the Office of Hearings and Appeals within 10 days of the scheduled informal hearing. The parties shall be notified of the determination. If the Director declines to request a hearing the employee shall be notified within 10 days of the scheduled informal conference and informed of his right to request a hearing on his own behalf.

(b) The employee may request a hearing with the Office of Hearings and Appeals after 60 days have elapsed from the filing of his application.

§ 830.15 Formal adjudicatory proceedings.

(a) Formal adjudication of a complaint filed under this part shall be conducted in the Office of Hearings and Appeals under 43 CFR Part 4.

(b) A hearing shall be held as promptly as possible consistent with the opportunity for discovery provided for under 43 CFR Part 4.

(c) Upon a finding of violation of section 830.11 of this part, the Secretary shall order the appropriate affirmative relief including, but not limited to, the rehiring or reinstatement of the employee or representative of employees to his former position with compensation. At the request of the employee a sum equal to the aggregate amount of all costs and expenses including attorneys' fees which have been reasonably incurred by the employee for, or in connection with, the institution and prosecution of the proceedings shall be assessed against the person committing the violation.

(d) On or after 10 days after filing an application for review under this part the Secretary or the employee may seek temporary relief in the Office of Hearings and Appeals under 43 CFR Part 4.

[FR Doc.77-35049 Filed 12-5-77;2:30 pm]

[4310-05]

PART 837—ABANDONED MINE RECLAMATION FUND—FEE COLLECTION AND COAL PRODUCTION REPORTING

Final Rules

AGENCY: Office of Surface Mining Reclamation and Enforcement, Department of the Interior.

ACTION: Final rules.

SUMMARY: These regulations provide each coal mine operator with methods to determine his reclamation fee obligation to the Abandoned Mine Reclamation Fund (fund), provide instructions for the proper payment of the reclamation fee, and provide for the maintenance of production records.

EFFECTIVE DATE: December 8, 1977.

ADDRESS: Director, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, Washington, D.C. 20240, 202-343-4237.

FOR FURTHER INFORMATION CONTACT:

Paul Reeves, 202-343-4237.

SUPPLEMENTARY INFORMATION: Proposed rules implementing section 402 of the Surface Mining Control and Reclamation Act of 1977 were published in the FEDERAL REGISTER on September 7, 1977. Public hearings on the proposed rules were held on September 20, 1977. At the close of the comment period on October 7, 1977, comments had been received from 21 commenters.

The purpose of these regulations is to provide the operator with the method by which his reclamation fee will be determined and inform him of his obligation to maintain adequate production records to verify his payment.

The Office of Surface Mining Reclamation and Enforcement (OSM) has made a number of changes of a non-substantive editorial nature. Changes also have been made in response to public comments.

EDITORIAL CHANGES

1. The definition of coal preparation has been deleted because use of the phrase in § 837.16 has been dropped. Records must be kept which reflect the amount of all coal consumed by an operator for any purpose. The intent is made clearer by merely dropping the term.

2. "Parr's formula" referred to in the definition of lignite has been reprinted verbatim to avoid possible confusion and the necessity to cross-reference. It should be noted that the Annual Book of ASTM Standards is the accepted work in the field, and formulae in the publication must be relied on for determination of the other factors in the formula.

Other changes have been made in the regulations and are discussed in relation to the specific comments received.

COMMENTS

1. One commenter suggested that subbituminous coal with a calorific value of less than 8300 Btu's per pound, moist, and mineral-matter-free should qualify for the lower fee applicable to lignite. This comment was not accepted. The statutory definition of lignite requires that the coal must meet not only the calorific value specification but also be "consolidated" and "lignitic". Subbituminous coal does not fulfill these conditions regardless of its Btu value.

2. Several commenters raised questions as to who is an operator responsible for payment of the fee. Section 402 of the Act requires that all operators pay the fee. Section 701 of the Act defines "operator" as the "person * * * engaged in coal mining who removes * * *" the coal. Commenters pointed out that in some cases the one who removes the coal is actually a contractor who may be paid only for his services and who has no ownership or beneficial interest in the coal. The number and variety of business arrangements employed in the coal industry make it difficult to further define "operator" without considering the specific facts of particular cases. We believe that Congress intended the burden of fee payment to fall upon the person who stands to benefit directly from the sale, transfer, or use of the coal. This intent will guide the Office in making decisions as to who is liable for the fee. The identification of operators will be made in light of the realities of the business world and will not turn solely on a literal interpretation of the word "removes".

OSM intends to send a preprinted Coal Production and Reclamation Fee Report form to all operators who are listed on the Mining Enforcement and Safety Administration's (MESA's) operator-mine identification number list. By using MESA's list, a dual identification system will not be necessary, and administrative and recordkeeping costs to the government and the coal mine operators will be reduced. OSM will make adjustments to the MESA list as necessary.

It is anticipated that many of the problems of determining liability for the fee among parties to particular business arrangements will be alleviated as production and supply contracts are negotiated and renegotiated. Contractual agreement for determining liability for the fee may be a helpful guide in determining liability for the fee. It should be emphasized, however, that the Office intends to collect the proper reclamation fee for each ton of coal produced for sale, transfer, or use.

3. One commenter recommended that the fee not be paid on reclaimed coal since the mining of such coal reduces an existing environmental impact of past mining and thereby achieves a purpose of the Act. The recommendation has not been accepted. The Act requires that all coal mining operations subject to the Act be liable for payment of the fee and defines these operations to include the mining of reclaimed coal. It is the intent of the regulations to impose the fee only once on each ton of coal; however, it is the operator's obligation to maintain records showing previous payment of the reclamation fee on reclaimed coal deposits.

4. Two commenters argued that because operators conducting mining operations on previously mined and unreclaimed lands would enhance the recovery of these lands, such operators should receive a credit to offset their total fee obligation. This recommendation has not been accepted because the Act requires that operators of all coal mining operations pay the fee.

5. Two commenters argued that the proposed regulation requiring an operator of an in situ mining operation to pay a reclamation fee should be changed since such a requirement exceeds the rulemaking authority provided under the Act. The provision remains in the final rules. Adequate authority to promulgate such a requirement exists since the Act requires that all mining operations be subject to the fee at an appropriate rate and the process of in situ distillation or retorting is included within the definition of surface coal mining operations.

6. Several commenters questioned the definition of the word "value" and requested that the definition be more specific. It was suggested that the term "value" exclude all royalties, severance

taxes, other taxes and this reclamation fee. In the final rules, "value" has been redefined to clarify that gross value is determined at the time of initial bona fide sale, transfer of ownership, or use and this is consistent with the determination of when the fee is to be computed. Further, it is only logical and equitable that the reclamation fee required by these regulations not be considered in the computation of the value, because without including the fee in the calculation of value, the lower percentage rate fee may apply. Severance taxes and royalties are costs of doing business analogous to other costs and must be considered in the determination of the value of the coal.

7. One commenter asked whether the regulations required the fee to be paid on clean coal or run-of-mine coal. Section 837.12 (a) and (b) of the regulations specify that the fee be paid on each ton of coal produced for sale, transfer, or use and that the fee shall be determined at the time of initial bona fide sale, transfer of ownership, or use by the operator. For example, if the initial transaction is based on the weight of run-of-mine coal then the reclamation fee must be paid for each ton of run-of-mine coal sold, transferred, or used. If the initial transaction is based on the weight of clean coal, then the reclamation fee must be paid on each ton of clean coal sold, transferred, or used.

8. A number of comments requested that some allowances be made for situations where shipping receipts indicating actual tonnage are not received in time to report production during the calendar quarter in which the fee is due. A suggested solution was that estimated fee payments be permitted with later adjustments made as necessary. No change is made because Section 402(b) of the Act requires payment "no later than thirty days after the end of each calendar quarter."

9. Comments were received requesting that persons operating more than one mine be permitted to submit a single reporting form and a single check to cover all operations. This recommendation was partially accepted. For effective enforcement and administrative purposes, it is necessary to have a separate production report for each mine. A single check covering multiple operations, accompanied by a separate report for each mine, is permitted by the final regulations and should reduce paperwork to some extent.

10. Numerous comments objected to the requirement in § 837.16 that "any" book or record be made available for inspection and copying to the fee compliance officer. The concern was for overly broad inspection rights and the confidentiality of business information copied by the officer. The regulations have been revised to expressly limit the fee compliance officer's right to inspect such books and records necessary to substantiate the accuracy of reports and payments. This provision makes clear that the standard for such inspection is relevancy. Further, the right to copy price information is limited to those cases where the fee is based on percentage of value. If the flat cents-per-ton fee is paid, price information is not relevant. Customer identity cannot be similarly protected because it may be necessary to verify tonnage with customers. Information copied will be subject to disclosure in accordance with the Freedom of Information Act.

11. One commenter interpreted § 837.16 to require the maintenance of production records at each mine site and requested that the regulations be altered to permit centralized record collection where a central accounting procedure is used. Section 837.16(b) requires that the fee compliance officer shall have access to the mine in order to verify compliance. Section 837.16(c) requires that the fee compliance officer be afforded access to necessary books and records. Neither paragraph requires that records be kept at a specific location. Records may be kept at centralized locations, and the operator will be required to identify the location of all such records on the Coal Production and Reclamation Fee Report form.

12. Several commenters suggested that operators not be required to maintain voluminous records for seven years. Actual truck receipts need not be kept for the full term, but normal business records which include the information required to be kept by § 837.16 must be kept. The retention period was shortened from seven years to six years in conformity with the Federal statute of limitations applicable to enforcement actions.

Effective Date

It is the Department's policy in most cases to make final regulations effective 30 days after the date of publication. However, these regulations are effective on the date of publication because section 402 of the Act requires that the fee be paid on coal produced in the fourth calendar quarter of 1977.

Information Collection Provisions

Section 837.15 prescribes the use of OSM Form 837–1, each calendar quarter, to report information determined by this Department to be necessary to the performance of its responsibilities under the Act. The General Accounting Office, pursuant to 44 U.S.C. 3512, has determined that use of this form does not impose an unreasonable burden on operators, and, accordingly, § 837.15 is effective on December 8, 1977.

Section 837.16 requires all operators to collect and retain certain information. By publication of these final regulations, this Department has determined that such information is necessary to the performance of its responsibilities under the Act and must be collected and retained. Accordingly, the requirements of § 837.16 are adopted, subject only to review by the General Accounting Office, pursuant to 44 U.S.C. 3512, to assure that they impose a minimum burden upon operators in the manner in which the information is proposed to be obtained. This § 837.16 will be effective January 29, 1978 or on the date of GAO clearance, whichever is earlier.

Drafting Information

The principal authors of these final regulations are George Williams, Surface Mining Task Force, and Edward Clair, Office of the Solicitor, Department of the Interior.

Dated: December 1, 1977.

Leo M. Krulitz,
Solicitor of the Interior.

In consideration of the comments received and pursuant to the authority of sections 201(c) and 402 of the Surface Mining Control and Reclamation Act of 1977, 30 CFR Chapter VII is amended by adding a new Part 837, to read as follows:

Sec.
837.1 Scope.
837.2 Objectives.
837.3 Responsibility.
837.5 Definitions.
837.11 Applicability.
837.12 Reclamation fee.
837.13 Fee computations.
837.14 Determination of percentage based fees.
837.15 Reclamation fee payment.
837.16 Production records.

Authority: Sec. 201, Pub. L. 95–87, 91 Stat. 445 (30 U.S.C. 1201).

§ 837.1 Scope.

This part sets out the procedures for the collection of fees for the Abandoned Mine Reclamation Fund (fund).

§ 837.2 Objectives.

The objectives of this part are to establish—

(a) Methods for determining the reclamation fee payable on coal production.

(b) Procedures for paying the reclamation fee to the Director.

(c) Requirements for production recordkeeping and reporting.

§ 837.3 Responsibility.

(a) The Secretary of the Interior administers the fund.

(b) The Director, under the general direction of the Assistant Secretary, Energy and Minerals, is responsible for administering the provisions of this part.

§ 837.5 Definitions.

As used in this part—

Anthracite, bituminous and subbituminous coal means all coals other than lignite coal.

Calendar quarter means a 3-month period within a calendar year. The first calendar quarter begins on January 1 of a calendar year and ends on the last day of March. The second calendar quarter begins on the first day of April and ends on the last day of June. The third calendar quarter begins on the first day of July and ends on the last day of September. The fourth calendar quarter begins on the first day of October and ends on the last day of December.

Fee compliance officer means any person authorized by the Secretary to exercise his authority in matters relating to this part.

In situ coal mining means the process of recovering energy from coal in its natural geological location by igniting the coal seam and recovering the gas at the wellhead.

Lignite coal means consolidated lignitic coal having less than 8,300 British thermal units per pound, moist, and mineral-matter-free. British thermal units per pound, moist and mineral-matter-free, are determined by Parr's formula, page 213, equation 3, D–388 (reapproved 1972), Part 26, 1976 Annual Book of ASTM Standards as follows:

Moist, Mm-free Btu=
(Btu−50S)/[100−(1.08A+0.55S)]×100
where:
Mm=mineral matter
Btu=British thermal units per pound (calorific value)
A=percentage of ash, and
S=percentage of sulfur
"Moist" refers to coal containing its natural inherent or bed moisture, but not including water adhering to the surface of the coal.

Reclaimed coal means coal recovered from a deposit that is not in its original geological location. Examples of these deposits are refuse piles or culm banks; refuse, culm or retaining dams and ponds that are or have been used during the mining or preparation process; and stream coal deposits.

Surface coal mining means the extraction of coal from the earth by removing the materials over the coal seam before recovering the coal and includes auger coal mining.

Ton means 2,000 pounds avoirdupois (0.90718 metric ton).

Underground coal mining means the extraction of coal from the earth by developing entries from the surface to the coal seam before recovering the coal by underground extraction methods and includes in situ mining.

Value means gross value at the time of initial bona fide sale, transfer of ownership, or use by the operator, but does not include the reclamation fee required by this part.

§ 837.11 Applicability.

The regulations in this Chapter apply to all surface coal mining and reclamation operations except—

(a) The extraction of coal by a landowner for his own non-commercial use from land owned or leased by him;

(b) The extraction of coal for commercial purposes by surface mining which affects two acres or less during the life of the mine;

(c) The extraction of coal as an incidental part of Federal, State, or local government-financed highway or other construction; and

(d) The extraction of coal incidental to the extraction of other minerals where coal does not exceed 16⅔ percent of the mineral tonnage removed for commercial use or sale.

§ 837.12 Reclamation fee.

(a) The operator shall pay a reclamation fee on each ton of coal produced for sale, transfer, or use, including the products of in situ mining.

(b) The fee shall be determined by the weight and value at the time of initial bona fide sale, transfer of ownership, or use by the operator.

(c) If the operator combines surface mined coal, including reclaimed coal, with underground mined coal before the coal is weighed for fee purposes, the higher reclamation fee shall apply, unless he can substantiate the amount of coal produced by each mining method by acceptable engineering calculations or other reports which the Director may require.

(d) In computing the tons of coal produced for reclamation fee purposes in the fourth calendar quarter of 1977, the operator may deduct the tons of coal immediately available for sale, transfer, or use on September 30, 1977, from that coal sold, transferred or used during the fourth calendar quarter of 1977. If the operator makes this deduction, he shall attach to his fourth quarter, 1977, OSM form 837–1, a sworn and notarized statement of the amount of coal immediately available for sale, transfer or use on September 30, 1977, and the quantity of such coal produced by surface and underground mining respectively.

§ 837.13 Fee computations.

(a) *Surface mining fees.* The fee for anthracite, bituminous, and subbituminous coal, including reclaimed coal, is 35 cents per ton unless the value of such coal is less than $3.50 per ton, in which case the fee is 10 percent of the value.

(1) If the value of a ton of coal is equal to or greater than $3.50 per ton, multiply the number of tons produced in the calendar quarter by $0.35. Example: If the tonnage is 1,000, then 1,000 tons×$0.35=$350, which is the fee.

(2) If the value of a ton of coal is less than $3.50 per ton, multiply the value of a ton of coal by the total number of tons produced in the calendar quarter by 0.1. Example: If the value of a ton of coal is $2 and the tonnage is 1,000, then $2×1,000 tons×0.1=$200.

(b) *Underground mining fees.* The fee for anthracite, bituminous, and subbituminous coal is 15 cents per ton unless the value of such coal is less than $1.50 per ton, in which case the fee is 10 percent of the value.

(1) If the value of a ton of coal is equal to or greater than $1.50 per ton, multiply the number of tons produced in the calendar quarter by $0.15. Example: If the tonnage is 1,000, then 1,000 tons×$0.15=$150, which is the fee.

(2) If the value of a ton of coal is less than $1.50 per ton, multiply the value of a ton of coal by the total number of tons produced in the calendar quarter by 0.1. Example: If the value of a ton of coal is $1 and the tonnage is 1,000, then $1×1,000 tons ×0.1=$100, which is the fee.

(c) *Surface and underground mining fees for lignite coal.* The fee for lignite coal is 10 cents per ton unless the value of such coal is less than $5 per ton, in which case the fee charged is 2 percent of the value.

(1) If the value of a ton of lignite is equal to or greater than $5 per ton, multiply the number of tons produced in a calendar quarter by $0.10. Example: If the tonnage is 1,000, then 1,000 tons ×$0.10=$100, which is the fee.

(2) If the value of a ton of lignite is less than $5 per ton, multiply the value of a ton of lignite by the total number of tons produced in the calendar quarter by 0.02. Example: If the value is $4 and the tonnage is 1,000, then $4×1,000 tons×0.02=$80, which is the fee.

(d) *In situ coal mining fees.* The fee for in situ mined coal, except lignite coal, is 15 cents per ton based on Btu's per ton in place equated to the gas produced at the site. The fee for in situ mined lignite is 10 cents per ton based on the Btu's per ton of coal in place equated to the gas produced at the site. For example, if the Btu value of in situ coal is determined to be 23 million Btu's per ton, then for every 23 million Btu's of gas produced at the wellhead, one ton of coal will be deemed produced for the purposes of this part.

(1) The Btu value of a ton of in place coal shall be determined by analyses, certified by an independent laboratory, of the coal seam that is effected for potential Btu value of a ton of in place coal.

(2) For anthracite, bituminous, and subbituminous coal the fee shall be computed as follows: $F=(G/C)\times V_1$.

(3) For lignite coal the fee shall be computed as follows: $F=(G/L)\times V_2$.

(4) For the purposes of this paragraph:

F=Reclamation fee.
C=Million Btu's per ton of coal in place.
L=Million Btu's per ton of lignite in place.
G=Gas produced at the wellhead in million Btu's.
V_1=$0.15/ton equivalent; or if the value of a ton of coal equivalent is less than $1.50, multiply the value by 0.1 and substitute the result for V_1 in the appropriate formula.
V_2=$0.10/ton equivalent, or if the value of a ton of lignite equivalent is less than $5 multiply the value by 0.02 and substitute the result for V_2 in the appropriate formula.

§ 837.14 Determination of percentage based fees.

(a) If the operator submits a fee based on a percentage of the value of coal, he shall include with his fee and production report documentation supporting the alleged coal value. Based on this information and any additional documentation, including examination of the operator's books and records, that the Director may require, the Director may accept the valuation submitted by the operator, or may determine the value of the coal.

(b) If the Director determines that a higher fee shall be paid, the operator shall submit the additional fee plus statutory interest within thirty days of

notification by the Director that an additional fee payment is due.

§ 837.15 Reclamation fee payment.

(a) Each operator shall pay the reclamation fee on a calendar quarter basis.

(b) The fee for the fourth calendar quarter of 1977 shall be paid no later than January 30, 1978.

(c) Each operator shall use OSM Form 837–1, Coal Production and Reclamation Fee Report form, for each quarterly payment period for each mine.

(d) The reclamation fee payment for each calendar quarter shall be paid no later than 30 calendar days after the end of the calendar quarter. Delinquent payments are subject to an interest charge at the statutory rate.

(e) The OSM Form 837–1 and check or money order for each coal mine or check or money order for all of the operator's mines represented by individually enclosed OSM Forms 837–1 shall be made payable to Director, Office of Surface Mining Reclamation and Enforcement and shall be sent in the same envelope to:

Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, P.O. Box 25065—DFC, Denver, Colo. 80225.

§ 837.16 Production records.

(a) Each operator shall maintain, on a current basis, books and records that contain at least the following information and data—

(1) Tons of coal sold or transferred, amount received per ton, name of party to whom sold or transferred, and the date of each sale or transfer.

(2) Tons of coal used by the operator and date of consumption.

(3) For in situ coal mining operations, total Btu value of gas produced, the Btu value of a ton of coal in place certified by an independent laboratory, and the amount received for gas sold, transferred or used.

(b) The fee compliance officer shall have access to the mine for the purpose of determining compliance with the regulations in this part.

(c) Each operator shall make any book or record necessary to substantiate the accuracy of reports and payments available at reasonable times for inspection and copying by the fee compliance officer. If the fee is paid at the maximum rate, the fee compliance officer shall not copy information relative to price. All information copied will be protected in accordance with the Freedom of Information Act.

(d) The operator shall maintain books and records for a period of 6 years from the end of the calendar quarter in which the fee was due.

[FR Doc.77–35050 Filed 12–5–77;2:30 pm]

federal register

TUESDAY, DECEMBER 13, 1977

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Care Financing Administration

Public Health Service

■

PROPOSED RESTRICTIONS APPLICABLE TO STERILIZATIONS FUNDED BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[4110-35]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Care Financing Administration

[45 CFR Part 205]

[42 CFR Part 50]

PROPOSED RESTRICTIONS APPLICABLE TO STERILIZATIONS FUNDED BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

AGENCY: Health Care Financing Administration, Public Health Service, Department of Health, Education, and Welfare.

ACTION: Proposed rules.

SUMMARY: The Department proposes new rules to govern Federal financial participation in sterilizations funded through various Departmental programs. These proposed rules are appropriate because of the Department's accumulating experience with the current rules governing sterilizations and in light of a recent court decision. The intended effect of these proposed rules is to specify the precise circumstances under which Federal Funds may be used for sterilization purposes. Current policies remain in full force pending adoption of these proposed rules.

DATES: Comments must be received on or before March 13, 1977.

FOR FURTHER INFORMATION CONTACT:

For the Public Health Service: Marilyn L. Martin, Room 722H (Hubert H. Humphrey Building), 200 Independence Avenue SW., Washington, D.C. 20201, 202-245-7581. For the Health Care Financing Administration: Emily J. Nichols, Room 4513, Switzer Building, 330 C Street SW., Washington, D.C. 20201, 202-245-0701 (HCFA).

SUPPLEMENTARY INFORMATION: The Department of Health, Education, and Welfare proposes new rules to govern Federal financial participation in sterilizations funded through various Departmental programs. These rules revise existing rules at 42 CFR 50.201-204 and 45 CFR 205.35, and supplant the current moratorium on sterilizations of people under 21 or mentally incompetent, first declared by the Secretary on July 27, 1973, see 38 FR 20930 (August 3, 1973). New rules are appropriate in light of the Department's accumulating experience with the current rules governing sterilizations and in light of the recent decision of the United States Court of Appeals for the District of Columbia Circuit in *Relf* v. *Weinberger*, No. 74-1797 (decided September 13, 1977). In that case, the court took note of the Department's professed intention to issue new rules and of its obligation to utilize informal rulemaking procedures.

STATUTORY PROVISIONS PERTAINING TO STERILIZATIONS

The Department funds family planning services, including sterilizations, under several Federal statutes. Three agencies within the Department are responsible for administering programs under which sterilizations are performed—the Medicaid Bureau (MMB) of the Health Care Financing Administration (HCFA), the Public Health Service (PHS), and the Administration for Public Services (APS) of the Office of Human Development Services (OHDS).

1. THE MEDICAID PROGRAM

The medical assistance (Medicaid) program under title XIX of the Social Security Act, 42 U.S.C. 1396, et seq., which is administered by MMB, provides for Federal matching of reimbursements for sterilizations pursuant to section 1902(a)(13) and 1905(a)(4)(C) of the Act, 42 U.S.C. 139a(a)(13) and 1396d (a)(4)(C). Those provisions require State Medicaid plans to provide "family planning services and supplies furnished (directly or under arrangements with others) to individuals of childbearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies * * *". The Medicaid Bureau has not defined family planning services by regulation; however, MMB policy has been to consider sterilization as a federally funded family planning service.

2. THE TITLE XX SOCIAL SERVICES PROGRAM

Title XX of the Social Security Act, which is administered by APS, authorizes grants to States for social services, including family planning services. See section 2002(a)(1) of the Act, 42 U.S.C. 1397a(a)(1). Regulations at 45 CFR 228.63, applicable to title XX published in the FEDERAL REGISTER at 42 FR 5861 (January 31, 1977), provide that "(c) where a State authorizes sterilization as a family planning service, it must comply with the provisions of 45 CFR 205.35."

3. THE AFDC PROGRAM IN THE 50 STATES AND THE DISTRICT OF COLUMBIA

While title XX itself does not mandate the provision of family planning services, title IV-A effectively does mandate such services in a State's title XX plan. In order for a State to qualify for Federal financial participation under title IV-A of the Social Security Act (Aid to Families with Dependent Children), the State's plan must provide that family planning services will be provided under title XX. Section 402(a)(15) of the Social Security Act, 42 U.S.C. 602(a)(15), as amended by Pub. L. 93-647 (the enacting title XX legislation), requires that the State's title IV-A plan provide:

> As part of the program of the State for the provision of services under title XX * * * for the development of a program, for (persons eligible for AFDC benefits) for preventing or reducing the incidence of births out of wedlock and otherwise strengthening family life, and for implementing such program by assuring that in all appropriate cases (including minors who can be considered to be sexually active) family planning services are offered to them and are provided promptly * * * to all individuals voluntarily requesting such services, but acceptance of family planning services provided under the plan shall be voluntary on the part of such members and individuals and shall not be a prerequisite to eligibility for or the receipt of any other services under the plan * * *

4. THE AFDC AND AGED, BLIND AND DISABLED PROGRAMS IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

In Guam, Puerto Rico, and the Virgin Islands, five titles of the Social Security Act are relevant to the provision of sterilizations. Titles I, X, XIV and XVI, providing for grants for assistance and services to the aged, blind and disabled, are now in effect only for Guam, Puerto Rico and the Virgin Islands. (In all other jurisdictions those titles have been superseded by the new title XVI (Supplemental Security Income) and title XX (Social Services.)) Each of those titles provides, at subsection (c)(1) of sections 3, 1003, 1403 and 1603, 42 U.S.C. 303(c)(1), 1203 (c)(1), and 1353(c)(1) and 381, respectively, that in order to qualify for Federal payments the State plan must provide that the State agency must make available "at least those services to help them attain or retain capability for [self-support or] self-care which are prescribed by the Secretary." (The bracketed words do not appear in title I.) 45 CFR 222.59, applicable to the original adult titles, authorizes family planning as an optional service under those titles. 45 CFR 222.7 (also applicable to the original adult titles) provides that "eligible individuals must be free to determine whether to accept or reject services from the agency."

Title IV-A reads virtually identically for Guam, Puerto Rico and the Virgin Islands as for the other States except that the provision in section 402(a)(15) referring to title XX does not apply. In these jurisdictions section 402(a)(15) requires that the title IV-A plan itself must provide for family planning services.

5. PROGRAMS ADMINISTERED BY THE PUBLIC HEALTH SERVICE

Title V of the Social Security Act, which is administered by PHS, requires each State, as a condition to the receipt of formula grant funds for maternal and child health and crippled children's services, to include in its State plan a program of family planning service projects. The program or project must offer reasonable assurance, particularly in areas with concentrations of low-income families, of satisfactorily helping to reduce the incidence of handicapping conditions caused by complications associated with childbearing and to reduce infant and maternal mortality. See section 505(a)(8) of the Act, 42 U.S.C. 705(a)(8).

The Public Health Service also funds sterilizations under title X of the Public Health Service Act, which authorizes the Secretary to make grants and contracts for family planning projects which offer a "broad range of acceptable and effective family planning methods." Section 1001(a), 42 U.S.C. 300(a). In addition, family planning services are included in the care offered by community health

centers under section 330 of the Public Health Service Act, 42 U.S.C. 254c, and in the migrant workers health program under section 319 of the Act, 42 U.S.C. 247d.

Public Health Service personnel perform sterilizations in PHS hospitals, in the Indian Health Service, and in other direct programs. Although these rules govern only federally funded sterilizations, they will be made applicable to these direct programs by administrative directive.

Finally, section 205 of Pub. L. 94–63, 42 U.S.C. 300a–8, makes it a felony, punishable by a fine up to $1000, and by imprisonment of up to one year, or both, to coerce any person to undergo an abortion or sterilization through the threat of withholding any service or program receiving Federal financial assistance.

Current Policies

Departmental policies with regard to Federal financial participation in sterilizations are found in the existing rules, 42 CFR 50.201–50.204 and 45 CFR 205.35, and in the moratorium on any sterilization of individuals under 21 or legally incapable of consenting to be sterilized declared by the Secretary on July 27, 1973, 38 FR 20930 (August 3, 1973). These policies are still in effect and will remain in full force until the date these proposed rules become effective. In brief those policies are:

1. Federal financial participation is available only in the sterilization of people at least 21 years old who are mentally competent under State law. In other words, Federal funding is not available for any sterilization of a person who is either under 21 or who is mentally incompetent.

2. Federal financial participation is available in the sterilization of people over at least 21 years old only where informed consent, as defined and required by the current rules, is obtained. In all except so-called "therapeutic" sterilizations, informed consent must be obtained at least 72 hours prior to the sterilization.

Discussion of the Major Issues

1. The competing policies and the need for public comment

Regulation of Federal financial participation in sterilizations is governed by two principles. First, Congress, is enacting the various programs through which sterilizations are funded, recognized sterilization as a valid family planning technique and intended it to be freely available to the population eligible for family planning assistance. Equally significant, however, is that in virtually every provision in which the Congress authorized Federal funding of sterilization, it also required that the acceptance of such services be voluntary. See, e.g., Social Security Act sections 402, 508, and 1905(a), 42 U.S.C. 602, 708, and 1396(d), and Public Health Service Act section 1007, 42 U.S.C. 300a–5. See also S. Rep. No. 1230, 92d Cong., 2d Sess. 295–98 (1972) (legislative history to 1972 family planning services amendments to Social Security Act). Thus, the Congress wrote into law its determination that no person be coerced, through direct or devious means, into undergoing a sterilization.

The Department fully appreciates the importance each of these twin policies. Mature people, understanding the nature and consequences of sterilization procedures, should have access to sterilizations unimpeded by unnecessary procedural requirements. At the same time, the Department is aware of serious allegations of cases in which patients were coerced into being sterilized, and the Department is equally committed to preventing abuses wherever sterilizations are paid for with Federal funds. Thus, the Department seeks to prevent situations in which a patient decides to undergo a sterilization because of lack of information as to the nature and consequences of the procedure, because of lack of mental capacity to understand those nature and consequences, because of fear that refusal to be sterilized will result in reprisals such as withdrawal of Federal benefits, or because of susceptibility to duress at times of extreme stress associated with labor, childbirth or hospitalization. In drafting proposed rules, the Department has sought readily enforceable rules that minimize the opportunities for sterilization abuse. Consequently, the proposed rules contain few provisions for exceptions or allowances for special circumstances.

There is an inevitable tension between the dual policies of making sterilizations freely available and of preventing sterilization abuse. As a general matter, the greater the access to sterilizations the greater the possibilities for abuse. Similarly, stringent procedural requirements to control abuse may artificially inhibit patient demand for sterilizations, whereas the absence of such procedures may constitute an invitation for abuse. The policy balance must be struck separately with regard to virtually each and every regulatory option. Where to strike that balance, however, depends to some degree upon informed predictions as to its consequences, with regard to both sterilization availability and steriliaztion abuse.

The Department has found, however, that existing information does not permit precise predictions as to the effects of proposed choices. Indeed, there is serious question whether it is even possible to generate the type of comprehensive data that would permit "scientific" policy making in this difficult area. Systematic data on sterilization abuse, for exmaple, are extremely difficult to collect. First, there is the difficulty of defining sterilization "abuse"; some may argue that every violation, no matter how technical, of existing requirements constitutes abuse, while others might argue that only certain requirements are so fundamental that their violation is abusive. Second, assuming it is possible to define "abuse" satisfactorily, there is no mechanism whereby instances of abuse may be regularly and systematically identified, since abusers cannot be expected to report their conduct and those abused may not have the means or knowledge necessary to bring instances of abuse to the attention of those studying the problem.

The Department is therefore particularly eager to receive comments on these proposed rules, recognizing that individual case histories, no matter how compelling, with respect to both the need for sterilization and with respect to sterilization abuse may not accurately portray the actual consequences of alternative policy choices. Comments will be especially helpful if they are addressed to demonstrating why a particular balance between availability and abuse-prevention policies should be drawn at a given place. Comments should explain why any alternative choices are more likely to minimize overall hardships. Comments should explain why, for example, there would be more suffering because of the unavailability of sterilizations for people under 21 than there would be because of sterilization abuse if some lower minimum age were used in the final rules. The Department recognizes that such information may be difficult to provide, but to the extent available it would greatly inform the Department's exercise of its discretion. In the absence of systematic data, the Department will be forced to rely on anecdotal evidence and its own assessment of the risks and benefits of alternative policy choices. To be sure, however, the Department is also interested in receiving comments that reflect individual experiences and views with respect to these proposed rules. Finally, since the Department expects final rules to be applied administratively to programs in which the Department itself provides sterilizations as in the Indian Health Service, the Department solicits comments from people with an interest in those programs.

Among the issues as to which the Department seeks comments are:

1. The appropriateness of the definition of sterilization.

2. The appropriateness of excluding hysterectomy as a family planning technique.

3. The appropriateness of a 30-day waiting period.

4. The effectiveness of the consent procedures envisioned by the proposed rules.

5. The appropriateness of establishing 21 as the minimum age for Federally funded sterilizations.

6. The appropriateness of funding sterilizations of mental incompetents with the capacity to give informed consent.

7. The effectiveness of procedures in the proposed rules designed to ensure that mental incompetents are not sterilized without their informed consent.

8. The appropriateness of not financially participating in the sterilization of mental incompetents incapable of giving informed consent to be sterilized.

9. The appropriateness of extending special procedures to the sterilization of institutionalized people.

It is understood that this list of issues is by no means exhaustive, and the Department solicits comments of whatever nature on all aspects of these proposed rules.

2. SECTION-BY-SECTION ANALYSIS

Each section of the proposed rules is set out in this part of the Notice, followed by a brief discussion of its requirements. Generally, the text is set out as it will appear in both titles 42 and 45 of the Code of Federal Regulations, with the bracketed section numbers applicable to title 42. Where the text of the proposed rules differ, they are set out separately, with the title 45 rules appearing first.

§ 205.35–1 *Applicability.*

Text of proposed rule.

This section applies to programs administered under Titles I, IV–A, X, XIV, XVI, XIX, and XX of the Social Security Act.

§ 50.201 *Applicability.*

Text of proposed rule:

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

These paragraphs state the programs to which the proposed rules are applicable. It is anticipated that these rules will be made applicable by administrative directive to programs in which the Department directly provides sterilizations, as in the Indian Health Service.

§ 205.35–2 [§ 50.202] *Definitions.*

Text of proposed rule:

(a) "Sterilization" means any medical procedure or operation for the purpose of rendering an individual permanently incapable of reproducing.

The definition in the proposed rules makes no distinction between so-called "therapeutic" and "non-therapeutic" sterilizations. Any procedure performed for the purpose of rendering the patient permanently incapable of reproducing, regardless of whether the procedure is performed for medical reasons or for the convenience of the patient, will therefore be subject to the proposed rules. Thus, for example, a tubal ligation, whether performed because of concern that a pregnancy could endanger the health of the patient or because the patient did not wish to bear any more children would be subject to the procedures specified in the proposed rules.

The statutes authorizing Federal financial participation in sterilization nowhere distinguish between "therapeutic" and "non-therapeutic" sterilizations, and, as both the District Court and the Court of Appeals noted in the *Relf* case, it is unlikely that Congress intended that procedures designed to ensure informed consent would apply to one but not the other. *See Relf* v. *Weinberger*, No. 74–1797, slip. op. at 11 n.6 (D.C. Cir. September 13, 1977).

The Department thinks it unlikely, however, that Congress, by enacting legislation designed to promote family planning for convenience and other purposes, intended in doing so to impose identical procedural requirements on all medical procedures which have the effect of rendering a patient permanently incapable of reproducing. Some procedures ought not to be considered "sterilizations," even though sterility might result. Thus, for example, a removal of a cancerous uterus would not be deemed a sterilization, for it would not be performed for the purpose of rendering the patient incapable of reproducing, even though it would have that unavoidable effect.

The proposed rules do not define sterilization to include other forms of birth control, that is, procedures that render a person only temporarily incapable of reproducing.

Text of proposed rule:

(b) "Informed consent" (to a sterilization procedure) means a written authorization to be sterilized given by the person to be sterilized and given voluntarily and with an understanding of the nature and consequences of the procedure to be performed.

The definition of informed consent encompasses the two elements of voluntary action: (1) It must be knowing, that is the patient must fully understand the nature of the procedure and the significance of his/her action and (2) it must be entirely a product of the patient's free will. For purposes of these rules, informed consent must be given in writing in the manner specified by the rules.

Text of proposed rule:

(c) *"Consent form"* means a written document which states the requirements for informed consent as set forth in section 205.-35–3 [50.203].

Authorized consent forms must be used for giving informed consent under the proposed rules. Procedures for completing the consent forms are discussed elsewhere in this Notice.

Text of proposed rule:

(d)) "A mentally incompetent individual" means one who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

This definition includes includes all people who have been adjudicated incompetent by Federal or State courts and those who are in fact incompetent under Federal or State law but who have never been so adjudicated.

Text of proposed rule:

(e) "A sterilization review committee" means a committee designated by the State Agency to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

And

50.202(e) "A sterilization review committee" means a committee designated by the program or project to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

Under one version of the proposed rules, sterilization review commitees would review applications for sterilizations by mentally incompetent patients and patients in institutions to determine their capability to give informed consent and whether they have in fact given their informed consent to be sterilized. Under another version, review commitees would review applications for sterilizations only by patients in institutions. The commitee would be composed of a physician, an attorney, a social worker, and another person who would advocate the patient's position. Because there is wide variation in conditions in various States with respect to such matters as the numbers and geographical dispersion of patients who, although mentally incompetent would nonetheless seek to be sterilized, and the presence of existing mechanisms to which a sterilization review committee could be appended, it is proposed to leave to the States, programs or projects the creation of mechanisms for the establishment and operation of such committees. In addition, procedures already required by State law may well be adequate to satisfy the review committee requirement. If at all possible, the Department does not desire to supplant or duplicate existing mechanisms.

The Department recognizes, however, that the nature and composition of sterilization review committees is a matter as to which there may be substantial variation of opinion. For this reason, the Department solicits comments on at least the following questions:

1. Is there a need for sterilization review committees, and if so, is the committee as envisioned by the proposed

2. Should the composition of the committee be in accordance with the formulation of the proposed rules?

3. Should final rules specify in greater detail the composition, responsibilities, and procedures for sterilization review committees? Specifically, should final rules specify such matters as the number of committees each State, program, or project must establish, their geographical location, whether they must be permanent or ad hoc bodies, and internal administrative procedures designed to ensure confidential treatment of patient records and effective liaison with State agencies and courts?

4. What State or local review committee procedures are now in effect, and how do they operate to prevent sterilization abuse?

5. Should the rule allow States, programs, or projects to utilize existing committee structures and procedures for the purpose of reviewing sterilization, subject to Departmental approval?

Text of proposed rule:

(f) "Hysterectomy" means a medical procedure or operation for the purpose of removing the uterus.

This item states the generally accepted medical definition of hysterectomy.

Text of proposed rule:

§ 50.202(g) The "Public Health Service" means the Health Services Administration, Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, and all of their constituent agencies.

§ 50.202(h) The "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

These definitions are self-explanatory.

§ 205.35–3. [§ 50.203] *Consent Procedures.*

Text of proposed rule:

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this paragraph.

This sentence states the general rule that for the purposes of these rules a person will not be deemed to have given his/her informed consent to be sterilized unless a consent form is completed in accordance with all the requirements of this section.

Text of proposed rule:

(a) *Preparing to Obtain Informed Consent.* An individual who obtains informed consent for a sterilization procedure must provide orally *all* of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw his/her consent to the procedure at any time prior to the sterilization without affecting his/her right to future care or treatment, and without loss or withdrawal of any Federally-funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) A full description of the benefits or advantages he/she may expect to gain as a result of the sterilization;

(4) Advice that the sterilization procedure is considered to be irreversible;

(5) A thorough explanation of the specific sterilization procedure to be performed;

(6) A full description of the discomforts and risks which may accompany and follow the performing of the procedure including an explanation of the type and possible effects of any anesthetic to be used;

(7) Advice that the sterilization will not be performed for at least 30 days; and

(8) An opportunity to ask and have answered any questions he/she may have concerning the sterilization procedure.

This item explains the information that a prospective patient must have for his/her assent to be sterilized to be deemed "informed". This provision, however, in no way limits the information that should be given to a patient seeking sterilization if in the judgment of the physician or the person who obtains the patient's consent form more information should be provided.

The patient's consent should be secured under circumstances free of pressure or coercion. Generally, a patient's consent should not be secured while the patient is in labor, during or immediately following delivery, or in conjunction with an abortion.

Although the patient will be provided much of the information in writing, the proposed rules require all information also to be given orally. Both the District Court in the *Relf* case and a recent report by the General Accounting Office concerning sterilization practices in the Indian Health Service concluded that essential information must be communicated orally, especially for people of limited literacy.

Foremost among the information that must be provided is the advice that a patient is free not to be sterilized. The patient must be advised that he/she is free not to consent or to withdraw consent previously given, and that a refusal to be sterilized will not result in the withdrawal of any Federally-funded program benefit, nor will such a refusal affect the patient's right to future care or treatment (including sterilization). It is expected that this advice will be communicated at the outset of any discussion of sterilization with a prospective patient.

The patient must be given all the important facts about sterilization. He/she must be told that sterilization is different from all other forms of birth control because it is irreversible. The patient must be told about both the advantages and disadvantages of sterilization, and about the nature and availability of alternative forms of birth control. Birth control information should include methods available to both the patient and his/her partner.

The patient must also be told of the nature of the surgical procedure that is proposed. This advice must contain a thorough explanation of the procedure and a full description of its discomforts and risks, particularly as compared to other sterilization procedures. The patient also should be adivsed about discomforts and risks that relate to the particular anesthetic to be used.

The patient should also be told that the sterilization will not be performed for at least 30 days, and that he/she may withdraw his/her consent at any time prior to the sterilization.

Finally, the patient must be offered an opportunity to ask and have answered any questions concerning the proposed sterilization.

The Department solicits comments concerning the necessity of providing patients with the foregoing information and as to what additional information, if any, should also be provided.

(b) *Filling out the consent form.*

The items in this paragraph are designed to ensure that the information required by the preceding paragraph is in fact communicated to the patient and that the patient's consent is in fact voluntary.

Text of proposed rule:

(1) *Language of the consent form.* The consent form should be in the primary language of the patient. If the consent form is not in the primary language of the patient, an interpreter must be made available to assist the individual.

Text of proposed rule:

(2) *Provisions for the handicapped.* Suitable arrangements must be made to ensure that consent information is effectively communicated to blind, deaf, and other handicapped patients.

These two items are designed to ensure that information necessary for informed consent is communicated to those whose primary language is other than English and to handicapped people. Where possible, the consent form should be in the primary language of the patient; if this is not possible, an interpreter must be made available. If the patient is blind, the consent form should be read to him/her, and similar arrangements must be made to ensure effective communication of consent material to deaf patients and to patients with other handicaps.

(3) *Signatures on the consent form.* The consent form must be signed and dated by:

(i) The patient; and

(ii) The interpreter, if one is provided; and

(iii) The individual who obtains the consent of the patient; and

(iv) The physician who will perform the sterilization procedure.

(4) *Required certifications.* (i) The person securing the patient's consent must certify by signing the consent form that, before the patient signed the consent form, he/she advised that patient had no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the elements of informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(ii) The physician performing the sterilization must certify by signing the consent form that, immediately prior to the performance of the sterilization, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the elements of informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized. The physician will further certify that, to the best of his/her knowledge and belief, at least 30 days passed from the date upon which the patient signed the consent form until the date upon which the sterilization was performed.

(iii) The physician performing the sterilization must, in cases where court orders are required by this section, certify, by signing the consent form, that he/she was provided with a copy of the court order prior to the performance of the sterilization.

The proposed rules would require various signatures on the consent form to provide evidence that the requirements of the rules have been met. The patient's signature would be his/her expression of informed consent, and the interpreter's signature evidence that he/she had provided assistance to a patient whose primary language was not in English.

The proposed rules would also require the signature of the person who obtains the patient's consent, for example, a social worker in a family planning clinic or a physician's assistant. This person often plays a critical role in explaining sterilization to prospective patients, and the proposed rules would require him/her, by signing the consent form, to certify that he/she communicated the information necessary for a patient to give informed consent. The proposed rules

would allow the attending physican to obtain the patient's consent.

A person obtaining the patient's consent must attest to whether, to the best of his/her knowledge and belief, the patient in fact gave his/her informed consent to be sterilized. The person obtaining consent must also certify as to the patient's *appearance* of mental competence. It is not the intention of the proposed rules to place upon people obtaining consent the duty of conducting an independent inquiry into the mental competence of prospective patients seeking sterilization. Neither, however, is it the intention of the proposed rules to permit those obtaining consent to ignore clear evidence of a patient's mental incapacity.

Where a person obtaining the patient's consent is unable to make a required certification, under one version of the proposed rules the sterilization may not go forward. Under an alternative, where the sole issue is the patient's mental competence, the sterilization may go forward only if the requirements in section 205.35–5 (50.205), relating to sterilizations of mental incompetents, have been followed.

The proposed rules do not require an auditor/witness to be present or to sign the consent form. The Department believes that while a patient should be able to have another person present during counseling and consent sessions, respect for the patient's privacy dictates that the presence of a witness not be mandated.

Certification obligations would also be imposed upon physicians performing sterilizations, for physicians have a nondelegable responsibility to ensure that they perform sterilizations only upon patients who have given their informed consent. Consequently, physicians would be required to certify that, immediately prior to the performance of the sterilization, they orally communicated the information necessary for a patient to give informed consent and to certify further that the patient in fact gave informed consent. As with people obtaining patients' consent, physicians would be required to certify as to the patient's *appearance* of mental competence. The phyisican also would be required to certify that to the best of his/her knowledge and belief the required waiting period passed before the sterilization was performed. Ordinarily this last requirement would be satisfied by the physician noting that the sterilization was to be performed more than 30 days after the date appearing next to the patient's signature on the consent form. The required waiting period is discussed elsewhere in this Notice.

In cases where the sterilization is performed upon a person whom a court determined had given informed consent, the physician would be required to certify that he/she received a copy of the court's order prior to the sterilization. Among other purposes, this provision is designed to protect physicians from liability for performing unauthorized sterilizations.

Text of proposed rule:

(c) *Following State and local procedures.* In addition to the consent procedures required by this part, any requirement of State or local law, except one of spousal consent, must be followed.

This provision embodies the policy of the proposed rules not to supplant more stringent State and local requirements. Less stringent State and local requirements will of course be complied with through compliance with the proposed rules. Spousal consent requirements are excepted because of their almost certain unconstitutionality in light of *Planned Parenthood of Central Missouri* v. *Danforth*, 428 U.S. 52 (1976).

The Department is not certain about the extent to which existing State and local laws with respect to sterilization have the effect of denying access to sterilizations to those who would otherwise be eligible for them under these rules. Comments are solicited on the question as to the extent to which final rules should supplant State and local requirements.

§ 205.35–4 *Sterilization of a mentally competent individual aged 21 or older.*

Text of proposed rule:

Federal financial participation is available in expenditures for a sterilization of a mentally competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 205.-35–3.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

and

§ 50.204 *Sterilization of a mental competent individual aged 21 or older.*

Text of proposed rule:

Programs or projects to which this subpart applies shall perform or arrange for the performance of a sterilization of a mental competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in section 50.203.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

These provisions set out the basic requirements for the vast majority of sterilizations in which Federal financial participation would be available under the proposed rules. The individual must have given his/her informed consent; at least 30 days must have elapsed between the date of informed consent and the date of the sterilization; and the patent must be at least 21 years old.

The requirements for informed consent have already been discussed in this Notice.

The 30-day Waiting Period. The Department is aware that there is substantial controversy over the length of time that should be required between rendition of informed consent and the sterilization operation. Some may argue that any "consent" obtained while a woman is hospitalized for childbirth or an abortion is necessarily involuntary. It may be asserted, in addition, that under any circumstances a hospital environment may be alien and frightening to patients and is therefore inherently coercive. The Department believes that any waiting period should be sufficient to remove the patient from the extreme emotional stress often associated with the latter stages of pregnancy as well as labor and delivery. Regardless of where informed consent is given, any waiting period also must be of sufficient duration to permit reflection and discussion with family and friends concerning this irreversible surgical procedure.

On the other hand, too long a waiting period might impose substantial inconvenience and additional expense if it is of sufficient duration as to require two hospitalizations. It may also be asserted that many women are reluctant to seek medical care and will not seek to be sterilized unless they can both choose and obtain sterilization incident to childbirth.

The Department has weighed these competing considerations, and its current thinking is that 30 days is the minimum period for necessary consultation and reflection. A waiting period of this duration, while sufficient to ensure that a decision to be sterilized is not made and effectuated during hospitalization for abortion or childbirth, will not necessarily result in multiple hospitalizations, since informed consent for sterilization can be obtained during pre-natal care or otherwise well in advance of delivery.

The Department has also considered proposing different waiting periods keyed to the type of sterilization and the place where it is to be performed, with different waiting periods for outpatient facilities and hospitals. Similarly, proposed rules could conceivably allow for waiver of the waiting period in exceptional circumstances, for example where a sterilization is arranged for over 30 days in advance of anticipated delivery date but there is a premature delivery. These alternatives may be in theory quite sound, but the Department is skeptical about their enforceability and concerned about the possibilities for abuse.

The Department does not consider a waiting period of less than 30 days as *necessarily* coercive; similarly, it understands that the failure of the proposed rules to provide for waivers or to differentiate between sterilization procedures and the environments in which they may be performed might result in individual cases of inconvenience and hardship. These factors are more than counterbalanced, however, in the Department's current view, by the need to ensure adequate time for reflection and consultation in an environment free from coercion. The Department is reluctant to introduce different standards based on factual circumstances that are not readily identifiable and verifiable on

a sample, audit basis. Consequently, differential waiting periods and waivers of waiting periods have been considered and rejected.

As with other issues with respect to sterilizations, reasonable people may hold strongly conflicting views. The Department therefore solicits the comments of interested parties on the issue of the waiting period, particularly with respect to the following questions:

1. What are the purposes of a waiting period?

2. What length of time is sufficient to accomplish those purposes?

3. What are the detriments of a lengthy waiting period?

4. What are the advantages or disadvantages of including waiting periods of varying duration depending on the type of sterilization procedure and the facility where performed (clinic or hospital)?

5. What are the advantages or disadvantages of permitting waivers of the waiting period in exceptional circumstances?

6. Can rules including waiting periods of varying duration be enforced, or would the result primarily be more instances of of abuse?

The Minimum Age of 21. As discussed above, the statutes themselves present an inevitable tension between two competing interests: assuring maximum availability of family planning services and at the same time assuring that those services are offered on a purely voluntary basis, free of coercion or pressure. To achieve a balanced accommodation between these two purposes, the regulations establish a Federal standard of voluntariness.

The United States Court of Appeals for the District of Columbia Circuit in its September 13, 1977 decision in *Relf* v. *Weinberger* recognized the Secretary's authority to set a uniform Federal standard:

> Where federal funds are authorized by Congress to be expended for sterilizations which are voluntary in nature, the question of what constitutes voluntariness in this context would appear to be one of federal law. In formulating standards for this purpose, it is surely true that state legal requirements cannot be controlling by their own force. A federal standard may still of course, to the extent the federal agency devising the standard finds wise or helpful, take note of state law and utilize available state legal mechanisms in designing and effectuating the federal standard. But how a federal statute is to be implemented remains a matter as to which federal law is supreme, and the agency charged by Congress with implementation is not bound to shape its concept of voluntariness to the contours of state law. *See generally* Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52 (1976); Wyatt v. Aderholt, 368 F. Supp. 1383, 1384 (M.D. Ala. 1974). *Relf* v. *Weinberger*, No. 74–1797 (D.C. Cir. September 13, 1977), slip. op. at 10 n.3.

Similar conclusions were reached recently by two Federal District Courts in decisions upholding the moratorium on Federal funding of sterilizations for those under 21 years old. *See Peck* v. *Califano*, U.S.D.C. D. Utah, Civil Action No. C 76–229 (June 30, 1977), and *Voe* v. *Califano*, U.S.D.C. Conn., Civil Action No. N–77–195 (July 14, 1977).

Given the Department's authority to establish uniform standards of voluntariness, three questions are raised with respect to age. First, should determinations of capacity with respect to age be made on a State-by-State or case-by-case basis, or should generally applicable standards be set? Second, if a minimum age is set, what should it be? Third, should Federal financial participation ever be available in sterilizations of people below the minimum age?

With respect to the first question, determinations of legal capacity to give informed consent made solely under State law would produce the anomalous result of the Department withholding funds for the sterilization of a 20-year-old in one State, while funding sterilizations of younger people in others. According conclusive effect to State law would also necessitate the extremely difficult determination of the age of consent for purposes of sterilization under varying State laws, some of which confer the status associated with the age of majority upon so-called emancipated minors or upon minors who have contracted a legal marriage, others of which confer competence for different purposes at a variety of ages. Moreover, it would be costly and perhaps impractical for the Department to mandate case-by-case inquiries into the maturity and judgment of prospective patients. Consequently, the Department believes that it has no alternative but to engage in line-drawing and set a single uniform standard, recognizing the inevitability that gross distinctions do not always adequately reflect differences of maturity and judgment.

A single standard necessarily divides persons who seek sterilizations into two groups: those over the the minimum age, for whom funds are made available; and those below it, for whom funds are withheld. This age classification is not, however, unconstitutional. The District Courts in *Voe* and *Peck*, discussed above, sustained against constitutional challenge the Department's current bar on funding sterilizations for individuals who are under age 21 or mentally incompetent. In doing so the courts relied heavily upon the Supreme Court's recent decision in *Maher* v. *Roe*, 45 U.S.L.W. 4787 (U.S. June 20, 1977), which held in essence that since the Constitution does not mandate the funding of medical care, governmental limitations on provision of such care must be upheld if they bear a rational relationship to a permissible legislative purpose. Thus, as in *Maher*, the proposed rules are not subject to the holding of *Roe* v. *Wade*, 410 U.S. 113 (1973), that the Constitution forbids the government to prevent or penalize the exercise of the right to procreative privacy. The age limitation does not interfere with an individual's decision whether to bear or beget a child, but merely withholds Federal funding of one particular means of effectuating the decision not to bear or beget a child.

Assuming the validity of a uniform minimum age, the second question, as to what is the appropriate minimum age, is one as to which reasonable people may have strongly disparate views. There is general agreement that at some age an individual is so immature and his/her judgment so uninformed that it is reasonable to presume that he/she is incapable of giving informed consent, and that therefore his/her assent to be sterilized cannot be said to be "voluntary" within the meaning of the family planning statutes. Moreover, minors have in the past been subject to sterilization abuse, although there may be some disagreement as to how widespread these abuses have been.

But beyond these general principles, there remains strong disagreement on the question as to where the line should be drawn. The Department is aware of the competing considerations: if the minimum is too high people needing sterilizations who might be able to give their informed consent will not be able to get them; but if the minimum age is too low, people without sufficient maturity or judgment to resist coercion may be forced into sterilizations they do not want. Resolving these tensions has proven to be quite difficult and vexing. Much of the evidence of hardship due to unavailability of sterilizations and hardship due to sterilization abuse is extremely compelling. But it is also only anecdotal. In the absence of substantial and systematic evidence as to where the balance of hardship lies, the Department is proposing 21 as the minimum age, recognizing the imperfection of any age chosen, in the belief that there is reason to be concerned whether people under that age generally have the judgment, experience and maturity to make voluntary decisions to be sterilized.

The third question is whether the proposed rules should provide for sterilization of people below the minimum age under extraordinary circumstances, and if so, what should those circumstances be? Although recognizing that severe hardships can befall a person under 21 who cannot use other forms of birth control if sterilization is unavailable, the Department is proposing that Federally-funded sterilizations not be available, under any circumstances, to people under 21.

There is serious question, given the presumption of lack of capacity on the part of a person under 21 to consent to be sterilized, whether the Department has the legal authority to fund any sterilizations of people below that age, since the family planning statutes require that the receipt of sterilization services be "voluntary." The issue is not free from doubt, since the doctrine of substituted consent, in which parents or guardians are empowered to make decisions on behalf of those incapable of doing so themselves, has been occasionally accepted with respect to other critical decisions. Equally important is that any exception would be difficult to monitor and could create substantial possibilities of abuse. Without evidence

of widespread compelling need, and without reason to believe that substantial incidents of abuse would not occur, the Department is reluctant to participate financially in the sterilization of people under 21.

The Department is eager to receive comments on the question of minimum age. It would be helpful if the comments could address themselves to the following issues, among others:

1. What is the evidence of sterilization abuse of people under 21 (or 18)?

2. Is there evidence that substantial numbers of people under 21 (or 18) have been denied necessary sterilization services under the current moratorium?

3. What form does sterilization abuse of people under 21 (or 18) take?

4. What are the circumstances under which it might be appropriate to fund sterilizations of people below the minimum age specified in the proposed rules? How could such exceptions be monitored to avoid abuse?

205.35–5 *Sterilization of a Mentally Incompetent Individual Aged 21 or Older; Sterilization of an Institutionalized Individual Aged 21 or Older*

Text of proposed rule:

(a) Federal financial participation is unavailable in expenditures for a sterilization of a person who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Federal financial participation is unavailable in expenditures for a sterilization of any individual institutionalized in a correctional, or mental or other facility *unless:*

(1) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 205.35–3;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205. 35–3(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized.

or

(a) Federal financial participation is unavailable in expenditures for a sterilization of a mentally incompetent individual, or any individual institutionalized in a correctional, mental or other facility *unless:*

(1) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 205.35–3;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized.

(b) Federal financial participation is unavailable in expenditures for the sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a).

and

§ 50.205 *Sterilization of a mentally incompetent individual aged 21 or older; sterilization of an institutionalized individual aged 21 or older*

Text of proposed rule:

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any person declared mentally incompetent by a State, Federal or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any individual institutionalized in a correctional, mental or other facility unless:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedure prescribed in section 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized.

or

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual or any individual institutionalized in a correctional, mental or other facility *unless:*

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in section 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a).

These provisions embody two alternative responses to the issue of suitability of funding sterilization for two groups of people particularly vulnerable to sterilization abuse—mentally incompetent people and people in mental, correctional or other institutions.

Mental Incompetents. Two alternative formulations are proposed with respect to people who are mentally incompetent under Federal or State law. Under the first version, Federal funds would not be available for the sterilization of any person declared incompetent by a Federal, State, or local court, or incompetent in fact under Federal or local law. This is the Department's current policy, embodied in the moratorium in effect since 1973, on the funding of sterilization of mental incompetents.

The advantages of the moratorium have been its relative simplicity, consequent ease of application and its apparent prevention of substantial sterilization abuse of mentally incompetent people. Further, the Department has not been made aware of significant hardships traceable to the moratorium.

The current moratorium, however, has some serious disadvantages. It is possible that the moratorium results in substantial unnecessary suffering by denying access to sterilizations by people who want them and who—regardless of label imposed upon them by a finding of incompetence—are fully capable of understanding the nature and consequences of and voluntarily consenting to a sterilization. Indeed people may be adjudicated incompetent for limited purposes only, such as the conduct of financial affairs, and yet are fully capable of rendering informed and voluntary consent to be sterilized. In addition, continuing the absolute bar to the funding for sterilization of persons incompetent in fact but not so adjudicated leaves the physician

in an impossible dilemma and without any avenues of redress. Being uncertain as to the patient's competence, and without access to a review committee and court hearing, the physician will decline to sterilize the patient. It may be that the moratorium thereby has the unintended effect of denying sterilizations to people who would not be adjudicated incompetent but whom physicians are reluctant to sterilize because of possible liability.

The Department stresses that it does not have adequate data on the numbers of mentally incompetent people who desire and are capable of consenting to sterilizations. Should comments uncover evidence of substantial desire for sterilizations among the mentally incompetent capable of consent, a system of safeguards would need to be constructed to avoid creating a serious potential for sterilization abuse. The second alternative proposed in these rules is intended to construct such a system.

The Department seeks to avoid any coerced sterilizations of the mentally incompetent. Because mental incompetents are presumptively incapable of informed consent, the procedures under this alternative are directed to the end of assuring that assent to sterilization is indeed voluntary and informed. The Department intends to re-evaluate this section in light of the comments received to determine whether these—or any procedures will be adequate to forestall coerced sterilizations.

As with respect to setting minimum ages, the Department, in interpreting the Federal statutory standard of voluntariness, has the legal authority to administer a single, uniform standard of mental competence. See *Relf* v. *Mathews*, supra.

The fact that a patient has been adjudicated incompetent under State law would not settle the issue of Federal law as to whether the patient had voluntarily consented to be sterilized. If the Department decides to fund sterilization of mentally incompetent patients it would do so only if the patient "understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a)" and had given informed consent in accordance with the proposed rules. This standard by necessity calls for case-by-case determination.

Under this alternative regulation, persons adjudicated incompetent or incompetent in fact would be eligible for Federally funded sterilizations if they are capable of rendering informed and voluntary consent to be sterilized. Thus, for example, a patient as to whom a physician had any serious question as to his/her mental competence could be sterilized in accordance with the procedures mandated by this subsection.

Mental incompetents seeking to be sterilized would first give their informed consent to a proposed sterilization in the manner prescribed in section 205.35–3 [50.203] As with all other sterilizations—and for the same reasons—no federally funded sterilization could go forward before the expiration of 30 days after informed consent had been given, and no federally funded sterilization could be performed on a patient less than 21 years old.

Following the initial steps, the proposed sterilization would be presented to the sterilization review committee described earlier in this Notice. As previously indicated, the Department currently intends to leave the method of convening and the procedures for operating sterilization review committees to the States, programs, or projects. Existing procedures under State law may also be adequate to satisfy the review committee requirement. The rules do, however, require the presence of a physician, (other than the one proposing to perform the sterilization) lawyer, social worker and patient advocate.

The sole inquiry for the sterilization review committee would be whether the patient had the capacity to give and had in fact given his/her informed consent; it would not be empowered to consider the wisdom of the patient's choice. If informed consent had indeed been given, the committee would not be empowered to override the patient's choice on the basis of his/her "best interests." The committee would likewise not be empowered under these rules to consider whether sterilization would be in the "best interest" of one who could not understand the nature and consequences of the proposed sterilization.

The patient, as the proponent of the sterilization, would be required to demonstrate to the review committee that all the requirements for informed consent had been met, that he/she understood the nature and consequences of the proposed sterilization, and voluntarily consented to be sterilized. This inquiry subdivides into two parts: The question of patient's capacity to understand and appreciate the information given to him/her as part of the consent process, and the question whether the patient had in fact voluntarily given informed consent in the manner prescribed by these rules. The proposed rules specify the "nature and consequences" that the patient must understand; they are those delineated by section 205.35–3(a) as the minimum information the patient must receive if his/her consent can be said to be "informed."

The Department believes that, in addition to the patient advocate, legal counsel is necessary to protect the patient's rights. Since the inquiry is by definition into the patient's capacity, however, and circumstances will vary, it is difficult to predict whether the attorney would be acting in the best interests of his/her client in arguing for or against the proposed sterilization. Because of this unpredictability the Department believes that counsel would be most helpful to the patient and the review committee by marshalling and presenting the evidence both for and against the proposed findings.

If a sterilization review committee does not make the findings that would be required under the proposed rules, the sterilization could not be federally funded. Where the committee makes the required findings, the matter would then be presented to a court for its de novo consideration.

The proposed rules envision a rather limited role for courts to which petitions from review committees would be presented. The sole issue before the court would be whether the patient had the capacity to and did give informed consent to be sterilized. The proposed rules could not and would not requrie or empower courts to order federally funded sterilizations, so there is no reason for State courts to fear liability for ordering sterilizations. *Cf. Spartman* v. *McFarlin*, 522 F.2d 172 (7th Cir.), cert. granted, ____ U.S. ____ (1977).

A related issue is whether State courts would in fact assert jurisdiction over petitions from sterilization review committees. The Department, of course, has no power to create jurisdiction in State courts, and State courts may not exercise jurisdiction they do not have. However, since determinations of incompetence and commitment to institutions are often made by courts, it is believed that State courts have jurisdiction over the incompetent and institutionalized individuals to empower inquiry into the presence of informed consent for a sterilization.

Proceedings before courts reviewing petitions from sterilization review committees would be the same as those earlier described with respect to review committees. Thus, the proponent of the sterilization would bear the burden of proof, and the patient and the court would be assisted by counsel presenting the evidence for and against the required findings.

As with other strelization issues, the Department understands that there may be divergent views on the proper treatment of mental incompetents. Comments are therefore solicited, particularly with respect to the following issues:

1. Should the Department fund sterilizations of people who are mentally incompetent under State law? Under what circumstances?

2. Should the class of those requiring special protection be more broadly defined to include those, who although not incompetent, are mentally impaired? How would this group be described?

3. What have been the effects of the current moratorium upon people who would be eligible for sterilization under this section of the proposed rules?

4. What reason is there to believe that funding sterilizations of mental incompetents under any circumstances would result in sterilization abuse?

5. What reason is there to believe that the procedures required by this subsection of the proposed rules will be adequate to prevent coerced sterilizations or sterilizations of those unable to give informed consent? Would other procedures, such as resort to the American Arbitration Association, be more effective?

The mentally incompetent without the capacity to give informed consent. Under

either proposed version of the rules with respect to the funding of sterilization of the mentally incompetent, no funds would be available for sterilization of people who lack the mental capacity to give informed consent. This is the Department's current position on this issue. For purposes of these rules, people who cannot understand the nature and consequences of a proposed sterilization—that is, the minimum information set out in section 205.35–3(a) that must be understood for consent to be deemed "informed"—are considered to lack the mental capacity to consent to a sterilization. There are classes of people so profoundly retarded as to be unable to utilize temporary forms of contraception and for whom the bearing or begetting of a child may bring only confusion, fear, or indifference. The profoundly retarded may be totally incapable of caring responsibly for their children, many of whom may be profoundly retarded themselves. Instead, the burden may be shifted to parents, guardians or other custodians, perhaps raising burdens to intolerable limits and increasing the pressures for institutionalization of people who might be otherwise better served in non-custodial environments. In short, there is a class of people whose continued fertility may be against their best interests and that of society.

There are, however, compelling countervailing considerations. Although the issue is not free from doubt, there is serious question whether the Department has the legal authority to fund sterilizations for people who lack the mental capacity themselves to satisfy the statutory standard of voluntariness. Even assuming the validity of the doctrine of substituted consent in this context, the statutes give no guidance as to the circumstances under which a guardian could request sterilization in the patient's name. Without explicit congressional guidance in this sensitive and troubling area, the Department is reluctant to conjecture as to the circumstances under which Congress intended the Department to fund sterilizations of those without the mental capacity to give their informed consent.

In addition, there is reason to fear that any exception for sterilization of the profoundly retarded would create myrid possibilities for sterilization abuse. The Department wishes to avoid wholesale sterilization of mental incompetents for the convenience of their guardians and custodians, and fears that any exception to a ban on Federal financial participation in the sterilization of the profoundly retarded would prove extremely difficult to police. Finally, as previously discussed, there have been few reports of hardships occasioned by the present moratorium on payment for sterilization of mental incompetents.

These issues are deeply troubling, and the Department welcomes the comments of interested parties. Comments may be directed to the following issues, among others:

1. What is the Department's legal authority to fund sterilizations of people who lack the mental capacity to give informed consent?

2. Has the present moratorium on federally funded sterilizations of mental incompetents produced severe hardships? Of what nature?

3. If the Department were to fund sterilizations of the profoundly retarded, under what circumstances should it do so?

4. Would funding sterilizations of the profoundly retarded under exceptional circumstances inevitably lead to substantial sterilization abuse?

People in institutions. Under both proposed versions of this part of the rules, special procedural protections would be required for the sterilization of people in mental, correctional or other institutions. Although the Department is uncertain as to the number of institutionalized people seeking sterilizations, is is imperative that this group, no matter how small, be accorded special protections to counteract the enhanced opportunities for coercion inherent in a custodial environment.

The procedures proposed are the same as those proposed for mental incompetents, and they are directed towards the same goal—determining whether the patient has in fact given informed consent to a proposed sterilization. The Department believes that these procedures, described earlier in this Notice, are generally properly tailored to protect people in institutions.

One possible exception concerns the role of counsel for the institutionalized patient at committee and court proceedings. Since, unlike the situation with respect to mental incompetents, the inquiry would not be focused primarily on the issue of the patient's mental capacity, there is little reason to fear that an attorney supporting his client's request for a sterilization will not be acting for his client. But there may be some benefit, as a check upon abuse, in having an attorney present evidence against a finding that the patient in fact consented to be sterilized. For this reason, the Department has proposed that counsel for the institutionalized patient at committee and court proceedings present evidence for and against the requisite findings.

The Department solicits comments on the proper treatment of proposed sterilizations of people in institutions, including comments directed at the following issues:

1. What is the evidence of sterilization abuse of people in institutions?

2. Are identical procedures necessary or appropriate to protect the interests of mentally incompetent people and people in institutions?

3. What should be the role of counsel, if any, at committee and court proceedings?

§ 205.35–6 *Sterilization of a mentally competent or incompetent individual under the age of 21.*

Text of proposed rule:

Federal financial participation is unavailable in expenditures in the sterilization of individuals under 21 years old.

and

§ 50.206 *Sterilization of a mentally competent or incompetent individual under the age of 21.*

Text of proposed rule:

Programs or projects to which this subpart applies shall not perform or arrange for the performance of sterilizations of individuals under 21 years old.

These sections state the absolute rule, for the reasons discussed earlier in this Notice, that Federal financial participation would be unavailable in the sterilization of individuals under 21 years old.

§ 205.35–7 *Sterilization by hysterectomy.*

Text of proposed rule.

Federal financial assistance for family planning purposes is unavailable for participation in any hysterectomy performed for the purpose of rendering an individual permanently incapable of reproducing, unless [exception, with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

and

§ 50.207 *Sterilization by hysterectomy.*

Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy for the purpose of rendering an individual permanently incapable of reproducing, unless [exception, with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

The statutes under which the proposed rules are being issued authorize the expenditure of Federal funds for "family planning" services. In enacting these statutes, Congress clearly imposed upon the Department the responsibility to determine what services fall within the statutory authorization. For example, section 1001(a) of the Public Health Service Act, 42 U.S.C. 300(a), authorizes the Secretary to arrange for the provision only of "acceptable and effective" family planning methods. The Department believes that it has no less of a responsibility to fund only "acceptable and effective" family planning methods under its other programs; indeed, section 1903(a)(5) of the Social Security Act, 42 U.S.C. 1396b(a)(5), imposes this same duty upon the Department in the Medicaid program by providing for a special rate for Federal matching of State family planning expenditures.

There is virtual unanimity within the medical profession that hysterectomy, in the adsence of other clinical indications, is not an appropriate or even acceptable

means of sterilization. It is widely accepted that hysterectomy is a much more dangerous form of female sterilization than the various types of tubal ligations. One study, for example, concluded that "the complication rate of simple vaginal hysterectomy was 10 to 20 times higher than the complication rate of tubal sterilization procedures." L. Hibbard, Sexual Sterilization by Elective Hysterectomy, 112 Am. J. Obstet. Gynecol. 311, 317 (1972). It is believed that a comparison of mortality rates would be similarly striking.

Hysterectomies are also many times more expensive than other female sterilization procedures. A tubal ligation can be performed usually within a one-day hospital stay, and in some cases on an outpatient basis. In contrast, hysterectomy is a more drastic surgical procedure, often requiring hospitalization for as much as 5 to 7 days.

Because of these considerations, hysterectomy is virtually universally decried when used for sterilization purposes alone. The American College of Obstetricians and Gynecologists, for example, takes the position that whenever a hysterectomy is performed solely for sterilization purposes, the case automatically should be referred to a physician's committee for peer review. *See* ACOG, Model Screening Criteria, 18 (1977). Other authorities have concluded that hysterectomy is not a valid sterilization technique. *See, e.g.*, Dyck, F. Murphy & J. Murphy et al. Effect of Surveillance on the Number of Hysterectomies in the Province of Saskatchewan, 296 N.E.J. Med. 1326, 1328 (1977); Testimony of Kenneth J. Ryan, M.D., Chairman, Department of Obstetrics and Gynecology, Harvard University School of Medicine, in Hearings on Important Cost and Quality Issues of Health Care Before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, 95th Cong., 1st Sess. at 350 (1977).

On the basis of these authorities, and in the belief that they represent the overwhelming preponderance of opinion in the medical profession, the Department is proposing not to fund sterilizations by hysterectomy. In spite of this apparent unanimity, however, the proposed rules have been written so as to provide for Federal financial participation in hysterectomies for family planning purposes under exceptional circumstances, of which the Department is presently unaware, in which sterilization by hysterectomy would be medically appropriate, should any such circumstances be described in public comments received by the Department. If such an exception is added to this provision, the Department will have to consider possible safeguards to protect against abuse. Such safeguards might include additional documentation requirements or a required consultation with an additional physician. In any event, sterilizations by hysterectomy for which there might be non-family planning justifications could still be Federally funded if they meet the criteria of other provisions authorizing funding for medical assistance.

The Department solicits comments on the appropriateness of sterilizations by hysterectomy, including comments directed at the following issues:

1. Are there any circumstances under which performing a hysterectomy for sterilization purposes is generally accepted as appropriate?

2. Should any other mechanism, for example requiring additional documentation or second physician consultations, be utilized to deal with the question of sterilization hysterectomies?

Text of proposed rule:

(b) Federal financial participation is available in a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative, if any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgment of receipt of the foregoing information.

and

(b) Programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative, if any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgment of receipt of the foregoing information.

Even though hysterectomy is not acknowledged as an acceptable family planning technique, it undeniably always has the effect of rendering a patient permanently incapable of reproducing. The Department wishes to ensure that patients fully understand the family planning consequences of hysterectomies.

To accomplish this end, the proposed rules require that whenever a Federally-funded hysterectomy is performed, the person securing the patient's authorization for the surgery (or, where applicable, the authorization of the patient's representative) inform the patient and her representative that the hysterectomy will render the patient permanently incapable of reproducing. To ensure compliance with this provision, the proposed rules further require the patient or her representative to acknowledge, in writing, receipt of the information that the hysterectomy will render the patient permanently incapable of reproducing.

It should be noted that this provision imposes no requirements as to the circumstances under which authorization for a hysterectomy must be obtained or the people from whom it must be obtained. The Department at present does not have reason to believe that authorization for hysterectomies, like all other purely medical procedures, is not routinely and properly obtained. The proposed rules, therefore, would require the provision and acknowledgment of receipt of the requisite information only on the same basis and under the same circumstances as upon which authorization is already being obtained.

Comments are solicited with respect to this provision, particularly with respect to the following questions:

1. Is the proposed rule adequate to ensure that patients are apprised of the inevitable consequences of hysterectomies?

2. Are existing procedures adequate to ensure that patients are apprised of the inevitable consequences of hysterectomies?

§ 205.35–8 *State Agency Requirements.*

Text of proposed rule:

(a) A State plan under Title I, IV–A, X, XIV, XVI, XIX, or XX of the Social Security Act must provide, with respect to sterilization procedures or hysterectomies for which payment is made under the plan, (1) that all requirements of this section be met; and (2) that the State will provide legal counsel for the patient at all review committee and court proceedings described in this section.

(b) The State Agency shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The State Agency shall submit other reports as required and when requested by the Secretary.

and

§ 50.208 *Program or project requirements.*

Text of proposed rule:

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, (1) meet all requirements of this subpart; and (2) provide legal counsel for the patient at all review committee and court proceedings described in this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

The proposed rules provide that a State plan under title I, IV–A, X, XIV, XVI, XIX, or XX of the Social Security Act, with respect to sterilization procedures or hysterectomies for which payment is made under the plan, and a program or project, with respect to sterilization procedures or hysterectomies supported by the Public Health Service, must provide (1) that all requirements of this section be met; and (2) that the State, program, or project will provide legal counsel for the patient at all sterilization review committee and court proceedings described in this section. The State Agency, or program or project, must maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years. The appro-

priate State Agency, program, or project must submit other reports as required and when requested by the Secretary.

§ 205.35–9 *Federal financial participation.*

Text of proposed rule:

(a) Federal financial participation is not available in expenditures for sterilization procedures unless a facsimile of the consent form appended to this section or another form approved by the Secretary is used for purposes of this section.

(b) Federal financial participation under title XIX of the Social Security Act is unavailable in any sterilization or hysterectomy for which the State Agency has paid without first having received documentation showing that the requirements of this section have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledgements of receipt of hysterectomy information.

(c) Federal financial participation is available in expenditures for the review committee and legal counsel where required by this section.

and

§ 50.209 *Use of Federal financial assistance.*

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this subpart or another form approved by the Secretary is used for purposes of this section.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledgements of receipts of hysterectomy information.

(c) Federal financial assistance administered by the Public Health Service may be used for the expenditures for the revivew committee and legal counsel where required by this section.

The proposed rules provide that Federal financial participation would not be available in expenditures for sterilization procedures unless the consent form contained in the appendix to the regulations or another form approved by the Secretary is used for purposes of this section. To facilitate enforcement, the appropriate State Agency, program, or project may not pay for any sterilization procedure or hysterectomy without first receiving documentation showing that the requirements of these rules have been met. Documentation includes consent forms, sterilization review committee certifications, court orders, and acknowledgements of receipt of the information that a hysterectomy will render the patient permanently incapable of reproducing. The proposed rules also provide that Federal financial participation is available in expenditures for the sterilization review committee and legal counsel where required by the regulations.

INVITATION TO COMMENT

Interested persons are invited to submit written comments, suggestions or objections concerning the proposed regulations to, for the Public Health Service, Marilyn L. Martin, Room 722H (Hubert H. Humphrey Building), 200 Independence Avenue SW., Washington, D.C. 20201 and, for the Health Care Financing Administration, Administrator, HCFA, P.O. Box 2366, Washington, D.C. 20013, on or before March 13, 1977. All comments received in timely response to this Notice will be considered and will be available for public inspection at the following offices during regular business hours.

Public Health Service, Room 722H (Hubert H. Humphrey Building), 200 Independence Avenue, SW., Washington, D.C. 20201.

Health Care Financing Administration, Room 5225, Switzer Building, 330 C Street, SW., Washington, D.C. 20201.

It is proposed to make these rules effective upon republication in the FEDERAL REGISTER.

NOTE.—The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A–107.

It is therefore proposed to amend 42 CFR Part 50 Subpart B, and 45 CFR, Chapter II, Part 205 as set forth below.

Dated: November 30, 1977.

JULIUS B. RICHMOND,
Assistant Secretary for Health.

ROBERT A. DERZON,
Administrator, Health Care Financing Administration.

NOVEMBER 30, 1977.

Approved: December 1, 1977.

JOSEPH A. CALIFANO, Jr.,
Secretary.

1. Section 205.35, Part 205, Chapter II, Title 45 of the Code of Federal Regulations is revised to read as set forth below:

§ 205.35–1 Applicability.

This section applies to programs administered under Titles I, IV–A, X, XIV, XVI, XIX, and XX of the Social Security Act.

§ 205.35–2 Definitions.

(a) "Sterilization" means any medical procedure or operation for the purpose of rendering an individual permanently incapable of reproducing.

(b) "Informed consent" (to a sterilization procedure) means a written authorization to be sterilized given by the person to be sterilized and given voluntarily and with an understanding of the nature and consequences of the procedure to be performed.

(c) "Consent form" means a written document which states the requirements for informed consent as set forth in Section 205.35–3.

(d) "A mentally incompetent individual" means a person who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

(e) "A sterilization review committee" means a committee designated by the State Agency to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

(f) "Hysterectomy" means a medical procedure or operation for the purpose of removng the uterus.

§ 205.35–3 Consent procedures.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this paragraph.

(a) *Preparing to obtain informed consent.* An individual who obtains informed consent for a sterilization procedure must provide orally *all* of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw his/her consent to the procedure at any time prior to the sterilization without affecting his/her right to future care or treatment, and without loss or withdrawal of any Federally-funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) A full description of the benefits or advantages he/she may expect to gain as a result of the sterilization;

(4) Advice that the sterilization procedure is considered to be irreversible;

(5) A thorough explanation of the specific sterilization procedure to be performed;

(6) A full description of the discomforts and risks which may accompany and follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(7) Advice that the sterilization will not be performed for at least 30 days; and

(8) An opportunty to ask and have answered any questions he/she may have concerning the sterilization procedure.

(b) *Filling out the consent form.*—(1) *Language of the consent form.* The consent form should be in the primary language of the patient. If the consent form is not in the primary language of the patient, an interpreter must be made available to assist the individual.

(2) *Provisions for the handicapped.* Suitable arrangements must be made to ensure that consent information is effectively communicated to blind, deaf, and other handicapped patients.

(3) *Signatures on the consent form.* The consent form must be signed and dated by:

(i) The patient; and

(ii) The interpreter, if one is provided; and

(iii) The individual who obtains the consent of the patient; and

(iv) The physician who will perform the sterilization procedure.

(4) *Required certifications.* (i) The person securing the patient's consent must certify by signing the consent form that, before the patient signed the consent form, he/she advised the patient

that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the requirements for informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(ii) The physician performing the sterilization must certify by signing the consent form that, immediately prior to the performance of the sterilization, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the elements of informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized. The physician will further certify that, to the best of his/her knowledge and belief, at least 30 days passed between the date upon which the patient signed the consent form and the date upon which the sterilization was performed.

(iii) The physician performing the sterilization must, in cases where court orders are required by this section, certify, by signing the consent form, that he/she was provided with a copy of the court order prior to the performance of the sterilization.

(c) *Following State and local procedures.* In addition to the consent procedures required by this part, any requirement of State and local law, except one of spousal consent, must be followed.

§ 205.35–4 Sterilization of a mentally competent individual aged 21 or older.

Federal financial participation is available in expenditures for a sterilization of a mentally competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in § 205.35–3.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

§ 205.35–5 Sterilization of a mentally incompetent individual aged 21 or older; sterilization of an institutionalized individual aged 21 or older.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any person declared mentally incompetent by a State, Federal or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any individual institutionalized in a correctional, mental or other facility unless:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in § 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized.

or

(a) Federal financial participation is unavailable in expenditures for a sterilization of a mentally incompetent individual, or any individual institutionalized in a correctional, mental or other facility unless:

(1) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in § 205.35–3;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized.

(b) Federal financial participation is unavailable in expenditures for the sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in § 205.35–3(a).

§ 205.35–6 Sterilization of a mentally competent or incompetent individual under the age of 21.

Federal financial participation is unavailable in expenditures in the sterilization of individuals under 21 years old.

§ 205.35–7 Sterilization by hysterectomy.

(a) Federal financial assistance for family planning purposes is unavailable in any hysterectomy performed for the purpose of rendering an individual permanently incapable of reproducing, unless [exception, with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

(b) Federal financial participation is available in a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative, if any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgement of receipt of the foregoing information.

§ 205.35–8 State Agency requirements.

(a) A State plan under Title I, IV–A, X, XIV, XVI, XIX, or XX of the Social Security Act must provide, with respect to sterilization procedures or hysterectomies for which payment is made under the plan, (1) that all requirements of this section be met; and (2) that the State will provide legal counsel for the patient at all review committee and court proceedings described in this section.

(b) The State Agency shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The State Agency shall submit other reports as required and when requested by the Secretary.

§ 205.35–9 Federal financial participation.

(a) Federal financial participation is not available in expenditures for sterilization procedures unless a facsimile of the consent form appended to this section or another form approved by the Secretary is used for purposes of this section.

(b) Federal financial participation under title XIX of the Social Security Act is unavailable in any sterilization or hysterectomy for which the State Agency has paid without first having received documentation showing that the requirements of this section have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledge-

ments of receipt of hysterectomy information.

(c) Federal financial participation is available in expenditures for the review committee and legal counsel where required by this section.

2. Sections 50.201–204, Subpart B, Part 50, Chapter I, Title 42 of the Code of Federal Regulations are revised to read as set forth below:

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

(a) "Sterilization" means any medical procedure or operation for the purpose of rendering an individual permanently incapable of reproducing.

(b) "Informed consent" to a sterilization procedure means a written authorization to be sterilized given by the person to be sterilized and given voluntarily and with an understanding of the nature and consequences of the procedure to be performed.

(c) "Consent form" means a written document which states the requirements for informed consent as set forth in § 50.203.

(d) "A mentally incompetent individual" means a person who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

(e) "A sterilization review committee" means a committee designated by the program or project to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

(f) "Hysterectomy" means a medical procedure or operation for the purpose of removing the uterus.

(g) The "Public Health Service" means the Health Services Administration, Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

(h) The "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

§ 50.203 Consent procedures.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this paragraph.

(a) *Preparing to obtain informed consent.* An individual who obtains informed consent for a sterilization procedure must provide orally *all* of the following information or advice to the individual who is to be sterilized.

(1) Advice that the individual is free to withhold or withdraw his/her consent to the procedure at any time prior to the sterilization without affecting his/her right to future care or treatment, and without loss or withdrawal of any Federally-funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) A full description of the benefits or advantages he/she may expect to gain as a result of the sterilization;

(4) Advice that the sterilization procedure is considered to be irreversible;

(5) A thorough explanation of the specific sterilization procedure to be performed;

(6) A full description of the discomforts and risks which may accompany and follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(7) Advice that the sterilization will not be performed for a least 30 days; and

(8) An opportunity to ask and have answered any questions he/she may have concerning the sterilization procedure.

(b) *Filling out the consent form.* (1) *Language of the consent form.* The consent form should be in the primary language of the patient. If the consent form is not in the primary language of the patient, an interpreter must be made available to assist the individual.

(2) *Provisions for the handicapped.* Suitable arrangement must be made to ensure that consent information is effectively communicated to blind, deaf and other handicapped patients.

(3) *Signatures on the consent form.* The consent form must be signed and dated by:

(i) The patient; and

(ii) The interpreter, if one is provided; and

(iii) The individual who obtains the consent of the patient; and

(iv) The physician who will perform the sterilization procedure.

(4) *Required certification.* (i) The person securing the patient's consent must certify by signing the consent form that, before the patient signed the consent form, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the requirements for informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(ii) The physician performing the sterilization must certify by signing the consent form that, immediately prior to the performance of the sterilization, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the requirements for informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized. The physician will further certify that, to the best of his/her knowledge and belief, at least 30 days have passed between the date upon which the patient signed the consent form, and the date upon which the sterilization was performed.

(iii) The physician performing the sterilization must, in cases where court orders are required by this section, certify, by signing the consent form, that he/she was provided with a copy of the court order prior to the performance of the sterilization.

(c) *Following State and local procedures.* In addition to the consent procedures required by this part, any requirement of State and local law, except one of spousal consent, must be followed.

§ 50.204 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of a mentally competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 50.203.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

§ 50.205 Sterilization of a mentally incompetent individual aged 21 or older; sterilization of an institutionalized individual aged 21 or older.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any person declared mentally incompetent by a State, Federal or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any individual institutionalized in a correctional, mental or other facility *unless*:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in § 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that

all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in § 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in § 50.203 (a), and that the patient has voluntarily consented to be sterilized.

or

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual, or any individual institutionalized in a correctional, mental or other facility *unless*:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in § 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of sterilization;

(3) The individual is at least 21 years;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in § 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in § 50.203 (a), and that the patient has voluntarily consented to be sterilized.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in § 50.203 (a).

§ 50.206 Sterilization of a mentally competent or incompetent individual under the age of 21.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of sterilizations of individuals under 21 years old.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy for the purpose of rendering an individual permanently incapable of reproducing, unless [exception with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

(b) Programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative, if any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgment of receipt of the foregoing information.

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, (1) meet all requirements of this subpart; and (2) provide legal counsel for the patient at all review committee and court proceedings described in this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used for purposes of this section.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledgments of receipt of hysterectomy information.

(c) Federal financial assistance administered by the Public Health Service may be used for the expenditures for the review committee and legal counsel where required by this section.

APPENDIX: REQUIRED CONSENT FORM

NOTICES Your decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving Federal funds.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from _____
(doctor or clinic)

When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment and I will not lose any help or benefits from programs receiving Federal funds such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I understand that the sterilization must be considered permanent and not reversible. I have decided that I do not want to become pregnant, bear children or father children.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and freely chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by Federally funded programs.

I am _____ years old. I was born on ____ day _____ _____ month year

I, _____, hereby consent of my own free will to be sterilized by _____ _____ by a method called _____ _____.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health, Education, and Welfare or

Employees of programs or projects funded by that Department but only for purposes of research or for determining if Federal laws were observed.

You are requested to supply the following information, but it is not required:

_____

Race and ethnicity designation (please check)

Black (not of Hispanic origin) _____

Hispanic _____

Asian or Pacific Islander _____

American Indian or Alaska native _____

White (not of Hispanic origin) _____

_____ _____ _____/ ___/_____

Patient's Signature Date: Month Day Year

Where the consent form is not in the primary language of the patient:

I have read the consent form to_____ _____ in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

_____

Interpreter Date

Before _____ signed this consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.
name of individual

I counseled the patient that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the patient that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the patient is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequenee of the procedure.

Signature of person obtaining consent Date

Facility

Address

PHYSICIAN'S STATEMENT

Immediately before I performed a sterilization operation upon _____

Name of patient

I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the patient that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the patient that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief at least thirty days have passed since the patient consented to the sterilization.

To the best of my knowledge and belief the patient is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

Physician

Date

Alternative final paragraph for use where court order is required:

To the best of my knowledge and belief the patient is at least 21 years old. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure. I have been provided with a copy of the attached court order.

Physician

Date

[FR Doc.77-35424 Filed 12-12-77;8:45 am]

[4110-35]

Public Health Service

[42 CFR Part 50]

[45 CFR Part 205]

PROPOSED RESTRICTIONS APPLICABLE TO STERILIZATIONS FUNDED BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CROSS REFERENCE: For a document proposing rules on restrictions applicable to sterilizations funded by the Department of Health, Education, and Welfare, See FR Document 35424 under Health Care Financing Administration in Part III of this issue.