DEPARTMENTAL GRANT APPEALS BOARD

Department of Health and Human Services

SUBJECT: Idaho Professional Review Organization DATE: December 8, 1981
Docket No. 81-109
Decision No. 236

DECISION

Introduction

The Idaho Professional Review Organization (IPRO) appealed the Health Care Financing Administration's (Agency) decision to terminate its grant, No. 99-P-99517/10, effective September 30, 1981. The determination provided that the grant be extended, if necessary, to permit this Board to make a final decision. In its appeal letter, dated July 17, 1981, IPRO requested a hearing pursuant to §1152(d)(2) of the Social Security Act (Act). A hearing before the Presiding Board Member was held in Seattle, Washington, on September 9 and 10, 1981. This decision is based on the Record in this case, which includes the written submissions of the parties and the evidence presented at the hearing (as recorded in the transcript (Tr.) of the hearing). 1/ Based on the analysis below, we conclude that IPRO's grant should not be terminated.

1/ Below, we refer to: IPRO's "Notice of Appeal and Request for Formal Hearing," dated July 17, 1981, as the Notice of Appeal; IPRO's "Additional Arguments, Explanations and Documents in Support of Appeal (Appellant's Brief)," dated August 24, 1981, as the Appeal Brief; the "Response of the Health Care Financing Administration," dated August 21, 1981, as the Agency Response; the Administrative Record submitted in conjunction with that response as AR; and the "Reply of the Idaho Professional Review Organization, Inc.," dated September 2, 1981, as the Reply Brief; the parties' post-hearing briefs dated October 13, 1981 (Agency) and October 15, 1981 (IPRO), as Agency Post-hearing Brief and IPRO Post-hearing Brief.

On November 20, 1981, the Agency submitted a copy of the decision in Region X Peer Review Systems, Inc. v. Schweiker, Civil No. C-2-81-1067 (S.D. Ohio, October 1, 1981). By memorandum dated November 30, 1981, IPRO responded that "the decision contains no legal holdings or findings of fact of any particular relevance to the issues before this Board." We agree that the opinion of the district court regarding the termination of that PSRO's long term care review activities does not have any bearing on issues in this case.

This decision is divided into three sections. The first provides general background information on the Professional Standards Review Organization (PSRO) program and the nationwide evaluation of PSROs which led to this dispute. The second discusses the evaluation of IPRO - how it was conducted, and what general objections IPRO raised regarding the evaluation and the criteria used in the evaluation. The third section sets out the Board's findings and conclusions on whether IPRO should receive any additional points for the contested criteria.

I. General Background

A. Information on the PSRO Program

The 1972 Amendments to the Social Security Act provide for the creation of PSROs, administered and controlled by local physicians, and designed to involve local practicing physicians in the review and evaluation of health care services covered under Medicare, Medicaid, and the Maternal and Child Health programs. (Title XI, Part B, of the Act.) PSROs are responsible, in specifically designated geographic areas, for assuring that the health care paid for under these programs is medically necessary and consistent with professionally recognized standards of care. The PSROs also review whether the health services are provided at the level of care which is most economical, consistent with the patient's medical care needs. The major focus of the PSRO program has been on review of inpatient hospital services. While PSROs are also charged with review responsibilities in other health care settings, budget restrictions have limited the PSROs' ability to review outside the hospital setting.

The PSROs are responsible for developing and operating a quality assurance system based on peer review of the quality and efficiency of services and continuing education. In hospitals, the peer review system must include: concurrent review, which is review focusing on the necessity and appropriateness of inpatient hospital services performed while the patient is in the hospital; medical care evaluation studies, which are assessments, performed retrospectively, of the quality or nature of the utilization of health care services and assessments of the PSROs' impact where corrective action is taken; and profile analysis, which is the analysis of patient care data to identify and consider patterns of health care services. (See, e.g., PSRO Program Manual, Chapter VII, p. 1, March 15, 1974.)

The Act, and regulations governing the program, provide that a PSRO is "conditionally designated" for a period of time, and that there will be an agreement between the Secretary and the PSRO "fully designating" the PSRO after it has satisfactorily performed PSRO functions during its trial period as a conditional PSRO. After

a maximum of six years, a conditional PSRO must be fully designated or it can no longer participate in the program. (Section 1154(b) and (c) of the Act.) A fully designated PSRO may be terminated only after an opportunity for a hearing, upon a finding by the Secretary that the PSRO "is not substantially complying with or effectively carrying out the provisions of such agreement." (Section 1152(d) of the Act.)

B. The Nationwide Evaluation of PSROs

The Agency has stated that it implemented a nationwide evaluation of the performance of PSROs in response to proposals by the President, in February and March, 1981, to phase out the PSRO program within three years, and to reduce funding for fiscal year 1981. In June, 1981 Congress approved a rescission of $28,701,000 from the PSRO program. (Pub. L. No. 97-12, Title I, Chapter VIII; 94 Stat.3166.) The Agency maintained that the legislative history of the rescission bill indicated that the Agency was to accomplish the rescission by terminating ineffective PSROs. (Agency Response, pp. 3-4, 9.)

The Agency stated that in order to identify ineffective PSROs, it developed evaluation criteria to measure performance, and asserted:

> [t]hese criteria were based on the requirements for PSROs imposed by the PSRO statute and regulations, and further interpreted through the PSRO Program Manual and Transmittals. Many of the criteria were based on those used to convert PSROs from conditional to fully designated status.... Because of the Presidential and Congressional mandates to terminate ineffective PSROs, however, more emphasis was placed in this most recent evaluation on the effectiveness and the actual impact of a PSRO's activities. Although the weight attached to certain areas changed, these criteria impose no new responsibilities on the PSROs.

(Agency Response, pp. 9-10.) The Agency further explained that the major change from the criteria previously used to assess PSROs was the increased emphasis on cost effectiveness examined in Part I of the evaluation criteria, and the PSRO's impact on the utilization and quality of health care services examined in Part III. (Agency Response, p. 5.) The proposed criteria were sent to all PSROs for review and comment on March 20, 1981. After considering the comments received and implementing some of the suggestions, the Agency distributed the final version of the criteria to all PSROs on April 15, 1981. The criteria were not promulgated as a regulation nor published in the Federal Register.

The final version of the criteria was sent to the Agency's Regional Offices to be completed for each PSRO, along with instructions for the evaluation. The evaluations were conducted by the Agency's project officer. The instructions included the following:

> Performance described in the indicators must be sustained throughout calendar year 1980 or the most recent grant period (period should cover 12 months). If another time period is to be considered, it is specified in the instructions for that item within the criteria set.
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> Each scoring level, positive or negative, must be reasonably verifiable by previous site visit, reports, grant applications, PSRO reports, correspondence or other relevant documentation. The Project Officer should assure the completeness of documentation on each PSRO. PSROs may be consulted for additional information.
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> The Central Office [CO] scoring methodology will be sent to each RO [Regional Office] following CO receipt of the evaluations. After CO has completed scoring ROs will be notified of the scores of each PSRO for verification.

(Agency Response, second attachment to Exhibit B.)

The Agency stated that in order to insure uniformity and objectivity, the "Regional Offices were instructed that no consideration was to be given to factors not included in the criteria" (Agency Response, p. 5), and representatives from the central office staff were sent to the regions to review the evaluations and determine the validity of the supporting documentation. (Agency Response, p. 6; Tr., p. 292.) The Director of the Division of Program Operations for the PSRO program testified that the central office also conducted telephone conferences with regional personnel to discuss the evaluation criteria. She said that in order to have consistent application of the criteria, the Agency's central office sent the regions a "Question and Answer" packet which listed the questions that staff in the various regions had raised and the responses of the central office. (Tr., p. 292; see also, Exhibit H-9.)

C. The Format of the Evaluation Criteria and the Scores Needed to Pass

The evaluation was composed of criteria which measured three areas of performance: Part I -- organization and program management; Part II -- performance of review: compliance and process; and Part III -- performance of review: impact/potential impact. Each criterion

was assigned a point value which the Agency awarded to a PSRO if it "met" the criterion or, with some criteria, the points were awarded based on the PSRO's level of performance, as described in the criteria. In order to pass the evaluation, a PSRO needed a total score of 1105 (of the 2350 available points) and passing scores on two of the three parts.

Part I evaluated organization and management by examining the following areas: commitment of the PSRO Board and committees; administration and financial management; cost efficiency and relations with the State. A PSRO needed 190 of the 300 available points to pass this part. Part II examined performance of PSRO review based on compliance with established review processes including the acute care review process, special actions taken to address identified problems such as the modification of a review system and adverse actions, medical care evaluation studies, the adequacy of the PSRO's data system, and the use of profiles. A PSRO needed 400 of the 850 available points to pass this part. Part III evaluated PSROs on the basis of their impact and potential impact on utilization objectives and the quality of health care. A PSRO needed 515 of 1200 available points to pass this part. (See Agency Response, p. 6.)

II. The Evaluation of IPRO

A. Summary of the Scores Awarded IPRO and How the Evaluation of IPRO Was Conducted

The Agency awarded IPRO a base score of 983 points, 122 short of the 1105 needed to pass the evaluation. IPRO passed Part I with 218 points; IPRO did not pass Parts II or III; IPRO's score of 385 for Part II was 15 short of the 400 needed to pass; and the score of 380 on Part III was 135 short of the 515 needed to pass.

The project officer testified that she received the evaluation criteria in mid-April, 1981 and was directed to complete the evaluation by April 24, later extended until April 30. She said that IPRO's Executive Director was at a meeting in the Regional Office around the 14th of April, and that she informed him at that time that the process was going to begin on April 16. She testified that on the 16th she began gathering data and that on April 20, 1981 she called the Executive Director and asked him for documentation on certain criteria. (Tr., pp. 336, 391.) Of that conversation, she said:

> I went through each of the items that were marked met and emphasized to them that I could not mark anything met unless I had written evidence that something occurred and that based on all our files and our information ... I didn't have enough information to mark certain items met.

(Tr., p. 337.) She said that some time later that day she made a memorandum to the file regarding that call. (Tr., p. 397.) She said that "it's routine for us when we have a call like this to document it, particularly this being the first one and going through the entire document." (Tr., p. 338.)

The memorandum read as follows:

> I called Lee and Bob [IPRO's Executive Director and a staff member] and read through all the "not mets" or "possible not mets" on IPRO's evaluation. Upon discussion of each, IPRO staff either agreed items were "not met" or agreed to submit supporting documentation by the end of the week as to why they feel item should be met.

(AR, p. 169.) The project officer testified that in her discussions with the Executive Director he said that several of the criteria were not applicable to IPRO. She said she informed him that she did not have the option to mark criteria "not applicable." (Tr., pp. 338-39.) It was on the basis of this telephone call that many of the disputed criteria were marked "not met." (See the AR.) She said that she had other telephone conversations with IPRO representatives to request additional information but did not make a record of those other calls. (Tr., p. 398.) The project officer said that, at the time the criteria were marked, the project officers in her region had conference calls with the central office to discuss the criteria. (Id.) She then sent the evaluation to the Agency's central office to be scored. 2/

B. Burden of Proof

IPRO claimed that the Agency had the burden of proof to justify its decision to terminate IPRO's grant because §556(d) of the Administrative Procedure Act (APA) states that, in adjudicatory hearings, "[e]xcept as

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2/ IPRO claims that its evaluation was scored twice by the Agency. (See Exhibit B to the Appeal Brief, and pp. 11-12; Tr., pp. 38-39.) IPRO presented the June 18, 1981 letter terminating IPRO as evidence to support its allegation. The letter stated that IPRO had not met Parts I & II when in fact IPRO did not pass Parts II & III. (Notice of Appeal, p. 2; June 18, 1981 letter from Acting Director, HSQB). As further evidence, IPRO stated that it received its termination letter a few days after the other PSROs received theirs. (Tr., pp. 157-58.) The Agency denied that IPRO was scored more than once and submitted that the error in the termination letter was a typographical error, and that IPRO's letter may have arrived a few days later because Federal Express does not deliver in Idaho, and therefore, a different carrier was used for IPRO. (See Tr., pp. 342, 291-92.) IPRO did not supply any other support for this claim. Thus, we find the Agency's position, on balance, to be substantially supported by the Record.

otherwise provided by statute, the proponent of a rule or order has the burden of proof." (See, e.g., Appeal Brief, pp. 2-11.) The Agency responded that this case is not an APA proceeding and that the burden is on IPRO to show cause why it should not be terminated based on the Agency's evaluation of IPRO's performance. (Tr., p. 28.) The Agency argued that the APA burden of proof requirements do not apply here because, although IPRO is entitled to a "formal hearing" under the Social Security Act, the Act:

> does not include the trigger language set forth in the APA which is an adjudication to be determined on the record.... What we have is a proposal by the Agency based on a budget decision and it is their [IPRO's] burden to show that in fact we have not applied the criteria in a rational and proper way.

(Tr., p. 28.)

The Board concludes that the APA burden of proof provision does not apply in this proceeding. Section 556(d) applies only to hearings required by §553 or §554. Section 553 applies to rulemaking and IPRO did not contend that it is applicable here. Section 554 applies:

> (a)... in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing.... (emphasis added.)

The statutory provision under which the PSRO was afforded this hearing before the Board (§1152(d)(2) of the Social Security Act) provides that an agreement with a PSRO may be terminated by the Secretary "after providing such organization with an opportunity for a formal hearing on the matter." While this is an adjudication in which the determination is required by the PSRO statute to be made after an agency hearing, the statute does not require that the determination be made on the record. The absence of the underlined words is significant.

IPRO cited American Trucking Associations v. United States, 344 U.S. 298 (1953), as authority for its position that the burden of proof standard of §556(d) applies in this proceeding. (Appeal Brief, p. 4.) This case is by no means the last word of the Supreme Court on this question, but in any event, American Trucking Associations does not support IPRO's argument. IPRO correctly stated that in American Trucking Associations the Supreme Court basically held that, unless the Agency's governing statutes required a hearing on the record, the Agency would not be bound by the APA burden of proof standard. IPRO then quoted the "opportunity for a formal hearing" language of the PSRO statute, and concluded that "[t]his requirement for a formal hearing on the record appears to dovetail closely with that found in the Administrative Procedure Act." (emphasis added.)

(Appeal Brief, pp. 4-5.) The words "on the record" are not to be found in the statute providing for this hearing, however. The statute provides only "an opportunity for a formal hearing on the matter." The word "formal" does not necessarily mean the same as "on the record," nor do we find anything in the context of the Act as a whole which would lead us to conclude that Congress intended that an APA hearing was required.

More recent Supreme Court cases show that the omission of the words "on the record" can be determinative. In United States v. Allegheny-Ludlum Steel Corporation, 406 U.S. 742, 757 (1972) the Supreme Court said that:

> ... Sections 556 and 557 need be applied "only where the agency statute, in addition to providing a hearing, prescribes explicitly that it be 'on the record.'"

The next year the Supreme Court followed the Allegheny-Ludlum principle in United States v. Florida East Coast Railway Company, 410 U.S. 224 (1973). The Board therefore concludes that the hearing in this case is not required by statute to be "on the record" and is therefore not subject to the technical burden of proof rule in §556(d) of the APA. 3/

Nevertheless, the Board holds that the Agency does bear a burden, to support its determination that IPRO did not meet certain criteria. The Agency must show a reasonable basis for its determination on the contested criteria in order for the Board to uphold that determination. This does not mean, however, that IPRO has no corresponding obligation. As appellant, it is incumbent on IPRO to demonstrate where the Agency's

3/ Allegheny-Ludlum and Florida East Coast Railway were both rulemaking cases under §553 of the APA. The principle enunciated in those cases (i.e., that Sections 556 and 557 are not triggered by a hearing requirement that does not include statutory language for determination "on the record") should be the same for adjudications because the same "trigger" language appears in §554. Sections 556 and 557 apply under §553(c) "[w]hen rules are required by statute to be on the record after opportunity for an agency hearing." Section 554, headed "Adjudication," applies by definition "in every case of adjudication revised by statute to be determined on the record after opportunity for an agency hearing." §554(a). (Emphasis added.) The meaning of the term "hearing" itself can vary depending upon whether the context is rulemaking or adjudication, but IPRO has raised no question in this case about the adequacy of the due process protections accorded.

evaluation of IPRO lacked a reasonable basis 4/ or to show either that IPRO met the criteria or performed at a certain level described in the criteria.

C. IPRO's Objections to How the Evaluation Was Conducted

IPRO claimed that in making its decision to terminate IPRO's grant, the Agency "failed to follow the regulations, guidelines and internal memoranda of the Department," and that "[i]t is axiomatic in administrative law that the agency must comply with its own rules and regulations." (Appeal Brief, pp. 6-7.) IPRO claimed the project officer violated the Agency's own instructions on completing the evaluation, specifically that she took on an adversarial approach to her dealings with IPRO; that she based her decision on the April 20 telephone call, rather than following Agency instructions requiring that she "assure documentation" of each criterion; and that she failed to ask for additional documentation if she was not satisfied with what IPRO had provided. (See, e.g., Appeal Brief, pp. 3-11; IPRO Post-hearing Brief, pp. 8-10.)

IPRO also contended that "no notice was given to IPRO that in fact its grant was being considered for revocation." (Appeal Brief, p. 8.) IPRO claimed its staff was told instead that the evaluation was for the purpose of ranking PSROs nationwide in case of future funding cutbacks. (Appeal Brief, p. 23.)

The Agency maintained that the project officer made every effort to obtain information about IPRO's activities and to conduct the evaluation in a manner fair to IPRO. The project officer said that she contacted IPRO staff on several occasions to discuss the evaluation and to obtain documentation from IPRO which would allow her to mark the criteria "met." She said she had no interest in seeing IPRO's grant terminated. (See Tr., pp. 336-43.)

As a practical matter, the Board need not reach the issue of whether certain criteria were improperly marked "not met" because the project officer allegedly did not obtain documentation. The Board has accepted and considered all relevant documentation which IPRO submitted in support of the criteria, even if the project officer did not consider the material in making her decision.

In response to IPRO's objection to the Agency's use of the alleged admissions by the Executive Director in the April 20 call, the Board determined that it would not hold IPRO to those alleged admissions for any criterion

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4/ In those cases where a criterion was marked "not met" because there was no evidence that IPRO performed the activity at issue, the Board considered the very lack of documentation as a reasonable basis for the Agency's determination. (See, e.g., criterion II.B.1(b).)

which IPRO claimed it met, where IPRO submitted evidence in support of that claim. The Board so determined because the contact report summarizing this one call (AR, p. 169) did not list which criteria IPRO admitted it had "not met," and it did not refer to the criteria which IPRO objected to as "inapplicable" (even though the project officer testified that IPRO did so object, see Tr., pp. 338-39). The Board did find the call to be evidence of an admission in cases where IPRO objected to the call but did not contend, nor submit any information to support, that it met the criteria.

The Board is also not persuaded that IPRO was unaware that its grant could be terminated as a result of the evaluation. IPRO admitted that it received a copy of the final version of the criteria. (Tr., p. 194.) The cover letter dated April 15, 1981, stated that: "[t]he Administration's PSRO budget proposal provides funds for only the most effective PSROs to be continued. PSRO effectiveness will be determined through the application of the performance criteria." The letter also stated that PSROs would be ranked based on the scores they received on the evaluation and that PSROs could be terminated based on that ranking. (Exhibit B to Agency Response.) The Board concludes that IPRO was on notice that it could be terminated based on this evaluation.

D. IPRO's Objection to Certain Criteria Used in the Evaluation

IPRO objected to certain criteria which the Agency used in conducting this evaluation. IPRO claimed that some of the criteria were inapplicable to it and that, as a result, IPRO was unfairly denied points it needed to pass the evaluation and retain its funding. (Appeal Brief, pp. 20-23.) IPRO claimed that these criteria were originally developed "to provide a rank ordering of all PSROs in the nation so that if Congress began to cut funding, only the most effective PSROs would receive the scarce resources available," and argued that "for the purposes of reviewing an on-going grant, however, the criteria make no sense." (Appeal Brief, p. 20.) IPRO claimed that it is an effective PSRO, given the limitations of its geographical location and the resistance it received from Idaho physicians. (Tr., pp. 45-51.) IPRO maintained that it did not pass this evaluation in part because IPRO was denied points for not doing things required to pass the criteria, but which were unnecessary for IPRO to perform its duties as a PSRO. (See, e.g., criteria I.D.1., I.D.3., II.A.3., II.B.1(f), (g), and II.B.2(d), (e), and (f); Appeal Brief, pp. 20-23.) In support of its claim that the evaluation did not accurately reflect its performance as a PSRO, IPRO submitted that it had recently passed the Agency's annual evaluation and another Agency evaluation performed when it was fully designated less than six months prior to this evaluation. (Tr., p. 16.)

The Agency admitted that the evaluation had two purposes - - to identify those PSROs that, notwithstanding budgetary considerations, did not meet minimum program performance requirements and must therefore be terminated; and to develop a ranking of PSROs based on performance to be used in the event that Congress approved the budget rescission. (Agency Response, p.4.) The Agency maintained, however, that the criteria used here did not impose any new obligations on PSROs and are based on past evaluation criteria, the PSRO statute, regulations, the Program Manual and Agency Transmittals. (Tr., pp. 284-89; see also, Agency Response, pp. 4-5.) The Agency asserted that any change in the result since prior evaluations was due to the emphasis on the PSRO's impact on the quality and cost of health care. (Agency Response, p. 5.) The Agency asserted that this change in emphasis was in response to statements by Congress and the President. The Agency also explained that the evaluation for full designation involved a different time frame. The Agency's witness said that the evaluation for full designation "was a snapshot in time whereas this evaluation was trying to look at sustained performance over a certain time frame." (Tr., p. 288.)

The Agency's witness also stated that in selecting criteria for the evaluation the Agency recognized that PSROs had different methods of performing, and that the criteria allowed for such differences by requiring a PSRO to achieve only 1105 of 2350 available points (and minimum scores on only two parts). (Tr., p. 288.)

IPRO did not persuasively rebut the Agency's assertion that the criteria were based on reasonable program requirements and that a minimally performing PSRO could achieve 1105 of the 2350 available points. The Board will not substitute its judgment on program policy for reasonable policy choices of the Agency charged with administering the program. See, e.g., Wisconsin Department of Health and Social Services, Decision No. 116, August 16, 1980; New York Department of Social Services, Decision No. 101, May 23, 1980; Family Health Care, Inc., Decision No. 147, January 29, 1981. In those cases, the Board said that it will not interfere with an Agency's exercise of its discretion if the Agency acts in accord with the rules and regulations, and the discretion is exercised in a reasonable manner. IPRO did not show that it was unreasonable for the Agency to expect PSROs to perform the activities described in the criteria. IPRO also did not show that the Agency's decision requiring a PSRO to achieve minimum scores on two parts and less than one-half of the total available points in order to pass, did not compensate reasonably for any situation unique to this PSRO.

III. The Board's Assessment of the Specific Criteria in Dispute

This section of the decision sets out each criterion in dispute (in the same order as it appeared in the evaluation criteria), the arguments of the parties regarding whether IPRO should receive points for the

criterion, and the Board's findings and conclusions. The Board has found that IPRO should receive an additional 144 points for a total of 1127; IPRO needed a total of 1105 points to pass this evaluation. With these additional points IPRO has also passed two of the three parts of the evaluation. See discussion of criteria I.B.4, I.B.6.b., II.B.2(c), II.C.1, and III.A.

Part I of the Evaluation Criteria: Organization and Program Management

IPRO scored 218 points in this part; 190 were needed to pass. The Board concludes that IPRO should receive an additional 19 points in this part. IPRO disputes the Agency's marking of the following criteria in this part:

> CRITERIA SECTION B. Administrative and Financial Management
> CRITERION I.B.4. Submitted reports, proposals, plans, etc. are well-developed and accurate. Less than 10% require Regional Office to request revision or greater depth.

The Agency did not award IPRO the 15 points available for this criterion because the Agency determined that "well over 10 percent require substantial revision and supplementation." (AR, p. 11.)

In support of marking this criterion "not met," the Agency submitted the following documents: IPRO's Focused Review Plan (AR, pp. 170-87), Quality Review Plan (AR, pp. 188-271), Profile Analysis Plan (AR, pp. 272-96), Quarterly Progress Reports (AR, pp. 297-305), Surgical Procedures Review Plan (AR, pp. 306-11), Hospital Memorandum of Understanding, (AR, pp. 312-18) and Grant Application (AR, pp. 319-64.) See also, Agency Response, pp. 12-17; Tr., pp. 344-64.

IPRO objected to the use of this documentation, claiming that much of it was dated in 1981, while the the evaluation period was calendar year 1980. IPRO argued that since the Agency's instructions for completing the PSRO performance evaluation stated that the evaluation period was to be either "calendar year 1980 or the most recent grant period (period should cover 12 months)," the evaluation should be based on calendar year 1980. IPRO argued that its latest grant began March 1981, and using that grant period would not cover 12 months.

The Agency Response stated that, with some exceptions, the evaluation period for IPRO was calendar year 1980 (p. 7), but also stated (at p. 36) that "[t]he basic period of assessment for the evaluation appealed here was February 28, 1980 to May 4, 1981."

At the hearing, however, the parties agreed that the period of the evaluation for IPRO was its last complete grant period of March 31, 1980 to March 31, 1981. (Tr., p. 10; see also, Agency Post-hearing Brief, p. 1.)

IPRO also argued that it met this criterion, and that the relevant documentation regarding the quality review plan "merely shows that appellant IPRO personnel diligently prepared the quality review plan and responded to input from Region X staff." With regard to the profile analysis documentation, IPRO stated that it "merely indicates that ... IPRO should develop a plan by the 1st of December, 1980, for agency approval." (Reply Brief, p. 8.) In addition, IPRO maintained that the grant application is an inappropriate document to consider in this context since, by its nature, the approval process is more analogous to arms-length contract negotiations between parties. (See Reply Brief, pp. 7-13.)

Finding: IPRO should receive the 15 points.

The criterion required a determination that less than 10% of "submitted reports, proposals, plans, etc.," require revision or greater depth. The Agency has not stated a reasonable basis to support its determination that IPRO has "not met" this criterion since the Record does not indicate how many documents were considered in making this determination, whether multiple submissions of the same document were counted as one submission or several, or which time period was in fact used as the basis for marking this criterion "not met."

It is not clear from the Record that the Agency followed its own instructions, which required the Agency to base its evaluation on calendar year 1980 or the last grant period (which must be a 12 month period). The Agency's submissions refer to several possible evaluation periods (February 19, 1980 to May 4, 1981, calendar year 1980, and IPRO's last grant period -- March 31, 1980 to March 31, 1981), and the Agency's supporting documentation spans a time period from April 1980 to June 1981. In addition, the Agency admits that items 1-4 referred to at AR 170 (which includes the Focused Review Plan) should not be considered by the Board because they do not pertain to the relevant time period. (Tr., p. 352; see also, items at AR, pp. 188, 272, 296, 306, 312, 319.)

The Board can not sustain the Agency's scoring of this criterion based on the information in the Record because much of the documentation is outside the period of the evaluation (the last grant period), and there is no indication of how the Agency determined what percentage of IPRO's submissions during the evaluation period required revision.

> CRITERIA SECTION B. Administrative and Financial Management
> CRITERION I.B.6.b. Audit findings indicating deficiencies in accounting systems and/or financial management. Findings are defined as.... Inability to allocate costs.

The Agency did not award IPRO the four points available for this criterion because the Agency determined that audits of IPRO in September 1979 (ACN-10-06900) and September 1980 (ACN 10-06904) indicated "that in certain areas the PSRO failed to allocate costs in accordance with established Agency policies." (Agency Response, pp. 17-18; see also, Tr., pp. 159, 201, 364.) In accordance with the instructions, the Agency marked this criterion on the basis of the most recent and second most recent audits performed.

The Agency's summary explaining how this criterion was marked stated, "Audit No. 10-06904 was resolved by reducing the PSRO's subsequent grant award by the unexpended or carryover funds of $65,806." (AR, pp. 365, 368.) A summary of audit findings and recommendations for 10-06904 and 10-06900 also stated that "a financial adjustment should be made for excess contributions to the pension fund." (AR, pp. 367, 369.) The Audit Clearance Document for 10-06900 stated: "[a]ction Taken on Finding: This amount was never charged on the expenditure report for the audit period in question. This amount will be claimed on the SF-269 as an expense in the subsequent accounting period. In the future the PSRO will monitor expenses more closely and adhere to DFAFS regulations for anticipated expenditures." (AR, p. 367.) The Audit Clearance Document for 10-06904 stated: "[a]ction Taken on Finding: The $2,332 cited by the Audit Agency as being an overcontribution to the pension fund as of 6/30/79, was used to reduce contributions in the following quarters." (AR, p. 369.)

Finding: IPRO should receive the 4 points.

The Agency's submissions do not provide a reasonable basis for the determination that IPRO is unable to allocate costs. The Agency did not explain, or submit documents which would explain, the connection between the determination regarding carryover funds and the Agency's claim that IPRO demonstrated an inability to allocate costs. The Agency did not show any correlation between the payments to the pension fund and a finding regarding IPRO's ability to allocate costs. The July 17, 1981 letter submitted by the Agency regarding a later audit is outside the evaluation period, and in any event, the letter states that "IPRO's implementation of procedures to accurately identify the differences between the functional parts of the budget is acceptable." (AR, p. 372; see also, Tr., pp. 159-61, 201-02, 364-65.) The project officer did not supplement this information with her testimony at the hearing. She said only that she marked the criterion "not met" because "that deficiency or problem showed up two years in a row ... it dealt with allocation of costs and their pension plans in particular." (Tr., p. 366.) The Board cannot sustain the Agency's scoring of this criterion based on the information in the Record.

> CRITERIA SECTION D. Relationship To State. Indicators of State Relationships:
> CRITERION I.D.1. PSRO communicates with State to resolve any issues related to review.
>
> CRITERION I.D.3. PSRO has modified review system to accommodate State defined needs where problems were identified by PSRO and/or State (e.g., pre-surgical review, weekend admissions, etc.).

The Agency did not award IPRO the ten points available for each of these criteria because the Agency determined that "IPRO did not provide documentation of any activity to support marking this [I.D.1.] criterion met," and that, "the PSRO Executive Director agreed via telephone (4/20/81) that this [I.D.3.] criterion was not met." (AR, p. 376.) The Agency also asserted that there was no documentation of communication with the State. (See Agency Response, p. 19; Tr., pp. 365-66.) IPRO's position was that it did in fact communicate with the State but there had not been problems during the evaluation period which needed to be resolved.

The Agency maintained that these two criteria, and the method by which they were scored, were valid indicators of a PSRO's capability. The Agency submitted that the PSRO statute and regulations, specifically 42 CFR 463, require a close working relationship with the State and that it is inconceivable that in a productive relationship there are no problems to resolve. The Agency stated:

> ... IPRO's admission indicates a total lack of interaction with the state. IPRO argues that it should in effect be given points for doing nothing when the question is intended to reward those PSROs that do have an active productive relationship with the state.

(Agency Response, p. 20; see also, Tr., p. 294.)

IPRO asserted that, as a seven year old PSRO, its problems with the State had been worked out in prior years and, therefore, these criteria were not applicable to IPRO. (See Exhibits H-1, H-4, Tr. pp. 19, 71-75, 112-17, 134-36, 161-65, 202-04, 294, 365, 405-08.) IPRO argued that without a showing by the Agency that there were bad relations between IPRO and the State, IPRO was entitled to the points for these criteria. (Reply Brief, p. 20.)

IPRO also stated that the Executive Director did not admit to the project officer that IPRO had not met these criteria and claimed that "there had been no activity from the State to either resolve disputes or a formal request from the State to modify IPRO's review process." (Reply Brief, pp. 17-18.) IPRO argued that its relationship with the State is good and submitted the following statement from the Chief of the State's Bureau of Benefit Payments:

> [t]he State has not identified any potential problem areas which would require IPRO to make modifications in their review procedures. I am confident that, if we had identified such problem areas, IPRO would have responded to the needs of the State Agency.

(Exhibit H-1.) The President of IPRO's Board of Directors, Dr. John Meyer, stated that "there were no direct contacts [with the State during the evaluation period] either adverse or positive, and basically my judgement is that the program was operating satisfactorily. We had anticipated their needs." (Tr., pp. 72-73.) The Executive Director also testified that IPRO communicates with the State "as needs dictate." (Tr., p. 161.) He stated that there was communication during the period of the evaluation, specifically, "the State addressed a particular potential problem with leaves of absence for Medicaid beneficiaries. They brought it to our attention and we addressed the issue appropriately." (Tr., p. 162.) He later clarified that this took place in 1978. (Tr., p. 202.) The Executive Director also stated that he served on State committees but that those committees were not related to PSRO activities. (Tr., p. 204.)

Finding: IPRO should not receive the 30 points.

The Board is not persuaded that IPRO should receive these points based on its claim that it did not find it necessary to take the actions described in the criteria. The Agency can reasonably choose to award points to PSROs which modify their activities based on communication with the State. Although IPRO maintained that the State has not identified problems to resolve, the criteria did not require that problems be identified, or communication initiated, by the State. The Agency can reasonably expect PSROs to play an activist role in identifying and resolving problems.

We also find that the Record does not indicate that IPRO has met these criteria. Even without relying on IPRO's alleged statement in the April 20 telephone call that these criteria were "not met," IPRO admitted that it had minimal, if any, contact with the State during the evaluation period, and IPRO did not show that it engaged in the activities outlined in the criteria during the evaluation period.

Part II of the Evaluation Criteria: Performance of Review Operations - Compliance and Process

IPRO received 385 of 850 available points for this part; 400 points are needed to pass. The Board concluded that IPRO should receive an additional 80 points in this part and thereby achieve the minimum passing score for this part. IPRO disputed the Agency's scoring of the following criteria:

> CRITERIA SECTION A. Acute Care Review. Indicators of acute care review process are:
> CRITERION II.A.2. PSRO is reviewing medical necessity of selected surgical procedure(s) on a presurgical basis and/or PSRO is reviewing the appropriate setting for selected surgical procedures.

The Agency did not award IPRO the 20 points available for this criterion because the Agency determined that IPRO's Executive Director agreed via telephone that this criterion was "not met." (AR, p. 377.) The project officer also testified that "the basis for marking this criterion not-met was verbal verification by [the Executive Director] that they were not doing presurgical review." (Tr., pp. 388-90.)

The Agency maintained that IPRO indicated to the project officer that there were no problems in Idaho that indicated a need for these procedures, but that some of IPRO's impact objectives identified problem areas that could have been reviewed for medical necessity on a presurgical basis or for appropriate setting. (AR, p. 378.)

The only IPRO response in the Record concerning how this criterion was marked was that "[n]o argument or documentation was presented by the Agency to justify the subtraction of 20 points from the IPRO score. Since no argument is presented, there is simply no justification for the reduction of the score by 20 points...." (Reply Brief, p. 22.)

Finding: IPRO should not receive the 20 points.

IPRO did not claim, nor does the Record indicate, that IPRO was performing presurgical review during the evaluation period. The Board concludes that the Agency stated a reasonable basis for its determination and that IPRO failed to submit any evidence to show that it had earned the points.

> CRITERIA SECTION A. Acute Care Review
> CRITERION II.A.3. PSRO has recommended rebuttal or revocation of waiver of liability for a class of cases or an institution as a whole within past 24 months.

The Agency did not award IPRO the 30 points available for this criterion because the Agency determined that IPRO's Executive Director admitted this criterion was not met. (AR, p. 378.)

The Agency's position was that monitoring to ensure that rebuttal or revocations of waivers of liability take place when necessary is an essential element of the PSRO review system. The Agency referred for support to an Agency policy statement (Transmittal No. 94) which sets

out a PSRO's responsibilities, and the procedures for evaluating a provider's "waiver of liability" status. (Agency Response, p. 21.) The Agency asserted that IPRO's claim that there were no problems indicates IPRO was not adequately monitoring the care under its review. (Tr., pp. 366-68.)

The Agency stated that providers of health care are awarded a "waiver of liability" which allows them to be paid when certain non-covered services are provided, based on the presumption that they could not have known that the care was not covered. Rebutting this presumption in a particular case, or revoking it for a particular provider, would result in the denial of payment for those non-covered services. (See Tr., pp. 366-67.)

IPRO maintained that no recommendation of rebuttal or revocation of waiver of liability was necessary within the past 24 months. (Notice of Appeal, p. 4.) IPRO argued that the Agency has not presented any evidence that a rebuttal or waiver of liability was necessary, but rather conjectured without further evidence that if it was not done, IPRO was not performing properly. (Reply Brief, p. 21.)

Finding: IPRO should not receive the 30 points.

The Board is not persuaded that IPRO should receive the points based on its claim that it did not find it necessary to take the actions described in the criterion. The Agency may reasonably choose to award points to PSROs which perform an authorized PSRO function which the Agency considers important. IPRO did not claim, nor does the Record indicate, that IPRO has met this criterion.

> CRITERIA SECTION A. Acute Care Review
> CRITERION II.A.4. PSRO has "carved out" medically unnecessary days during a certified stay in the past 24 months ("Carved out" means denied days within the total stay).

The Agency did not award IPRO the 20 points available for this criterion because the Agency determined that the "documentation of one denied day (in 12 months) plus the PSRO statement 'on rare occasion' was not sufficient to satisfy the substantial performance requirement found in the instructions for completion [of the evaluation]." (AR, p. 379; see also, AR, pp. 22, 381; Tr., pp. 167-72, 205A-07, 5/ 210-15, 368.) The Agency's instructions for filling out the evaluation stated that performance of the activities outlined in the criteria must be sustained throughout the evaluation period.

5/ The pages in the transcript were incorrectly numbered as 204-205-206-205-206-207, etc. The Board has renumbered the second reference to 205 and 206 as 205A and 206A.

The Agency maintained that "carving out" medically unnecessary days was a good indicator of the skill with which a PSRO performed its review functions. The Agency gave the following as an example of a carved out day:

> A patient enters the hospital for diagnostic tests and surgery is scheduled for several days later. Although medically unnecessary, the patient remains in the hospital until the surgery is performed. The days necessary for the tests and the surgery are approved but the unnecessary days in the hospital between the two events must be carved out and those days disallowed.

(Agency Response, p. 22.)

IPRO maintained that "while rarely, IPRO has indeed carved out days within a patient's stay for reasons of level of care." (Appeal Brief, p. 14.) IPRO defined a carved out day as:

> during a patient's length of stay within the hospital, for one reason or another, that the level of care has gone down below the acute level and at that point in time, the PSRO serves a denial and that following that denial and the issuance, the patient's condition deteriorates to the point where they are again at the acute level and the PSRO recertifies them. (emphasis added.)

(Tr., pp. 167-68.)

IPRO submitted as evidence five examples of denials of payment. The Agency did not contest that the first example was a valid denial. The four other examples stated the reasons for denial as "leave of absence from hospital." (Exhibit 1 to Appeal Brief.) The project officer had considered only the first example when she made her evaluation and denied points for this criterion. IPRO maintained that the project officer should have requested additional information and documentation if the example presented by IPRO was insufficient to meet this criterion. (Reply Brief, pp. 23-24.)

The Agency argued that "leave of absence" denials are not denials based on the PSRO's determination but are instead, "coverage determinations requiring automatic denials by the intermediary...without any type of PSRO medical necessity determination." (Agency Post-hearing Brief, p. 5.) The Agency cited the Medicare Manual and 42 CFR 463.26 in support of this statement. The Agency also argued that the absence of an appeal right from the PSRO denial for leave of absence was further evidence that this was not a medical necessity determination, as 42 U.S.C. 1320c-8 provides a right of appeal from that kind of PSRO determination.

IPRO rejected the Agency's reliance on the Medicare manual to support its claim that leave of absence denials are not denials within the meaning of this criterion. IPRO argued:

> ...the Medicare reimbursement Manual really does not say that IPRO's actions are improper or irrelevant to the carved out procedure. It simply states in Section 3104.4 that days on which a patient began a leave of absence are not to be counted. The manual does not state who is to determine when the leave of absence began and ended.

(IPRO Post-hearing Brief, p. 20.)

Finding: IPRO should not receive the 20 points.

Even by IPRO's own definition of "carved out," the leave of absence denials did not qualify because a denial based on a patient's absence from the hospital was not necessarily related to a change in the patient's "level of care." Although there is one example of a carved out day which the Agency does not contest, the criterion requires more than one example. While the Agency arguably could interpret the plural "days" to mean "day" in the context of a single stay, the fact is that the Agency does not do so, and the criterion says what it says — i.e., "days."

> CRITERIA SECTION A. Acute Care Review
> CRITERION II.A.6. PSRO monitors samples of focused out cases.

The Agency did not award IPRO the 15 points available for this criterion because the Agency determined that "[t]he PSRO did not provide documentation to support the criterion that focused out cases are systematically monitored." (AR, p. 383.) The project officer testified that "focused out cases are those where you have determined that something is not a problem and therefore you do not spend your resources on it." She said that, when there has been "focusing out," the only review that occurs is monitoring to see whether a problem has emerged in that area or hospital. (Tr., pp. 370-71.)

The Agency maintained that IPRO used random sampling instead of concentrating review on the identified problems and that, if there were no properly "focused out" cases, there could be no sampling of those focused out cases. (See Agency Response, p. 23; AR, pp. 178, 382; Tr. pp. 98-101, 295, 350, 369, 373.) According to the Agency, the purpose of focused review is to conserve the resources of the PSRO by focusing on problem areas in need of special attention. The Agency maintained that IPRO did not identify and examine particular problems, but, rather, used methods called "body

systems" (which identified patients for PSRO review by general areas such as "Cardiovascular" and "Urinary System" without regard to whether a problem existed in that area) and "terminal digit "(which involved a random selection based on patient identification numbers). (Agency Response, p. 23.) The Agency rejected both these methods of selecting which patients the PSRO would review, claiming that they waste resources by sampling without focusing on problem areas and without a defined objective.

IPRO maintained that it has met this criterion, and argued that the information and documents on which the Agency relied to determine that IPRO did not meet this criterion were not relevant because they were generated after the evaluation period. (See AR, pp. 171-87; Reply Brief, pp. 24-26; Tr., p. 103.) The Agency agreed that items 1-4 listed at AR, p. 170 (which encompass AR, pp. 171-79) should not be considered. (Tr., p. 352.)

Regarding IPRO's method of focusing review, Dr. Meyer testified that terminal digit is "a focusing methodology within the plan," rather than the IPRO's entire focusing plan.

> ...Our focusing program has to be described with the two elements. The focusing in our data gathering, and then extracting from that information and from other episodic reports the information that we receive from our field people, our profile analysis, getting our problem pool from there, and then coming up with problem-oriented focusing which is the final element of our plan. They are all in the plan....

(Tr., p. 103.)

Finding: IPRO should not receive the 15 points.

Even if we do not consider the documentation which was generated after the evaluation period (which ended March 31, 1981), the Record does not indicate that IPRO monitored samples of focused out cases. The two documents generated during the evaluation period are a memorandum from IPRO's Executive Director confirming that IPRO was switching from the body system to the terminal digit system, and comments by the project officer to the effect that "terminal digit" was not an acceptable method because it did not focus on problem areas. (See AR, pp. 184-85.) Except for the general statement by Dr. Meyer that terminal digit is just one element of its focused review, IPRO did not submit any evidence to indicate that terminal digit or some other element of its review system focused on problem areas. And, even if we did accept that the terminal digit system does focus, the Board still could not conclude that IPRO has met the criterion. The criterion

requires the PSRO to monitor samples of those cases which its system "focused out." Even if we were to accept that IPRO's method does "focus," IPRO has not presented any evidence that it monitors samples of the "focused out" cases.

> CRITERIA SECTION II.B. Special Actions to Address Identified Problems. Subsection 1. Modification of Review System CRITERION II.B.1(b) PSRO modified system is based on data and reflects PSRO objectives.

The Agency did not award IPRO the 15 points available for this criterion because the Agency determined that although "the first part was met... there was no link between IPRO's review system and its stated objectives." (Tr., p. 372; see also, AR, pp. 182-87.) 6/ The Agency said that IPRO has failed to implement focused review and has not implemented any other meaningful modified review system, further arguing that:

> IPRO has failed to present any evidence that it had implemented an acceptable modified review system, that the system it did implement was based in any way on any type of data collected, or that it was based in any way on the PSRO's stated objectives.

(Agency Response, p. 25.)

IPRO argued that the main document on which the Agency relied was the project officer's memorandum, dated May 20, 1981, and that it was irrelevant because it was generated after the evaluation took place. (See AR, p. 177.) IPRO argued that the same was true of the other documents in the Record. IPRO did not submit any information in support of its claim to have met the criterion. (Reply Brief, pp. 27-28.)

6/ In support of its determination to deny points on this criterion, the Agency submitted information regarding IPRO's "body system," a memorandum dated March 18, 1981 from IPRO's Executive Director regarding the body system and terminal digits system, and a May 20, 1981 letter from the project officer regarding the terminal digit system. (See AR, pp. 384-89, 170-87.) Although the Agency originally submitted a Small Hospital Waived Review Plan in support of this determination, the Agency withdrew this document and placed it in the section supporting Criterion II.A.6. (See Tr., p. 372.)

Finding: IPRO should not receive the 15 points.

The Board concludes that the Agency stated a reasonable basis for marking this criterion "not met." IPRO objected to some of the documents submitted by the Agency but did not contest that its review systems were the body system and terminal digit system which are discussed in those documents. Although the documents may have been generated after the evaluation period, they refer to IPRO's activities during the evaluation period and are therefore relevant. But, even without these documents, the Board could not conclude that IPRO has met this criterion. The issue here is whether the "PSRO modified system is based on data and reflects PSRO objectives," and there is no evidence in the Record to support such a finding.

> CRITERIA SECTION II.B. Special Actions to Address Identified Problems. Subsection 1. Modification of Review System
>
> CRITERION II.B.1(d) PSRO is focusing its review system based on identified problems in admission policies, such as weekend admissions, Monday discharges, etc.
>
> CRITERION II.B.1(e) PSRO is addressing identified problems through education.
>
> CRITERION II.B.1(f) PSRO is addressing identified problems by performing preadmission review.
>
> CRITERION II.B.1(g) PSRO is addressing identified problems by performing preprocedure review.

The Agency did not award IPRO any of the 45 points available for these criteria because the Agency determined that "IPRO's Executive Director agreed via telelphone [that] these criteria were not met." (AR, p. 390.)

IPRO claimed it should receive the 15, 10 and 10 points for II.B.1(d), (f), (g), respectively, because these criteria were not relevant to IPRO, and IPRO had not identified the type of problems listed in the criteria. (See Exhibit 2 to Appeal Brief; Tr., pp. 173, 215, 373-74.) IPRO claimed that it should receive the 10 points for II.B.1(e) because it met this criterion. (See Exhibit 2; Tr., p. 374.)

The Agency maintained that, contrary to IPRO's assertions that there were no problems identified, IPRO's Impact Objectives for 1981 and 1982 identified problem areas which IPRO could have reviewed (to satisfy criteria II.B.1 (d), (f), and (g)). As examples, the Agency referred to:

- Data indicating Idaho's length of stay [of patients in hospitals] without operation for certain fractures are consistently above regional average.
- A 1980 study that the more costly procedure of abdominal hysterectomy was being performed when a vaginal hysterectomy in specific instances would reduce patient length of stay and cost.
- HCFA reports on surgical rates for 1973-76 which show that Idaho's rate per 1000 eligibles is approximately 50% greater than the regional and national rates.
- A utilization index indicating that chest pain was the 18th major discharge diagnosis for Medicare/Medicaid patients in Idaho.

(Agency Response, pp. 26-27; see also, AR, pp. 325, 343, 345, 350.) The Agency maintained that these problems could have been the basis for further examination, and when appropriate, further action by IPRO. The Agency asserted (at p. 27):

> ... these types of actions go to the heart of the PSRO program and its basic objectives for identifying services that are unnecessary, of poor quality, or provided at an inappropriate level of care. IPRO's statement that no problems existed in ... Idaho during the evaluation period is just not credible given the possiblities of problem identification discussed above.

IPRO maintained that it would be a useless exercise to focus review systems based on identified problems in admission policies or address identified problems by performing preadmission and preprocedure review when in fact there were no such problems identified.

IPRO objected to the Agency's reliance on the telephone conversation between the project officer and the Executive Director as the basis for marking these criteria "not met" without any additional support. IPRO also objected to the use of the impact objectives to support the Agency's actions and argued that "the government...seeks to turn against IPRO its own efforts to comply with the government's requirement to establish impact objectives." (Reply Brief, p. 29.) IPRO characterized the objectives as "an analysis by IPRO of the problems which have occurred in Idaho and their objectives to be met in 1981 and 1982 to solve these problems." (Id.)

Regarding II.B.1(e), the project officer testified that in order to mark this criterion "met," she was looking for such things as "medical directives, educating the medical staff, or the medical society's use of physician assistants or advisors doing education to M.D.'s, local specialists putting on training programs." (Tr., p. 374.)

IPRO claimed that it addressed identified problems through education, (Notice of Appeal, pp. 6-7) and submitted as support a letter from IPRO's Medical Director to a Hospital Administrator, notifying him that an IPRO study indicated the hospital, and particularly, a doctor at the hospital, performed a particular type of surgery four times as often as the State average. The letter said that IPRO intended to conduct more studies on this matter, and offered the hospital "technical or administrative assistance." (Exhibit 2 to Appeal Brief.) 7/ The Executive Director stated that the letter to the hospital was a step in the education process, but admitted that it did not indicate an established educational program. (Tr., p. 216; see also Tr., pp. 173, 215.)

Finding: IPRO should not receive the 45 points.

The Board is not persuaded by IPRO's claim that it should receive the points for II.B.1(d), (f), and (g) because IPRO did not find it necessary to take the actions described in the criteria. The Board is also unpersuaded by IPRO's claim that it is unfair to look to its stated impact objectives in marking these criteria. A PSRO's objectives reflect the PSRO's determination of the problems which it will attempt to resolve. It is reasonable to look to these objectives in light of claims by IPRO that it could not take the actions outlined by the Agency in the criteria because there were no problems. IPRO did not show that the Agency acted unreasonably in choosing to award points to PSROs which performed the review activities outlined in the criteria. Further, to award points for no effort under a criterion would indirectly penalize PSROs which adaquately identified and acted on problems.

The Board also finds that the Record does not indicate IPRO addressed identified problems through education (II.B.1(3)). The letter IPRO submitted in support of its claim to have met this criterion shows that only on one occasion IPRO identified a problem and offered assistance. The letter does not show that IPRO conducted, or participated in, any educational activities or programs.

> CRITERIA SECTION II.B. Special Actions to Address Identified Problems. Subsection 2. Adverse Actions
>
> CRITERION II.B.2(a) PSRO has a defined set of procedures for dealing with potential or actual sanctionable actions.
>
> CRITERION II.B.2(b) Warning letter(s) to institution(s) and/or practitioner(s) issued on actions which could lead to potential sanctions.

7/ IPRO originally claimed that the letter marked Exhibit 2 was evidence that IPRO met criterion II.B.1.(d), but the Executive Director later admitted that Exhibit 2 does not support IPRO's claim to have met that criterion. (Tr., p. 216.)

CRITERION II.B.2(c) PSRO has documentation of resolution of problem(s). Worked with institution(s) and/or practitioner(s) thereby eliminating the need to proceed with sanction recommendation.

CRITERION II.B.2(d) PSRO prepared recommendation(s) on sanction to Secretary forwarded to appropriate party.

CRITERION II.B.2(e) PSRO has undertaken special investigations or reviews of questionable activities by practitioners or institutions at request of State, PI, OPI, HSQB, or other governmental agencies and reported results.

The Agency did not award IPRO any of the 180 points available for these criteria because the Agency determined that IPRO's "Executive Director agreed via telephone that these [II.B.2(a),(d),(e)] criteria were not met" (AR, p. 391), and that IPRO did not provide documentation to support points for II.B.2(b) or (c). (AR, pp. 392-95; see also, Tr., pp. 374-76.)

The Agency argued that Section 1157 of the Social Security Act requires that if a PSRO finds that health care practitioners or providers are not meeting their obligations (as set out in Section 1160 of the Act), the PSRO should report these findings to the Agency so that the Agency may determine whether to invoke a sanction. The Agency argued that: "this PSRO has failed completely to carry out the most minimal of required activities." (Agency Response, pp. 29-30.) An Agency witness stated that these criteria were included in the evaluation because it "is a statutory thing that Congress considered important as an action that a PSRO may take, and it is an indication of an actively performing PSRO...." (Tr., p. 323.) The Agency witness stated that she did not know how many PSROs nationwide had met these sanction-related criteria, or how many sanction actions there were in process or recommended at the time. (Tr., pp. 322-24.)

IPRO claimed that it should have received these points because these criteria were not applicable to IPRO and it was not necessary for IPRO to take sanction actions. (Appeal Brief, p. 20.) IPRO's Executive Director testified that, although the PSRO did not have established procedures (as required by II.B.2(a)), the procedures could be developed concurrently with the identification of a problem. (Tr., p. 205.) Dr. Meyer testified that IPRO seeks to resolve its problems without a sanction recommendation, if possible, because sanction actions involve costly, time-consuming litigation. He said: "[p]ersuasion, education, example are the only reasonable ways. Sanction may be inevitable, but sanction is a last-ditch stand...I feel the high importance placed on sanction and sanction type activities in this rating is inappropriate."

(Tr., p. 139.) IPRO also argued that these criteria were improperly marked "not met" based on the Executive Director's statement that the actions were unnecessary. (Reply Brief, p. 31; see also, Tr., pp. 165-67, 204-07, 216-29.)

IPRO asserted that it met criteria II.B.2(b) and (c), and submitted Exhibit 3 8/ to its Appeal Brief in support of that claim. Exhibit 3 included an excerpt from minutes of a local review committee meeting during which an audit of a hospital was discussed. The minutes stated that deficiencies had been corrected by the hospital and that the Executive Director noted that "sanction proceedings are available but this is a lengthy procedure." The minutes also stated that IPRO took no action in this matter because the medical staff at the hospital were aware of the problems. The second page of the Exhibit is an excerpt from a Board of Directors' meeting in which the progress of two studies is discussed. Regarding an "endarterectomy study" the minutes stated that IPRO staff discussed the study, and "staff were instructed to contact the Chief of the Medical staff at Hospital #13-003 with this information and offer consultation to help correct this problem." Regarding a "craniotomy study," the minutes stated "[t]he results of this study [were] presented... and the hospital's medical staff has taken actions to correct this problem."

IPRO maintained that the local review committee minutes show that the potential for sanctions was discussed, and that the minutes of the Board of Directors' meeting show that problems regarding craniotomies were addressed and steps were taken to correct the problems. (See Appeal Brief, p. 15; Reply Brief, p. 32; Tr., p. 174.) According to IPRO, these documents demonstrate that "IPRO has worked with institutions, particularly the hospitals through its audit procedures, to resolve problems which thereby eliminated the need to proceed with sanction recommendations." (Appeal Brief, p. 15.)

The Agency contended that the minutes of the meeting during which sanctions were discussed are not sufficient to support:

> that there was any problem resolution, active involvement of the PSRO in the efforts directed at problem resolution; that the PSRO actually considered the problem of sufficient magnitude that if it persisted the PSRO would initiate the Sanction process. Therefore, in the absence of documented problem resolution and active involvement of the PSRO the criterion was marked not met.

(AR, p. 393; see also, Agency Response, p. 31.)

8/ IPRO's Executive Director stated that some of the documents in Exhibit 3 were not presented to the project officer at the time of the evaluation. (Tr., p. 218.)

Finding: IPRO should not receive the 120 points for II.B.2(a), (b), (d), and (e). IPRO should receive the 60 points for II.B.2(c).

There was much discussion at the hearing about the importance and role of sanctions to the functioning of a PSRO. The statutory scheme is as follows: Sanctions are imposed against practioners 9/ who violate their obligations under §1160(a) of the Social Security Act. Those obligations are to ensure that services to beneficiaries under the Act are provided only when, and to the extent, medically necessary; that the services are of the quality which meets professionally recognized standards; and that there is evidence of medical necessity and quality in the form required by the PSRO in the exercise of its functions. PSROs have overall responsibility to ensure that practitioners meet their obligations under Section 1160(a). If a PSRO finds that a practitioner has violated its obligations, and the practitioner fails to correct its actions, the PSRO gives the practitioner notice of the finding, and an opportunity for discussion. The PSRO then makes a report and may recommend sanctions to the Secretary of HHS. The Secretary then decides whether to impose sanctions. The sanctions which the Secretary can impose are: to exclude the practitioner from eligibility to be reimbursed for services provided under the the Act, either permanently or for a shorter period of time, or, to require the practitioner to pay a monetary penalty. If a sanction is imposed, the practitioner has the right to an administrative hearing, and subsequently, to court review of the hearing. (See §§1157 and 1160 of the Act, 42 CFR Part 474; PSRO Program Manual, Chapter XX, October 21, 1977.) The Program Manual also states that PSROs are expected to use voluntary, educational methods, and/or denial of payment as the initial and primary methods of correcting behavior which is inconsistent with a practitioner's legal obligations under Section 1160(a).

Although the Agency may have overstated its case when it said that a PSRO which does not engage in sanction activities is not performing "the most minimal of required activities," the Board cannot agree with IPRO's claim that the Agency acted arbitrarily in awarding points for sanction related activities.

Although IPRO argued strongly that the Agency placed undue emphasis on this formal method of correcting inappropriate action by practitioners, the Agency argued with equal strength that an active sanction program is an important part of a good PSRO program. IPRO has not persuasively rebutted the Agency. IPRO has indicated that the Agency might reasonably have a different policy, but the Board will not substitute its judgment for the Agency's in matters of program policy where there are several policy choices and the Agency

9/ Reference to practitioners also includes other providers of health care.

selected one which, though contested, is not unreasonable. In developing criteria to determine which PSROs are most effective, it is not unreasonable, (and certainly not inconsistent with the statute) for the Agency to reward an active sanctions policy. As we have stated before, it is not unreasonable for the Agency to award points to PSROs which perform activities authorized by the PSRO statute and regulations. Also, criterion II.B.2(c) provides points to PSROs which opt for other methods of resolving problems, so that IPRO's approach is accomodated in the criteria.

Having concluded that the Agency can reasonably award points for sanction activity, the Board concludes that IPRO should not receive the 10 points for II.B.2(a) because, even if we do not consider the supposed admission in the April 20 telephone call, IPRO admitted at the hearing that it does not have established procedures for dealing with sanctions. It is not unreasonable for the Agency to award points only to PSROs which have established procedures for performing activities authorized by the PSRO statute and regulations.

The Board concludes that IPRO should not receive the 60 points for II.B.2(b) because, even if we do not consider the April 20 telephone call, there is no evidence in the Record to indicate that IPRO sent warning letters on actions which could lead to potential sanctions. The documents to which IPRO referred in Exhibit 3 made no reference to sending warning letters. In addition, IPRO's Executive Director admitted that Exhibit 3 did not support IPRO's claim that it sent warning letters. (See Tr., p. 219.)

The Board concludes that IPRO should not receive the 30 points for II.B.2(d) because IPRO did not contend, and the Record does not indicate, that IPRO has forwarded a sanction recommendation to the Secretary.

The Board concludes that IPRO should not receive the 20 points for II.B.2(e) because IPRO did not contend, and the Record does not indicate, that IPRO has undertaken any special investigations of the type described in the criterion.

The Board concludes that IPRO should receive the 60 points for II.B.2(c). Although Exhibit 3 by itself is insufficient evidence that IPRO met this criterion, there is persuasive evidence in the testimony regarding IPRO's activities pertaining to craniotomies, which IPRO presented concerning criterion III.C. The Record indicates that IPRO documented the resolution of a problem with a physician who was found to be performing a high number of craniotomies; that IPRO, through its local review committee, presented the information to the medical staff of the hospital where this physician practiced; and that this action resulted in a limitation on that physician's medical privileges. (See Reply Brief, pp. 40-43; Tr., pp. 88-92, 120-25, 185-87, 222-28.) The minutes of the Board of Directors' meeting supported this testimony. In finding that IPRO has met this criterion, the Board

has determined only that IPRO resolved a problem by working with institutions, thereby eliminating the need to proceed with a sanction recommendation. This does not bear on our finding regarding criterion III.C., discussed below.

> CRITERIA SECTION II.B. Special Actions to Address Identified Problems. Subsection 2. Adverse Actions
> CRITERION II.B.2(f) PSRO has removed delegation from at least one hospital under review or hospitals are non-delegated for concurrent review.

The Agency did not award IPRO the 30 points available for this criterion because the Agency determined that IPRO's "Executive Director agreed via telephone that [this] criterion was not met." (AR, pp. 391, 65.) IPRO claimed that it had only four delegated hospitals; that it had extensively monitored these hospitals; and that it had found no reason to remove delegation from these hospitals. 10/ (Reply Brief, pp. 33-34; Tr., pp. 54-60, 104-07, 113, 376.)

The PSRO statute and regulations provide that a PSRO may delegate, to hospitals determined capable, any and all review functions required by the program; that the PSRO is to monitor the hospitals to assure they were properly performing the delegated functions; and that the PSRO is to withdraw delegation in whole or in part if the hospitals do not perform their obligations. (See §1155 of the Act, 42 CFR 466; Tr., p. 55; Agency Response, p. 31.)

The Agency challenged IPRO's claim that it effectively monitored the delegated hospitals (Tr., p. 106), and emphasized the PSRO's duty to reassume responsibilities for review when delegated hospitals are not performing effectively. (Agency Response, p. 31.)

Dr. Meyers testified that most of the approximately 50 hospitals in Idaho are small, widely separated, and ill-prepared by resources and personnel to do their own review, and therefore IPRO did not delegate to them. He stated that the criterion unfairly denied points in the evaluation to

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10/ IPRO's brief stated that IPRO felt that to remove delegation from hospitals granted that status would create animosity and chaos, but Dr. Meyer testified at the hearing that this was not the reason IPRO did not remove delegation from these hospitals. (See Reply Brief, p. 34; Tr., p. 106.) Dr. Meyer also testified that in addition to the four delegated hospitals, IPRO has approximately 12 hospitals which have "limited delegation" for the purpose of conducting Medical Care Evaluation Studies. (Tr., p. 105.)

PSROs that delegated skillfully and prudently. (Tr., p. 57.) He asserted that IPRO properly monitored the delegated hospitals and "found nothing in those reviews to justify the withdrawal or modification of those delegations." (Tr., p. 56.)

Finding: IPRO should not receive the 30 points.

IPRO did not show that the Agency acted unreasonably in determining that IPRO did not meet the criterion. IPRO did not contend, and the Record does not indicate that IPRO performed the activities required to meet (and receive points for) this criterion. IPRO's claim, essentially, was that it did not need to perform the activity described in the criterion, not that the criterion was unreasonable on its face. This is an insufficient basis to overturn the Agency's decision. The criteria allowed PSROs to earn a potential 2350 points for performing a variety of activities, but required that PSROs attain a total score of less than half that amount in order to pass the evaluation. Under these circumstances, an otherwise reasonable criterion, which awards points to PSROs that perform an activity authorized by statute and regulations, is not made unreasonable by the fact that a PSRO may not have had occasion to perform that activity.

> CRITERIA SECTION II.C. Medical Care Evaluation Studies /Quality Review Studies
> CRITERION II.C.1. QA [quality assurance] plan includes a detailed procedure to assure that topics are based on known or suspected problems important to patient care outcomes, and contains a method to prioritize problem areas in selecting study topics for a given year.

The Agency did not award IPRO the 20 points available for this criterion because the Agency determined that IPRO "did not provide documentation to support marking the criterion met." (AR, p. 396.) The Agency characterizes IPRO's objection to how this criterion was marked as, "[IPRO] now alleges that the Quality Assurance Plan is a new requirement currently in the approval process...." (But, as discussed below, IPRO claims this is a mischaracterization of its argument.) The Agency maintained that QA plans are not new requirements and that IPRO submitted a "deficient" draft of its plan on September 29, 1980. The Agency asserted that substantial revisions were required but IPRO had not, as of August 3, 1981, submitted a corrected plan. (Agency Response, p. 32.) The project officer testified regarding Agency requirements for QA plans and stated that she "marked the criterion not met because the method to prioritize the problem area was not detailed as to who was involved and whether it was hospital staff and that sort of thing." (Tr., p. 357-60, 377; see also, AR, pp. 192-266.)

The project officer testified, and Agency memoranda in the Administrative Record stated, among other things, that IPRO's QA plan:

- lacked objectives and instead included broad goals which did not include specific measurable steps on how to reach those goals;
- needed to include criteria for monitoring studies by delegated hospitals;
- needed to focus on problems; and
- needed to include information on how hospitals are going to be monitored and what technical assistance IPRO will provide.

(See AR, pp. 189, 217-20; Tr., pp. 257-60.) IPRO submitted another draft of its plan after it received those comments from the Agency.

IPRO maintained that this criterion should have been marked "met," not because quality assurance plans are a new requirement, but because "new expectations have been developed for meeting this requirement." (Reply Brief, p. 35.) IPRO claimed that its earlier submissions of its QA plan reflected the "state of the art" for quality assurance plans and that any deficiencies in the plan were a result of "the inability of the agency to communicate a desire to have these plans meet new requirements." (Id.) IPRO challenged the assertion that the plan submitted in August, 1980 was inadequate, and stated that revisions required as of August 3, 1981, "are outside of the review period for the performance of evaluation.... The fact that IPRO may or may not have failed to submit a corrected plan as of August 3, 1981, is not germane to this appeal." (Id.; Notice of Appeal, p. 10.)

IPRO submitted Exhibit 12 in support of its position. IPRO identified Exhibit 12 as an excerpt from the Quality Assurance Plan and stated that the plan was submitted to Region X for review and comment numerous times during the evaluation period. (See also, Tr., pp. 181, 376; AR, pp. 192-98.)

IPRO's plan stated that each year IPRO would develop a list of six to eight problems or areas of concern based on data available from the following sources:

- Data generated from hospital abstracting systems, national PSRO data, length of stay (LOS), procedures/diagnoses, and mortality.
- Documented proof of problem or potential area of concern; for example, through concurrent review, QPC (Quality of Patient Care) findings, etc.
- Input from hospitals, interactions with practitioners, providers, Medicare, Medicaid and other health agencies.

The plan also stated that "the most severe problems will be given priority status. If a choice between two equally serious problems must be made, it will be recommended that the number of patients affected by the problem be the basis for problem selection." (AR, p. 195.) The plan then listed and ranked the severity of several categories of problems.

Finding: IPRO should receive the 20 points.

The Board concludes that the Agency has not stated a reasonable basis for its determination that IPRO has not met this criterion. The Board finds that the Agency's emphasis on how often IPRO had to revise its plan is inappropriate. The Board also finds that IPRO's failure to submit its revisions according to deadlines set by the Agency is not relevant. The criterion does not specify that the number of revisions, or the timely manner in which they are made, are critical factors. A reading of the latest version of IPRO's QA plan indicates that IPRO incorporated all the suggestions for revisions made during the evaluation period by the project officer and central office. (See suggestions at AR, pp. 217-20; revised plan at AR, pp. 192-216.) In addition, the project officer testified that prior to the submission of the latest draft, which she admitted she thought would be the last draft (Tr., p. 360), "we had gone over all the comments again ... I tried to help them develop it [the plan] so that we didn't leave any holes or anything in the quality review plan...." (Tr., p. 359.) She then submitted the plan to central office on March 24, 1981 for review. According to a memorandum in the Record, dated June 11, 1981, (AR, p. 191), the Agency's central office had additional suggestions for IPRO's plan. The Agency did not show that without these additions the plan could not "assure topics are based on known or suspected problem areas important to patient care outcomes." In addition, the Agency did not show that IPRO failed to address any of the objections the Agency had raised. It is not reasonable to penalize IPRO for failing to include information that was suggested after the period of the evaluation.

> CRITERIA SECTION II.C. Medical Care Evaluation Studies/
> Quality Review Studies
> CRITERION II.C.5. Reaudits (follow-up) conducted on at least one half of the studies that resulted in deficiencies by at least one year after the required follow-up.

The Agency did not award IPRO the 15 points available for this criterion because the Agency determined that IPRO's documentation was not sufficient to support a scoring of "met." Regarding the documentation submitted,

the Agency stated, "[t]he PSRO simply lists the area wide audit topics without time frames. No documentation on other audits was included. The documentation did not address the volume of reaudit activity completed underway, or planned." (AR, p. 397; see also, Agency Response, p. 32.) The project officer also testified that in the last three quarters of 1980 IPRO had 229 studies and had restudied only 29 of those. (Tr., p. 379.)

IPRO maintained that it did require follow-ups and submitted Exhibit 4 in support of its claim. (See also, AR, p. 399; Tr., pp. 174, 228, 377-78). Exhibit 4 is a document, entitled "Reaudits-Area-Wide," listing seven topics, with an indication of whether a reaudit was completed or whether a year had not yet passed. IPRO argued that if the document submitted in support of a criterion was insufficient, "the project officer should have indicated such, in writing, and requested further documentation." (Reply Brief, p. 36.)

Finding: IPRO should not receive the 15 points.

The Board concludes that the Agency stated a reasonable basis for marking this criterion "not met," and that IPRO's claim to have met the criterion is not supported by the evidence in the Record. IPRO's Executive Director testified that the information in Exhibit 4 applied to the period of the evaluation (Tr., p. 175), but also admitted that the exhibit did not indicate the total number of studies IPRO had done, and that he did not know how many had been done. (Tr., p. 229.) Even if the project officer arguably should have requested additional information during the evaluation, IPRO has had the opportunity to submit evidence to this Board, but did not do so. IPRO claimed that Exhibit 4 provided additional information to support its claim, but Exhibit 4 and AR 399 appear to be the same document.

> CRITERIA SECTION II.C. Medical Care Evaluation Studies/ Quality Review Studies
> CRITERION II.C.7. Areawide studies or multihospital studies have demonstrated improved care across area hospitals in 90% of studies.

The Agency did not award IPRO the 15 points available for this criterion because the Agency determined that the documentation IPRO provided was "only a list of study topics and there has been no documentation of improvement in care." (AR, pp. 400-02; see also, Agency Response, p. 33.)

IPRO maintained that it met this criterion and submitted Exhibit 5 in support of this claim. Exhibit 5 included a list of area-wide audits and reaudits, a memorandum dated February, 1981 regarding reaudits of Hospitals #21 and #36, and three documents, undated, and with no indication of their source,

which referred to area-wide studies regarding chest pain, vaginal versus abdominal hysterectomy, and endarterectomy. The Executive Director identified Exhibit 5 as "a list of area wide audits we have completed and a list of reaudits proposed." (Tr., p. 175.) IPRO claimed that "[t]his documentation shows that the IPRO area-wide audit and reaudit system showed improved care achieved in all cases where these further studies were conducted." (Appeal Brief, pp. 16-17; see also, Notice of Appeal, p. 10; Tr., pp. 175, 230-31, 379.)

Finding: IPRO should not receive the 15 points.

The Board concludes that the Agency stated a reasonable basis for marking this criterion "not met," and that IPRO's claim to have met this criterion is not supported by the evidence in the Record. A list of area wide audits without any reference to the results, or any mention of the effect on health care, does not satisfy the requirements of this criterion.

> CRITERIA SECTION E: Profiles
> CRITERION II.E.2. PSRO routine reports provide for a systematic comparison of institutions, practitioners, and diagnostic groups in order to identify potential problems. The reports are case-mix adjusted and prioritize possible utilization problems based on the potential for reducing inappropriate use.

The Agency did not award IPRO the 30 points available for this criterion because the Agency determined that "[t]he PSRO Executive Director and the Data Manager agreed via telephone (4/20/81) that routine reports are not case-mix adjusted and do not prioritize possible utilization problems based on the potential for reducing inappropriate use." (AR, p. 404; Agency Response, p. 33.)

The project officer testified that in her conversation with IPRO representatives, IPRO "agreed that they had no way to prioritize utilization problems based on the potential for reducing inappropriate use, and they also submitted no information on the case-mix." (Tr., p. 380.) The Agency asserted that:

> case-mix is a sophisticated data system and it is essential that a satisfactorily functioning PSRO look at data by case-mix. Raw data will not properly identify problems. Case-mix allows the PSRO to look at 'like' cases so that, for example, length of stay of a tonsillectomy is not compared to length of stay for brain surgery."

(Agency Response, p. 34; see also, Tr., pp. 379.)

IPRO maintained that this criterion was met. IPRO asserted that although routine reports are not case-mix adjusted, "problem areas are identified through routine reports," and "the thrust of this criterion is met by IPRO's current activities." (Reply Brief, pp. 37-38.)

Finding: IPRO should not receive the 30 points.

IPRO admitted that it did not meet the literal requirements of the criterion (in that its routine reports are not case-mix adjusted) but claimed that its reports accomplished the same result. IPRO did not, however, present any information about its routine reports or how those reports accomplished the same result. The Board cannot reverse the Agency's determination based on IPRO's unsubstantiated claim to have met "the thrust of this criterion."

Part III of the Evaluation Criteria - Performance of Review-Impact/ Potential Impact

IPRO received 380 of the 1200 available points in this section; IPRO needed 515 points in order to pass this section. The Board concludes that IPRO should receive an additional 45 points in this part. IPRO disputed the Agency's determination of points for criteria section III.A. and criteria section III.C.

CRITERIA SECTION A: Management Objectives

Section A rated a PSRO's objectives based on whether they met one of five stated levels for calendar years 1979 and 1980, or the last and current grant period, not to exceed 24 months. IPRO was scored at a "level 2" for the last grant period of March 1980-1981 and the current grant period of March 1981-1982. (Agency Response, p. 37; Tr. pp. 381-86.) IPRO maintained that it should have received a "level 4" for those years. A PSRO scoring at a level 2 was awarded five points for the last grant period and 10 points for the current grant period; a PSRO scoring a level 4 was awarded 50 points for the last grant period and 80 points for the current grant period.

Level A.2. reads as follows:

> PSRO has great difficulty setting objectives which comply with criteria: objectives do not reflect significant problems; do not have measurability; have insufficient or unrealistic methodologies, that is, methodologies which by themselves could not accomplish intended outcome; lack time frames; do not follow prescribed grant application format. Or, the PSRO was unable to develop acceptable

> objectives in a timely fashion, i.e., preaward, without extensive technical assistance involving prolonged mediation by the project officer which required additional face-to-face or telephonic negotiation and that at times required specific intervention from higher level and Regional and/or Central office staff.

Level A.4. reads as follows:

> PSRO sets 4-8 objectives each grant period which met the criteria addressed in III.A.2., and reflect the activitiy and priorities of the PSRO. The objective methodologies and measurements have been developed so as to require only minimal modifications during the grant cycle (minimal modifications include refinement of data measurements, shifting of time frames by no more than 30 days, etc.).

The project officer testified that she marked this criterion based on the requirements prior to the "or" in level 2. (Tr., p. 381.) The Agency said that no greater score was given because IPRO's objectives for both years lacked time frames, identified problems lacked significance, methodologies were insufficient, objectives lacked measurability, and the grant application format was not followed. The Agency stated that IPRO "still requires (after 2 1/2 years of objective setting) extensive technical assistance in order to meet minimal criteria for objectives." (See AR, pp. 405-06; Agency Response, p. 34; Tr., pp. 231-36, 380-86.)

The Agency stated:

> The PSRO submitted objectives which had very little breadth and depth, furthermore, as their own progress reports indicate, these "problems" had been verified or developed by the PSRO prior to their submission as objectives. In fact the great majority of these so-called problems were discovered to be coding errors and thus excused as objectives by the PSRO. All this with no specific objective-related impact or substitution of new objectives.

(AR, p. 406)

IPRO maintained that it should have been scored at Level 4 because it had 4-8 approved objectives, and submitted Exhibit 7 in support of its claim. (See Tr., pp. 176-77, 425; Notice of Appeal, p. 12; Appeal Brief, pp. 17-18; Reply Brief, pp. 38-40.) Exhibit 7 contained IPRO's objectives for 1980-81 and 1981-82. (See also, AR, pp. 158-61, 321-51, 354, 362-65.)

IPRO maintained that Exhibit 7 shows that "the objectives were developed based upon guidance and direction provided by Region 10 through the project officer... and there was no great difficulty in developing objectives." (Appeal Brief, p. 18.) IPRO also argued (at p. 18) that:

> [i]n any event, the difficulty of developing objectives in the grant application and planning process is irrelevant to the effectiveness of a PSRO. The question is and should be whether the goals and objectives are properly defined, are significant and have indeed been developed and accepted by appellee. In this case, this is exactly what occurred.

IPRO challenged the Agency's statements regarding the need for technical assistance, claiming, "any dialogue with the project officer or departmental officials has only been that necessary to the incorporation of the latest state of the art management/objectives." (Notice of Appeal, p. 12.) IPRO also argued that it was unfair to be downgraded for using technical assistance when the Agency offered it in the form of a grant to participate in objective setting. (Tr., pp. 183-85.)

Finding: The Board concludes that the Record does not support the Agency's determination that IPRO's objectives had the deficiencies set out in level 2. Essentially, the only difference between the portion of level 2 on which the Agency based its determination, and level 3 is that level 3 requires an absence of the deficiencies described in level 2. 11/ Therefore, the Board concludes that IPRO should receive at least a level 3. Level 3 reads as follows:

> PSRO met objectives which minimally met the criteria (in III.A.2.). Experience shows that the PSRO has had to make extensive major modifications (50 percent or greater of the objectives in either of the two grant cycles being evaluated) of the objectives during or at the end of the grant cycle. Major modifications being changes in the methodology or proposed outcome which might have been accounted for if the objective had been adequately developed prior to submission.

PSROs scoring at a level 3 were awarded 20 points for the last grant period and 40 points for the current grant period (as contrasted with 5 and 10 for level 2).

11/ Level 3 also requires a determination that at least 50 percent of the objectives require modification in methodology or proposed outcome. Although the Record does not indicate that such a determination was made, the extent of modification differentiates between levels 3 and 4, not between 2 and 3.

The project officer testified about the alleged deficiencies in the objectives for the current grant period which led her to award IPRO a level 2; she did not testify regarding any specific deficiencies in the objectives for the last grant period. For the current period, she commented on Objective 2, at AR, p. 343, regarding hysterectomies. She said the objective was not measureable because there was no indication of the source of the 27% figure (which she also said should have read 24%). (Tr., p. 384.) She explained that to be measureable it should include specific numbers such as "from 4.5 days to another level of care." (Tr., p. 385.) She said that although the objective alleged that there was "high utilization," it did not contain any numbers to define "what high utilization is." (Id.) She also said that the methodology was weak because IPRO's planned intervention was at an inappropriate time.

The project officer's criticisms were addressed to a preliminary version of the objectives. The preliminary version which appears at AR 343 read as follows: "[r]educe the number of abdominal hysterectomies which may be performed as vaginal hysterectomies by 27% by January, 1981." (AR, p. 328; see also Exhibit 7 to Appeal Brief.) The revised objectives IPRO submitted on January 28, 1981 (AR, pp. 322-52) appear to respond to those concerns. The objectives in the latest version read as follows:

> [r]educe the number of abdominal hysterectomies which may be performed as vaginal hysterectomies by 24% from 1.53 cases/1000 eligibles to 1.17 cases/1000 eligibles by January 31, 1982.

The later version incorporated the additional information the project officer stated was necessary. The project officer's comments regarding utilization were also addressed in the later version, which stated:

> [t]he IPRO Data Department performed a utilization index for the first six months of 1980, which indicated that 179 hysterectomies were performed in the state, 109 were abdominal and 70 were vaginal or a ratio of 1.56:1.

This appears to respond to the Agency's concern regarding numbers to indicate "what high utilization is."

The project officer also testified regarding the alleged deficiencies in Objective 3, on reducing the rate of cholecystectomies performed. (Tr., pp. 385-86.) Of the objective, she said, (at p. 385):

> Basically it's the same problem, they didn't have data source, they didn't have measureability... and the intervention step came at an inappropriate time, so their methodology was very weak....

The objective to which she referred at AR, p. 345, had also been revised; the earlier version to which she referred read as follows:

> To reduce the Medicare rate of cholecystectomies performed from 4.5 per 1000 eligibles 5% by January 31, 1982.

The revised version submitted to the Agency on January 28, 1981, (at AR, p. 332) stated that the objective was to reduce the rate "from 4.5 per 1000 eligibles, 5%, to 4.0 per 1000 eligibles by January 31, 1982." Both versions indicated that Agency "reports on surgical rates for 1973 and 1976 show Idaho's rate per 1000 eligibles to be approximately 50 per cent greater than regional and national rates both in provider and beneficiary studies." The later version added that the source of the information was "PHDDS data." Again, it appears that the project officer's concerns were addressed in the later version of the objectives.

In addition, the project officer's testimony about the 1981-1982 objectives is contradicted by a site report she wrote, dated February 10, 1981, in which she stated that IPRO's objectives were "acceptable" (it specified that objectives 1,3, and 4 were acceptable "per IPRO's revision of 1/28/81"). (AR, p. 332.) The site report commends IPRO staff "on their excellent expansion of the proposed impact objectives and for including quality of care issues as well as utilization issues in these objectives." (Id.) This memorandum did not indicate that the objectives had the deficiencies described in level 2.

The Board concludes, in addition, that the Record does not support the Agency's determination that the objectives for the last grant period merit a level 2. IPRO submitted seven objectives for the last grant period in support of the claim that it merited a level 4. Objectives 1, 2, and 3 identified a potential "high utilization problem," but concluded that there was in fact no high utilization. They stated that high utilization had been suspected because of errors in the coding of data. These three objectives were therefore deleted. (This, however, is less than the "great majority" which the Agency claimed were deleted because of coding errors. See AR, p. 406.)

The Agency has not shown that the other four objectives for the last grant period are markedly different from the current objectives, and a reading of the objectives does not support the Agency's finding that they lack measurability and specificity. The Agency did not present any explanation besides the bare assertion that these objectives had the type of deficiencies described in level 2, to support its determination.

Having determined that the Record does not indicate that the basis for the Agency's determination was correct, the Board finds that IPRO should receive at least a level 3 for both sets of objectives. IPRO claimed that it merited a level 4.

Whether IPRO should be scored at a level 4 depends on the extent of modification that is required of the objectives. Besides requiring that the objectives minimally meet the level 2 criteria, level 3 stated: "[e]xperience shows that the PSRO has had to make extensive major modifications (50% or greater of the objectives in either of the two grant cycles being evaluated) either during or at the end of the grant cycle." It defines major modifications as: "changes in the methodology or proposed outcome which might have been accounted for if the objectives had been adequately developed prior to submission." Level 4 stated: "[t]he objective methodologies and measurements have been developed so as to require only minimal modifications during the grant cycle (minimal modifications include refinement of data measurements, shifting of time frames by no more than 30 days, etc.)."

The Board cannot make a finding on the extent of modification which would be required based on the information currently in the Record, and therefore cannot find that IPRO did or did not merit a level 4. Neither the Agency nor IPRO presented information regarding the extent of modifications that would be required for these objectives. It is not clear how, at the time of the evaluation (in May, 1981), the Agency could have determined whether IPRO's objectives for the current grant period (which did not begin until March, 1981) would require modifications "during the grant cycle."

In addition, level 4 requires that the objectives "reflect the activities and priorities of the PSRO;" and there is insufficient information in the Record to indicate whether IPRO met that requirement.

The Board would have remanded the issue of whether IPRO met level 4 to the Agency for a determination, but for the fact that with a level 3 score IPRO achieved sufficient points to pass this evaluation.

CRITERIA SECTION C: Impact - Quality

Section C rated a PSRO's documented impact on the quality of care. PSROs were awarded from 0 to 350 points, depending upon the Agency's determination of which of four levels a PSRO had attained. IPRO scored a level two; PSROs scored at level two were awarded 50 points. IPRO claimed it should have been scored a level three; PSROs scored at level three were awarded 250 points.

Level C.2. reads as follows:

> PSRO documented isolated quality impact, affecting only a few physician or patient groups. Changes were small and insignificant. PSRO may have had some influence in causing impact, but failed to make any case that it was primarily responsible.

Level C.3. reads as follows:

> PSRO documented quality impact. Documents showed impact encompassed significant proportion of physicians or patients (10%-25%) or at least one pattern of life threatening incidence was reduced; (1) Change was clearly significant in that it improved patient care management or outcome of care for a selected category of patients by a small percentage of physicians; (2) Interventions by the PSRO seemed largely responsible for the impact, though other factors or trends may also have been significant; (3) Modified behavior patterns were clearly documented.

IPRO originally claimed to have met level 3 based on activities involving physicians who performed endarterectomies and craniotomies (Notice of Appeal, pp. 18-20; Reply Brief, pp. 40-43), but during the course of the hearing IPRO stated that it was relying on its activities regarding the craniotomies to support its claim that "at least one life threatening incidence was reduced." (Tr., pp. 86, 118.)

The Agency's stated basis for marking this criterion was:

> The PSRO has submitted no documentation in quality which would justify greater points. Though they do not specifically identify the "life threatening" situation which they purport should have been considered, it is our understanding that they make this claim on a study dealing with endarterectomy. Only the physician was identified in this study as having questionable practice patterns which were not specifically or directly life threatening. The PSRO, furthermore, has not documented that it took any specific interventions, but rather dropped the matter because the physician left the State. If the PSRO had considered the situation as one of life-threatening, would it not be logical to expect them to pursue the problem regardless of the fact the physician was not practicing in Idaho, but rather, elsewhere.

(AR, pp. 168, 406; see also Agency Response, pp. 12-13.)

The Agency's testimony at the hearing was that IPRO could not prove that intervention by the PSRO was largely responsible for the impact and that the project officer did not receive documents with statistics on impact until June 1981. (Tr., p. 386.) The project officer stated that if she had had statistics which showed change, that if the PSRO was responsible for the change, and that if it met the wording of the criterion, she would have scored this criterion differently. (Tr., p. 402.) She stated that IPRO presented baseline numbers of the craniotomies done but that to score IPRO at a higher level, she needed impact information showing the numbers after IPRO's interventions. (Tr., p. 403.) The project officer also stated:

> I would have to see proof that Idaho, IPRO was responsible for changing that physician's behavior, and that the medical staff wouldn't have done anything on their own.... I would like to see proof that Idaho actually made an impact and that they actually did something. I would need to see a definition of inappropriate. I still don't know, and IPRO did not define what appropriate versus inappropriate craniotomies and craniectomies were.

(Tr., p. 427.)

The Agency also stated that, "there are no statistics that indicate in any way that the procedures performed before were unnecessary, or that those not performed would have been appropriate. There is no indication that any PSRO criteria for expertise was ever used to evaluate this behavior." (Agency Post-hearing Brief, p. 13.)

IPRO contended that the Agency's statement of reasons for marking this criterion indicated a confusion regarding IPRO's activities involving the craniotomies. (See, e.g., Tr. p. 92). IPRO maintained that the situation in which a physician left the State involved the craniotomy study, and that in any event, IPRO did take further action after the physician left the State.

IPRO explained its activities as follows:

> [A physician] was performing a high number of these procedures [craniotomies]. IPRO was able to identify that this physician was involved in this incidence by utilizing IPRO's small area variation technique, since the provider based rate and beneficiary based rates were inexplicably higher than could be expected. IPRO therefore performed a limited quality assurance study to determine various aspects of outcome and 'redo' rates. Once this information was compiled, an IPRO staff meeting was held and it was determined that the

> situation warranted physician involvement and guidance. The information was taken to the appropriate local review committee (comprised of physicians and one hospital administrator in the immediate area). The committee reviewed the data and took the information as further evidence to warrant and substantiate a modification, by the hospital medical staff, of the affected physician's admitting and surgical privileges. Subsequent to this action, IPRO was informed by its local regional director in the area that the physician was moving from the area to Sacramento, California ... [and] in late January or early February, IPRO's Executive Director [called] ... the Executive Director of the Sacramento PSRO and informed him who this physician was and the statistical findings in Idaho.

(Reply Brief, pp. 40-43; see also Exhibit H-2; and Tr., pp. 88-92, 120-25, 185-87, 222-28.) In his testimony, Dr. Meyer explained that a craniotomy involved the opening of the bony tables of the head to do either exploratory or definitive procedures on brain tissue and stated that it was "absolutely" life threatening. (Tr., p. 87.) 12/

Dr. Meyer also stated that the Agency was aware of these activities because they were the subject of IPRO's Objective 6A for the last grant year. (Tr., p. 89.) In response to Agency questions about statistical data regarding these activities, Dr. Meyer responded that as a result of IPRO's activities there was 100 percent modification in that the offending doctor does not do the procedure any more. (Tr., p. 128.) The Executive Director denied the Agency's implication that IPRO's Medical Director should have done the study, stating that the medical director was consulted and that, "the logical progression then was to go to the local committee." (Tr., p. 240.)

IPRO's documentation regarding the craniotomy study is Exhibit 8 to its Appeal Brief. Exhibit 8 includes copies of stated objectives for the year, which are "to reduce by 50% the number of inappropriate craniotomies and craniectomies by March 31, 1981." The documents include as "Conclusions," information that as a result of the regional committee's report to the hospital, the surgeon was required to have consultation before surgery was recommended and an "assist only" limitation was placed on the surgeon. The documents also state that 39 craniotomies were performed in 1979, 18 percent by this physician; 21 craniotomies were performed in 1980, nine percent by this physician. Further:

12/ The Agency stipulated during the course of the hearing that the procedures were life threatening. (Tr., pp. 386, 79.)

> [t]he inappropriate craniotomies and craniectomies were reduced by 50% as doctor A needed surgical consultation before performing the procedure. In 1981 Physician A left the State of Idaho.... This reduced his inappropriate craniotomies and craniectomies completely in the State of Idaho.

(See 4th and 5th pages of Exhibit 8.) This information regarding IPRO's craniotomy activities also appears in the AR under the subsection for the 1978-1980 grant award though not in the identical form. (See letter dated January 30, 1981 from the Director of the Region X PSRO regarding IPRO's request for continued funding for the period March 31, 1981 through March 30, 1982; and AR, pp. 158-63.) This memorandum includes a statement of IPRO's progress toward the achievement of its objectives, specifically Objective 6.b, which was to reduce the number of inappropriate craniotomies and craniectomies by 50% by March 31, 1981. The Executive Director stated that had the project officer asked him for additional information documenting these activities, he could have provided that information.

Finding: The Board concludes that while it does not have sufficient information to award IPRO a level 3 based on its craniotomy activities, the Agency has not shown that its stated reason for marking this criterion at level 2 is valid. IPRO stated that it had additional statistical and other information which it could make available to the Agency in support of its claim that at least one pattern of life threatening incidence was reduced.

It is not clear from the record whether IPRO claimed impact because it identified a physician who performed a greater-than-average number of this type of surgery, or whether it determinated that the surgery performed by this physician was medically inappropriate (and if so, on what basis this determination was made, or whether such a determination is necessary). It may be, although the parties have not so indicated, that simply reducing the number of these operations would in fact be reducing a pattern of life threatening incidence. Although the Agency implied that IPRO did not fulfill this requirement because it delegated certain responsibilities to a local committee, the Agency did not show that such delegation was in fact inappropriate under the circumstances. The Record does include certain statistics regarding the numbers of craniotomies performed, but does not specify whether all those performed by the physician in question were considered inappropriate, whether any were so considered, and how the reduction in numbers compared with the State or national average for such operations. Without this type of information, the Board cannot determine whether or not IPRO merits a level 3 score.

But for the fact that IPRO has achieved sufficient points to pass this evaluation, the Board would have remanded this criterion to the Agency for further consideration.

IV. Conclusion

Based on the foregoing analysis, the Board has determined that the Record does not support the Agency's determination to terminate IPRO's grant, and that IPRO should have received at least the minimum required total score and at least minimum scores on two of the three parts required to pass the evaluation.

/s/ Cecilia Sparks Ford

/s/ Norval D. (John) Settle

/s/ Alexander G. Teitz
Presiding Board Member