

**ACTION:** Final rule; technical amendment.

**SUMMARY:** This final rule amends Public Health Service (PHS) regulations, which govern the sterilization of persons in federally assisted family planning projects, by making technical revisions to the "Required Consent Form".

**DATES:** This rule is effective March 14, 2003.

**FOR FURTHER INFORMATION CONTACT:** Evelyn Kappeler, Office of Population Affairs, 4350 East West Highway, Suite 200, Bethesda, Maryland 20814; telephone number: (301) 594-7608; e-mail address: [EKappeler@osophs.dhhs.gov](mailto:EKappeler@osophs.dhhs.gov).

**SUPPLEMENTARY INFORMATION:** On November 8, 1978, this Department published in the **Federal Register** (43 FR 52146), final rules prescribing the requirements for sterilizations funded under the various health programs administered by the Department. 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. These rules, including the appendix, have been codified at 42 CFR part 50, subpart B.

This final rule amends 42 CFR part 50 by revising the sterilization consent form contained in the appendix to subpart B. These amendments will make the codified PHS regulations conform with (1) recent government-wide directives issued by the Office of Management and Budget (OMB) concerning standards for maintaining, collecting and presenting Federal data on race and ethnicity for all Federal reporting purposes, and (2) the requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) regarding the respondent burden statement. In order to effect a change in the materials codified in the Code of Federal Regulations, however, the Department must issue these changes in the form of a final rule.

#### **Race and Ethnicity Data**

Although not required, respondents to the sterilization consent form are requested to supply information on their race and ethnicity. The sterilization consent form contains information collections subject to OMB approval under the Paperwork Reduction Act (PRA), and is being revised to reflect more recent guidance on the appropriate racial and ethnic information classifications.

After a comprehensive review process, including a notice and public

comment period, OMB revised its standards for the classification of Federal Data on Race and Ethnicity ("Statistical Policy Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting"). The revised classification provides minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting purposes. The standards were developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies. The standards provide two formats that may be used for data on race and ethnicity. Self-reporting and self-identification using two separate questions is the OMB preferred method for collecting data on race and ethnicity. To provide flexibility and ensure data quality, the OMB directs that separate questions be used whenever feasible for reporting race and ethnicity. Additionally, when race and ethnicity are collected separately, ethnicity must be collected first. If race and ethnicity are collected separately, OMB's minimum designations are as follows: Ethnicity—Hispanic or Latino; Not Hispanic or Latino Race; Race—American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White. Self-reporting or self-identification using two separate questions is the OMB preferred method for collecting data on race and ethnicity. The OMB standards also state that respondents shall be offered the option of selecting one or more racial designations. Consistent with these standards, this final rule adopts the two-question format with an instruction to "mark one or more" racial categories in the required sterilization consent form.

#### **Respondent Burden Statement**

The sterilization consent form is also being amended to incorporate the respondent burden statement, as required by the Paperwork Reduction Act. This will ensure that each respondent receives, directly, a copy of the required statement. Under the PRA, as well as the statute's implementing regulations (5 CFR part 1320), the term "burden" means the "total time, effort, or financial resources" the public expends to provide information to or for a Federal agency, including reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the collection of information; and transmitting or disclosing information.

Under the Paperwork Reduction Act, agencies must take into account the burden that their information collections impose on the public. This burden is balanced with the "practical utility" of the information to be collected. 44 U.S.C. 3502(2); 5 CFR 1320.3(b).

#### **Justification for Omitting Notice of Proposed Rulemaking**

Section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553) provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. DHHS has determined that it is unnecessary and impractical to follow proposed rulemaking procedures or to delay the effective date of this regulation, since this amendment is purely technical in nature, and simply amends the sterilization consent form to conform with current OMB directives regarding the classification of race and ethnicity data, which went through a notice and comment period, as well as to reflect the statutory requirements of the PRA.

#### **Regulatory Assessment Requirements**

This final rule implements technical amendments which have no substantive impact on the underlying regulations, and it does not otherwise impose or amend any requirements. As such, it is not a "significant regulatory action" subject to review by OMB under Executive Order 12866, entitled *Regulatory Planning and Review*. This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Furthermore, since the action does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. In addition, DHHS has determined that this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*. As there are no Federalism implications, a Federalism impact statement is not required.