**Supporting Statement for Information Collection Requirements**
**Contained the Public Health Service (PHS)**
**Sterilization Regulations and the PHS Sterilization Consent Form**
**42 CFR Part 50, subpart B**

## A. Background and Justification

1. Need and Legal Basis

In order to comply with the Paperwork Reduction Act of 1995, the Office of Population Affairs (OPA), Department of Health and Human Services (DHHS), requests that the Office of Management and Budget (OMB) approve for three years from approval date, the *"Consent for Sterilization Form*.@ Approval for the PHS information collection requirement contained in the sterilization consent form has been given under OMB number 0937-0166. (Attachment A)

This is a request for extension, of a currently approved collection for the disclosure and record-keeping requirements codified at 42 CFR part 50, subpart B (ASterilization of Persons in Federally Assisted Family Planning Projects@). A copy of the Public Health Service (PHS) regulation, 42 CFR Part 50, subpart B, is provided in Attachment B. These rules prescribe the requirements for sterilizations funded under the various PHS programs administered by the Department of Health and Human Services (HHS). Included with the portion of the rules pertaining to those programs administered by the PHS, as part of the appendix to subpart B, is a copy of the required sterilization consent form. The requirements apply when sterilization procedures are carried out by programs or projects funded by the PHS, under grant or contract. The requirements are as follows:

> 42 CFR 50.204 - Disclosure - Specifies information that must be provided to the individual in order to constitute informed consent.
>
> 42 CFR 50.205 and 50.208 - Record-keeping - Specifies the consent form that must be used, signatures and certifications required and record retention.

The requirements of the regulation result from several tragic incidents of sterilization abuse under Federal family planning programs that were brought to the Department's attention in 1973 (Relf v. Wienberger). In 1978, HHS published in the Federal Register, final rules prescribing the requirements for sterilizations funded under various health programs administered by the Department. The Department funds family planning services, including sterilizations, under several Federal statutes. The sterilization consent regulations set forth the procedures to be followed and information to be provided in order to assure informed consent. In brief, the regulation allows Federal funding of sterilizations only in cases where the individual requesting the procedure is at least 21 years of age,

mentally competent and has given informed consent at least 72 hours before the sterilization was performed. The regulations require a 30-day waiting period (but not more than 180 days), prohibit Federal funding of sterilizations of mentally incompetent individuals unless he or she had been declared competent for purposes which include the ability to consent to sterilization, and prohibits sterilizations for institutionalized persons.

The consent form (Attachment C) provides information to assure voluntary and informed consent to persons undergoing sterilization in programs for health services which are supported by federal financial assistance administered by the PHS. The consent form provides additional procedural protection to the individual, and the regulation requires that the consent form be a copy of the form that is appended to the PHS regulation. In 2003, the PHS sterilization consent form was revised to conform with OMB government-wide standards for the collection of race/ethnicity data and to incorporate the PRA burden statement as part of the consent form. (Attachment D)

2. Information Users

Consent forms are signed by individuals undergoing a federally funded sterilization procedure and certified by necessary medical authorities. Forms are incorporated into the patient's medical records and the agency's records. Through periodic site audits and visits, PHS staff review completed consent forms to determine compliance with the regulation. Thus, the purpose of the consent form is twofold. First, it serves as a mechanism to ensure that a person receives information about sterilization and voluntarily consents to the procedure. Second, it facilitates compliance monitoring.

Payments are disallowed for violations of the sterilization regulations requirements. In instances where widespread abuses are observed, a PHS program may be defunded. Examples of potential violations include disregard of mandatory waiting periods or the minimum age limit; sterilizations of mentally incompetent individuals; or lack of informed consent by the patient.

3. Improved Information Technology

This regulation in no way prescribes how the facility should prepare to maintain records. The programs are free to take advantage of any technological advance which they find appropriate for their needs.

4. Duplication of Similar Information

These are unique requirements which are specified in a way so as not to duplicate existing program or agency policy. The procedures required to assure informed consent are carried out once for each case of sterilization. No other forms unique to sterilization are required by the PHS agencies. The information obtained on the consent form is required by regulation, and is not collected by any other source.

5. Small Business

   All federally funded public health programs are required to follow the regulations regardless of their size. The consent form protects the individual by ensuring that he/she is aware of the risks, benefits, alternatives and consequences of sterilization. The burden cannot be reduced for small organizations without violating or failing to properly ensure the rights of individuals seeking sterilization.

6. Less Frequent Collection

   The disclosure requirements and consent form are used on a single time basis of individuals seeking sterilization involving PHS Federal financial participation.

7. Special Circumstances

   These requirements comply with all general information collection guidelines.

8. *Federal Register* Notice/Outside Consultation

   On May 31, 2006, the 60-day Federal Register notice was published and no public comments were received. A copy of the 60-day public notice, a summary of comments, and our response is provided is attached at _____.

9. Payment/Gift to Respondents

   No payment is made to respondents.

10. Confidentiality

    Entities that maintain the agency medical records may not under law disclose confidential information without the individual's consent. Information may be disclosed only in summary, statistical or other form which does not identify particular individuals.

11. Sensitive Questions

    The regulations require only disclosure of information to individuals seeking sterilization operation and informed consent of such individuals, not responses to sensitive questions.

12. Estimate of Burden

Sterilizations comprise about 2 percent of approximately five million family planning service users (100,000 sterilizations). From discussion with providers, practitioners, PHS staff and others, it is estimated that approximately one hour is necessary to inform the individual of the sterilization procedures and his/her rights. Therefore, the annual collection burden is: 1 hour/patient x 100,000 = 100,000 hours.

In addition to disclosure, we estimate 15 minutes per patient for record-keeping (i.e., filing and necessary documentation). Therefore, the annual record-keeping burden is 15 minutes x 100,000 records = 25,000 hours.

The total annual burden which appears in the information collection budget is 125,000 hours.

13. Capital Costs

N.A.

14. Cost to the Federal Government

We estimate the Federal cost to be the following:

10 regions x 1 hour per quarter x 4 quarters = 40 hours

8 chart audits annual x 84 grantees = 672 audits

672 audits x 2 hour per audit = 336 hours

Total hours = 336 hours

Total Federal annual cost = 336 @ $15 = $5040.00

15. Program or Burden Changes

This is an ongoing collection of information. The adjustment to the burden hours is a result of new estimates of the number of respondents, (e.g. individuals seeking sterilizations). The

change in burdent hours is not a result of program change. Based on previous Title X family planning program data, we estimated that 1 percent of the four million female planning service users relied on sterilization (own or their partner) as their contraceptive method. However, more recent program data indicate that closer to 2 percent of five million family planning users rely on sterilizations as their contraceptive method for a total of 100,000 estimated sterilization consent form users annually. It is estimated that approximately one hour is necessary to inform the individual of the sterilization procedures and his/her rights. The annual collection burden is: 1 hour/patient x 100,000 = 100,000 hours. In addition to disclosure, we estimate 15 minutes per patient for record-keeping (i.e., filing and necessary documentation). Therefore, the total annual burden is estimated to be 125,000 hours.

16. Publication and Tabulation Data

This information is not tabulated or published.

17. Display of Expiration Date for OMB Approval

The expiration date will be displayed on the information collection item.

18. Exceptions to the Certification Statement

N.A.

B. Collection of Information Employing Statistical Methods

Statistical methods are not used in this activity.

Attachments

A B Notice of OMB Action dated 8/25/2003
B B 42 CFR Part 50, subpart B
C B Consent for Sterilization Form OMB Approval No. 0937-0166
D B Federal Register Notice/March 14, 2003