1**Supporting Statement Part A for Information Collection Requirements**
HHS 42 CFR subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects

Ciara Davis, Ciara.Davis@hhs.gov , (202) 768-1920
Office of Population Affairs
1/13/2025

Supporting Statement for HHS 42 CFR subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects

A. Justification

1. Circumstances Making the Collection Necessary

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 a three-year renewal by the Office of Management and Budget (OMB) for the *"Consent for Sterilization Form*." Previously, approved for the PHS information collection requirement contained in the sterilization consent form under OMB number 0937-0166.

This is a request for a renewal of a previously approved collection for the disclosure and record-keeping requirements codified at 42 CFR part 50, subpart B, "Sterilization of Persons in Federally Assisted Family Planning Projects."

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 ePHS, 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 requirements.

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 (but not more than 180 days) waiting period, 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 prohibit sterilizations for institutionalized persons.

The consent form 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 either a copy of the form that is appended to the PHS regulation or another similar consent form approved by the Secretary. In 2003, the PHS sterilization consent form was revised to conform to OMB government-wide standards for the collection of race/ethnicity data and to incorporate the PRA burden statement as part of the consent form. In 2006 and every three years since, OMB has approved an extension of the information collection. Section 301 of the Public Health Service Act (42 U.S.C. 241).

2. Purpose and Use of Information

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. Use of Improved Technology and Burden Reduction

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. Efforts to Identify Duplication and Use 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. Impact on Small Business or Other Small Entities

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. Consequences of 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 Relating to the Guidelines of 5 CFR 1320.5

These requirements comply with all general information collection guidelines. The Information Collection Request fully complies with regulation 5 CFR 1320.5.

8. Comments in Response to Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice was published in the Federal Register on November 6, 2024, Vol. 89, No. 215; pp. 88055-6. No public comments were recieved.

9. Explanation of any Payment/Gift to Respondents

No payment is made to respondents.

10. Assurance of Confidentiality Provided to Respondents

The medical records maintained by agencies will be kept private to the extent allowed by law. Information may be disclosed only in summary, statistical or other forms which does not identify particular individuals.

11. Justification of Sensitive Questions

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

The form includes the collection of participant race and ethnicity. OPA requests permission to continue to collect the previously approved race/ethnicity items. OPA plans to update the sterilization informed consent regulations and form within the next year and will update the demographic information to reflect the updated 2024 Statistical Policy Directive No. 15 (SPD-

15) guidance at that time. Therefore, OPA anticipates revising this collection in the next year to adhere to the latest OMB guidance on the collection of race and ethnicity.

12. Estimates of Annualized Burden Hours

Sterilizations comprise about two percent of approximately five million family planning service patients (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 fifteen 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.

12.A Estimated Annualized Burden Hours

Type of Respondent	Information Collection	Number of Respondents	Number of Responses per Respondent	Average Burden per Response	Total Hours
Citizens Seeking Sterilization	Information Disclosure for *Sterilization Consent Form*	100,000	1	1	100,000
Citizens Seeking Sterilization	Record-keeping for *Sterilization Consent Form*	100,000	1	15/60	25,000
Total					125,000

12B. Estimated Annualized Cost

Type of Respondent	Information Collection	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Citizens Seeking Sterilization	Information Disclosure	100,000	$11.00	$1,000,000
Citizens Seeking Sterilization	Record-keeping	25,000	$11.00	$250,000
Total				$1,250,000

13. Estimates of Other Total Annual Cost Burden to Respondents or Record-keepers/Capital Costs

No start-up costs required. Clinicians will not need new information to utilize this form.

14. Annualized Costs to the Federal Government

Estimated Annualized Cost to the Federal Government

Number of Sterilization Patients	Number Chart Audits per Grantee	Total Number Chart Audits	Number Hours to Complete One Chart Audit	Cost per Chart Audit	Total Federal Annual Cost
100,000	5%	5,000	.5	$11.00	$27,500.00

We estimate the Federal cost to be the following:

5 percent of audits annually x 100,000 national sterilization patients = 5,000 audits
5,000 chart audits x .5 hours to complete = 2,500 hours
Total Federal annual cost = 2,500 hours @ $11.00/hour = $27,500.00.

15. Explanation for Program Changes or Adjustments

This is a renewal with no changes. The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

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

Not applicable. There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

Statistical methods are not used in this activity.