

DEPARTMENTAL GRANT APPEALS BOARD

Department of Health and Human Services

SUBJECT: North Carolina Statewide Family  
Planning Program  
Docket No. 79-179  
Decision No. 114

DATE: August 1, 1980

DECISION

The North Carolina Statewide Family Planning Program (grantee) applied for review of a decision issued by the Public Health Service (PHS) Regional Grant Appeals Board with respect to discretionary grants for family planning services (PHS Docket No. 79-3). The PHS Regional Grant Appeals Board had 1) upheld the Region IV disallowance of costs for nontherapeutic sterilizations performed on persons under age 21; 2) reversed the Region's disallowance of sterilization costs, incurred in the fiscal year ending June 30, 1974 (FY '74) and in the month of July 1974, questioned for lack of the proper notice on the consent form; and 3) upheld the Region's disallowance of costs, incurred in the remainder of FY '75 or in FY '76, questioned for lack of the proper notice.

Grantee has not appealed that portion of the PHS decision related to sterilizations performed on persons under age 21. In response to a request by the Board, PHS has identified the amount remaining in dispute as \$81,257.05, and grantee has stated that it has no evidence to disagree with this figure.

We have determined that there is no dispute as to a material fact and that this case should be decided on the basis of the written record. This consists of the grantee's application for review, the PHS response to the appeal, and the parties' responses to an Order to Show Cause issued by the Board Chairman.

Background

Section 1001(a) of Title X of the Public Health Service Act authorizes the Secretary to "make grants to ... public or non-profit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods...." 42 U.S.C. 300. The Secretary has interpreted this section and other family planning provisions to authorize Federal funding of sterilization services. Although Congress had provided that all family planning should be on a voluntary basis, there were initially

no specific regulations governing the circumstances under which there could be Federal funding of sterilizations. After national attention was drawn to the problem of improper coercion of needy persons to submit to sterilization upon threat of loss of welfare benefits, the then Department of Health, Education, and Welfare (HEW) published a notice in August 1973, 38 FR 20930, that it was adopting guidelines for issuance, by HEW agencies, of regulations to insure informed consent and voluntariness in Federally funded sterilizations. Following publication of the guidelines, PHS issued such regulations, published in final form on February 6, 1974, 39 FR 4730. The effective date of the February 6 rules was delayed several times pending the outcome of several court cases.

On March 15, 1974, the District Court for the District of Columbia, in Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C. 1974), found the February 6 rules to be invalid. Among other defects, the Court found that the rules were arbitrary and unreasonable in that they did not require that legally competent persons be properly advised that their Federal benefits could not be terminated by reason of a decision not to be sterilized. The District Court declared in its Order that the regulations were defective in authorizing the provision of Federal funds without requiring that such advice be given prior to obtaining consent and "without further requiring that such advice also appear prominently at the top of the consent document...." 372 F. Supp. at 1205. PHS then published on April 18, 1974, at 39 FR 13872, a new Subpart D to 42 CFR Part 50 to replace the regulation struck down in Relf. In addition to other requirements for informed consent for sterilizations, these regulations provided that --

Each consent document shall display the following legend printed prominently at the top:

NOTICE: 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. 42 CFR 50.202(d)(7)(iii).

The regulations had an effective date of April 18, 1974.

The North Carolina State Board of Health, Department of Human Resources, received funding for its Statewide Family Planning Program under Section 1001 of the PHS Act, including funding for the budget periods coextensive with FY '75 and FY '76. An audit, apparently performed in the Fall of 1975, and supplemented in the Fall of 1976, identified sterilizations funded through grantee for which the consent documents did not contain the NOTICE required by the regulations, and this formed the basis for the disallowance by Region IV, upheld in part by the PHS Board.

Grantee does not deny that the consent documents in question did not contain the required NOTICE but asserts basically that 1) grantee made a good faith effort to meet the informed consent requirements but was hampered in its effort by Region IV's unresponsiveness; and 2) PHS improperly made the NOTICE a "proxy" for compliance with the informed consent requirements.

### Good Faith

The record does indicate that grantee attempted to develop a consent document which would meet the regulatory requirements and that PHS failed to act in a timely manner to approve the forms or to assist the grantee in developing an adequate form. The PHS Board specifically stated that it "recognized the good faith efforts made by the grantee in trying to develop the appropriate informed consent documents and the delays it encountered." (PHS Board Decision, p. 3.) The PHS Board concluded, however, that this did not excuse the failure to include the NOTICE on whatever consent forms were in use. The PHS Board pointed out, and the record supports, the fact that grantee does not claim any lack of awareness of the NOTICE requirement. The April 18, 1974 regulations were noted in "Remarks" appearing on the Notice of Grant Award for the budget period beginning July 1, 1974 and, at least as early as July 16, 1974, the grantee informed its providers of the consent requirements, including provision for the NOTICE. Based on these factors, the PHS Board concluded that "the fact that the NOTICE did not subsequently appear on consent forms was due to the grantee's lack of monitoring of its service providers." (PHS Board Decision, p. 3.)

While the PHS Board does not discuss the basis for its finding that grantee failed to monitor its service providers adequately and that finding is not supported by any direct evidence in the record, it appears to be a fair implication that, if grantee had more closely monitored whether the providers were meeting the requirements, there would have been better compliance. Grantee attempts to excuse itself from a duty to monitor compliance. Grantee had agreed with its providers that the most efficient method for insuring that forms met the regulatory criteria would be for grantee to work with regional officials to develop an acceptable form. Grantee argues that only PHS could provide "definitive" guidance with regard to consent documents, and that, where PHS could not stipulate how the requirements of the regulation could be met, the onus should not be placed on grantees to attempt to comply. (Grantee's Response to Order, p. 2.)

It is clear, however, that some form had to be in use while the approval process was ongoing. Although compliance with certain of the requirements (such as, inclusion of a description of alternatives to sterilization) would involve a subjective judgment as to what was intended and guidance from PHS might be critical, compliance with the NOTICE requirement could have

been accomplished without such guidance. The wording of the NOTICE was specified in the regulation, as was the requirement that the NOTICE be placed prominently at the top of the document.

The PHS Board nevertheless allowed grantee until August 1, 1974, as a reasonable period of time in which to implement the NOTICE requirement imposed on April 14, 1974. The PHS Board concluded, however, that after that period of time, the failure to comply should not be excused even in light of the grantee's good faith efforts and the unresponsiveness on the part of the Regional Office.

We agree. As noted by this Board in previous decisions, an agency disallowance based on the unambiguous terms of a validly promulgated regulation should not be overturned on the basis of purely equitable arguments. See, e.g., New Mexico Department of Human Services, DGAB Docket Nos. 78-32-MM-HC, 79-33-MM-HC, 79-37-MM-HC, Decision No. 70, December 11, 1979.

#### The NOTICE as a Proxy

Grantee's second major argument, that it was invalid and arbitrary for PHS to use the NOTICE requirement as a "proxy" for other informed consent criteria, also lacks merit.

Grantee states that the NOTICE is only a "small segment of informed consent" and, in a program like grantee's, is "much less important than other aspects of consent." (Application for Review, p. 2.) Grantee explains that welfare recipients were not handled directly by grantee's project, since they were eligible for Medicaid-supported sterilizations, so the NOTICE was not as important for sterilizations funded by grantee. According to grantee, the important point is that "individuals fully understand the sterilization procedure and its consequences." (Application for Review, p. 2.)

Grantee may be correct that the problem of threat of loss of benefits would not be as great where the recipients of services are not "welfare" beneficiaries (although the familyplanning project itself was a Federally funded program providing benefits to the recipients in question). Regardless of the relative importance of the NOTICE requirement to grantee's project, however, it was a requirement imposed by regulation. Furthermore, the District Court in Relf considered such a notice to be an element of the voluntariness of consent within the meaning of the statute and, therefore, it cannot be regarded as a mere administrative requirement which might be less necessary in certain circumstances.

To the extent that PHS audited the grantee only for compliance with the NOTICE requirement, which as PHS points out is minimal in nature, grantee was not penalized but, to the contrary, perhaps benefited by not being audited for compliance with the more subjective elements of the informed consent criteria. The practicalities of grants administration sometimes preclude an agency from performing the type of comprehensive audit which would have examined compliance with all of the informed consent requirements.

Focusing on the readily identifiable element of inclusion of the NOTICE on the forms appears to have been a reasonable action, not prejudicial to the grantee.

Conclusion

For the reasons stated above, we uphold the decision of the PHS Regional Grant Appeals Board.

/s/ Donald G. Przybylinski

/s/ Robert R. Woodruff

/s/ Frank L. Dell'Acqua, Panel Chairman