requirement will adversely affect the health of minors.

Another health-related question raised in comments on the regulation pertains to the degree of health risk incurred by teenagers who use prescription contraceptives. The Department recognizes a difference of opinion among medical experts concerning the kinds and degrees of risk for teenagers involved in use of each various prescription contraceptive measures. However, clearly some measure of health risk does exist for contraceptives in the prescription category. The risk of taking oral contraceptives is such, for example, that patient package inserts containing warnings are required by the Federal government. Thus, the Department adheres to the view that parental notification is necessary to protect the health of the child.

In sum, we believe that the Congressional directive for family participation should be effectuated by the parental notification mechanism and that the opportunity that this notification presents for parental involvement in decisions regarding the use by minors of prescription drugs and devices will, on balance, be of benefit to the minors subject to the rule. However, in light of the various predictions concerning the consequences of this rule, we intend to monitor closely the effects of its implementation and to reconsider its appropriateness in light of any reliable data that are developed regarding its effects.

Effects on Family Planning Projects

Many letters from health-care providers complained that procedural costs necessitated by the parental notification provision of the regulations would pose severe hardships, especially after other recent funding cuts, and would detract notably from their ability to deliver services to eligible patients, a high proportion of whom are adolescents. Procedural costs related to notification and verification were detailed by many. Commenters also predicted that the requirement to determine whether a patient is emancipated or whether physical harm may result will generate further cost increases. Beyond the basic costs entailed in carrying out notification and verification, other costs were cited by some writers, such as for special staff training to handle any family conflict that might occur and for special media and public relations campaigns to clarify the regulations. A few commenters pointed out that the practice of clinic-hopping and giving false information each time would add to clinic expenses, since multiple health services are provided at initial visits.

We acknowledge that these requirements impose some additional costs and administrative burdens. We believe, however, that certified mail (with restricted delivery and return receipt requested) ensures parental notification and verification at minimal expense and at the same time effectuates the policies encompassed by the Department's approach to family involvement. The record-keeping is necessary for the Department to be able to monitor project compliance in this area to the same extent that we do for other program requirements. The Department estimates that counseling about the notice, processing the notification and verification, mailing, indirect expenses and the handling of exemptions will not impose substantial costs on projects.

A small number of comments discussed the impact of the regulation on family planning clinics which do not receive federal funds. These comments predicted that the regulation will impose significant costs on those programs. Some argued that the resources of clinics not receiving federal funds are not sufficient to serve the increased number of adolescents who will no longer go to the federally funded clinics. Other commenters argued that the regulation would reduce the number of adolescents seeking services from non-Title clinics, because teenagers will think that the notification requirement applies to all family planning clinics.

The Department views these concerns as highly speculative. We are not persuaded that the requirement will lead to a large shift of unemancipated minors to non-Title X clinics. In any event, we reiterate that this regulation imposes the parental notification requirement only on Title X projects.

Effects on Society

Several of those who opposed the regulation predicted that its implementation would impose major societal costs. They assumed a significant increase in adolescent pregnancies, with attendant costs for prenatal care and post-delivery support. Increased welfare and Medicaid expenditures were also predicted. Some of these letters cited lost human potential when adolescent pregnancies occur, claiming that 80 percent of adolescent mothers drop out of school and have fewer employment opportunities, and therefore have depressed earning and tax-paying potential.

Based as they are on assumptions regarding increases in adolescent pregnancies resulting from the notification requirement, these predictions are at least as conjectural as the underlying assumptions. In addition, they add another layer of assumptions, thus making the predictions even more difficult to accept. The Department will, of course, consider any reliable data that are developed with respect to these concerns and will reevaluate the regulation in light of such data.

III. Comments on Specific Provisions of the Rules

Notification Requirement

Proposed § 59.5(a)(12(i)(A) required that when prescription drugs or devices are provided to an unemancipated minor, the project must notify the minor's parents or guardian that they were provided within 10 working days following their provision. The project was required to tell the minor about the notification requirement prior to the provision of services.

Comment: Some of the specific comments on the notification provision addressed the timing of the notification. Some writers who supported the proposed regulations argued that parental notification should occur prior to the provision of service rather than 10 days following provision in order to enable the parents to discuss the decision regarding contraceptive use with the minor before it was implemented.

Some commenters question *who* must be notified. They asked whether the term "parents" means that both parents always must be notified. Raised as potential problems were cases where children live with only one parent, where both parents are unreachable, or where the teenager lives with neither parent (e.g., runaways, orphans, or immigrant teenagers whose parents are not in this country). Some commenters also argued that the logistical difficulties of notifying both parents would make the rule extremely costly and burdensome. Other urged that only one parent be notified where the two parents might be quite different in their likely reactions to notification of their child's contraceptive use or inquired whether the minor could designate

which parent to notify. Similarly, some commenters argued that siblings or other relatives should be listed as permissible alternates to parents for notification purposes.

Questions were also raised about the method of notification. Commenters criticized the proposed rule as vague, asking if notification could be done by telephone or mail, and if the latter, what type of mail. Some comments pointed out that if certified or registered mail is required, there will be significant costs to the projects in preparing and mailing the letters and handling necessary follow-up. Other pointed out that many parents who work during the day might be unable to receive registered mail, either because they were unwilling to pick it up or because of other problems (such as theft from mailboxes).

Many health professional who commented challenged the notification requirement on the ground that it would require them to violate State statutes requiring that family planning services be provided on a confidential basis. A few providers also stated that, where they provided services to a drug or alcohol abuser, they would be required to violate the Department's confidentiality regulations, 42 CFR Part 2.

Response: As already indicated in our discussion on *Comments on the Rule as a Whole*, the rules below retain the requirement that the notification be made within 10 working days following provision of the prescription drug or device to the patient. As stated above, we continue to believe that a Federal pre-service notification requirement is not consistent with the statute's goal of providing access to services. The 10-day rule will assure that parents can become involved on a timely basis and should serve to provide most of the benefits sought by those who supported notification prior to service. With respect to those commenters who questioned whether the rule would require repeated notifications, the answer is that it does not. Paragraph 59.5(a)(12)(i)(A) by its terms applies only to the "initial" provision of a prescription drug or device and when notification has been verified, no further notice is required for subsequent services.

The Department agrees with the points raised by many commenters concerning the practical difficulty of notifying both parents. Therefore, the term "parent or guardian" has been defined as "a parent or guardian residing with the minor or otherwise exercising ordinary parental functions with respect to the minor." We believe that this change addresses most of the logistical difficulties raised by various commenters. It is also consistent with the policy underlying the rule, in that it is the custodial parent who is likely to be the most concerned with and able to contribute to the minor's decision regarding contraception. As for the comments regarding orphans, we note that many will be covered by the "guardian" provision of the rule. Although we recognize that many runaways may be reluctant to have their parents contacted, it is our view that the Congressional policy of encouraging family involvement applies equally to such cases. Moreover, if the minor became a runaway because of physical abuse by a parent, the exemption of § 59.5(a)(12)(i)(B) would likely apply.

The Department has not accepted the suggestion to expand the class of persons to whom notification may be provided. While we recognize that in some cases siblings or other relatives exercise a quasi-parental influence on minors, we do not believe that it would be appropriate to permit the involvement of such relatives, in effect, to supersede the parent's or guardian's interest vis-a-vis the minor. Moreover, nothing in this rule precludes a minor from seeking the advice of such a relative, should the minor wish to do so.

While the Department, in general, has concluded that projects should be allowed administrative discretion in the implementation of these regulations, the notification and verification provisions are critical and we have decided to modify those provisions to spell out more clearly the kind of process to be used. The regulations as modified require that verification be accomplished by certified mail (with restricted delivery and return receipt requested), or similar evidence of notification (for example, a signed form, if the project has one). While this change leaves the projects with a degree of flexibility, it also provides, by the examples used, a minimum standard for verification. With regard to the record-keeping requirement of § 59.5(a)(12)(i)(D), the type of records kept will be a function of the notification method used.

With respect to the concerns voiced regarding the potential violation by health professionals of State confidentiality statutes, as noted earlier, no notification is undertaken until the minor is advised of the notification and consents to services knowing that notification will occur. Thus, we see no violation of State confidentiality statutes. For the same reason, the notification provision would not require providers to violate the Department's confidentiality regulations.

Verification Requirement

Proposed § 59.5(a)(12)(i)(A) required projects to verify that notification was received. Where the project was unable to verify receipt of the notification, it was prohibited from providing additional prescription drugs or devices to the minor.

Comment: Commenters, both for and against the proposed rules, criticized the verification requirement as unduly vague. Many questioned what methods of verification would suffice: oral acknowledgement, return receipts from registered mail notifications, or written "certificate of notice" signed by parents, minors and health care providers.

Commenters on both sides of the issue also criticized the requirement as too susceptible to fraud. In the case of return mail receipts, some writers pointed out that signatures on these could be forged. Other commenters questioned the degree of proof required in order for the project to verify that the minor's parents in fact received the notification and, on the assumption that some formal proof of identity would be required, stated that the requirement discriminated against persons without such papers.

A number of letters from providers questioned how the verification requirement would be applied. For example, a few writers questioned how parental refusal to acknowledge notification should be handled (how much follow-up effort should be made) and interpreted (i.e., as lack of verified notification, or as *de facto* consent). Similarly, questions were raised concerning what liability clinics would face in responding either positively or negatively to a continued request for prescription contraceptives from an adolescent in the face of parental objection after notification, particularly in cases where IUDs already have been inserted.

Response: The Department agrees with the comments criticizing the proposed verification requirement as too vague and full of loopholes. Therefore, § 59.5(a)(12)(i)(A) now specifies that documentary verification is required. It also provides that where, for example, certified mail is used, it must be done on a restricted delivery, return receipt basis, to assure that the parent or guardian actually receives the notification. A clinic may employ a different method of verification, but, under the rule, it must obtain a "similar form of documentation". That is, the documentation must be reasonably designed to assure that it was signed by the parent or guardian.

As to the situation where verification is not received, the rule is clear on its face that failure to obtain the requisite documentation means that additional prescription services may not be provided. The Department leaves to the judgment of the project personnel how much effort should be made a obtain verification, as such judgments will necessarily have to be made in light of the facts of each case. The question of the liability of a project which receives verification but where the parent indicates that he or she objects to continuation of service is one which is dependent on State law, and is a judgment that projects routinely make in providing services to minors.

Limitation to Prescription Drugs and Devices

Comment: Comments addressing specific provisions frequently criticized the fact that only prescription contraceptives are covered by § 59.5(a)(12)(i)(A). Some argued that parents have the right to know of any and all contraceptives given to their children. A related set of comments urged that nonprescription contraceptives should be included so that parents could be informed about contraceptives being dispensed to male children.

Many comments opposed the Department's singling out of prescription drugs and devices for regulation and challenged the health basis for the classification. These comments frequently pointed out that the health risks of prescription contraceptives are relatively small compared to the risk of pregnancy and argued that the prescription classification would therefore have a negative, rather then positive, impact on the health of teenage women. In this regard, the commenters frequently pointed to the fact that the classification includes the diaphragm, which poses no appreciable health risk. Some argued that use of diaphragms was no more likely to produce long-term consequences than spermicidal form or condoms which, as non-prescription methods, are not covered by the rule.

The prescription was also attacked as discriminating against women, in that it precludes use of all effective methods of female contraception without parental notification but does not preclude analogous male methods without parental notification.

A number of comments were received in support of the rule's limitation to prescription drugs and devices, however. These comments noted that while the pill and IUD have been shown to be safe for most women, studies have cautioned against an array of harmful side effects of these methods for some women.

The commenters favoring the prescription classification also argued that informing parents of their children's use of contraceptive drugs or devices would enable them to monitor for any possible occurrence of these side effects. These writers argued that, if parents were involved from the beginning, the minor would receive help in evaluating any health effects that might occur from using prescription contraceptives and support for seeking medical attention when needed. They also argued that it would be less likely that the adolescent would discontinue contraception at the first sign of complications or be inconsistent in the ongoing use of prescription contraceptives, since the adolescent would be able to discuss sexual activity and contraceptive use with an interested person, who would support acting prudently.

Response: The Department has retained the prescription classification as proposed. We recognize that parents have a legitimate concern in being informed of contraceptive use by their children. However, the statute expresses two competing concerns—providing adolescents with family planning services and encouraging family involvement—which the Department is required to weigh. In our judgment, the health risks generally associated with prescription drugs and devices dictate that steps be taken to promote family involvement in the prescription contraception decision that are otherwise not warranted in the case of nonprescription methods. It may be that after experience with the notification requirement in this critical area, the Department will wish to reconsider whether to broaden (or narrow) its application.

As discussed above, the Department does not agree with the projections made by many commenters as to the increase in teenage pregnancy likely to result from requiring notification of prescription methods. In this regard it should be noted that where a minor objects to notification, the project is free to provide the minor with nonprescription contraceptives and education concerning their use. In any event, it is our belief that the health concerns associated with the use of prescription methods are, as pointed out by many comments and discussed previously, sufficiently significant to justify providing parents with the opportunity to influence the contraceptive choice.

The prescription classification has not been changed to exclude the diaphragm, as urged by many comments. In the Department's view, it is reasonable to defer to the medical judgments made at the State and Federal levels regarding the general health consequences of drugs and devices. See, for example, the safety, and health criteria for prescription drugs set out in 21 USC 353.

As discussed more fully above, the commenters' arguments with respect to gender discrimination are without merit. The prescription classification does not affect all women, just those choosing prescription methods. Moreover, should a male prescription method become available, it would apply to male adolescents also.

Exception for Adverse Physical Harm

Proposed § 59.5(a)(12)(B) provided that a project is not required to comply with the parental notification requirement when "the project director determines that such notification will result in physical harm to the minor by the parents or guardian." The preamble to the proposed rules explains that the exception—

> Was meant to apply to cases where there is evidence of a history of child abuse, sexual abuse, or incest, or where there are other substantial grounds to determine that notification would result in physical harm to the minor by a parent or guardian. The exception does not apply to cases where notification would result in no more than disciplinary actions of an unsubstantial nature. 47 FR 7700.

Comment: The physical harm exception frequently elicited substantial public response. A few commenters supported the exception as consistent with the statute and their views of the custodial rights and responsibilities of parents and the law regulating parent-child relationships.

Most letters, while not rejecting the exception provision, suggested various modifications. A number of these urged that the scope of the exception be broadened in several respects. Several commenters believed that the exception should be broadened to include harm of a mental or emotional nature, arguing that such harm is as damaging to an adolescent as physical harm. Other commenters felt the exception should be broadened to cover cases in which someone other than the parent might harm the child, such as another sibling unhappy because of resulting restrictions on behavior that might be imposed upon that sibling as well. Still other commenters argued that the exemption category was too narrowly drawn because it did not include all potential victims, such as boyfriend who might be subjected to harm from the

minor's father. Others argued that notification would put undue stress on parents themselves.

Many of the comments criticized the exception as vague and ambiguous. Some noted that physical harm was not defined and suggested that the type and degree of physical harm be defined. A number of comments questioned the "substantial/unsubstantial" discussion in the preamble to the proposed rules which is quoted above, pointing out that such terms are vague and open to varying interpretations by project directors. Some letters argued that the lack of precision in the concept of substantial physical harm opened up the possibility that the exception provision could be stretched to, in effect, swallow the rule. For example, a project director might determine that, if the girl's fear of parental notification would lead her to drop contraception while remaining sexually active, the girl should be judged as subject to physical harm in the form of threatened pregnancy. Others argued that the exception did and should cover such physical harm, citing pregnancy of an unwed teenager as an adverse physical health consequence likely to result if parental notification would inhibit the teenager's use of contraception. Still others argued that vagueness of the concept of substantial physical harm would deter project directors from applying the expception even where warranted.

A related concern, based on the substantial physical harm discussion and the requirement that the projects keep records of the factual basis for exception determinations, was with the degree of investigation and documentation required in order for the exception to be applied. A number of commenters assumed that the exception could not be applied unless the project obtained concrete evidence of past physical abuse, such as medical or court records. Several of these commenters thought the prospect of documenting a history of child abuse, sexual abuse, or incest was so burdensome and costly that the provision would never be used. Others argued that the requirement would require modification of the standard informed consent form normally signed by the teenager so that the exempted teenager would know that her record could be opened to inspection as is allegedly provided by § 59.5(a)(12)(i)(D). Others commenters feared that enough information about the child and family might be conveyed to others to constitute a breach of confidentiality if the clinic undertook any form of investigation regarding abuse. Still others said there are ethical and legal obligations to report evidence of child abuse to the proper authorities and that the requirement would therefore add further costs to clinic functioning.

Several letters commented on the difficulty of gauging the probability that physical harm will occur with the needed degree of accuracy, with some concluding the exception provision will not ensure that physical harm will not occur. The question of legal liability in this matter was often raised by lawyers, doctors, and clinic staff. In particular, it was questioned whether the project director is legally responsible if the minor's parent does abuse her as the result of parental notification or if the parents learn that they were not notified because they were labelled as child abusers. Some commenters said the language of the provision should be clarified so that the exception could be granted if only one parent, not both parents, was determined to be a physical threat to the child. A few writers believed there was little need for such an exception provision since those teenagers subject to potential harm from parents would themselves be deterred from seeking services once they learned of the parental notification requirement.

Several comments from State agencies and other umbrella agencies criticized the exception provision as administratively unworkable. Where the grantee is, for example, a State and the project director a State official, it was argued that the project directors would simply be unable to make the requisite determinations.

Response: The Department recognizes the merit of the comments regarding the administrative problems caused by limiting the waiver authority to the project director. We have accordingly revised the exception to provide that a project director may delegate the authority to make such determinations to clinic directors. In our view, such personnel will be better able to make the substantive determinations called for, as they will have direct access to project records and be able to deal with the minor personally. Continuation of the requirement that a record of the factual basis of the determinations be kept will assure no loss of management control as a result of this change. In addition, as suggested by many comments, the exception has been changed to clarify that the harm need come from only one of the minor's parents.

The Department has not broadened the scope of the exception as urged by the comments. The difficulty of determining substantial mental harm and the inherent ambiguity and breadth of the concept lead us to conclude that expanding the exception to include such harm would create administrative problems and would expand the exception to a point where it might vitiate the rule. The suggestions that the exception be expanded to include other potential abusers besides the parent or guardian and other potential victims besides the minor are also rejected. The practical difficulties of determining the likelihood of harm, recognized by so many commenters, obviously increase as the connection between the notification and the projected result becomes more remote. Moreover, we believe that the cases of related abuse forecast by the comments will be exceedingly rare.

We do not accept the arguments that the type of physical harm falling within the exception needs further clarification. As stated in the preamble to the proposed rules, the exception is intended to cover cases where substantial harm is probable. As implicitly acknowledged by numerous comments, health professionals routinely make judgments about whether substantial harm has occurred and is likely to recur. To define further the degree of harm would in our view undesirably limit the flexibility of such professionals to apply the exception to the wide variety of fact situations they are likely to confront.

The comments arguing that the threat of pregnancy comes within the exception misread the exception. As written, the exception applies to harm to the minor *by a parent or guardian.* Presumably, a threat of pregnancy caused by the parent or guardian would not exist except in cases of incest; in those limited cases, as stated in the preamble to the proposed rules, the exception would apply.

The comments challenging the rule as imposing unduly costly investigation and documentation requirements generally misread the preamble statement quoted above. The intent of that statement was to describe the degree of probable physical harm required to come within the exception. While projects are required to describe the factual basis underlying determinations that the exception applies, the rule does not require investigation of medical and court records (which would generally be unavailable in any event). Rather, project or clinic directors are expected to apply the exception based on a reasonable professional judgment that a credible factual basis for it exists. Where the information received by the

project or clinic director is such as to require a report of abuse to the proper authorities, he or she will have to comply with responsibilities under State law. In this regard, we note that the rule does not expose project personnel to a potential liability that does not already exist, as the liability envisioned by the comments is a function of State reporting statutes, not this rule. Moreover, the decisions which the regulations require project personnel to make are not significantly different from many decisions which those professionals must make every day. Furthermore, family planning clinics in many areas presently require parental notification or consent, and we are unaware of any significant liability problem. Therefore, we do not anticipate that the regulations will add to the liability of project officials.

Definition of "Unemancipated Minor"

Proposed § 59.5(a)(12(i)(C) defined "unemancipated minor" for purposes of the notification requirement as "an individual who is age 17 or under and is not, with respect to factors other than age, emancipated under State law." Proposed § 59.5(a)(12)(ii) provided that projects must follow the applicable State law definition of "unemancipated minor" in complying with that requirement.

Comment: Numerous commenters questioned the "unemancipated minor" definition. Many commenters argued that it was inconsistent to defer to State laws that are more restrictive than the proposed definition of emancipation while at the same time overriding the legislative judgment of the 30 States which permit minors to consent to receiving birth control services.

A number of practical questions were raised with the definition, such as whether the word of the patient or official proof of age or emancipated status is required, and if so, what form of proof is required. A small number of comments disputed the Department's contention that the emancipation determination will not present special problems since clinics must currently decide whether minors are emancipated to obtain appropriate consent for provision of medical services. They asserted that, in most States, clinics are not now required to determine emancipation status in order to obtain consent for clinical services.

A few comments criticized the definition on the grounds that the ambiguity and lack of comprehensiveness of many State emancipation laws make the definition difficult to apply. For example, some stated that unmarried minors living with a male partner and receiving no support from parents are considered emancipated for some purposes and not for others under many State laws, or that many State laws do not specify the status of a minor when pregnancy ended in stillbirth. Other queried whether minors considered emancipated for receiving other medical treatment will be considered unemancipated when they seek prescription contraceptives.

A number of concerns were voiced about the potential for fraud inherent in application of the definition. For example, many commenters speculated that minors would lie about their age and obtain bogus identification cards. Other commenters questioned what the responsibility of the project would be for investigating or reporting such fraud.

Finally, many commenters argued that the regulation fails to distinguish between mature and immature minors and thus is unconstitutionally overly broad on its face. This argument is discussed in the section on the constitutional issues above. In addition, several commenters cited national and local clinic surveys which claimed that most unemancipated minors who are patients at family planning clinics are 16–17 years old and therefore probably fall within the mature minor category. Also, younger patients are more likely to have parental consent already, according to these surveys. On the other hand, a small number of comments argued that the mature minor doctrine is seriously flawed. According to these comments, the doctrine is vague and inconsistent, curtails custodial rights of parents without diminishing their responsibilities, and places minors in an undefined position between minority and majority. These commenters also argued that even if the mature minor doctrine applies to the provision of contraceptive services to minors, this application would not negate the right of parents to know what type of medical treatment their children are receiving from public agencies.

Response: The Department has retained § 59.5(a)(12)(i)(C) as proposed. We acknowledge that this definition does not treat as emancipated, for purposes of the notification requirement, minors who under State law can give legally effective consent for limited purposes. As stated by way of explanation of the definition in the preamble to the proposed rules, "if State law would treat persons age 12 or older as emancipated for purposes of consent to medical care, Title X projects would nonetheless have to treat them as unemancipated for purposes of [the notification requirement]." 47 FR at 7699. The definition of "unemancipated minor" does not override the legislative judgment of 30 States, as contended by many commenters. Minors served in those States continue, under the rule below, to be able to consent to receipt of prescription services. Moreover, the State laws in question generally do not deal with the issue of notification (as opposed to consent). Further, it is reasonable to set a Federal age standard to accomplish a Federal statutory purpose. See *Roe* v. *Califano*, 434 F. Supp. 1058 (D. Conn. 1977); *Naylor* v. *Weinberger*, C.A. No. 75–1790 (E.D. Pa. 1976). Additionally, although one section of the rule sets a Federal age of emancipation and another requires adherence to State law, these sections are not inconsistent; rather, they accomplish the goals of encouraging family participation, as required by statute, while clarifying the relationship between Federal and State law.

With respect to the practical concerns raised by the comments, projects should follow their established procedures (which may include requiring some proof of age) for determining when a minor is emancipated. While the concept of emancipation will vary somewhat from State to State and will require judgments on the part of project officials, these determinations are of the sort that project officials often make under current procedures. Accordingly, we conclude that the regulation will not materially add to project burdens.

We disagree with the comments challenging the definition as unconstitutional because it does not provide an exception for mature minors (except, of course, where the minor is emancipated under State law). As stated above, the court cases making the mature/immature distinction arose from governmental attempts to limit access to services and do not apply to situations where the government chooses to impose conditions on the financial assistance it provides. In addition, we believe that a mature minor exception in the definition would present major administrative difficulties for projects and enforcement difficulties for the government.

Exception for Venereal Disease

Proposed § 59.5(a)(12)(i)(E) provided that the notification requirement does not apply where prescription drugs are provided for the treatment of venereal disease. The preamble to the proposed rule stated that the exception for venereal disease "is consistent with the overriding public health necessity of ensuring prevention of infection of others." 47 FR at 7700.

Comment: The majority of the letters commenting on § 59.5(a)(12)(i)(E) used terminology divergent from that employed in this subsection. The term, "sexually-transmitted diseases" or "STD" was suggested instead of "venereal disease."

Comments supporting the exception generally mirrored the public health concerns addressed in the preamble to the proposed rules. Some of these comments pointed out that the safety of others is fostered when STD is treated, while the provision of contraceptives has implications for the physical health of only the patient. Other commenters argued that the prescription of drugs was "therapeutic" in the case of STD but not in the case of contraceptives. It was argued that direct and severe negative consequences to the patient follow non-treatment of STD, while failure to provide prescription contraceptives does not inevitably produce such serious medical complications. Other commenters said that there are no medically acceptable alternatives to immediate administration of therapeutic medication to someone with a potentially curable STD, while the provision of prescription contraceptives is but one of several strategies for preventing pregnancies, e.g., non-prescription methods or abstinence. A few commenters expressed the belief that the exemption had to be included because 50 States, the District of Columbia, and Puerto Rico have laws or regulations which allow minors to be examined and treated for STD without parental consent.

Occasionally, letters argued against the inclusion of an exemption for STD. Some argued that parents have the right to know if their child has STD, while a few others argued that parents should be notified about their child's treatment for STD, since the health risks of the antibiotics prescribed for such diseases are greater than those of prescription contraceptives. A few commenters suggested a modification of the proposed regulations to exempt adolescents being treated for STD from the requirement for parental notification for contraceptive services.

Many letters contained viewpoints about the probable impact of the regulations generally on the incidence of STD among adolescents. Some believed that the regulations would help curtail STD by causing adolescent sexual activity to decrease and by improving contraceptive practices of the sexually active through parental involvement in contraceptive decision-making. More frequently, however, commenters thought that the regulations would result in an upswing of STD among adolescents due to reduced attendance at family planning clinics. Information about STD, checkups for such diseases, and treatment of discovered cases provided at clinics in association with contraceptive services would allegedly be forgone.

A number of commenters argued that the exemption for STD exposed a basic inconsistency in the rule as a whole. They argued that, if the exemption derives from a concern that adolescents would not go to clinics for treatment of STD if parents were notified, the same logic applied to prescription contraceptives. Some also argued that the entire notification requirement should be dropped on the basis that adolescent pregnancy is as major a public health problem as STD is. Opponents of the proposed regulation also asserted that inclusion of the exemption recognizes that sexual activity among adolescents will continue regardless of these regulations.

Response: As suggested by many comments, the terminology of the exemption has been changed from "veneral disease" to "sexually transmitted disease." The exemption otherwise remains unchanged. The Department agrees with the commenters supporting the exemption that materially different considerations apply to the treatment of STD than apply to the prescription contraception decision. We reject the arguments equating the health risk to females of pregnancy to that of STD, as that argument does not consider the relevant risk in its entirety: The public health risk is not limited to females who forego contraception while engaging in sexual activity, but rather extends to the entire sexually active adolescent population. Moreover, as pointed out by many comments, there is no reasonable alternative to treatment in the case of STD, while a number of alternatives exist in the case of the prescription contraception decision. This consideration also justifies, in our view, not notifying the parents of minors being treated for STD.

For all these reasons, the Department also rejects the arguments that the STD exemption constitutes a fundamental inconsistency in the rule as a whole.

Requirement of Compliance With State Law

Proposed § 59.5(a)(12)(ii) required projects to comply with State laws requiring parental notification or consent to the provision of family planning services to persons who are unemancipated minors under State law.

Comment: A sizable minority of the comments discussed this provision of the proposed rule. Many commenters criticized the provision as inconsistent with the policy of "New Federalism" arguing that it would selectively defer to more restrictive State laws while overriding less restrictive State laws providing for confidential family planning services to adolescents. These commenters claimed that 30 States and the District of Columbia authorize minors to obtain family planning services or all health care including family planning on the basis of their own consent. Several of these commenters also claimed that 17 other States have granted physicians the ability to prescribe contraceptives to minors without parental consent or notification if deemed to be in the best interest of the minor. Several commenters asserted that either no State or only one State, Utah, requires parental notification of any kind and that Utah's statute is now subject to a constitutional challenge in light of *H.L. v. Matheson*, 450 U.S. 398 (1981), and is not being enforced.

Other commenters discussed administrative problems of the provision. They argued that unless State statutes providing for confidential family planning services for teenagers are repealed, Title X grantees who also receive State funds may violate either Federal regulations or State statutes in providing contraceptive services to adolescents.

Response: The proposed provision regarding compliance with State law remains unchanged in the rule set forth below. The Department notes that § 59.5(a)(12)(ii) is not inconsistent with State laws; on its face, it defers to State-imposed notification or consent requirements. Nor do we think that there is any inconsistency in deferring only to those State laws which impose parental notification or consent requirements going beyond the Federal mandates. As discussed above, we have deferred to the consent laws of all States, which are unaffected by any part of the rule. We recognize that conflicts may exist to the extent that States enact laws prohibiting parental notification. However, failure to defer to such laws is not indicative of a lack of consistency in the rule as a whole. Rather, in view of our belief that a parental notification requirement best accomplishes the intent of the 1981 amendment of section 1001(a), it would be inconsistent with this view were the Department to defer to contrary State laws.

With respect to the confidentiality problems under State laws, those

problems generally should not arise because the minor will have, in effect, consented to the parental notification. Projects are of course free to obtain written consents to such disclosures from the minors involved if they believe that it is legally advisable.

Definition of Low Income Family

Under the proposed rule, the definition of the term "low income family" at 42 CFR 59.2 would be revised to eliminate the requirement that minors be considered on the basis of their resources rather than those of their families.

Comment: A significant number of comments addressed the change in the definition of "low income family." A number argued that the change is an improvement, since the present definition has the effect of diverting limited Federal monies from those who most need financial assistance. Related comments stated that the change was justified because taxpayers should not subsidize health care which adolescents and their families could pay for themselves. Some of these commenters also argued that the present policy, by providing minors with free or below-cost services, allows them to avoid family participation in family planning services.

Many commenters criticized the change as unfair to poor and minority adolescents and argued that the current definition represents better public policy. It was argued in support of this position that adolescents earn little or no money on their own, the adults are often unwilling to disclose their incomes to children or to institutions, and that most adolescents do not have access to their families' income to pay for family planning services. A few commenters cited studies which found that teenagers' disposable income has little relationship to the income of their parents.

Other commenters discussed a report published by Chamie, *et al.*, "Factors Affecting Adolescents' Use of Family Planning Clinics," *Family Planning Perspectives*, (1982) in which 1,575 minor patients gave reasons why they used family planning clinics rather than private physicians. Answering a multiple-response question, 60 percent of the patients reported that they thought doctors were too expensive, and 43 percent of the patients said that they feared a private physician would inform their parents. These commenters predicted from this data that the change in definition would deter many adolescents from using family planning clinics.

A few comments from clinic staff members discussed the effects of the change in definition by describing the characteristics of their own clinic population. A small number noted that, among their patients, low income minors were likely to inform their parents and that middle class (and usually white) minors were least likely to inform their parents. They predicted that many of these middle class minors would stop using effective contraceptives, become pregnant, and be likely to abort the pregnancy because a child would disrupt their lifestyle and career plans.

Several commenters raised questions regarding the mechanics of the change. They questioned how family income would be assessed: would the word of the minor be acceptable or would a signed statement by the parents or official tax form be required. In addition, when the minor does not live at home or is in the custody of only one parent, they questioned whether the income of both parents must be considered.

Many comments opposing this provision argued that the change in definition would deter minors from seeking family planning services, and thereby violate the Title X provision regarding expanding services to adolescents. In this regard, some argued that the change is, *de facto*, a parental consent requirement, because it requires teenagers who cannot pay for themselves to ascertain and verify parental income prior to service; they alleged that if the parents refuse to disclose the family's income, it would effectively prohibit the teenager's receipt of family planning services, contrary to Congressional intent. They also asserted that the change is inconsistent with the requirement of sec. 1006(c) that "low income family" be defined so as to insure that "economic status shall not be a deterrent to participation" in family planning services.

Response: The proposed change in the definition of "low income family" is retained in the rule below. The Department continues to believe that it is inappropriate to target increasingly scarce Title X dollars to minors who, because of their family circumstances, can pay all or a portion of the cost of services.

The basic question raised by the proposed change is whether it will render family planning services unaffordable by adolescents. The Chamie study cited by many commenters indicates that approximately 50 percent of all adolescents already pay some amount for the services they receive. Moreover, because of its methodology, the study does not, in our view, clearly establish that lessening or eliminating the present subsidy will make the services unaffordable. We do not agree that children of middle class families will forgo family planning services because of the change in the definition of income. In the few cases where parents who are able to help pay for these services refuse to contribute, the clinics, in accordance with the existing language of the current regulations, will be able to adjust the fees. We also note in this regard that projects have significant latitude in establishing charging policy, as there is no Federal requirement that each service provided bear precisely its proportionate share of the project charge structure. Thus, where a project is concerned about the possible effect of the change, it has some flexibility in pricing its services. For these reasons, the low income provision is not a *de facto* consent requirement.

We also disagree with the contentions of opponents of the change that it violates Title X in various respects. For the reasons stated above, we do not think that the change will constitute an economic deterrent to services for adolescents whose families are not low income. Moreover, under section 1006(c), it is the income of the "family", not of the "person" that is relevant; thus, the definition below is more consistent with the statutory language on its face than was the prior definition. In addition, the legislative history of this provision makes clear that the focus of the provision was "medically indigent families" *See* H.R. Rep. No. 94–192 at 104; *see also* S. Rep. No. 94–29 at 93. The definition below is therefore completely consistent with sec. 1006(c).

The change in the definition is also consistent with the 1978 amendment to sec. 1001(a) requiring "services to adolescents." The regulation as a whole continues to require that such services be provided and, where the adolescent is from a low income family, that they be provided at no or reduced charge. The change hardly discriminates against the poorest adolescents, as charged by some commenters, since the change in the definition stands to benefit them the most by targeting scarce Federal dollars to them.

With respect to the administrative difficulties foreseen by some commenters, the Department disagrees that these should be materially different from any that now exist. At present, projects are required by section 1006(c) and § 59.2 to make income determinations for the purpose of determining whether patients are "low

income." This requirement continues to apply, and we assume that projects will continue to employ the procedures they have already developed to comply with the existing regulatory requirements.

Executive Order 12291

Some commenters stated that the Department failed to comply with the requirements of Executive Order 12291. As noted in the preamble to the proposed amendments, the Secretary concluded that these amendments are not major rules within the meaning of the Executive Order because they will not have an effect on the economy of $100 million or more or otherwise meet the threshold criteria. We have also considered the section 2 requirements of the Executive Order and, as reflected in the preamble to the notice of proposed rulemaking, have found (1) that we had adequate information concerning the need for and consequences of the requirements imposed by the amendments, (2) that the potential benefits to society outweigh potential costs to society, (3) that the amendments maximize the net benefits to society, and (4) that among the alternatives available to us, the requirements of these amendments involve the least net costs to society.

Paperwork Reduction

These amendments to the Department's Title X regulations contain requirements which have been reviewed and approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1980. The OMB control number assigned to these requirements is *0937-0111.*

Regulatory Flexibility Analysis

For the reasons stated in the preamble to the proposed rules, the Secretary certifies that an initial regulatory flexibility analysis is not required.

List of Subjects in 42 CFR Part 59

Family planning, Grant programs—health, Youth.

The HHS regulations governing grants for family planning services, 42 CFR Part 59, are hereby revised as set forth below.

Dated: January 5, 1983.

Edward N. Brandt, Jr.,

Assistant Secretary for Health.

Approved: January 7, 1983.

Richard S. Schweiker,

Secretary.

PART 59—[AMENDED]

§ 59.2 [Amended]

1. The last sentence of the definition of "low income family" in 42 CFR 59.2 is revoked and removed.

2. 42 CFR 59.5 is amended by adding thereto the following paragraph (a)(12), to read as follows:

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

(a) * * *

(12) Encourage, to the extent practical, family participation in the provision of the project's services to unemancipated minors. Notwithstanding any other requirement of this subpart, a project shall,

(i)(A) When prescription drugs or prescription devices are initially provided by the project to an unemancipated minor, notify a parent or guardian that they were provided, within 10 working days following their provision. The project must tell the minor prior to the provision of services about this notification requirement. As used in this subsection, the phrase "parent or guardian" shall refer to a parent or guardian residing with the minor or otherwise exercising ordinary parental functions with respect to the minor. The project shall verify by certified mail (with restricted delivery and return receipt requested), or other similar form of documentation, that the notification has been received. Where the project is unable to verify that notification was received, the project shall not provide additional prescription drugs or devices to the minor.

(B) A project is not required to comply with paragraph (a)(12)(i)(A) of this section where the project director or clinic head (when specifically so designated by the project director) determines that notification will result in physical harm to the minor by a parent or guardian.

(C) For the purposes of this paragraph (a)(12)(i), an "unemancipated minor" is an individual who is age 17 or under and is not, with respect to factors other than age, emancipated under State law.

(D) The project must keep records of notifications provided pursuant to the first sentence of paragraph (a)(12)(i)(A), and of verification that those notifications were received. The project must also keep records of the number of determinations made under paragraph (a)(12)(i)(B) and the factual basis for such determinations. The project must make records required by this subparagraph available to the Secretary on request.

(E) This paragraph (a)(12)(i) does not apply where prescription drugs are provided for the treatment of sexually transmitted diseases.

(ii) Where State law requires the notification or consent of a parent or guardian to the provision of family planning services to an individual who is an unemancipated minor under State law, provide such services only in the compliance with such law.

(Sec. 215, Public Health Service Act, 58 Stat. 690, 42 U.S.C. 216; Sec. 1006(a), Public Health Service Act, 84 Stat. 1507, 42 U.S.C. 300a-4(a); sec. 931(b)(1) of Pub. L. 97-35, 95 Stat. 570, 42 U.S.C. 300(a))

[FR Doc. 83-2125 Filed 1-24-83; 8:45 am]

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Wednesday, February 16, 1983

Claire del Real--(202) 245-6343

STATEMENT BY THOMAS R. DONNELLY JR.
ACTING SECRETARY OF HEALTH AND HUMAN SERVICES

On Feb. 14, U.S. District Judge Henry Werker issued a preliminary injunction blocking HHS from enforcing a rule requiring notification of parents when their minor teen-agers are given prescription contraceptives at family planning facilities that receive federal Title X funds.

We regret Judge Werker's decision. The Department of Health and Human Services continues to believe that the parental notification rule is legally sound, that it is authorized by law and consistent with the clear intent of Congress.

Consequently, the department will be appealing Judge Werker's injunction to the U.S. Circuit Court of Appeals for the Second Circuit, with a request that the appeal be heard on an expedited basis. In order to facilitate the appellate process, we are promptly filing a motion seeking to finalize Judge Werker's preliminary order. We believe this will assist us in obtaining prompt consideration by the Second Circuit of our position on appeal.

# # #

N.Y. Times; 2-27-83

Emergency Rooms Shut On Weekends in Mobile

MOBILE, Ala., Feb. 26 (AP) — To keep out people who cannot pay their bills, all but one of the six hospitals in Mobile closed their emergency rooms this weekend.

State Attorney General Charles Graddick unsuccessfully tried to prevent the University of South Alabama Medical Center from closing its emergency room. The State Supreme Court permitted the first closing on Feb. 11 and the legal battle appears at an end.

The medical center says the rising cost of caring for indigent patients has threatened its financial stability. Medicaid, the health program for the indigent, does not come close to meeting the cost, the medical center says.

For two weekends, five private hospitals maintained emergency room service for patients turned away from the medical center. But four dropped out and only Springhill Memorial Hospital said it would keep its emergency room open this weekend.

Before the weekend shutdown started, patients were referred to different hospitals through a Civil Defense telephone network. But one by one the private hospitals bowed out of the rotation system, until only Springhill remained open, accepting patients who have doctors as well as those who do not.

N.Y. Times; 2-28-83

Wednesday

Cigarette smokers, beware. The American Cancer Society, the American Heart Association and the American Lung Association will discuss proposed legislation to strengthen warnings on cigarette labels. 10 A.M., 2322 Rayburn.

Car Recalls: A subcommittee of the House Energy and Commerce Committee will hold a hearing on reasons for the Government's three-year delay in completing an investigation into defects in General Motors' 1980 X-cars. 9:30 A.M., Room 2322 Rayburn.

Medicare: A subcommittee of the House Select Committee on Aging will seek to determine the effect of proposed changes in Medicare benefits. 9 A.M., Room 2255 Rayburn.

THE GREEN SHEET

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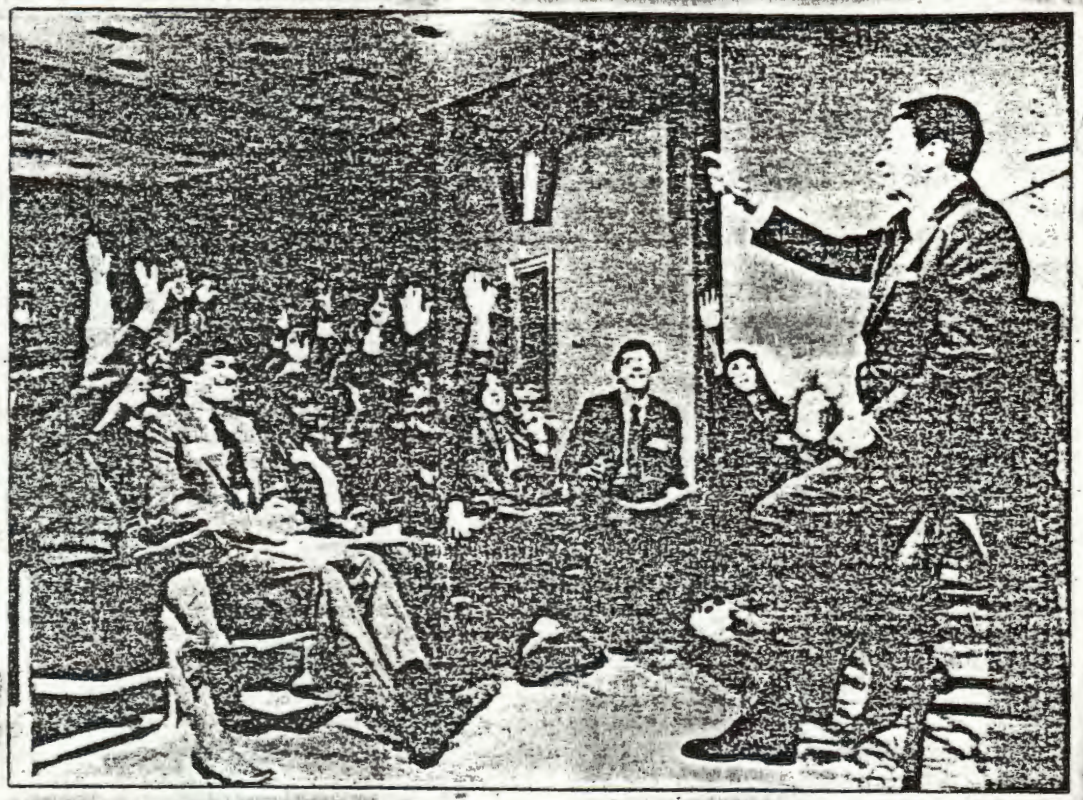
Address inquiries to:
Ronald Steele
Managing Editor
638E, Hubert H. Humphrey Bldg.
245-7263



Associated Press

President Reagan answers questions from a group of high school students during a cable television taping session.

Balt. Sun; 2-26-83

Reagan lectures teens on logic of 'squealing'

By Robert Timberg
Washington Bureau of The Sun

Washington — President Reagan told high school students yesterday that the government has no right to provide teenage girls with birth control pills and devices without informing their parents.

"Government can be a lot of things, but it can't be momma and poppa, and it shouldn't try," the president said when asked how he justifies a federal regulation — currently blocked by the courts — that would require federally financed clinics to so inform parents.

The president also said the congressional battle over his nominee for arms control director, Kenneth L. Adelman, "has been injurious to us in the eyes of our allies and friends."

He labeled the Senate Foreign Relations Committee "very irresponsible" for recommending Thursday that the full Senate reject Mr. Adelman and pledged to do "everything I can" to win his confirmation.

The committee, on a 9-8 vote, refused to endorse Mr. Adelman for the arms control post, but later agreed 14-3 to a compromise that allowed his name to go to the floor with an unfavorable report.

Mr. Reagan's comments came in a question-and-answer session with students from high schools in seven states, including several schools for the hearing impaired. The session was carried on television by the Cable Satellite Public Affairs Network.

Asked about his administration's so-called "squeal" or "snitch" rule, which would require clinics to inform parents when their teenage daughters are given prescription contraceptives, Mr. Reagan told his female questioner that she might not agree with his answer, "but maybe your parents will."

"I don't think government has a right to stick its nose into the family and tell parents what they can and cannot know about their children and, therefore, we put out that regulation," Mr. Reagan said.

Saying the rule has been criticized as interfering with the rights of young people, Mr. Reagan said providing contraceptives without informing parents was tantamount to government interfering in the relationship between parent and child.

He said the criticism amounted to saying, "We the government reserve the right to do something of this kind in collusion with your children and we're not going to let you know about it."

The administration has announced it will appeal two recent court decisions blocking family planning clinics from putting the rule into effect.

The National Women's Health Network yesterday began collecting signatures on a petition asking that President Reagan fire the woman regarded as the chief author of the rule.

The woman, Marjory Mecklenberg, is deputy assistant secretary for population affairs at the Department of Health and Human Services.

The Women's Health Network, the largest women's health organization in the country, estimates that implementation of the rule would cause at least 30,000 adolescents not to seek contraceptives from birth control clinics.