DEPARTMENTAL GRANT APPEALS BOARD

Department of Health and Human Services

SUBJECT: California Department of Health Services
Board Docket No. 80-61-CA-HC
Decision No. 123

DATE: October 2, 1980

DECISION

This is an appeal of a disallowance of $420,100 claimed by the State of California as Federal financial participation (FFP) under Title XIX of the Social Security Act (Medicaid) for non-therapeutic sterilization procedures paid for between February 21 and May 12, 1975. The disallowance was originally made August 5, 1976, by the Regional Commissioner, Region IX, of the Social and Rehabilitation Service (SRS) and reconsidered under 45 CFR 201.14 (SRS Docket No. ME-CA7601). The disallowance was affirmed by the Administrator of the Health Care Financing Administration (HCFA) on April 2, 1980. The State requested Board review on May 12, 1980.

This decision is based on the Administrator's disallowance letter; the State's request for review; the reconsideration file in ME-CA7601; an Order to Show Cause issued by the Board on July 2, 1980; and the parties' responses to the Order.

General Background

Congress has provided in Title XIX that a State is entitled to FFP in the costs of family planning services meeting certain requirements. Additional requirements may be imposed by the Secretary, consistent with the Secretary's authority under the Social Security Act to provide for the efficient administration of the Act. § 1102.

The Secretary has interpreted the family planning section of Title XIX to include sterilization services. There were initially no specific rules or regulations governing Federal funding of sterilizations although Congress had provided that all family planning should be on a voluntary basis. See, e.g., § 1905(a)(4)(C). 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 on August 3, 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. The

guidelines themselves were in the form of a memorandum to agency heads and were termed "General Guidelines Limiting Federal Financial Assistance for Sterilization of Minors and Other Legally Incompetent Individuals" (Guidelines). Accompanying the Guidelines was a direction to heads of affected HEW agencies to withhold FFP in sterilization of individuals "under the age of 21" or legally incapable of giving consent, pending publication of final regulations. This provision came to be known by agency officials as a "moratorium."

Following the publication of the Guidelines, the SRS, then administering the Medicaid program, published a notice of proposed rulemaking, paralleling the Guidelines, providing that FFP was available for sterilization of individuals under age 21, so long as there was committee review and compliance with other informed consent requirements. 38 FR 26459, September 21, 1973. A final regulation was published on February 6, 1974. This regulation required that state plans under Title XIX provide that there be no FFP in nontherapeutic sterilizations performed "on an individual who is under the age of eighteen or who is legally incapable of giving informed consent" unless certain procedures had been followed. 39 FR 4733. For purposes of this rule, the term "legally incapable of giving informed consent" was defined to include any person who "[u]nder State law is a minor whose consent to the sterilization would not be legally effective." 39 FR 4734. A basis and purpose statement in the preamble to the February 6 regulation explained in response to comments why the age limit for committee review was set at 18 and stated that "absolute denial of sterilizations to persons under eighteen regardless of the circumstances is unacceptable to the Department." 39 FR at 4731.

The effective date of the February 6 regulations was delayed pending the outcome of several cases filed in Federal district court challenging the rules. 39 FR 5315, February 12, 1974; 39 FR 9178, March 8, 1974. These district court actions were consolidated for purposes of a decision issued on March 15, 1974, in Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C. 1974). The District Court permanently enjoined the use of Federal funds "for the sterilization of any person who ... is in fact legally incompetent under the applicable state laws to give informed and binding consent to the performance of such an operation because of age or mental capacity...." 372 F. Supp. at 1204.

The February 6, 1974 rules were also found to be 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 since they authorized the provision of Federal funds without requiring such advice 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.

New regulations were published on April 18, 1974, to "replace" the February 6 regulations struck down in Relf. 39 FR 13872, 13887. These regulations contained the following provision at § 205.35 of 45 CFR with respect to FFP under Titles XIX, IV-A and VI of the Social Security Act:

> No nonemergency sterilization may be performed unless legally effective informed consent is obtained from the individual on whom the sterilization is to be performed. 45 CFR 205.35(a)(1)(ii).

This regulation, using a "legally effective" consent test and not specifying a minimum age, was in effect during the time period relevant to this appeal.

The preamble statement to the April 18, 1974 regulation (incorporated by reference from the preamble statement to 42 CFR Part 50, Subpart B, published on the same date) referred to the 1973 Notice of Guidelines, stating that it --

> provides that pending the effective date of the final regulations Federal financial participation should be withheld from any sterilization procedure performed on an individual who is under the age of 21 or who is himself legally incapable of consenting to the sterilization.

The preamble further stated:

> The purpose of this document is to adopt regulations in accordance with the Court Order [in Relf] with respect to persons legally capable of consenting to a sterilization while continuing in effect the moratorium set forth in the previous notice of the Department with respect to sterilization of individuals under the age of 21 or legally incapable of consenting to the sterilization. 39 FR 13873.

In addition to the requirement for "legally effective" informed consent, the new § 205.35 listed basic elements of informed consent and required that these be detailed in a written consent document provided to the individual to be sterilized. Paragraph 205.35(a)(2)(i)(F)(3) specified:

> 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.

The effective date of the new regulation was stated to be April 18, 1974. 39 FR 13887. On the same date, the Acting Commissioner of the SRS issued Program Instruction MSA-PI-74-14 instructing states to complete an attached preprinted state plan amendment and to submit it by July 2, 1974. The amendment basically certified compliance with § 205.35.

Case Background

The State of California provides for family planning services under Title XIX through its State plan for a program of medical assistance, called Medi-Cal. California apparently did not submit the plan amendment relating to § 205.35 until March 28, 1975, but, as approved by the regional office, the plan amendment carried an effective date of February 21, 1975.

The regional office subseqently performed a sample review of claims for sterilization procedures paid under Medi-Cal between February 21 and May 12, 1975. Apparently, a sample of 369 claims was drawn randomly from the universe of 4,427 claims. According to HCFA, of the claims sampled: "20 (5.4% of the sample) were not acceptable because the patient was under 21 years of age, 267 (72.4%) did not have consent forms containing the notice that no benefits provided by programs or projects receiving Federal funds may be withdrawn or withheld by reason of the person's decision not to be sterilized, and another 45 claims (12.2%) were unacceptable because the consent forms did not conform to other requirements of 45 CFR 205.35." (Administrator's Decision, p. 1.) Based on this review, the Regional Commissioner made, and the Administrator upheld, a disallowance of $420,100 of the total $472,576 in FFP related to the 4,427 claims.

The Notice Provision

A substantial portion of the disallowance was based on the reviewers' finding that 72.4% of the claims sampled did not have consent forms containing the notice that no benefits could be withdrawn or withheld by reason of an individual's decision not to be sterilized.

The State argued that a reasonable period of time was necessary for implementation of its State plan amendment (not effective until February 21, 1975), since a regulation which contemplates the use of specific printed forms is not self-executing. According to the State, "HCFA has traditionally recognized that 'lead time' in complying with new federal requirements is necessary, the only question being what is reasonable." (Letter of May 12, 1980, p. 3.) During prior reconsideration the State argued that a longer lead time was necessary here because of the emotionally charged nature of the requirements. (Reconsideration file, Tab 20, p. 6.)

The State's argument does not have merit. The regulation in question was published April 18, 1974. The program instruction issued the same date instructed the State to submit the appropriate plan amendment by July 2, 1974. By not submitting the amendment until 1975, the State gave itself lead time in which to prepare to meet the requirements.

While some of the other provisions of § 205.35 might be more difficult to put into effect, implementation of the notice requirement could be accomplished merely by including in any consent form the language set forth in Paragraph 205.35(a)(2)(i)(F)(3) in prominent print at the top of the form. The State has not shown that this requirement was controversial, or that it was not feasible for the State to meet the requirement.

Furthermore, even though in some cases HCFA may have permitted longer "lead time," there is no requirement that HCFA permit such "lead time" for every regulation. With respect to this particular provision, moreover, it is questionable whether HCFA could have permitted such lead time. While the Administrator did not rely on the decision in Relf, the District Court's opinion, quoted above, indicates that the Court considered the notice to be a prerequisite to consent being "voluntary" within the meaning of the family planning statutes. Thus, the notice requirement is distinguishable from those regulatory requirements which are merely administrative in nature.

In response to the analysis of this issue set forth in the Board's Order to Show Cause, the State presented no further argument. Accordingly, the disallowance is upheld with respect to costs of sterilizations performed without the proper notice.

Unspecified Regulatory Requirements

The State challenged as "contrary to due process and basic fairness" the part of the disallowance related to the reviewers' finding that 12.2% of the sampled claims were "unacceptable because the consent forms did not conform to other requirements of 45 CFR 205.35." (Letter of May 12, 1980, p. 5.) The State claims that no report of the reviewers' findings was given to the State and that it has received no response to requests for clarification of what "other requirements" are referred to as a basis for the disallowance. The reconsideration file supports the State's position that it requested more specific information on this point. (Reconsideration File, Tab 6, pp. 2, 3; Tab 9.)

While the burden of documenting the allowability of costs falls, generally, on the State, the Agency must articulate a basis for a disallowance determination. Under the 201.14 procedures, "findings of fact" were required, § 201.14(b)(2)(v), and, under Part 16, a notification of disallowance must "set forth the reasons for the disallowance in sufficient detail to enable the grantee to respond...," § 16.91(a).

To respond to the vague charge that "other requirements" were not met, the State would have to prove that, for each claim, all of the requirements of § 205.35 were in fact met. In light of the diverse nature of the § 205.35 requirements (including provision for a 72-hour waiting period, counseling as to appropriate alternative procedures, and documentation requirements) this burden should not be placed on the State where the Agency presumably

had in its possession a report detailing the specific defects for each claim in the sample. HCFA now admits, in response to the Board's Order, that it cannot locate the documents on which this part of the disallowance was based.

Accordingly, the disallowance is reversed with respect to costs allegedly not meeting "other requirements" of § 205.35.

Sterilization of Individuals under Age 21

In California, the age of majority is 18 years. The State claims that FFP should be available in costs for sterilizations of individuals between 18 and 21 because these individuals were capable of giving "legally effective" informed consent within the meaning of § 205.35. The State argues that it was reasonable, under the circumstances, to interpret the Department's references to persons under age 21 as references to minors. We agree. The 1973 Guidelines refer to sterilization of minors and the February 6, 1974 regulations and preamble discuss an age limit in terms of age of majority. The preamble statement to the April 18, 1974 regulations describes the purpose of continuing the moratorium in terms of compliance with the court order in Relf, which measured age of consent by state law. HCFA has presented no evidence or argument to show that the State had actual notice that the Department would interpret the moratorium as a prohibition on FFP of all sterilizations of individuals under age 21, regardless of effectiveness of consent under State law.

If the moratorium were a rule standing alone, perhaps the ambiguities associated with it would place an obligation on the State to seek clarification. Here, however, the preamble statement accompanied a formal regulation which used a test of legal effectiveness of consent. While we do not find it necessary to reach the issue here, it is also arguable that, to the extent the preamble is inconsistent with the formal regulation, the formal regulation would control. As the State also points out, the preprinted state plan amendment transmitted with Program Instruction MSA-PI-74-14 refers only to "legally effective" consent.

There is a reference in MSA-PI-74-14 to the moratorium as a "prohibition" of FFP, unlike the preamble which continues the moratorium in effect without describing what that effect is. On the other hand, MSA-PI-74-14 has the same defect as the preamble statement. That is, under the circumstances, it was more reasonable to interpret it as applying only to minors, than to read it as establishing a uniform minimum age for Federal funding purposes.

HCFA argues that the Federal courts have held that the moratorium was binding on the states, relying primarily on Voe v. Califano, 434 F. Supp. 1058 (D.Conn. 1977). The issue decided in Voe, however, was very limited, and is not dispositive here. In that case, the Court explicitly stated that the sole issue before it was the validity of applying a certain age requirement under the Constitution. Apparently, the parties had stipulated that there

was a minimum age requirement for the program; at least, the Court did not address that question. Furthermore, in Voe the state program itself limited funds for sterilizations to individuals 21 years of age or older, giving the Court an independent basis for applying that limitation.

We do not contest the assumption in Voe that the Department may impose such limits; we find only that this was not done here. When the Department chooses to limit FFP to a particular category for some good reason such as uniform administration of a program, it should state the limitation so that the grantee understands it.

Accordingly, we reverse the disallowance of FFP in costs of sterilizations of individuals between 18 and 21 years of age.

Conclusion

For the reasons stated above, we uphold the disallowance of costs associated with sterilizations for which the consent forms did not contain the required notice and reverse the disallowance of costs of sterilizations of individuals under age 21 and of sterilizations allegedly not meeting unspecified requirements of § 205.35.

In its Order, the Board requested the parties to identify how the total $420,100 disallowed should be broken down as it relates to the three separate bases for disallowance. The parties' calculations differed. HCFA did not articulate the basis for its calculations but submitted specific figures. The State's approach was based on an average Federal share per claim. HCFA has identified $77,665 ($23,544 + $54,121) as the amount related to the two issues on which we find for the State. Accordingly, the disallowance should be reversed in at least that amount. Under the State's method, an additional $4,583.88 would relate to these two issues. Thus, HCFA should examine its records and, if it can not substantiate its figures, consider a withdrawal of $4,583.88 of the remaining disallowance.

/s/ Nell Minow

/s/ Donald G. Przybylinski

/s/ Norval D. (John) Settle, Panel Chair