DEPARTMENTAL GRANT APPEALS BOARD

Department of Health and Human Services

SUBJECT: California Department of Health Services
Docket No. 79-66-CA-HC
Decision No. 209

DATE: August 31, 1981

DECISION

The California Department of Health Services (State) appealed a determination by the Director, Medicaid Bureau, Health Care Financing Administration (Agency), disallowing $5,029,165 in Federal financial participation (FFP) claimed under Title XIX (Medicaid) of the Social Security Act for sterilization procedures paid for between May 13, 1975 and June 30, 1977. Negotiations between the parties have resulted in resolution of a number of issues involved in the appeal. For reasons stated below, we have decided the remaining issues, primarily concerning adequacy of consent to be sterilized, in part for the State and in part for the Agency.

This decision is based on the State's application for review and its supplement; the Agency's response; the transcript of a hearing held on May 6, 1981; exhibits submitted at the hearing; post-hearing briefs; and other submissions by the parties.

General Background

Congress provided in Title XIX that a State is entitled to FFP (at a 90% rate) in the costs of family planning services meeting certain requirements. Section 1903(a)(5). The Secretary has interpreted family planning to include sterilization services, although initially there were no specific rules or regulations governing sterilizations. Congress had provided, however, 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 needy persons coerced to submit to sterilization by threat of loss of welfare benefits, the Department (then HEW, now HHS) began to develop regulations to ensure informed consent and voluntariness in Federally funded sterilizations. The history of these proceedings is discussed in detail in previous Board decisions. Maryland Department of Health and Mental Hygiene, Decision No. 85, February 28, 1979; California Department of Health Services, Decision No. 123, October 2, 1980. For purposes of this decision, these are relevant: a 1973 "moratorium" on FFP in certain sterilizations; the court's decision in the case of Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C. 1974); and regulations at 45 CFR 205.35, published April 18, 1974 (39 FR 13887).

The "moratorium" was a direction to heads of HEW components administering family planning programs to withhold FFP in sterilization of individuals "under the age of 21" or legally incapable of giving consent, pending issuance of regulations requiring informed consent in Federally funded sterilizations. The moratorium accompanied Departmental guidelines for development of informed consent regulations, and was published with the guidelines as a Federal Register Notice on August 3, 1973. 38 FR 20930. Regulations issued pursuant to the guidelines on February 6, 1974 were struck down in the Relf litigation. The District Court in that case permanently enjoined the use of Federal funds "for the sterilization of any person ... legally incompetent under the applicable state laws to give informed and binding consent...." 372 F.Supp. at 1204. The District Court further found the February 6 rules to be defective because they authorized Federal funds without requiring that legally competent persons be advised that their Federal benefits could not be terminated by reason of a decision not to be sterilized and without requiring that such advice "appear prominently at the top of the consent document...." 372 F.Supp. at 1205.

The April 18, 1974 regulations were published to replace those struck down in Relf. Section 205.35 of 45 CFR contained requirements for Title XIX state plans, including that no nonemergency sterilization could be performed unless "legally effective" consent was obtained. No minimum age for consent was specified in the regulation; however, the preamble to the regulation referred to "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 ...." 39 FR 13873.

In addition to the requirement for "legally effective" consent, Section 205.35 provided that no nontherapeutic sterilization could be performed sooner than 72 hours following the giving of consent. Paragraph 205.35(a)(2)(i) defined informed consent as--

> ...the voluntary, knowing assent from the individual...after he has been given (as evidenced by a document executed by such individual):
>
> (A) A fair explanation of the procedures to be followed;
>
> (B) A description of the attendant discomforts and risks;
>
> (C) A description of the benefits to be expected;
>
> (D) Counseling concerning appropriate alternative methods; and the effect and impact of the proposed sterilization including the fact that it must be considered to be an irreversible procedure;

(E) An offer to answer any inquiries concerning the procedures;

(F) An instruction that the individual is free to withhold or withdraw his or her consent to the procedure at any time prior to the sterilization without prejudicing his or her future care and without loss of other project or program benefits to which the patient might otherwise be entitled....

Paragraph 205.35(a)(2) provided for two possible methods of documentation: provision of either (1) a written document "detailing all of the basic elements of informed consent" (referred to by the parties as a "long form") or (2) a "short form written document indicating that the basic elements of informed consent have been presented orally to the patient."

Finally, Paragraph 205.35(a)(2) 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.

The California State Medicaid (Medi-Cal) plan provided, effective February 21, 1975, that "requirements of 45 CFR 205.35(a) are met ... which include those related to: (1) Voluntary request, legally effective informed consent, time limits ..., and written consent documents; ...."

Case Background

In 1977, the Regional Medicaid Bureau (Region IX) undertook a review to determine whether the State had obtained informed consent for all sterilizations for which claims were paid between May 13, 1975 and June 30, 1977. Since, at the time, the State had not established procedures to collect informed consent documents at a central place and since approximately 20,000 sterilizations had been performed during the review period, the reviewers determined to use statistical sampling methods for their review. The reviewers requested the State to provide a summary of the universe of claims and then a sample listing of 440 sterilization "cases."

Each "case" in the sample consisted of provider claims for services to the same recipient. 1/

The reviewers found, based on their examination of consent forms for the sample cases, that although the State had promulgated informed consent regulations and had transmitted the requirements to all Medicaid physician providers, the consent forms used were "eclectic in design and rarely in compliance with Federal regulations." (Report on California's Informed Consent Sterilization Review, Fall 1977 (Report), p. 3, Attachment to Exhibit I, State's Application for Review.) The reviewers attributed this to the State's regulations, which left the responsibility for design of an informed consent form to the individual providers. Out of the "final sample" of 418 cases, 2/ the reviewers found that 188 cases failed to meet one or more Federal requirements.

The reviewers found that 1) in 176 cases there was either no informed consent form at all or the consent form used did not contain a notice concerning benefits; 2) in 20 cases the recipient was under 21 years of age; and 3) in 2 cases the recipient was not mentally competent to give informed consent. (Report, p. 6.) The reviewers did not base their findings on Section 205.35, but described these "requirements" as deriving from the court's order in the Relf case, relating to notice that benefits could not be lost, and from the "moratorium." Additional findings, since resolved, related to whether the sample claims were for family planning services and to the rate of FFP properly claimed for the services. (Report, pp. 5, 7.) Although the State had been involved initially in drawing the sample for the reviewers, the State was not informed of the results of the review until it received the Director's disallowance letter, dated March 9, 1979. (Application for Review, p. 2; Transcript, pp. 29, 202.) The

1/ There was some misunderstanding between the State and the Agency as to whether the sample listing included only services directly related to the sterilization procedure, for which the State had claimed 90% FFP, or included other services, provided to the same recipient, for which the State had claimed only 50% FFP. Subsequent to the Board's hearing, the parties informally resolved issues related to the rate of FFP claimed. (See Agency's Submission of August 10, 1981.)

2/ There were 22 cases originally included in the sample of 440 and then dropped by the reviewers (generally because of inability to locate providers or providers' position that the information was confidential). Treatment of these 22 cases was the subject of extensive testimony at the hearing but is no longer in dispute.

disallowance letter described the reviewers' findings in generally the same terms as the report. 3/

Extrapolating from the sample findings on the 188 cases and from findings relating to the proper rate of FFP, the Director determined that the State had claimed $5,029,165 in unallowable costs.

This determination was appealed to the Board by letter dated March 23, 1979, in which the State raised various issues related to the adequacy of consent, the rate of FFP, and the sampling methodology. The appeal was supplemented by letter dated June 1, 1979. In the supplementary letter, the State indicated that it was undertaking a survey of patient consent information for each of the 188 sample cases. Board proceedings were delayed while the State attempted to accumulate documentation of informed consent. The State's efforts included mailing a form letter, dated June 13, 1979, requesting documentation from providers on the sample listing. A follow-up letter, dated October 10, 1979, was sent in those cases where the response to the first letter was insufficient. Where the provider had refused to release information without the patient's permission, a letter was sent from the State's Office of Legal Services, advising the provider of its legal obligation to produce the documents. Documentation gathered through this effort was analyzed and presented to the Agency's regional office for review. The regional office disagreed with the State's evaluation that some of the documentation was adequate. When Board proceedings resumed, the Agency responded to the appeal on September 5, 1980, stating for the first time that the sample cases failed to meet Federal requirements based on Section 205.35.

The State has never factually disputed the reviewers' findings that 20 of the persons sterilized were under age 21 or that 2 persons were mentally incompetent (State's Post-Hearing Brief, p. 7, n. 4.), but challenges the legal basis for the disallowance based on age. In addition, the State has now accepted the disallowance with respect to 148 of the 188 questioned sample cases (Confirmation of Prehearing Conference Calls, Attachment II), and certain issues regarding the rate of FFP claimed and the sampling methodology have been resolved

---

3/ There was some question within the Agency at the time as to whether the regulations at 45 CFR 205.35 would provide an independent basis for disallowance, since those regulations impose State plan requirements but do not specifically address the availability of FFP. (Transcript, pp. 241,283). The Agency has since taken the position that, where a State plan requires compliance with Section 205.35, payments which do not comply are not payments "under the State plan" within the meaning of Section 1903(a)(1) of the Social Security Act. (Agency response, p. 10.)

by the parties as a result of post-hearing negotiations. At the hearing, the State presented evidence and argument concerning 40 "contested" cases which the State asserts meet informed consent requirements.

This decision will first discuss the "age 21" issue, then address general legal arguments relevant to all 40 contested cases, and, finally, examine individual issues raised in the 40 cases.

Individuals Under Age 21

The State admits that some of the disallowed claims were for sterilization of individuals between the ages of 18 and 21. The Agency's position is that the disallowance is required by the "moratorium" on sterilization of individuals "under age 21" continued in effect by the Federal Register preamble to Section 205.35. 4/ The State argues that the regulation requires only "legally effective" informed consent, that 18 was the age of consent in California, and that an ambiguous statement in a preamble should not take precedence over the wording of a codified regulation. The State further argues that it did not have actual notice that the term "under age 21" in the moratorium was not intended to refer to age of majority under State law, and, therefore, under the Board's rationale in California Department of Health Services, Decision No. 123, October 2, 1980, the disallowance should be reversed.

Decision No. 123 involved sterilization costs claimed by the State of California for the period February 21 to May 12, 1975. The Board held that consent of individuals between the ages of 18 and 21 in California was "legally effective" within the meaning of Section 205.35. The Board reversed the disallowance insofar as it related to individuals between 18 and 21, since the preamble statement concerning the "moratorium" was ambiguous and inconsistent with the regulation. The Board agreed with the State, given the history of the development of the informed consent requirements, that it was reasonable for the State to interpret the age reference in the "moratorium" to mean age of majority, finding also that the State did not have actual notice of a contrary interpretation.

Since the disallowance before us now involves a later time period, the threshhold issue is whether the State had actual notice during that period that the "moratorium" was intended as an absolute prohibition on FFP in sterilization of individuals under age 21, regardless of State law. The Agency relies on Identical Memorandum No. 75-16, dated September 24, 1975, and addressed to State Title XIX Agencies,

4/ Age is the sole basis for the disallowance in 2 of the 40 contested cases (Case Nos. 220 and 325) and an additional ground in 9 other cases.

including California, from a Regional Commissioner. (Agency Hearing Exhibit D.) This memorandum advises that FFP will be withheld for certain violations, including "sterilization of an individual under the age of 21." Like Agency transmittal MSA-PI-474-14, discussed in Decision No. 123, however, the memorandum suffers from the same ambiguity as the preamble statement concerning the "moratorium," given the circumstances. We do not think it sufficient to give the State notice that the State's interpretation, which was consistent with the regulation, was incorrect. Moreover, the State has testified without rebuttal that an Identical Memorandum is a type of transmittal generally used by the Agency for information purposes, not for action purposes. (Transcript, p. 246.) Our conclusion that the State did in fact view the requirement as majority rather than "age 21" is supported by the fact that a Medi-Cal Bulletin issued May 1975, informing providers of sterilization requirements, included that the "beneficiary is 18 years of age or older...." (Exhibit 2, Supplement to Application for Review.)

Accordingly, for reasons stated above and explained more fully in Decision No. 123, the disallowance is reversed with respect to the grounds that the individuals sterilized were under age 21.

General Issues Common to the 40 Cases

Parties' Arguments

The State claims that it was extremely prejudicial to the State that the only legal defect cited in the Director's disallowance letter with respect to the consent forms was the lack of notice concerning benefits, whereas the Agency now relies on other requirements of Section 205.35 as a basis for the disallowance.

The State points out that the record retention requirement for support of Medicaid claims is three years and that, by the time the State learned (in March 1981) of other alleged defects in the consent forms, "no records concerning the audit period [1975-1977] remained within the retention period." (State's Post-Hearing Brief, p. 8.) In view of its "good faith" in accepting the disallowance for those cases which it determined clearly violated Section 205.35, the State argues, the Board should consider the prejudicial effect of the Agency's actions in reviewing the 40 contested cases and "apply a lenient standard to the documentation in view of the State's inability to do a fair records search directed at the non-compliance first alleged" two years after the disallowance letter. (State's Post-Hearing Brief, p. 9.)

The Agency responds that the State itself delayed in requesting details on the additional legal bases (after receiving the Agency response in September 1980) and that the State had ample opportunity to prepare its case for the evidentiary hearing held on May 5 and 6, 1981.

The State also argues that the Board's general approach in reviewing the documentation should be "to determine whether the process of informed consent ... appears to have been fairly complied with." (State's Post-Hearing Brief, p. 9.) While recognizing that Section 205.35 provides both for a process of informed consent and for documentation that the process occurred, the State has "concentrated on showing that the first element exists, even where the documentation might be less complete than one might expect the State to produce had it been fairly asked to do so." (State's Post-Hearing Brief, p. 10; see, also, Transcript, p. 374.) In support of this position, the State asks the Board to contrast the "general requirements" of Section 205.35 with current regulations at 42 CFR 441.250 et seq., which require use of a specific consent form (published as an appendix to the regulation) or "another form approved by the Secretary." (42 CFR 441.258(a).) According to the State, strict compliance can only be demanded "[w]here the regulations make it eminently clear what is required...." (State's Post-hearing Brief, p. 10).

The Agency's position is that the regulations are clear, that the State incorporated the regulatory provisions in its State plan effective February 21, 1975, and that the disallowed amounts, not expended as medical assistance in accordance with the State plan, are therefore unallowable under Section 1903(a)(1) of the Act.

Discussion

The State has not advanced its arguments as a basis for overturning the entire disallowance. Rather, the State has asked us to use a "lenient" standard because of prejudice and to focus on the "process" of informed consent rather than the documentation requirements. We are not persuaded to adopt the State's approach for several reasons.

First, the State has not shown that Section 205.35 does not apply here. Under 45 CFR 16.8(a), the Board is bound by applicable laws and regulations. Thus, we cannot substitute our view of what constitutes the "process" of informed consent for requirements clearly established by Section 205.35. In particular, Section 205.35, while not as explicit as the current informed consent provisions, specifically addresses methods of documentation. Thus, we are dealing with more than a general requirement for documentation of grant costs. In fact, under the regulation, the written consent document executed by the

patient is part of the consent process itself and cannot be viewed as a separate, merely administrative requirement.

Second, while the State's argument concerning prejudice does raise a serious question as to whether the State has had a meaningful opportunity to show that it did meet Section 205.35 requirements, this argument is highly speculative. The State has not alleged, nor produced any evidence, that any provider possessed documentation (other than that already submitted) but had destroyed it when the retention period expired. It is highly unlikely that this occurred in view of the reviewers' efforts, within the retention period, to obtain the documentation (Transcript, pp. 49-54; Report, pp. 2-3). Also, while the specific objective of subsequent efforts by the State was to show that the notice concerning benefits had, in fact, been given, the June 13, 1979 letter to providers also requested documentation which, if provided, would have shown whether other requirements were met. 5/

We also note that the reviewers' report, transmitted to the State with the disallowance letter, mentioned the general insufficiency of the forms examined. (Report, p. 3.) The report stated that in some of the 176 cases the reviewers were unable to obtain any informed consent document at all. (Report, p. 6.) The Agency cannot be expected to detail defects in documents which it has never seen and should not be precluded from amending a disallowance when subsequently documentation is produced.

On the other hand, the State's efforts to overcome the disallowance were initially directed primarily at showing that the notice concerning benefits was actually given (Transcript, pp. 369-370), and it is reasonable to conclude that the State's approach might have been different had it been informed that it would need to produce documentation on all Section 205.35 requirements. Some of the providers did respond to the State's letters and submit documentation solely on the notice requirement, which had been emphasized. (See Letter of October 10, 1979, Exhibit 3 to State's Submission dated November 6,

---

5/ The June 13 letter requested the provider to submit the following data:

a. A copy of any consent form(s), any variety, given by the patient.
b. A statement from you, the provider, as to your practice or procedures used on verbal presentations to patients on sterilizations.
c. A copy of the patient's file relative to the sterilization process or procedures.
d. Copies of any documents signed by a witness relative to the sterilization of the patient...

1979; Transcript, pp. 229-230.) Because the disallowance is based on extrapolation from a sample, each case for which the State could have shown compliance has increased significance.

Moreover, while Section 205.35 is not as vague as the State would have us believe, it does lack clarity in certain respects. Even the Federal reviewers were confused on some aspects of the requirements, such as the distinction between the notice and an instruction concerning benefits (See, e.g., Transcript, pp. 102, 104, 127, 132), and, while the State did not develop a model form for its providers to use during the relevant time period, the Agency itself, as late as May 13, 1975 (over a year after publication of Section 205.35), was reluctant to designate any particular form as an "official" one.

Based on these considerations, where Section 205.35 requirements are clear, we have examined the 40 cases primarily to determine whether the provider has produced documentation defective on its face. In these cases, it is improbable that additional documentation sufficient to overcome any defect would have been produced even if requested in a timely manner. Where the requirements are unclear, however, we have taken this into account in deciding what is necessary to show compliance.

This approach is consistent with the original Agency position, which was based primarily on the lack of the Relf notice, but also recognizes that Congress intended family planning to be voluntary and that the State plan had incorporated all Section 205.35 requirements.

Below, we discuss issues common to more than one contested case from the sample. Our examination of the individual items, in light of our decisions on the common issues, is set forth in an Appendix to the decision.

The "F Instruction"

Paragraph (a)(2)(i)(F) of Section 205.35 requires as a basic element of informed consent --

> An instruction that the individual is free to withhold or withdraw his or her consent to the procedure at any time prior to the sterilization without prejudicing his or her future care and without loss of other project or program benefits....

The parties have referred to this element as the "F instruction."

Documentation requirements of the section include that each consent document shall display "printed prominently at the top" the following:

> 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.

This is sometimes called a Relf notice since it is derived from the court's decision in that case.

With respect to certain documents submitted by the State during these proceedings, the Agency alleges that, although the notice requirement is met, the document is defective because there is no "F instruction." This position is based on an interpretation that the notice and instruction requirements are separate. The State argues that it is an "equally fair reading" of the regulation that the notice and instruction can be one and the same. In support of its argument, the State points to testimony of the Federal reviewer in which he failed to clearly distinguish the notice and the instruction. (Transcript, pp. 102, 104, 127, 132.)

Even if the reviewer had not confused the requirements, however, we would agree with the State that the regulation is not clear on this point. The instruction is one of the basic elements of informed consent. The notice is part of the documentation requirements and could reasonably be viewed as a method of implementation of the instruction. The Agency has pointed to nothing which would have given the State timely notice that the regulation required that a consent document contain both the notice at the top and an instruction in the body of the document. The regulation is reasonably susceptible of an interpretation which would allow the notice effectively to subsume the instruction. To hold to the contrary would favor an interpretation fostering a redundant action not specified in the regulation. Accordingly, we reverse the Agency's findings based on this alleged defect.

Location and Form of the Notice

Section 205.35 provides that each consent document shall display the notice concerning benefits "printed prominently at the top." A number of the consent forms submitted in the 40 cases do not have the required notice at the top, but do contain statements concerning benefits; in some cases, these statements are prominent.

The State's explanation is that, during the early period of implementing informed consent requirements, "... consent forms were not printed by the State, but were composed by the physicians. On occasion, a document would evidence a clear intent to be fairly in compliance with the requirements, but would contain a defect in form." (Post-Hearing Brief, p. 12.) The Agency has held the State to a strict interpretation of the regulation.

We do not agree with the State's position that any statement concerning benefits shows fair compliance with the requirements. The requirement that the notice be "printed prominently at the top" is clear and goes to the substance of whether the document evidences that the patient actually received the notice. Accordingly, we uphold the Agency on this point, even where the form contains a statement concerning benefits if it is not both prominent and at the top.

Group 6 Cases - CONSENT FOR NONEMERGENCY STERILIZATION Form

Background and Argument

The State's letter of October 10, 1979, informed each provider to whom it was sent that the provider's response to the June 13 letter "did not provide sufficient evidence to support our claim that your patient was informed of the right of refusal." The October 10 letter further stated, "If the basic elements of informed consent ... were presented orally and a signed consent form ... was not obtained from this patient and signed by an auditor-witness to the oral presentation, please send the enclosed form to the patient to confirm he or she has been given the required information prior to the sterilization services." The wording of the form enclosed, titled CONSENT FOR NONEMERGENCY STERILIZATION, is as follows:

> This is to advise _____ , M.D. regarding
> (physician)
> the elective sterilization performed on _____.
> (date)
>
> I gave my consent and approval for the elective sterilization. I was also informed I would not lose or jeopardize any public benefits or future medical services to which I might otherwise be entitled if I changed my mind at any time before the sterilization was performed.
>
> Date _____ Signed _____
> Witness _____

In the cases referred to by the parties as the Group 6 cases, a signed CONSENT FOR NONEMERGENCY STERILIZATION form has been submitted, together with other documents. The State argues, "We do not claim that this type of retroactive documentation may ever be substituted for pre-sterilization compliance with the process required by the regulations. However, we do believe that such a statement by the patient may fill in for missing or ambiguous documentation where there is other evidence that adequate pre-sterilization consent was obtained." (Post-Hearing Brief, p. 12.)

We agree with the State that this retroactive documentation cannot be substituted for pre-sterilization compliance with the process required by the regulation. However, we view the process of consent required by the regulation to mean more than that the patient must have received the notice concerning benefits prior to the sterilization. The process of consent contemplated by the regulation includes provision of a written consent document containing the required notice. This ensures that the patient receives the notice prior to giving consent by signing the form. Otherwise, the information provided through the notice to the effect that the patient may withhold consent in the first instance without loss of benefits would be meaningless. The Relf decision indicates that voluntariness encompasses both the right to withhold consent and the right to withdraw it once it is given, and the regulation reflects both aspects.

Thus, the State's after-the-fact CONSENT is insufficient in two respects: it does not evidence that the notice was given in the prescribed manner nor that the information provided allowed the patient to refuse to give consent initially as well as to change his or her mind after consenting.

On the other hand, there are three of the Group 6 cases (Nos. 378, 394, and 400) where the State has submitted other documents which evidence that the patient actually signed a consent form containing the required notice printed prominently at the top. Although the October 10 letter requested CONSENT forms "if a signed consent form was not obtained," the physicians in these cases have stated that they used a form containing the notice. The Agency has not challenged the veracity of those statements. In these cases, the CONSENT provides additional evidence to show that the notice was actually given in the manner required by the regulations.

Accordingly, we sustain the disallowance on the basis of lack of the proper notice in all of the Group 6 cases except the three mentioned above, where the Agency is upheld on other grounds.

Long Form/Short Form

Section 205.35 contemplates two possible methods of documentation of informed consent: a written consent document "detailing" all of the basic elements (long form) or a "short form written consent document indicating that the basic elements of informed consent have been presented orally to the patient." The short form must be signed by the patient and by an auditor-witness to the oral presentation, and be supplemented by a written summary, signed by the person obtaining the consent and the auditor-witness. (Documentation requirements (1) and (2) of Paragraph (a)(2)(i)(F).)

The alleged defect with respect to a number of the cases is that the consent document is a short form, not supplemented by a written summary. The State points to the confusion exhibited by the reviewers

as well as the Agency's witness at the hearing as to whether certain forms were intended as long or short forms, and contends that a number of the forms which the Agency designated as short forms could have qualified as long forms.

The regulation draws a distinction between "detailing" the basic elements and "indicating" that the elements have been presented orally. The State's witness testified that "in describing a medical procedure, that medical description can be extremely brief or it can be extremely lengthy. To a physician, the term tubal ligation, bilateral or unilateral, is a term of art. It has a description ... It means a certain type of procedure ... ." (Transcript, pp. 382-383.) The State in its Post-Hearing Brief, however, refers to the "requirement of the regulations" as "that a 'long' form must contain in its body the information provided to the patient, while a 'short' form must only state that it was provided ...." (p. 15). Since what is important in the long form is that it provide information to the patient regarding the basic elements, cryptic language which would be sufficient for a medically trained person would not appear to qualify a form as long.

While the State is correct that the regulation does not give adequate notice of the "precise limits" of what constitutes a long form, the regulation is clear enough to inform the State that a document merely listing what the basic elements are would not be sufficient. The long form must not just list elements such as "a description of the attendant discomforts and risks" or "a description of the benefits to be expected" but must, in the State's own words, provide information to the patient concerning those discomforts, risks, and benefits. Moreover, some of the documents which the State seeks to characterize as long forms are signed by an auditor-witness, which further indicates that they were intended as short forms.

Based on this analysis, we have concluded that most of the forms which the State contends are long forms do not "detail" the basic elements. 6/

The Written Summary

With respect to those cases where we have concluded, either based on the above analysis or the State's admission, that the form submitted is a short form, we must address the Agency's allegation that Section 205.35 requirements were not met because the short form was not supplemented by a written summary.

6/ With respect to the documentation in Case No. 379, however, we agree with the State that it qualifies as a long form for reasons stated more fully in the Appendix.

In determining whether the State's evidence is sufficient to show that the written summary requirements were met, we have considered the following factors: the regulatory requirement for a written summary is not entirely clear; the State was possibly prejudiced since lack of a written summary was not originally cited as a defect in the cases; and, a transmittal to Medi-Cal providers failed to reference the written summary requirement. While the first two favor the State, the third does not.

The Federal regulation is clear that the short form should be supplemented by a written summary and that that summary should be signed by the person obtaining consent and by the auditor-witness. As the State points out, however, the regulation does not clearly require that the written summary be retained. The regulations can reasonably be read to provide for the written summary as a document to be given to the patient, since it is to summarize the oral presentation given to the patient and be signed by the physician rather than the patient. In light of this ambiguity, the State's general request to the providers for documentation (in its June 13, 1979 letter quoted in footnote 5 above) may have been insufficient to produce the written summaries. Thus, there is some question whether the State's opportunity to dispute the Agency on this point was meaningful. On this basis, it might have been reasonable to presume compliance with the requirement had the State shown that it was properly implemented.

A Medi-Cal Bulletin, issued May 1975, sets forth Medi-Cal regulations on sterilizations. (Exhibit 2 to State's Submission of June 1, 1979.) Although those regulations provide for evidencing informed consent by means of a short form document, there is no reference in the publication to the need to supplement the short form with a written summary. (p. 7, citing Section 51305(e) of Medi-Cal regulations.) Although an earlier Medi-Cal Bulletin set forth the Federal requirements, in view of this defect in the requirements as transmitted to the providers in May 1975, we cannot presume that written summaries complying with Federal requirements existed and were given to the patients.

These considerations have lead us to adopt the following approach in reviewing the State's evidence with respect to the written summary requirement. Where the State has provided a signed consent form which itself refers to supplementation by a written summary, we have accepted that as sufficient to show that Federal requirements were met and a complying summary existed. Where there is no statement in the form that a written summary was provided, we have examined the evidence to determine whether any of the State's documentation constitutes a written summary complying with the requirements or otherwise shows that a complying summary existed, but have not required of the State the quantum of evidence which we might have required under other circumstances. This approach is reflected in our analysis of specific cases.

The 40 Contested Cases

The attached Appendix contains our findings on the 40 contested cases from the sample. To the extent that our findings rest on the legal conclusions discussed in the body of the decision, we have only indicated the result, either for the Agency or for the State. Where our findings turn on the sufficiency of the evidence, we have included a discussion of the specific documentation submitted. (State's Hearing Exhibit D, Agency's Hearing Exhibit G.) The cases are discussed in the order in which the parties addressed them at the hearing. Except where necessary to the discussion, we have not repeated for each case the defects alleged by the Agency, since they are clearly set out in the Agency's Post-Hearing Brief.

Calculation of the Disallowance

Subsequent to the hearing in this case, having resolved issues related to the statistical sampling methods used and the rate of FFP claimed, the parties recalculated disallowance amounts based on assupmtions as to whether the Board would find for the State or the Agency on various issues. Except for a small adjustment to which the parties have agreed, the maximum disallowance (if we found for the Agency on all 40 contested cases) would be $2,377,001, and the minimum disallowance (if we found for the State on all 40 contested cases) would be $1,807,391, since the State has admitted violations in 148 sample cases. (Agency's Submission of August 10, 1981, p. 2.)

Since our decision is split, part for the State, part for the Agency, the precise amount disallowed will need to be recalculated. While we uphold the Agency's findings on 27 of the contested cases, we note that the final findings in some of those cases are based on defects which the Agency might reasonably consider to be de minimis. For example, certain findings are based solely on the defect that the notice, otherwise prominent, is not "at the top" or that the written summary was not signed by the witness. While we are compelled to find for the Agency in these cases by the clear wording of the regulation, the Agency may decide that it does not wish to extrapolate these de minimis violations to the entire universe of the State's claims.

Since the parties have agreed on the method of calculation, we assume that there will be no further dispute concerning this. If there is, the parties may return to the Board.

Conclusion

For reasons stated above, we uphold the Agency's findings in 27 of the 40 contested cases and reverse those findings in 13 cases. The precise amount of the disallowance based on these findings is to be determined by the parties. The parties have already agreed that the

disallowance for the 148 uncontested cases should be $1,807,391, and that the Agency overstated the unallowable cost by approximately $2,652,164 ($5,029,165 - 2,377,001).

/s/ Donald F. Garrett

/s/ Norval D. (John) Settle

/s/ Cecilia Sparks Ford, Panel Chair

APPENDIX

This Appendix contains our findings on the 40 contested cases, as explained at page 16 of the decision. Findings for the State are are indicated by State, and for the Agency by Agency.

#8 State.

#42 Agency. The Agency determined that this was a short form not supplemented by a written summary. We agree that the form is not a long form, since it merely lists the basic elements rather than providing information concerning them. We also agree that a "Sterilization Consent" document, primarily designed to release the physician of any liability, does not evidence compliance with written summary requirements. There is a typewritten statement on this document followed by typed initials which are apparently those of the physician and witness. Even though this statement says that the patient "understands that the procedure is designed to produce sterility but that it has a failure rate of 4 to 5 per thousand and if successful is irreversible," there is no reference to other basic elements. Thus, this is insufficient as a summary of the oral presentation.

#129 Agency. The Agency determined that this was a short form not supplemented by a written summary. We agree that the form is not a long form, since it merely lists the basic elements. The State has submitted a letter from the physician, dated in 1979. While this letter describes what the physician explained to the patient, it is not signed by the auditor-witness. Moreover, it does not refer to a written summary supplied at the time. It is, therefore, insufficient to show compliance with the requirements.

#275 Agency. The physician's consent document does not indicate that the patient was given an explanation of the procedures as required by Paragraph (a)(2)(i)(A). Although there is in the record a hospital form which states that the patient has a right to be informed of the nature of the procedure, this form specifically states that it "is not intended to be a substitute for THOSE EXPLANATIONS which ARE TO BE PROVIDED BY MY PHYSICIAN(S)." Moreover, this form was not signed until 2/15/77 and therefore is insufficient to show that the patient received and explanation prior to signing the consent document on 1/27/77.

#317 State. The Agency determined that the long form submitted for this case was defective since it did not detail counseling concerning alternative methods as required by Paragraph (a)(2)(i)(D). The form does state, however, that "All other alternative methods for contraception have been considered," and we think that this is sufficient detail for this particular patient since notes from the patient's records indicate previous use of such alternatives.

#379 State. The Agency argued that the State's documentation in this case constituted only a short form. We disagree. One of the documents submitted would only qualify as a short form if taken alone. However, it may be reasonably read together with three other documents signed the same day. These four pages describe the basic elements in reasonable detail, and qualify as a long form.

#220 State.

#325 State.

#74, 84, 114, 214, 229 Agency. There is a statement concerning benefits on each form but it is not printed "at the top," and therefore, does not meet the notice requirement, clearly specified in the regulation.

#257 Agency. There is a statement concerning benefits but it is not "prominently at the top" and, also, refers only to withdrawal of consent, not withholding of consent.

29 Agency. The Agency determined that this was a short form not supplemented by a written summary. No documentation has been submitted except the form, which merely lists the elements and does not refer to a written summary. Thus, there is no basis on which to conclude that the requirement was met.

13 State. The Agency determined that the short form was not supplemented by a written summary. The form does, however, contain a handwritten note from the witness, who was also the interpreter, saying she explained the procedure. Signed physician's records state that the procedure was thoroughly explained to the patient and note, "of interest is the fact that the interpreter herself has had a laparoscopic tubal transsection and therefore was able to verbalize the concepts adequately." The statement also mentions other basic elements. We do not think this documentation fails to meet the requirements merely because the physician and witness signed different summaries.

40 Agency. The Agency determined that this was a short form not supplemented by a written summary. The State contends that there is a form which should qualify as a long form and which was first called that by the Federal reviewer. Although the documentation submitted includes two forms, one apparently obtained by the doctor and one by the hospital, both merely list the basic elements rather than providing information concerning them. Nothing in the documentation indicates that either form was supplemented by a written summary.

59 Agency. The Agency determined that this was a short form not supplemented by a written summary. A statement by the physician, dated 1979, indicates that the patient was given a Planned Parenthood booklet concerning sterilization during prenatal visits and sterilization was discussed and that, when it was determined that a "C-section" was necessary for the delivery of the patient's baby, the physician rediscussed the matter since this required a change in method of sterilization. While there is nothing in the regulation concerning the time at which the written summary must be drafted, the regulation does require that the written summary be signed by the auditor-witness. This statement was not. Also, while it may be reasonable to assume that the Planned Parenthood booklet summarized the basic elements which were provided orally to the patient, there is nothing in the record on which to base a finding that the booklet itself was signed and could, therefore, meet the written summary requirement.

#172 State. The Agency determined that this was a short form not supplemented by a written summary. The form itself refers to "an oral explanation supplemented by a written summary" of the basic elements and this is sufficient to show that the Federal regulation was met.

#178 State. The Agency determined that there was no written summary, but the form itself refers to one.

#231 Agency. The Agency determined that, among other defects, the form failed to indicate that an offer to answer inquiries was made, as required by Paragraph (a)(2)(i)(E). We agree. In addition, a letter from the physician dated in 1979 does not mention any such offer, and there is no other evidence that it was made.

#236 State. The Agency determined that this was a short form not supplemented by a written summary. The State contends that the form qualifies as a long form, but we do not need to reach this issue since there is a document in the record which complies with the written summary requirements. A document signed by the patient and a witness states that "I have read and understand Dr. Moss's brochure entitled 'Vasectomy' ... I have discussed the operation of vasectomy with Dr. Moss and all of our/my questions have been answered." Although the State has not pointed it out, this document also contains handwriting which we have determined is Dr. Moss's signature, since it is practically identical to his signature on another document in the file. Reference to the brochure, which was the basis of the oral discussion, is sufficient to summarize that discussion.

#238 Agency. The Agency determined that this was a short form not supplemented by a written summary. We agree that the form is not a long form, since it merely lists the basic elements. An after-the-fact letter from the physician states: "This 23 year old woman had chronic pelvic inflamatory disease with irregular periods and did not desire any more children nor did she wish to take birth control pills. She strongly wished not to become pregnant and at her insistence I performed the tubal ligation after repeatedly discussing the situation with her for about three months." Even if this were sufficient to summarize a discussion of all the basic elements, however, it fails to comply in that it is not signed by the auditor-witness.

#251 Agency. The Agency determined that this was a short form not supplemented by a written summary. We agree that the form is not a long form, since it merely lists the basic elements. There is in the record an after-the-fact statement by the physician performing the sterilization as to what he explained to the patient "following notification of the delivery [of the patient's baby] by the attending physician." The delivery was on September 22, 1975. The consent form was signed by the patient on September 8, 1975, however. Space on the form for the physician's name was not filled in. Based on this evidence we conclude that the alleged summary was signed neither by the auditor-witness nor by the person obtaining the consent and, in any event, did not summarize the oral presentation on which consent was based.

#264 Agency. The Agency determined that this was a short form not supplemented by a complying written summary. The patient's charts contain doctor's notes stating, "Desires sterilization - understands and accepts risks and complications. Understands possiblility of failure and irreversibility." These notes also refer to the procedure to be performed but are not signed by an auditor-witness. Although other documents in the record, apparently intended as releases of liability, are witnessed, they do not summarize the basic elements. Therefore, none of the documents shows compliance with the regulation.

#272, 276, 309, 413 State. The Agency determined that there was no written summary, but the form itself refers to one.

#175 Agency. The Agency determined that, among other defects, the form did not contain the notice. While there is a statement concerning benefits on the form, it is not printed "at the top."

#184 Agency. The Agency determined that, among other defects, the form did not contain the notice. There is a statement concerning benefits on the form, but it is not printed "at the top."

#157, 237, 300, 388, 399, 432 Agency. These are "Group 6" cases where the State attempted to cure the alleged defect of the lack of the proper notice through its CONSENT form, obtained after-the-fact. We agree with the Agency in these cases for reasons stated in the body of this decision and since there is no other evidence that a complying notice actually was "printed prominently at the top" of a consent form.

#378, 394, 400 Agency. These are "Group 6" cases where there is evidence in the file sufficient to show that the patient actually received a short form containing the required notice. However, there is no documentation to show that the short form was supplemented by a written summary and other documents submitted, while arguably summarizing the oral presentation, are not signed by an auditor-witness.