

DEPARTMENTAL GRANT APPEALS BOARD

Department of Health and Human Services

SUBJECT: Prince George's Foundation for Medical Care, Inc. DATE: December 31, 1981
 Docket No. 81-106
 Decision No. 241

DECISION

Introduction

The Prince George's Foundation for Medical Care, Inc. (PGFMC) appealed the Health Care Financing Administration's (Agency) decision to terminate its grant, No. 97-P-99636/3, effective November 30, 1981. The determination provided that the grant would be extended, if necessary, to permit this Board to make a final decision. In its appeal letter, dated July 16, 1981, PGFMC requested a hearing pursuant to §1152(d)(2) of the Social Security Act (Act). A hearing before the Presiding Board Member was held in Washington, D.C., on September 14 and 15, 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 set out below, we conclude that PGFMC's grant should not be terminated.

1/ Below we refer to PGFMC's "Notice of Appeal," dated July 16, 1981, as Notice of Appeal; PGFMC's "Grant Termination Appeal" file dated July 16, 1981, as PGFMC Appeal; the "PGFMC Grant Termination Appeal Supplement," dated July 30, 1981, as PGFMC Appeal Supplement; the "Response of the Health Care Financing Administration," dated August 24, 1981, as Agency Response; the Exhibits submitted in conjunction with that response as Agency Exhibit; the "PGFMC Grant Termination Appeal Supplement II," dated September 10, 1981, as PGFMC Appeal Supplement II; the parties' post-hearing briefs dated October 9, 1981 as Agency Post-hearing Brief and PGFMC Post-hearing Brief.

On October 22, 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 letter dated October 27, 1981, PGFMC responded that "we consider this opinion irrelevant to the case at bar." 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 the 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 PGFMC - how it was conducted, and what general objections PGFMC raised regarding the evaluation. The third section sets out the Board's findings and conclusions on whether PGFMC 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:

These 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. 8-9.) 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. 4.) 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 or 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, with instructions for marking 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.

. . .
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.

. . .
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.

(See, e.g., Agency Exhibit C.)

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," and representatives from central office staff were sent to the regions to review the evaluations and determine the validity of the supporting documentation. (Agency Response, pp. 4-5.) Mr. Paul Mendelsohn, Senior Public Health Analyst for the PSRO program, testified that the central office also conducted telephone conferences with regional personnel to discuss the evaluation criteria. (Tr., p. 246.) He 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. (Id.)

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, e.g., Agency Response, p. 7.)

II. The Evaluation of PGFMC

A. Summary of the Scores Awarded PGFMC

The Agency awarded PGFMC a base score of 935 points, 170 points short of the 1105 points needed to pass the evaluation. PGFMC passed Parts I and II with 250 and 575 points respectively. PGFMC did not pass Part III; PGFMC's score of 110 was 405 points short of the 515 needed to pass.

B. PGFMC's Objections to the Criteria

PGFMC presented a number of arguments contesting the validity of the national evaluation process and of individual criteria. (See, e.g., PGFMC Post-hearing Brief, pp. 1-2.) The Board finds it unnecessary to address PGFMC's arguments since the Board has determined that PGFMC should have been awarded a sufficient number of points to pass the evaluation.

C. Deference to the Agency's Determination

The Agency contended that in judging the evaluation process:

[T]he Board must note how the government worked to assure that the process was even-handed and how it was uniformly

applied not just to PGFMC but to every PSRO in Region III (Philadelphia) and across the country.

(Agency Post-hearing Brief, p. 10.)

The Agency argued that if the Board is satisfied that the evaluation was fairly designed and applied, the Agency's administrative decision to terminate PGFMC's grant should be accorded deference by this Board and accordingly upheld.

The Board has previously stated 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. (See, e.g., Wisconsin Department of Health and Social Services, Decision No. 116, August 14, 1980; New York Department of Social Services, Decision No. 101, May 23, 1980; Family Health Care, Inc., Decision No. 147, January 29, 1981.)

Nevertheless, the Agency had a burden to support its determination that PGFMC did not meet certain criteria. The Agency had to show a reasonable basis, supported by the Record, for its determination on the contested criteria in order for the Board to uphold the determination. PGFMC had a corresponding obligation, as the appellant, to demonstrate where the Agency's evaluation of PGFMC lacked a reasonable basis ^{2/} or to show either that PGFMC met the criteria or performed at a certain level described in the criteria. (See, e.g., Idaho Professional Review Organization, Decision No. 236, December 8, 1981.)

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

This portion of the decision sets out each criterion in dispute (in the same order as it appears in the evaluation criteria), the arguments of the parties regarding whether PGFMC should receive points for the criterion, and the Board's findings.

^{2/} In those cases where a criterion was marked "not met" because there was no evidence that PGFMC 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.2(d).)

Part I of the Evaluation Criteria: Organization and Program Management

PGFMC received 250 of 300 possible points on this part; 190 points were needed to pass. PGFMC disputed the Agency's scoring of the following criterion in this part:

CRITERIA SECTION D. Relationship to State. Indicators of State relationships:

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 had originally scored this criterion as "not met" by PGFMC. However, based on testimony adduced at the hearing and discussions with different people within the Agency, the Agency determined that PGFMC had indeed met this criterion. (See, Tr., p. 420.) Therefore, PGFMC should receive the 10 points for this criterion.

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

PGFMC received 575 of 850 possible points in this part; 400 points were needed to pass. The Board has determined that PGFMC should receive an additional 110 points for this part. PGFMC disputed the Agency's scoring of the following criteria in this part:

CRITERIA SECTION A. Acute Care Review. Indicators of acute care review process are:

CRITERION II.A.1. The review process is resulting in the issuance of at least 10 denials per 1000 discharges under review.

Although this criterion was marked as "not met" on the evaluation, the Agency subsequently conceded that PGFMC had met this criterion and should be awarded 15 points. (See, Agency Response, p. 18; Tr., p. 38.)

CRITERION II.A.2. PSRO is reviewing the 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 PGFMC the 20 points available for this criterion because the Agency determined that PGFMC did not implement its process of presurgical review within the period of the evaluation. (See, Agency

Response, p. 19; Tr., p. 438.) The project officer testified that the documentation submitted by PGFMC for this criterion consisted of revised Hospital Services Regulations issued by the State of Maryland Department of Health and Mental Hygiene. (See, Agency Exhibit A, Tab C, pp. 000081-000086.) The regulations required preprocedure review for Medicaid patients. The project officer stated that "the process was implemented by the PSRO [PGFMC] effective January 1, 1981." (Tr., p. 438.) The Agency contended that, in accordance with the "Instructions for Completing the PSRO Performance Evaluation," the proper rating period for PGFMC was calendar year 1980. (See, Agency Exhibit C.) The Agency argued that since PGFMC's date of implementation, January 1, 1981, was outside the evaluation period, the criterion was properly marked "not met."

PGFMC argued that it became involved in presurgical review in June, 1980 in connection with the development of a cost containment program in conjunction with the State of Maryland. (See, PGFMC Appeal Supplement II, Sec. II.A.2; Tr., p. 39.) The Executive Director testified that after June 1, 1980 he spent many hours with state officials developing the policies and procedures of the program. (Tr., p. 39.) Thereafter, PGFMC's Board of Directors reviewed the program at their November 10, 1980 meeting. (Id.) The program was referred to PGFMC's Executive Committee which subsequently authorized the implementation of the program on December 24, 1980. (Id.) PGFMC asserted that its December, 1980 implementation date was attested to by the Acting Director, Medical Assistance Compliance Administration, State of Maryland. (See, PGFMC's Appeal Supplement II, Sec. II.A.2.)

The Agency contended that even if it were to accept PGFMC's argument that the program was implemented on December 24, 1980, the criterion would remain properly marked as "not met." (Agency Post-hearing Brief, p. 6; Tr., p. 438.) To meet the criteria the instructions required that the performance be "sustained" throughout the rating period. (See, e.g., Agency Exhibit C.) The Agency argued that the implementation of the review program on December 24, 1980 could not be used to show sustained performance throughout the rating period and, therefore, the criterion was "not met" by PGFMC. (Agency Post-hearing Brief, p. 6; Tr., pp. 438-439.)

Finding: PGFMC should not receive the points for this criterion.

The instructions for completing the evaluation read as follows:

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. (emphasis added)

(See, e.g., Agency Exhibit C.)

The Board agrees with the Agency's interpretation of this instruction as it pertains to the proper rating period for PGFMC. The instruction was aimed at evaluating the most recently completed 12 month period. PGFMC's grant period ran from October 1 through September 30. In April, 1981, when the evaluation took place, PGFMC was in the seventh month of its current grant. Since this was less than a 12 month period, it was an improper period for purposes of this evaluation.

PGFMC's most recently completed (12 month) grant period was October 1, 1979 through September 30, 1980. Since calendar year 1980 (January 1 through December 31, 1980) covered a more recent overall time frame, it was the proper period for the evaluation under this instruction.

The evidence presented by PGFMC at best shows PGFMC as having a review program newly in place in December, 1980. No evidence was presented exhibiting actual performance in 1980 under this program. In fact, the Executive Director testified that "[a]s a practical matter, we did not receive a form until after the first of the year [1981]." (Tr., pp. 109-110.)

Even if evidence of actual review beginning December 24, 1980 had been presented, the Board would conclude that PGFMC did not meet the criterion as it failed to "sustain" such performance throughout calendar year 1980. Performance during the last 7 days of 1980, representing less than 2% of the total days in a calendar year, does not represent sustained performance under any reasonable interpretation but instead indicates isolated or beginning performance under the program. In either case, the Board concludes that the criterion was correctly marked as "not met."

In finding against PGFMC, the Board finds unpersuasive PGFMC's argument that it began developing its presurgical review program in June, 1980. The criterion requires that the PSRO "is reviewing" presurgical procedures; which reasonably implies that actual review (as opposed to preparing for such review) is taking place. Therefore, the Board finds that it was reasonable for the Agency not to consider the development stage of PGFMC's presurgical review program since the clear language of the criterion states "is reviewing."

CRITERIA SECTION B. Special Actions to Address Identified Problems.

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.

The Agency did not award PGFMC the 15 points available for this criterion because the Agency determined that PGFMC was not focusing its review by admission date. (Tr., p. 440.) The project officer testified that his determination resulted from a telephone call to PGFMC's Executive Director in which the Executive Director responded "no" to the project officer's question of whether PGFMC was focusing by admission date. (Id.)

PGFMC contended that it performed the focusing activities since 1979. This performance was mandated by a Memorandum of Understanding (MOU) between PGFMC and the State of Maryland Medicaid Agency, effective July 1, 1979. (See, PGFMC Appeal Supplement II, Sec. II.B.1(d); Tr., p. 40.) PGFMC alleged that its performance under the MOU was attested to by the Acting Director, Medical Assistance Compliance Administration, State of Maryland, in a letter dated September 4, 1981. (Id.)

In response to PGFMC's argument, the project officer testified that this national evaluation "is restricted, with the exception of a bonus point, to acute review." (Tr., p. 442.) The Agency contended that the additional information presented concerning weekend admissions related to reviews conducted at a chronic disease hospital. (Id.) The Agency argued that in this case the chronic disease hospital was not an acute care facility and, therefore, was not a proper subject of this evaluation. (Id.) As such, the criterion was properly marked as "not met."

Finding: PGFMC should receive the 15 points available for this criterion.

The Board concludes based on the evidence submitted that PGFMC "met" this criterion. The MOU, page 2, Section A.3, states:

To provide, through PSRO review, the following services . . . :

- a. Admission review and certification or denial, . . . of selected admissions for medical necessity and appropriate utilization. PSRO will monitor Friday and Saturday non-emergency admissions prior to certification to assure medical necessity.

(PGFMC Appeal Supplement II, Sec. II.B.1(d)).

As the project officer agreed, the MOU speaks specifically to the monitoring of weekend admissions. (See, Tr., p. 475.) The effective date of the MOU was July 1, 1979 and the Executive Director testified that PGFMC continued to perform the review. (See, Tr., p. 40.) The Agency did not dispute that the review described in the MOU meets the criterion, nor did the Agency dispute PGFMC's continued performance under the MOU. Therefore, the Board finds that PGFMC has performed the type of review required in the criterion.

The Agency's argument that PGFMC performed this review solely in a chronic disease hospital is not substantiated in the record. The project officer testified that it was his understanding that the PGFMC's review was restricted to the chronic disease hospital which was funded as part of PGFMC's long-term care program. (See, Tr., pp. 440-441.) However, page 2 of the MOU states that the PSRO review will take place in "short-term general hospitals, ^{3/} chronic hospitals and private psychiatric hospitals." (See, PGFMC Appeal Supplement II, Sec. II.B.1(d).) As the project officer agreed, these are not all long-term care facilities. (See, Tr., p. 475.) Since PGFMC performed the required review and the Agency has failed to refute PGFMC's evidence that the review took place in short-term care facilities, the Board finds that PGFMC has met the criterion and is entitled to the 15 points.

CRITERION II.B.1(f): PSRO is addressing identified problems by performing preadmission review.

The Agency did not award PGFMC the 10 points available for this criterion because the Agency determined that PGFMC did not implement its process of preadmission review within the period of the evaluation. (Agency Response, p. 20.) As with criterion II.A.2., the documentation submitted by PGFMC was the Maryland Hospital Services Regulations. (See, e.g., Agency Exhibit A, Tab C, pp. 000081-000086.) The Agency contended that these regulations did not become effective until January 1, 1981. (Agency Response, p. 20.) Therefore, the Agency argued, although "[p]reauthorization is required in certain instances" under these regulations, the effective date for implementation of the regulations was outside the time frame of the evaluation. Accordingly, the criterion was properly marked as "not met." (Id.)

^{3/} Although the Agency stated that this national evaluation was restricted to acute care facilities, the Agency has not provided a definition of what it considered to be an acute care facility other than to contrast it with a long-term care facility. (See, e.g., pp. 112, 441.) Since the Agency did not argue that short-term general hospitals were not acute care facilities and the project officer agreed that they are not long-term care facilities, we find the short-term general hospitals were properly subject to this evaluation.

PGFMC contended that it implemented preadmission review for a chronic disease hospital on January 17, 1977. (PGFMC Post-hearing Brief, p. 6; Tr., p. 40.) PGFMC submitted as evidence of review in the chronic disease hospital the September 4, 1981 letter from the Acting Director, Medical Assistance Compliance Administration, State of Maryland. (See, PGFMC Appeal Supplement II, Sec. II.B.1(f).) PGFMC contended that it instituted preadmission review in all acute care facilities on December 24, 1980 in accordance with regulations issued by the State of Maryland Medicaid Agency. (PGFMC Appeal, Part II, p. 4.) PGFMC argued that these activities satisfy the requirements of the criterion.

The Agency argued that PGFMC's implementation of preadmission review in December, 1980 did not meet the instructions requirement of "sustained" performance and, therefore, the criterion was "not met." With regard to the chronic disease hospital, the Agency contended that such a hospital was a long-term care facility, as indeed, PGFMC treated it as part of its long-term care program. (See, Tr., p. 476.) As a long-term care facility, it was not subject to this evaluation as only acute care facilities were being reviewed. (Id. at p. 441.)

Finding: PGFMC should not receive the points for this criterion.

The Board concludes for the following reasons that PGFMC has not met this criterion.

The instructions for completing the evaluation required that performance be sustained throughout the rating period. As was previously noted under criterion II.A.2. (see, pp. 7-9 of Decision), the Board does not consider performance by PGFMC in the last seven days of 1980 sufficient to meet the requirement in the instructions that such performance be sustained throughout the rating period. Therefore, implementation of preadmission review on December 24, 1980 was not sufficient to meet the criterion.

With regard to the review in the chronic disease hospital, it was undisputed that PGFMC treated the chronic disease hospital as part of its long-term care program. (See, Tr., p. 112, 476.) PGFMC provided no evidence to support its contention that the chronic disease hospital was actually an acute care facility other than a claim that it was treated as a long-term care facility because the government regulations so required. (Id.) The Board finds PGFMC's evidence unpersuasive and insufficient to overcome the inference arising from its undisputed treatment of the facility as part of its long-term care program.

CRITERION II.B.1(g). PSRO is addressing identified problems by performing preprocedure review.

The Agency did not award PGFMC the 10 points available for this criterion because the Agency determined that PGFMC did not implement its process of preprocedure review within the period of the evaluation. (See, Agency Response, p. 21; Tr., p. 443.) As in criteria II.A.2. and II.B.1(f), the documentation submitted by PGFMC was the Maryland Hospital Services Regulations. (See, e.g., Agency Exhibit A, Tab C, pp. 000081-000086.) The Agency contended that these regulations did not become effective until January 1, 1981. (Agency Response, p. 21.) The Agency argued that PGFMC's date of implementation was outside the period of the evaluation and, therefore, the criterion was properly marked as "not met."

PGFMC argued that it became involved in preprocedure review in June, 1980 in conjunction with a cost containment program instituted by the State of Maryland. (See, PGFMC Appeal Supplement II, Sec. II.B.1(g).) PGFMC argued that this program was implemented December 24, 1980 and, therefore, met the criterion. (Id.) In addition, PGFMC's Executive Director testified that PGFMC utilized the identical procedures for preprocedure review as for preadmission review. (Tr., p. 41.) PGFMC argued that it had performed these activities in a chronic care facility since 1977. (Id.) PGFMC submitted as evidence of performance of this review the September 4, 1981 letter from the Acting Director, Medical Assistance Compliance Administration, State of Maryland. (See, PGFMC Appeal Supplement II, Sec. II.B.1(g).) PGFMC argued that these activities satisfy the criterion.

With regard to implementation of preprocedure review in December, 1980, the Agency asserted that such review did not meet the instruction's requirement that performance be sustained and, therefore, the criterion was "not met." The Agency did not address the similarity in PGFMC's procedures regarding preadmission and preprocedure review.

Finding: PGFMC should not receive the points for this criterion.

As we previously noted (see, discussion of criteria II.A.2 and II.B.1(f)) the Board finds that performance in the last days of 1980 does not meet the requirement in the instructions that such performance be sustained throughout the rating period. Therefore, implementation of preprocedure review in December, 1980 is not sufficient performance to meet the criterion.

In addition, the Board finds unpersuasive PGFMC's argument equating preadmission and preprocedure review as evidence that the latter took place the same time as the former. PGFMC's Executive Director testified that both types of review used a form which the hospitals submitted to PGFMC. (See, Tr., p. 41.) It was not alleged that it was the same form or that the two procedures were performed simultaneously. On the contrary, the Executive Director's testimony shows that the two reviews were quite

different. The Executive Director stated that "preadmission review is simply a review of the patient regardless of the diagnosis or problem prior to admission," while preprocedure review is "more specifically related to surgery. . . ." (Tr., p. 41.)

In light of this testimony and the lack of other evidence, we fail to see how the confirmation of performance of preadmission review translates into confirmation of performance of preprocedure review. Accordingly, the Board concludes that PGFMC failed to meet this criterion.

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.

The Agency did not award PGFMC the 60 points available for this criterion because the Agency determined that the "documentation fails to demonstrate resolution of problems or behavior modification." (Agency Exhibit A, Tab E, p. 000117.)

The Agency asserted that this criterion "requires documentation of problem resolution where a sanction recommendation was at issue." (Agency Response, p. 22.) The Agency asserted that specific guidelines governing sanctions are set out in 42 CFR §474. The Agency argued that under §474.4 the PSRO was required, upon identifying a potential violation of a provider's obligation, to "first send the provider a written notice containing specific information relevant to the violation and the sanction process." (Id.) The Agency asserted that in the example submitted by PGFMC a sanction recommendation was not in issue and no sanction procedures had begun. (Id.; see also, Tr., pp. 443-447.)

PGFMC argued that the Agency's inferred interpretation of the criterion (i.e., that it was necessary to actually make a sanction recommendation) is inconsistent with the criterion itself. (See, PGFMC Appeal Supplement II, Sec. II.B.2(c); Tr., p. 45.) PGFMC argued that it operated under a sanction plan approved by the Agency. (Id.) The Executive Director testified that PGFMC's sanction plan "was a contract deliverable under its old contract with the Department [Agency]." (Tr., p. 50.) The Executive Director stated further that "[s]ince we have never received any written notification from the Department . . . I have reason to believe that the [sanction] plan has been approved." (Id.)

PGFMC asserted that its philosophy under the sanction plan was to deal "in-house, in-county, in-state" before referring a problem to the Agency. (Id.) PGFMC presented documentation and testimony detailing

four examples of intervention with hospitals and practitioners handled under this sanction plan. PGFMC argued that these four examples were evidence of eliminating the need to proceed with a sanction recommendation. (Id.)

Concerning the first example, PGFMC's Executive Director testified that PGFMC sent a letter to the Chairman of the State of Maryland Commission on Medical Discipline informing the Commission that a physician in Prince George's County was practicing medicine without a license. (Tr., p. 47; see also, PGFMC's Appeal Supplement II, Sec. II.B.2(c).) The Executive Director stated that as a result of PGFMC's intervention, "it was confirmed that the physician was practicing medicine without a license." (Id.) The physician died during the inquiry, mooted the issue. (Id.)

The second example involved a specific concurrent quality assurance (CQA) intervention on behalf of a patient to ameliorate poor care. (See, Tr., p. 48.) CQA is a system of concurrent monitoring to assure the provision of quality medical care. (See, PGFMC Appeal, Sec. III.C, Attachment 2.) This particular case involved inappropriate physician care. (Tr., p. 48.) The Executive Director testified that this case was referred to PGFMC's profile analysis committee to conduct a profile of the physician's practice. (Id. at p. 49.) No profile was performed because the physician removed the records from the hospital. (Id.) At that time the physician removed his practice to Montgomery County, and PGFMC referred the physician's name to the Montgomery County Medical Care Foundation. (Id.)

The third case involved a marginally capable physician. The Executive Director stated that PGFMC's data showed that the physician required more CQA intervention than any other doctor in Prince George's County. Action was taken with regard to this physician under PGFMC's sanction plan. A formal hearing was afforded the physician before PGFMC's sanctions committee. (Id. at p. 51.) The sanctions committee recommended that the physician's case be referred to the Maryland State Commission on Medical Discipline. (Id. at p. 52.) This action was taken. (Id.)

The fourth case involved a specific discharge plan in hospital 075. (See, Tr., p. 53.) The Acute Care Coordinator at the hospital identified 12 instances where poor discharge planning occurred in placing patients in nursing homes. (Id.) The Executive Director stated that this became a sanction issue because PGFMC "could have denied all 12 cases." (Id.) Instead, representatives from PGFMC and the hospital met to discuss the problem. During the meeting both the problem and possible sanctions PGFMC could impose if the problem was not corrected were

discussed. (Id. at pp. 58-59.) As a result of the meeting, the problem was corrected and since that time PGFMC has not had any CQA interventions specific to discharge planning in that area. (Id.)

The project officer testified that, in terms of this criterion, "sanction" has a specific meaning as defined in the Social Security Act. (Tr., p. 446; see, Social Security Act, Sec. 1160.) The project officer stated that the examples submitted by PGFMC fail to meet the criterion because "the vital part of the criterion, the issuance of the letter warning of official Social Security Act sanctions, never occurred." (Id.) In addition, the Agency contended that PGFMC's examples were not legally sanctionable - as defined in Section 1862(d) and (3) of the Act - and, therefore, PGFMC failed to meet the criterion. (Agency Post-hearing Brief, pp. 7-8.)

Finding: PGFMC should receive the 60 points available for this criterion.

The record indicates that PGFMC documented that it worked with institutions/practitioners to resolve problems in at least two cases (PGFMC's second and third examples). In fact the project officer testified that he agreed that PGFMC demonstrated the resolution of problems and behavior modification. (See, Tr., p. 484.) Based on this evidence the Board finds that PGFMC "met" this criterion.

In finding for PGFMC, the Board rejects the Agency's argument that this criterion requires the issuance of the letter warning of official Social Security Act sanctions. The criterion on its face makes no mention of such a requirement. In addition, another criterion - II.B.2(b) - dealt specifically with the issuance of warning letters to institutions and/or practitioners. 4/

We likewise are unpersuaded by the Agency's argument that PGFMC's examples are not legally sanctionable as defined in the Social Security Act. Under Section 1157 of the Act, a PSRO may identify a practitioner or health care facility whose behavior is in violation of Section 1160 obligations. One such obligation is to assure that health care services provided "will be of a quality which meets professionally recognized standards of health care." (Sec. 1160(a)(1)(B) of the Act.) Of the four examples submitted by PGFMC, at least the first three involve violations of this obligation and are, therefore, legally sanctionable. Since the criterion only requires one example, it is not necessary to determine whether PGFMC's fourth example is legally sanctionable.

4/ We note that the Agency determined that PGFMC met criterion II.B.2(b).

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

PGFMC argued that, under the sanction plan it operates, it is required to deal with problems "in-house, in-county, in-state" before forwarding a sanction recommendation to the Secretary. (Tr., p. 62; Appellant's Exhibit I.) Pursuant to the sanction plan, PGFMC informed the State of Maryland Commission on Medical Discipline on December 29, 1980 that a physician was practicing medicine without a license. (Id.) PGFMC contended that its use of the state commission was superior to using federal sanctions because the latter affects only Medicare and Medicaid patients while the former has the legal authority to affect physician behavior with regard to all patients, regardless of pay source. (See, Tr., pp. 62-63, 121-122.) Therefore, PGFMC argued that, although the criterion spoke of sending the sanction recommendation to the Secretary, PGFMC's action was consistent with its approved sanction plan and met the intent of this criterion. (Id.)

The Agency contended that the example submitted by PGFMC did not satisfy the criterion because, as the project officer testified, "even though it obviously was intended to be a punitive action, it is not a sanction under the Act and, therefore, does not qualify." (Tr., p. 448.)

Finding: PGFMC should not receive the points for this criterion.

PGFMC did not contend, and the record does not indicate, that PGFMC had forwarded a sanction recommendation to the Secretary. Though PGFMC may have done a useful thing by informing the State authority in accordance with its sanction plan, it did not do what the criterion specifically required. We find that it was reasonable for the Agency to award points to PSROs which performed activities authorized by the PSRO statutes and regulations. In addition, another criterion - II.B.2(c) - provided points to PSROs which opted for other methods of resolving problems.

CRITERIA SECTION C. Medical Care Evaluation Studies/Quality Review Studies

CRITERIA II.C.4. PSRO meets at least 75% of the numerical requirement of MCEs as outlined in Transmittal No. 43 or at least the minimum number of studies as outlined in Transmittal No. 100 if the PSRO has had an approved alternative review plan or the number approved by the Project Officer under other waiver provisions.

The Agency did not award PGFMC the 15 points available for this criterion because it determined that PGFMC failed to complete the required number of MCE studies. (See, Agency Response, p. 24.) The Agency determined that under Transmittal 43 PGFMC was required to complete 47 MCE studies. To meet the 75% requirement under this criterion, PGFMC would have to actually have completed 35 MCEs. The Agency determined that PGFMC completed only 16 studies and, therefore, no points were awarded. (Agency Response, p. 24; Tr., p. 449.)

PGFMC argued that it had an approved alternative, effective on July 1, 1980, to MCE Transmittal 43. The Executive Director testified that in February or March, 1980, PGFMC began development of a new care evaluation plan which would require quality review studies in addition to PGFMC performing CQA. (See, Tr., p. 73.) The plan was developed in accordance with the draft of the Agency's new quality review study. (Id. at p. 74.) PGFMC was told by the person who was the project officer at the time that the draft would be very similar to the final study and PGFMC should, therefore, use the draft in developing the new care evaluation plan. (Id.) The Executive Director testified that in April, 1980 he again checked with the new acting project officer about developing the plan in accordance with the draft transmittal, and that the acting project officer said it was "safe" since the final transmittal would not contain any major changes. (Id. at p. 75.) PGFMC argued that since it informed the Agency on several occasions "that we would implement that care evaluation plan on July 1, 1980, that we had not received any reason not to implement that plan," and that since "we had been encouraged to be a pioneer in developing a plan which, in fact, implemented Transmittal 100 at least six months before it had to be implemented," it had Agency approval to operate under its plan as an alternative to Transmittal 43. (Id. at pp. 75-76.)

PGFMC contended that it operated under Transmittal 43 from 1/1/80 - 6/30/80 and, with Regional Office approval, under Transmittal 100 as an alternative to Transmittal 43 from 7/1/80 - 12/31/80. (PGFMC Appeal, Part II, p. 7.) PGFMC presented two sets of figures which it alleged represents the number of studies required in 1980 under these transmittals:

	#1	#2
Required by # 43	: 25	31
Required by # 100	: 18	18
Total requirement in 1980	: 43	49

(See, PGFMC Appeal, Part II, p. 7; PGFMC Appeal Supplement II, Sec. II.C.4.)

Using the first set of figures, PGFMC argued that it "reported" 39 studies in 1980 which is 91% (39/43) of its 1980 requirement. (PGFMC Appeal, Part II, p. 7.) Using the second set of figures, PGFMC argued that it "performed" 45 studies which is 92% (45/49) of the required studies. (PGFMC Appeal Supplement II, Sec. II.C.4.) PGFMC argued that, in either case, the 75% requirement of the criterion was surpassed and, therefore, the 15 points should have been awarded. (Id.)

The Agency admitted that regulations (42 CFR 446.18) codifying the provisions for MCE studies established in Transmittal 43 also provided for alternative MCE study procedures. (Agency Response, p. 23.) The Agency asserted, however, that "such alternative plans must be submitted to HSQB and approved before implementation can begin." (Id.) The Agency argued that, although PGFMC may have had the project officer's approval to develop an approved alternative, it did not have express written authorization to implement an alternative to Transmittal 43. (Agency Post-hearing Brief, p. 9.) The Agency contended that PGFMC "informed the Regional Office on 1/14/81 that it implemented an alternative plan on 7/1/80." (Id.) Since PGFMC did not have approval to implement an alternative plan, it was obligated to meet the numerical requirements of Transmittal 43. The Agency contended that in any case, PGFMC completed only 16 MCEs and would fail the 75% requirement under either transmittal. (See, Tr., p. 449.)

PGFMC contended that "completion" is not the standard under Transmittal 100. (Tr., p. 532.) PGFMC argued that the "completion" standard under Transmittal 43 was changed to a "performance" standard under Transmittal 100. (Id.) The project officer testified that "[p]erformed certainly implies completed." (Id.)

Finding: PGFMC should not receive the points for this criterion.

The Board finds that PGFMC failed to meet this criterion. The evidence presented by PGFMC does not show that PGFMC completed 75% of the MCEs required under Transmittal 43 for the period 1/1/80 - 6/30/80.

Even in viewing the evidence most favorably for PGFMC, we find that it operated under Transmittal 43 from 1/1/80 - 6/30/80 and under Transmittal 100 from 7/1/80 - 12/31/80. We find, and PGFMC conceded, that the performance standard under Transmittal 43 is "completion." (See, e.g., Tr., p. 495.) Using the figures supplied by PGFMC, to meet the 75% requirement under this criterion for the first half of 1980, PGFMC should have completed 18 (75% of 25) studies under the first set of figures or 23 (75% of 31) studies under the second set. The "MCE Study Status Report" submitted by PGFMC shows that for the period 1/1/80 - 6/30/80 PGFMC completed

at most 14 MCE studies. (See, PGFMC Appeal, Sec. II.C.4, Attachment 1; see also, Agency Record, pp. 000128 - 000135.) Since PGFMC failed to complete the requisite number of studies under Transmittal 43 for the first half of 1980, we find that PGFMC did not meet the criterion.

In finding against PGFMC on this criterion, it is unnecessary to decide the question of whether or not PGFMC had an approved alternative to Transmittal 43 effective July 1, 1980. Likewise, the Board need not decide whether the performance standards are different under Transmittals 43 and 100. PGFMC's failure to meet the MCE study requirements under Transmittal 43 for the first half of 1980 renders these questions moot.

CRITERION II.C.6. PSRO systematically monitors delegated hospitals' MCE/QRSs and evaluation is performed at least once per year.
PSRO evaluated its nondelegated Quality Review Program at least annually.

The Agency did not award PGFMC the 20 points available for this criterion because PGFMC presented "no evidence of systematic monitoring of delegated hospital MCEs." (Agency Exhibit A, Tab G, p. 000136.)

The Agency argued that PGFMC's monitoring plan did not require yearly evaluation of delegated review activities in accordance with Sec. E of Transmittal 43 which states:

After delegation, the hospital is responsible for conducting MCE studies in accordance with PSRO program requirements. . . . The PSRO must monitor the hospital's performance through on-site visits and periodic written reports (such as BQA Forms 131, 133 and 135), and where hospital performance is unsatisfactory, provide technical assistance or, if this fails to cause improvement, rescind delegation of the MCE study function.

(Agency Response, p. 26.) The Agency contended that PGFMC presented no documentation that it "monitored the hospitals' performance in this manner." (Id.)

The project officer testified that systematic review "refers to a periodic review of the entire system." (Tr., p. 452.) He stated that "the periodicity in this case is at least annual," and that the term "systematic" means looking "at how the system functions as opposed to looking at an individual component." (Id.) The project officer testified that PGFMC's documentation indicated that individual MCE studies were evaluated. (Tr., p. 451.) However, the project officer contended that this is

different from a systematic monitoring of the overall process.
(Id.) The project officer elaborated on this difference as follows:

[A] PSRO could be in receipt of any number of reasonably acceptable MCE studies, all of which would pass individual evaluation criterion that they use for evaluating an MCE, but still not have a plan that would be evaluated overall as an effective and comprehensive plan, and what we were searching for in this particular plan was whether there was indeed a systematic evaluation of the system, not just looking at individual MCE studies to see if they had criteria and physician inputs, and whatever else they might be looking at.

(Id. at pp. 451-452.)

PGFMC contended that its Delegated Hospital Monitoring Plan "indicates that PGFMC systematically monitors delegated hospitals' MCE/QRS." (See, PGFMC Appeal, Part II, p. 8.) In addition, PGFMC argued that the delegated hospitals were evaluated at least once a year. In support of its argument, PGFMC submitted copies of minutes of Board meetings and of Care Evaluation Committee meetings. (Id. at Sec. II.C.6.) PGFMC contended that these minutes show: "(1) the formulation of a Care Evaluation Plan; (2) the conversion to Transmittal 100 and (3) an evaluation of its quality assurance policy." (Id. at Part II, p. 8.)

The Executive Director testified that the documentation it presented clearly established monitoring activity other than the monitoring of individual MCE studies, for example, that PGFMC evaluated all four delegated hospitals prior to allowing them to implement the new Care Evaluation Plan. (Tr., p. 80.) As a result, only three of the four hospitals received delegation on the first attempt. (Id.) The fourth hospital was given technical assistance and received delegation later in 1980. (Id. at p. 82.) In addition, the Executive Director testified that he believed the submitted documentation shows site visits at hospitals to monitor MCE studies and directors' meetings where these issues were discussed. (Id.)

In response to PGFMC's argument that it assessed all four hospitals that applied for delegation in 1980, the project officer stated that "assessing the hospitals for delegation is different from monitoring." (Tr., p. 496.)

With regard to whether or not its monitoring was "systematized," the Executive Director stated that the delegated hospitals, in accordance with PGFMC's monitoring plan which utilized Transmittal 100 as a guideline, were responsible for submitting quarterly care evaluation reports to PGFMC's health study supervisor. (Tr., p. 81.) Delegated hospitals selected topics off an "issue list" and submitted quarterly report forms which included a study of the topic. (Id. at p. 82.) The Executive Director testified that the report form included a "statement of the issues, a list of the criteria included in the study, a statement of the study process, peer analysis -- that is, who reviewed what, a statement of intervention to protect problem resolution, and then a statement of follow-up mechanism to assure problem resolution or reduction." (Id.) The reports were submitted to the Health Studies Supervisor. The Executive Director stated that "we cannot complete our Federal reporting requirements without the receipt of those forms." (Id. at p. 83.) In addition, the supervisor went to the delegated hospitals to evaluate the studies. (Id.) PGFMC argued that these activities constituted a system for monitoring quality review studies. (Id.)

The Agency argued that the second part of the criterion was also "not met" as PGFMC presented no evidence showing an evaluation of its non-delegated quality review program. (Agency Response, p. 26; see also, Tr., p. 452.)

PGFMC contended that minutes of PGFMC's Board of Directors meetings indicated that PGFMC "decided not to pursue its request for a MCE waiver and instead voted to implement a new quality assurance program based upon the Department's draft policy." (PGFMC Appeal Supplement II, Sec. II.C.6.) PGFMC argued that in making this decision PGFMC "clearly evaluated its non-delegated quality review program." (Id.) PGFMC also submitted a copy of its Care Evaluation Committee Plan for Non-Delegated Hospitals as evidence of evaluating its non-delegated quality review program at least annually. (See, PGFMC Appeal Supplement II, Sec. II.C.6.)

The project officer testified that:

We did a review of all of the notes of the care evaluation committee and found no evidence of an evaluation of the non-delegated quality review program.

(Tr., p. 452.)

Finding: PGFMC should receive the 20 points available for this criterion.

The Board finds based on the evidence submitted that PGFMC systematically monitored delegated hospitals' MCE/QRs at least annually.

PGFMC has documented, and the project officer has agreed, that PGFMC's Care Evaluation Committee assessed all four hospitals which applied for delegation in 1980 under Transmittal 100. (PGFMC Appeal, Sec.II.C.6, Attachment 3.) The review included a comparison of the hospitals' quality assurance plans against specific delegation criteria. (Id.) In fact, one of the hospitals failed to receive delegation on the first attempt. (Id.) This was not an evaluation of individual MCE/QRSs, but was an overall evaluation of the hospitals' quality assurance plan. We find that PGFMC's process of evaluating these hospitals satisfied the systematic monitoring requirement of this criterion.

In finding for PGFMC, we find unpersuasive the project officer's objection to PGFMC's evidence that "assessing hospitals for delegation is different from monitoring." (Tr., p. 496.) Although the statement may be true, it does not address the question of whether PGFMC's assessment of the hospitals for delegation provides effectively the type of review of the hospitals' system of performing MCE/QRSs that the Agency desired. We find that PGFMC satisfactorily met this requirement.

The criterion also requires that the evaluation be performed at least once per year. Since PGFMC's evaluation of these hospitals took place in calendar year 1980 (see, PGFMC Appeal, Sec. II.C.6, Attachment 3), which is the rating period for PGFMC for purposes of this national evaluation, we find that the annual review requirement is met for this criterion.

In addition, contrary to the Agency's assertion, PGFMC was monitoring hospitals' performance through periodic reports as defined in Section E of Transmittal 43. Section E lists as an example of a periodic report BQA Form 135. PGFMC submitted as evidence for criterion II.C.4, as did the Agency, its BQA Form 135s for 1980. (See, PGFMC Appeal, Sec. II.C.4, Attachment 1; see also, Agency Exhibit A, pp. 000128-000135.)

We also find that PGFMC reviewed its non-delegated quality review program annually. The minutes of PGFMC's March 17, 1980 Board of Directors meeting included a discussion by PGFMC's Executive Director concerning quality assurance and the formation of the Care Evaluation Committee. (PGFMC Appeal, Sec. II.C.6.) PGFMC also submitted copies of minutes of subsequent meetings of the Care Evaluation Committee in which PGFMC's Care Evaluation Plan was developed. (Id.) This plan specifically coordinates quality assurance programs among both delegated and non-delegated hospitals. (Id. at Attachment 1.) Since PGFMC has shown that it reviewed its non-delegated quality review program in 1980, and the Agency has presented no contrary evidence, we find that PGFMC met the criterion.

CRITERIA SECTION D. Data System

CRITERION II.D.3. PSRO has systematic data monitoring system to assure quality and accuracy of the data collected and mechanisms for corrective action. This system should include reabstracting studies at least once per year, training programs for coding personnel, 10% error rate as threshold for action and at least yearly reabstracting evaluations of each facility.

The Agency did not award PGFMC the 15 points available for this criterion because the Agency determined "insufficient evidence [was] submitted." (Agency Exhibit A, p. 000142.) The project officer defined reabstracting as comparing an independent abstract against the original abstract to assure that data is being transferred accurately. (Id. at p. 502.) PGFMC has not disputed the project officer's definition of reabstracting. The project officer testified that with regard to systematic reabstracting, the documentation submitted by PGFMC concerned a problem dealing with the status of newborns. The project officer stated that:

The PSRO did indeed go out and look at coding for that particular problem area . . . , but that is reacting to a particular incident. It is not a systematic reabstracting.

(Tr., p. 455.)

PGFMC contended that the Agency originally asked for only one reabstraction letter to meet this criterion. (Tr., p. 88.) In response to the Agency's contention that one example is not sufficient, PGFMC has submitted copies of additional letters. (See, e.g., PGFMC Appeal Supplement II, Sec. II.D.3.) In addition, PGFMC submitted other forms which it contended showed that PGFMC was reabstracting the medical records every time it did a study. (Id.) PGFMC argued that this was systematic. The Executive Director testified that an additional example of how PGFMC monitored data was that the data manager "evaluates every single abstract . . . and personally contacts the review coordinators if there are problems in that abstract." (Tr., p. 89.)

The Agency contended that the process used by PGFMC of reviewing each individual abstract is not reabstracting. (Tr., p. 500.) The project officer testified that the failing of PGFMC's system is that "[t]here has been no validation of the accuracy of the transfer of data from the medical record to the abstract." (Id.)

With regard to the training programs for coding personnel, the project officer testified that "[t]here was no documentation of training for coders in calendar year 1980." (Tr., p. 456.)

PGFMC did not dispute the Agency's contention that there were no training sessions in 1980. PGFMC argued, however, that its review coordinators were also coders. The Executive Director testified that these employees "are trained in coding when they are new employees." (Tr., p. 86.) The Executive Director stated that PGFMC had no new employees in calendar year 1980 and, therefore, "there was no reason to send somebody to a coding seminar." (Id.) In addition, PGFMC submitted a copy of its Acute Review Coordinator Orientation and Training Plan. (PGFMC Appeal, Sec. II.D.3, Attachment 3.) PGFMC claimed that the plan contained an agenda for two days of training with specific reference to coding. (Tr., p. 87.) The Executive Director testified that to the best of his knowledge this was done in 1980. (Id.)

With regard to the "10% error rate as a threshold of action," PGFMC submitted its 1979 and 1980 PSRO Hospital Discharge Data Set (PHDDS) tapes which indicate an error rate of less than 1%. (See, PGFMC Appeal, Sec. II.D.3., Attachment 5.) PGFMC contended that this was evidence that PGFMC "has a systematic monitoring system to assure quality and accuracy of the data collected and mechanisms for corrective action." (Id. at Part II, p. 9a.)

The Agency contended that the 10% error rate as a threshold for action in the criterion is entirely different from the error rate on the PHDDS tapes. (Tr., p. 456.) The project officer testified that the 10% error rate "refers specifically to the error rate on studies of reabstractions." (Id.) The project officer stated further that the error rate cannot refer to the PHDDS submissions "because tapes with ten percent error would never be accepted." (Id.) The project officer explained that there were certain pieces of information "picked up" in the PHDDS system that are not collected in the data system. The project officer stated that:

It is entirely possible . . . for all the abstracts to be coded wrong, and still to be accepted by the PHDDS system with a very small percentage of errors.

(Id.)

Finding: PGFMC should not receive the points for this criterion.

The criterion required a system of data monitoring which included the reabstracting of studies at least once a year. PGFMC claimed that its system of data monitoring validated the transfer of data in the same manner as reabstracting. (See, e.g., Tr., p. 500.) We conclude that PGFMC failed to substantiate its claim.

The examples submitted by PGFMC used a sampling technique to identify miscoded cases. Sampling would appear to provide the type of validation of the accuracy of the transfer of data that the Agency desired. PGFMC's evidence is a sample conducted in four hospitals in response to Medicaid's concern with increased length of stay for "uncomplicated deliveries." (See, PGFMC Appeal Supplement II, Sec. II.D.3.) The documentation shows that PGFMC performed one study in four hospitals of this one particular situation. We find that, while PGFMC's sampling validated the transfer of data with regard to "uncomplicated deliveries," PGFMC presented no evidence indicating that sampling was conducted in other hospitals with regard to other types of medical abstracts. Without this evidence, we find that PGFMC's performance of sampling review in this isolated case does not constitute a system as required in this criterion.

We also find unpersuasive PGFMC's argument related to the data manager's review of each individual abstract. The review of a finished abstract is not an independent validation of the transfer of data to the abstract. Since PGFMC presented no other evidence explaining the type of review accomplished by the data manager, we conclude that the evidence does not support a finding that the type of review conducted by the data manager would accomplish the goals of reabstraction.

With regard to the "10% error rate," we find PGFMC's evidence unpersuasive in the face of the project officer's testimony. The project officer explained the difference between the error rate on the PHDDS tapes and that on the data system. (See, Tr., p. 456.) The project officer's testimony that different pieces of information were collected on the two tapes precludes an accurate comparison of the error rates of the tapes. Since PGFMC did not proffer any contradictory testimony, the Board concludes that PGFMC's documentation by itself is insufficient evidence to support PGFMC's claim and, therefore, PGFMC has failed to document a 10% error rate.

The Board rejects PGFMC's argument that since it hired no new employees in 1980 training sessions for coders were unnecessary. PGFMC 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 conducted training sessions for coders.

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

PGFMC received 110 of 1,200 possible points on this part; 515 points were needed to pass. The Board has determined that PGFMC should receive an additional 70 points for this part. PGFMC disputed the Agency's scoring of the following criteria in this part:

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.

PGFMC received a score of level "3" for both years; PGFMC maintained that it should have received a level "5" for those years. A PSRO scoring at a level "3" was awarded 20 points for 1979 and 40 points for 1980; a PSRO scoring at level "5" was awarded 70 points for 1979 and 130 points for 1980.

Level "3" read as follows:

PSRO set objectives which minimally met the criteria (in III.A.2.). 5/ Experience shows that the PSRO has had to make extensive major modifications (50 percent or greater of the objectives in either of the 2 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.

Level "4" read as follows:

PSRO sets 4-8 objectives each grant period which meet the criteria addressed in III.A.2., and reflect the activity 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 measurement, shifting of timeframes by no more than 30 days, etc.).

Level "5" read as follows:

PSRO sets 4-8 objectives which meet the criteria in III.A.2., and adequately reflect the activities and priorities of the PSRO. The objectives have alternative methodologies to assure success. The current objectives reflect extensive developmental work prior to their proposal. Such developmental work might

5/ The criteria in III.A.2. were: objectives do not reflect significant problems; do not have measurability; have insufficient or unrealistic methodologies; lack timeframes; and do not follow prescribed grant application format.

include the conduct of special MCEs, QRSs, or surveys, or the developmental analysis of special profiles or data reports. The problems being addressed are of broad scope and have especially ambitious outcomes/targets.

Mr. Paul Mendelsohn, Senior Public Health Analyst for the PSRO program, testified that the "objective setting process has evolved over three years," and for the past two years "the grants application package has had a very specific format requirement." (Tr., pp. 261-262.) He stated that the base level of acceptability of objectives was that the objectives were "impact oriented rather than developmental or process." (Id. at p. 262.) He stated that beyond this "the Bureau had five criteria for approving acceptable objectives." (Id.) He stated that those five criteria were that:

[The] objectives had to be measurable and related to data systems. The second criteria was that they had to be verified documented PSRO problems — not perceived problems.

. . .

They had to be — have specific time frames for performance which were reflected in a grant chart or time frame milestone chart of performance so that they could be monitored. And collectively they had to represent the priorities — they had to represent a priority that was consistent with the budget.

And then, lastly, the PSRO must have methodologies that are consistent and realistic with their budget and with that objective.

(Tr., pp. 262-264.)

Mr. Mendelsohn testified that in the process of measuring these objectives, five levels of scores were established. (Id. at p. 265.) Mr. Mendelsohn stated that:

[T]he first level was nothing. The PSRO did not have acceptable objectives. The second level, were those PSROs who after a great deal of effort, had minimally acceptable objectives.

The third level required that . . . the PSROs came in basically with objective sets that with some technical assistance and were good.

The fourth and fifth levels had things that were extra. In other words that they were particularly aggressive, that they had assured themselves against failure by having alternative methodologies.

(Tr., p. 265.)

The project officer testified that, in scoring this criterion, the Regional Office staff did an overall evaluation of PGFMC's 1979 and 1980 objectives. Based on this evaluation, PGFMC was awarded a level "3" for both 1979 and 1980. (Tr., p. 458.)

PGFMC argued that its documentation supported a score of level "5" for both 1979 and 1980. PGFMC contended that it had 15 HCFA-approved objectives in FY 79-80 and 8 in FY 80-81. (See, PGFMC Appeal, Part II, p. 10.) PGFMC submitted copies of these objectives as documentation. (Id. at Sec. III.A., 1979, Attachment 1; Section III.A., 1980, Attachment 1.) PGFMC asserted that it received no negative comments from the Agency on these objectives. PGFMC argued that, in fact, letters from Agency officials "clearly indicate federal enthusiasm with PGFMC activities related to objectives." (Id. at Part II, p. 10; see, e.g., Sec. III.A., 1979, Attachment 1.)

PGFMC argued further that all of its objectives for the two years met the Agency's criteria for objectives. (Id. at Part II, p. 10.) In addition, PGFMC contended that of the 15 objectives in FY 79-80, only 2 required modification (13%), and 12 were met (80%). (Id.) Similarly, PGFMC contended that 6 of the 8 in FY 80-81 objectives were already met and the other 2 were still being measured. (Id.)

The Agency contended that PGFMC had received negative comments concerning its objectives from the Agency. The Agency submitted a copy of a December 5 ^{6/} memorandum from the then project officer to the file as evidence of PGFMC's lack of progress on its objectives. (See, Agency Exhibit H.) The project officer stated on page 3 of the memorandum that "[d]ocumentation supporting the progress or lack of progress was not presented at this time." (Id.) The project officer stated further that he briefed PGFMC's Executive Director on what documentation the project officer expected the next time the progress was reviewed. (Id.)

^{6/} The year was deleted from the face of this document. Therefore, we cannot determine to which year's objectives the project officer's comments referred.

With regard to PGFMC's argument that it met 12 of 15 of its FY 79-80 objectives and 6 of 8 of its FY 80-81 objectives, the Agency argued that this was not a primary factor in this criterion. (Agency Response, p. 31.) The Agency contended that 100% of the objectives could have been met, but if they had "little breadth, depth, or significance or were inappropriately developed," the PSRO would receive only a minimally acceptable score. (Id.)

The Agency contended that no higher score than a level "3" should be awarded. The project officer testified that, although PGFMC had acceptable objectives that met the minimal criteria, he found that "a number of objectives had to be revised in terms of time frames and methodologies," and some had proved to be meaningless as the problems they were aimed at proved to be no problem at all. (Tr., pp. 459-460.) The project officer did not testify to any specific objectives that exhibited the above mentioned deficiencies.

The Agency argued that PGFMC's objectives "fail to deal in depth with utilization issues despite the fact that PGFMC has high utilization problems." (Agency Response, p. 29.) The Agency argued that this problem was discussed with PGFMC, but PGFMC "expressed a lack of interest in utilization objectives." (Id.) The Agency submitted a January 22, 1980 memorandum from the then project officer in which the project officer wrote that PGFMC's Executive Director had stated that:

The Board's [PGFMC] philosophy is to emphasize quality issues as opposed to utilization issues and is unlikely to change.

(Agency Exhibit A, p. 00147B.)

PGFMC's Executive Director testified that the Agency had long felt that PGFMC was unwilling to address utilization issues and, according to the Executive Director, as the Agency's memorandum correctly stated, he discussed this with the project officer. However, the Executive Director stated that he informed the project officer that "contrary to what he [the project officer] says, we [are] willing to look at utilization objectives." (Tr., p. 91.) PGFMC submitted as evidence of its concern with utilization objectives the agenda for the March 18, 1980 Profile Analysis Committee. (PGFMC Appeal Supplement II, Sec. III.A.) PGFMC contended that the agenda "dealt exclusively with utilization issues." (Id.; see also, Tr., p. 92.)

A second reason given by the Agency for not awarding PGFMC a higher score was that a "majority of objectives deals with LTC [long-term care] rather than acute care." (Agency Response, p. 29.) However, the project officer testified that this part of the Agency's response was erroneous. (Tr., p. 506.) The project officer further testified that this error

did not require an adjustment to PGFMC's score on this criterion because "it doesn't impact at all upon the evaluation of the quality of those objectives." (Id. at p. 507.)

The Agency also contended that PGFMC's objectives "were not measurable and did not reflect extensive developmental work prior to their proposal." (Agency Response, p. 29.) Furthermore, the Agency submitted a letter dated April 6, 1979 from the then project officer to PGFMC's Executive Director which the Agency alleged showed that PGFMC was notified that many of its objectives needed to be rewritten. (Agency Exhibit A, p. 00147C.)

PGFMC argued that the Agency misconstrued the April 6, 1979 letter. PGFMC contended that the letter stated that PGFMC's objectives were received by the Agency on January 23, 1979. PGFMC asserted that the letter clearly stated that the new format for objectives required by the Agency in Regional PSRO letter 79-4 was dated February 9, 1979. PGFMC argued that, since its objectives were written prior to the change in format, "it is reasonable to assume that the Foundation [PGFMC] had no way of knowing what specific format would be required." (PGFMC Appeal Supplement II, Sec. III.A.)

PGFMC further argued that the April 6, 1979 letter clearly showed that only one of twenty-one objectives (5%) needed to be rewritten. (Tr., p. 95.) The Executive Director testified that PGFMC accepted the Agency's comment on the one objective and that the objective "was rewritten, and all of the objectives were approved by the Department." (Id.)

The Agency's fourth reason for not awarding a higher score to PGFMC was that "[t]he objectives did not have alternative methodologies to assure success." (Agency Response, p. 29.)

PGFMC conceded that it did not have alternative methodologies in its grant package, but argued that the requirement was irrelevant in light of the percentage of objectives met by PGFMC. (Tr., p. 96.) The Executive Director testified that "for 1979, the Foundation [PGFMC] met 80 percent of its objectives, and in 1980 . . . we have met, or will meet 75 percent of the objectives." (Id.) In addition, the Executive Director stated that this Agency argument was the result of information contained in an Agency grant package used for 1980. (Tr., p. 96.) The Executive Director asserted that the information was not available for the 1979 objectives.

The final reason given by the Agency for not awarding PGFMC a higher score was that the "[o]bjectives' outcomes or targets were not especially ambitious." (Agency Response, p. 29.)

PGFMC referred to the April 6, 1979 letter from the then project officer to PGFMC's Executive Director and noted the last paragraph:

I appreciate PGFMC's efforts in presenting these ambitious and interesting objectives in advance of our request for them, and I look forward to seeing the process develop.

(PGFMC Appeal, Sec. III.A., 1979, Attachment 3.) (emphasis added)

The project officer testified that he would not describe PGFMC's objectives as ambitious. (Tr., p. 465.)

Finding: PGFMC should be awarded a level "4" for this criterion for both 1979 and 1980. Therefore, PGFMC should be awarded 50 points for 1979 and 80 points for 1980, or an additional 70 points over the 60 points awarded PGFMC by the Agency.

The Board's conclusion is based on the fact that each of the reasons given by the Agency for not awarding PGFMC a higher score on this criterion is substantially refuted by testimony and evidence produced by PGFMC; or is unsupported by any evidence in the record; or is related solely to the requirements for attaining a level "5" score (and one of the reasons has now been abandoned by the Agency; see, p. 26 above).

PGFMC documented that it set 15 objectives in FY 79-80 and 8 objectives in FY 80-81. (See, PGFMC Appeal, Sec. III.A., 1979, Attachment 1; Sec. III.A., 1980, Attachment 1.) The Agency did not contest the validity of these figures. In addition, since level "3" and level "4" both contained the same requirement that objectives meet the criteria in III.A.2, and the Agency determined that PGFMC met level "3", it follows that PGFMC met this requirement for level "4" also.

The difference between a level "3" and level "4" is the extent and type of modifications made of the PSRO's objectives. Level "3" required a finding that the PSRO made "extensive major modifications" of its objectives. Major modifications is defined as a change in the methodology or proposed outcome of the objectives. The extent of the modifications is quantified as greater than 50% in either of the two grant cycles. Level "4" speaks of "minimal modifications." Minimal apparently refers to the quantity and quality of the modifications. In terms of quantity,

since level "3" required 50% modifications, it can reasonably be inferred that "minimal" means something less than 50%. With regard to quality, "minimal" is defined as including, but is not limited to, the refinement of data measurement and the shifting of timeframes by no more than 30 days. Level "4" has an additional requirement that the objectives "reflect the activity and priorities of the PSRO."

Although the Agency produced evidence through the testimony of the project officer that a number of objectives had to be revised, the Agency made no attempt to document the number of revisions, the types of revisions, to what extent the objectives had to be revised, or to how many of PGFMC's objectives the revisions applied.

Level "4" requires only that the PSRO set 4-8 objectives that meet the standards of that level. PGFMC documented, and the Agency did not dispute, that PGFMC set 15 objectives in FY 79-80 and 8 objectives in FY 80-81. (See, PGFMC Appeal, Sec. III.A., 1979, Attachment 1; Sec. III.A., 1980, Attachment 1.) The only evidence presented by the Agency regarding this numerical requirement was the project officer's testimony that a "number" of objectives had to be revised. (See, Tr., pp. 459-460.) Also, level "4" specifically allows for the shifting of time frames by no more than 30 days. Again, the Agency made no attempt to document the number of days by which PGFMC shifted its time frames. Since the Agency included quantifiable requirements in the scoring of this criterion and yet failed to document the percentage of modifications or to refute PGFMC's figures, we conclude that this basis for not awarding PGFMC a level "4" score was unreasonable.

The Agency did submit a letter which the Agency alleged showed that a number of PGFMC's objectives had to be rewritten. (See, Agency Exhibit A, p. 00147C.) However, as PGFMC correctly pointed out, those revisions were to be made in accordance with a new format that was issued after PGFMC had submitted its objectives. Therefore, the Board finds that it was unreasonable to include those revisions in the number of modifications. On the other hand, this letter contains specific comments by the project officer on PGFMC's objectives. In his comments, the project officer recommended the rewriting of only two of 21 objectives. (Id.) This is far less than the 50% modification figure necessary to score a level "3".

Level "4" also required that the objectives "reflect the activity and priorities of the PSRO." In this regard, the Agency argued that PGFMC failed to deal in depth with utilization issues. We find that the Agency's argument is unsupported by the evidence in the record.

The Agency's evidence on this point was a memorandum to the file by the then project officer which simply states that PGFMC's Executive Director "stated that [PGFMC's] philosophy is to emphasize quality issues as opposed to utilization issues." (Agency Exhibit A, p. 00147B.) The Agency made no attempt to document the extent of PGFMC's involvement in utilization issues in relation to other issues, or the extent of the utilization problem. Indeed, it is entirely possible that quality issues were simply a higher priority for PGFMC than utilization issues.

There is nothing in the record to show that utilization issues were neglected. Indeed, PGFMC's evidence showed that utilization issues were discussed at committee meetings (See, PGFMC Appeal Supplement II, Sec. III.A.), and in fact utilization objectives were set for the years in question. (See, PGFMC Appeal, Sec. III.A., 1979, Attachment 1; Sec. III.A., 1980, Attachment 1.) Since the Agency did not present any evidence showing how the level of PGFMC's involvement in utilization issues did not "reflect the activity and priorities of the PSRO," and PGFMC showed that it addressed utilization issues, we conclude that PGFMC met this requirement of level "4".

The last two reasons given by the Agency for not awarding PGFMC a level greater than "3" were that:

- (1) the objectives did not have alternative methodologies to assure success; and
- (2) the objectives outcomes or targets were not especially ambitious.

(See, Agency Response, p. 29.)

These two requirements were not relevant to level "4". They were specific requirements of level "5" only and, therefore, PGFMC did not need to meet them to be awarded a level "4".

In determining that PGFMC should have been awarded a level "4", the Board rejected PGFMC's contention that it deserved a level "5" for both years. As is stated above, level "5" required that the PSRO's objectives have alternative methodologies to assure the objectives success. PGFMC conceded that its objectives did not have alternative methodologies, but argued that the requirement was irrelevant in light of the percentage of objectives PGFMC had met. (See, Tr., p. 96.) The Board finds PGFMC's argument unpersuasive. The Agency established alternative methodologies as a measure of level "5" objectives. As we stated previously, the Board will not substitute its judgment on program

policy for reasonable policy choices of the Agency (see p. 6 of this decision). PGFMC did not show that the Agency acted unreasonably in choosing to award additional points to PSROs whose objectives had alternative methodologies. Therefore, the Board finds that PGFMC should not receive a level "5" for this criterion.

Section III.B.1: Impact - Utilization (Objectives)

This criterion measures the impact on reducing hospital utilization as reflected in the PSRO's objectives.

Dr. Mendelsohn testified that the measurement of utilization impact was computed as follows:

[E]very objective dealing with utilization was translated from an impact standpoint into days saved. . . . The scores were then added. A fraction based on the total days certified by the PSRO as the divisor. The numerator was the total days saved by the PSRO by their objectives. . . . We got a fractional score . . . of the days saved by the PSRO through their objective process. . . . [W]e took all of the scores of all the PSROs, put them on a range . . . to establish the distributive scoring.

. . . .

It was distributed on a bell curve type of standard deviation.

(Tr., pp. 268-270.)

The Agency determined that PGFMC did not document any impact on utilization "resulting from a listed objective for calendar years 1979-1980" and, therefore, awarded PGFMC "0" points for this criterion. (Agency Response, p. 32.) The project officer testified that "the documentation submitted by [PGFMC] was that they were unable to complete the chart." (Tr., p. 466.) The project officer stated that PGFMC subsequently submitted documentation for arthroplasty (hip replacement). (Id.) The Agency determined that this hip replacement data was not for the relevant time period, and, therefore, it was not scored. (Id.)

PGFMC argued that it actively evaluated data regarding hip replacement since 1978. (See, Tr., p. 158; see also, PGFMC Appeal Supplement II, Sec. III.B.1.) Dr. Levy testified that as a result of a review of survey data for 1978 and 1979, a problem was identified regarding the length of stay for hip replacement. (Id.) Dr. Levy stated that PGFMC "subsequently entered in the 1980 objectives the fact that they

would attempt to reduce the length of stay." (Id.) Dr. Levy asserted that the impact of the objective was that "the length of stay was, in fact, reduced significantly." (Id. at p. 159.) In support of its claim, PGFMC submitted a chart which purports to show that PGFMC's actions under this objective accounted for a .44 percent reduction of all hospital days relating to hip replacement, thereby entitling PGFMC to 60 points under this criterion. (PGFMC Appeal, Sec. III.B.1.)

In responding to PGFMC's chart, the Agency contended that PGFMC used the wrong baseline period (1979) in completing the chart. The Agency argued that:

"[g]iven the timing of this proposed objective (submitted June 24, 1980 for its grant period 10/1/80 - 9/30/81), the only choice for a baseline period is the year preceding 10/1/80. Calendar (or fiscal) year 1979 is not an acceptable baseline period."

(Agency Response, p. 32.)

PGFMC argued that it was "aggressively evaluating data related to hip replacement since 1979." (PGFMC Appeal Supplement II, Sec. III.B.1.) PGFMC gave examples of a number of the activities conducted in evaluating the validity of the data, and stated that "[a]s a result, activity related to reducing hip replacement length of stay took place throughout 1980." (Id.) Based on these activities, PGFMC argued that "1979 is the appropriate comparison year." (Id.)

The Agency also argued that PGFMC's impact period was too short. (Agency Response, p. 32.) The Agency contended that the earliest PGFMC could correct the problem of length of stay for hip replacement would be 10/1/80. (Id.) The project officer testified that "the impact period for measurement of objectives must be a 12 - month period." (Tr., p. 513.) The Agency argued, therefore, that the three month impact period was unacceptable. (Agency Response, p. 32.)

PGFMC contended that the criterion did not state that impact must be measured over a period greater than three months. (Tr., p. 515.) PGFMC argued that since it was performing the impact activity in 1980, it was entitled to the points under this criterion. (Id. at p. 517.)

Finding: PGFMC should not receive the points for this criterion.

It was not disputed by the parties that this criterion concerned only PGFMC's listed objectives. Nor was it disputed that PGFMC listed this objective regarding hip replacement for the grant period 10/1/80 - 9/30/81.

In scoring this criterion, PGFMC's grant cycles were evaluated. (See, e.g., Tr., p. 517.) PGFMC's 1979 grant cycle ran from 10/1/78 - 9/30/79, and its 1980 grant cycle ran from 10/1/79 - 9/30/80. PGFMC did not list its objective dealing with hip replacement until 10/1/80. We find that PGFMC did not present any evidence that its activities relating to its objectives for the 1980 grant year had any impact on utilization. Therefore, PGFMC is not entitled to any points under this criterion.

In so finding, we reject PGFMC's arguments concerning the use of the three month period in 1980 as the impact period. The "General Definitions" listed under criterion III.B.1. defined impact and baseline period as follows:

Impact period - Usually the grant period, but never fewer than 12 months.

Baseline period - The immediate past corresponding period to the impact period. . . . [T]he number of months used should never be less than 12.

(See, e.g., PGFMC Appeal, Part I, Sec. III.B.1.)

The Agency specifically required that a 12 month period be used in measuring impact under this criterion. PGFMC did not argue that the requirement was unreasonable or of unnecessary length based on previous experience in measuring impact, and, in any event the Board will not substitute its judgment for the Agency's determination of what a suitable period should be to measure impact.

Similarly, we reject PGFMC's argument that the baseline period is 1979. The definitional section provided that the baseline period is the "immediate past corresponding period to the impact period" of at least 12 months. Since we have found that the impact period begins on 10/1/80, the baseline period is 9/30/79 - 10/1/80.

Section III.C: Impact - Quality

Under Part III.C., the PSRO was evaluated on its documented ability to achieve an impact on the quality of health services provided. PSROs were awarded from 0 to 350 points depending upon the Agency's determination of which of four levels the PSRO had attained.

The Agency determined that PGFMC had attained a level "2" in this area; accordingly, PGFMC was awarded 50 points. PGFMC argued that it should have been scored a level "4", and awarded 350 points.

Level "2" read 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 "4" read as follows:

PSRO produced documents claiming quality impact. Documents showed that impact encompassed an exceptionally high proportion (greater than 25%) of physicians or (greater than 25%) of patients (1) Change was clearly significant in that it improved the patient care management or outcome of care for a selected category of patients by a general percent 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; or at least one pattern of life threatening incidence was eliminated. PSRO fully demonstrated that its interventions were primarily responsible for the impact.

The Agency awarded PGFMC a level "2" because the Agency determined that PGFMC "documented isolated impact affecting only a few physician or patient groups. The changes resulting were either small or insignificant." (Agency Response, p. 33.)

The project officer testified that because of the numerical element contained in levels "3" and "4", a chart was completed for each PSRO indicating the percentage of patients or physicians "whose behavior was clearly impacted upon via the operations of the PSRO program." (Tr., p. 469.)

The project officer stated that the percentage computed for PGFMC was "significantly below 10 percent" and, therefore, only a level "1" or level "2" could be awarded. (Id.)

PGFMC contended that it should have been scored at a level "4". PGFMC argued that its CQA program, complemented by outcome-oriented validation studies produced sufficient impact to meet the percentage requirements of level "4". (PGFMC Post-hearing Brief, p. 7.) Alternatively, PGFMC argued that its interventions ameliorated both life threatening and non-life threatening situations thus satisfying the criterion. (Id.)

I. Whether PGFMC documented quality impact.

A. Is PGFMC's CQA program a valid measure of impact?

PGFMC argued that its CQA program "automatically identifies and corrects quality problems while the patient is hospitalized." (PGFMC Appeal, Part II, p. 12.) PGFMC asserted that its CQA review has "identified and resolved problems in the areas of allergy identification, continuity of resident housestaff management, repeat radiological examinations, ABG values not being dated, discharge planning, and physical therapy." (Id.) PGFMC contended that during 1979 and 1980, 61% of the patients it was responsible for reviewing received complete CQA review. (Id.) Of these patients, 1210 (3.15%) required PGFMC intervention to improve "patient care management." (Id.) PGFMC claimed it was solely responsible for those interventions. (Id.)

The basic components of PGFMC's CQA program are:

- 1) Concurrent monitoring by nurse review coordinators to assure the provision of quality medical care as represented by specific and generic criteria
- 2) Identifying cases, through the above stated processes, of non-compliance with the criteria.
- 3) Intervening in cases as appropriate to correct the ascertained deficiency.
- 4) Documenting impact which is the result of a PGFMC intervention.

(See, PGFMC Appeal, Tab III.C, Attachment 2.)

Dr. James D. Levy, Past President of PGFMC and present Vice-President for Professional Affairs at Greater Southeast Community Hospital, Washington, D.C., testified that:

What [PGFMC] has tried to do is to look at the process of care, as well as the outcome, and recognize that in general if your processes are appropriate, then generally your outcome and your length of stay will also be appropriate.

(Tr., p. 160.)

Dr. Levy testified that in this regard PGFMC had placed a major emphasis on admission policies, "making sure the admission is what it is supposed to be, that the orders are what they are supposed to be, that they are implemented in a timely manner." (Id. at pp. 161-162.) In addition, PGFMC had focused on communication between doctors and nurses, specifically in the area of allergy identification and patient drug reaction. (Id.) Dr. Levy stated that this was because "approximately 20 percent of all patients admitted to hospitals have some type of drug reaction." (Id.)

Dr. Levy stated that PGFMC had placed a great deal of emphasis on these components with the result being that the quality of care issue "probably impacts on about 61 percent of all the patients at . . . PGFMC." (Id. at p. 162.)

Dr. Levy testified as to examples of how PGFMC's system had an impact on the quality of care. One example dealt with a problem at a hospital where Arterial Blood Gas (ABG) lab values were not dated. (See, Appellant's Exhibit 2; Tr., p. 167.) This issue was detected through PGFMC's CQA program. Dr. Levy stated that doing ABG tests - analyzing blood for oxygen content or to determine the acid base - can be done as quickly as 15 minutes apart or it is not unusual to have them done 2 to 3 times in a day. (Tr., p. 168.) Therefore, if the ABG value is undated, in looking at the process of care without the information, it becomes "deleterious to the patient's care." (Id.) Therefore, Dr. Levy asserted, this is an impact issue as the patient could have received inappropriate care by having unlabeled ABGs. (Id. at p. 170.)

The second example Dr. Levy explained dealt with the issue of discharge planning. (See, generally, Appellant's Exhibit 2; Tr., pp. 170-174.) Dr. Levy stated that discharge planning is an acute care issue in that it is part of quality care in assessing "what this patient's ultimate outcome is going to be in regards to what their needs are." (Tr., p. 171.) Dr. Levy stated that "[y]ou are taking an acute situation and you are trying to tie it to their entire life." (Id.) Dr. Levy testified that PGFMC identified a discharge planning problem at hospital 075. (See, previous discussion p. 13 of this decision.) Dr. Levy stated that PGFMC's actions resolved the problem "which significantly improved patient management and patient outcome and patient care as far as what happened to those patients." (Id.)

The Agency contended that CQA is a review technique and does not by itself demonstrate impact. (See, Agency Response, p. 33.) Maureen Rothermich, a PSRO program official working in the quality assurance area, testified that PGFMC's CQA program by itself is not capable of having a significant impact on the quality of care. (Tr., p. 385.)

Ms. Rothermich testified that the three common elements of quality assurance are structure, process, and outcome. (Tr., p. 368.) She further stated that structural elements are not related to PSROs; therefore, PSROs are involved with process and outcome. (Id.) Ms. Rothermich stated that "it has been the general recommendation of the people within the program that PSROs have quality assurance programs that balance both process and outcome, that one not supercede the other. . . ." (Id.)

With regard to PGFMC's CQA program, Ms. Rothermich stated:

We viewed it as being primarily process oriented. They . . . isolated sorts of incidents of day to day activities surrounding patient care, and they did not utilize . . . things such as the PSRO management information, morbidity and mortality data. They did not do any outcome sort of oriented data collections of their own.

(Tr., pp. 369-370.)

Ms. Rothermich stated that "there has to be follow-up to show that those kinds of incidents have been corrected and they are not occurring again." (Id. at p. 413.)

PGFMC argued that it did follow-up studies of the interventions under its CQA program. Dr. Levy testified that, after a problem was identified and addressed, "the data [was] then subsequently collected and profiled to look and see whether or not there is truly a systems problem." (Tr., p. 169, see also, Tr., p. 184, 195.) In addition, PGFMC asserted, and the project officer agreed, that it did a quarterly review of all the hospitals within its jurisdiction and submitted it to the Agency. (Tr., pp. 521-522.)

The Agency argued that these quarterly reports were not evidence of monitoring but an indication of the "number of interventions taken by the review staff at each facility." (Tr., p. 522.) The project officer testified that the reports fail to measure the "changes in the outcome of the medical process." (Id. at p. 524.) The project officer stated that PGFMC "cannot generate a pattern from these isolated incidences." (Tr., p. 524.)

B. How do you compute the percentage of impact?

PGFMC contended that modified behavior patterns are clearly documented in the areas of ABG values, discharge planning, and house staff management. (See, PGFMC's November 25, 1981 Supplemental Memorandum, p. 2.) PGFMC

argued that the method of measuring the amount of impact in these three areas is "projecting demonstrated success against the true population benefiting from the altered conduct imposed by PGFMC." (Id.) Utilizing this method of computation, PGFMC contended that its measure of impact was as follows:

Type of intervention	# of patients affected
ABG Values	1,500
Discharge Planning	3,000
House Staff Management	<u>34,469</u>
Total	<u>38,969</u>

Total number of patients reviewed in 1979-80: 63,064.
Percentage Impact: 62% (38,969/63,064).

(Id. at Attachment A.)

The Agency contended that PGFMC's method of computing impact was incorrect. The Agency argued that impact is a "measure of change in incidence from one record-keeping period to another." (Agency's November 25, 1981 Memorandum, p. 1.) The Agency stated that the percentage can be expressed as a formula:

$$\frac{\text{Change in Incidence}}{\text{Discharges}}$$

(Id.)

Although PGFMC disagreed with the Agency's method of computing impact, PGFMC contended that even by utilizing this method PGFMC documented a 19 percent impact rate and was, therefore, entitled to a level "3". (See, PGFMC November 25, 1981 Supplemental Memorandum, p. 2.) PGFMC submitted a chart which purports to show a 19 percent impact rate on the following intervention issues: allergy identification, house staff management, ABG values, discharge planning, and continuity of physician management. (Id. at Attachment B.)

The Agency contended that PGFMC's chart "assumed an extrapolated improvement (or impact) that was contrary to the Agency's interpretation." (Agency's December 1, 1981 Memorandum, p. 1.) The Agency argued that since PGFMC's CQA program allowed for 100% sampling, actual figures should have been available and used in computing impact. (Id.)

The Agency argued that, by using the actual improvement or change (as contrasted to PGFMC's extrapolations), the total impact for the six identified areas was 1.4 percent. (Id. at p. 3.) The Agency maintained that PGFMC was entitled to a level "2" for this criterion.

II. Whether one pattern of life threatening incidence was reduced.

With regard to the correction of life threatening problems, Dr. Levy testified that PGFMC's activities have been "very, very positive." (Id.) One example, (see, Appellant's Exhibit 2(b)), concerned a patient's temperature. Dr. Levy stated:

[A] patient had a temperature of 101.4 that against - spiked the temperature - and finally the temperature went to 102.3. What happened was that the patient had a urinary tract infection, probably associated septicemia. An antibiotic was ordered.

(Tr., p. 181.)

Dr. Levy stated that, although this problem could have been discovered in other ways, PGFMC's program "participated in detecting the problem and taking action to see that the patient's health was protected." (Id.) Dr. Levy stated that there was an impact on the patient and on the general delivery of health care. (Id. at pp.181-182.)

Dr. Levy testified to a second example of acute care intervention (see, Appellant's Exhibit 2(c)) which was a situation where a new coordinator was reviewing records of a patient who had a fracture and a metastatic disease and discovered evidence that the patient's condition was deteriorating. (Tr., p. 182.) Dr. Levy stated that the problem PGFMC was addressing dealt with "how you monitor what is going on with patient care on a day to day basis." (Id.) In this case, it was discovered that the patient was receiving inadequate fluids. (Id. at p. 183.) Dr. Levy stated that "in fact, if reversal hadn't taken place, the patient could have well died." (Id.)

With regard to the examples submitted by PGFMC and testified to by Dr. Levy, Ms. Rothermich stated they were "isolated cases." (Tr., p. 385.) For example, Ms. Rothermich stated that in the case of the 102 degree fever, without a follow-up study no pattern can be established. (Id.) Without such a pattern it cannot be determined whether the problem was the night nurse's performance, the nursing unit, or the hospital in general. (Id.) Ms. Rothermich asserted that "[i]t is an isolated incident, and the impact as a result of that is minimal." (Id. at p. 386.)

Finding: PGFMC is not entitled to a higher level for this criterion.

The Board finds that, even if we accept PGFMC's argument that its CQA system complemented with follow-up studies can be a measure of

impact, PGFMC has not shown that its measure of impact is greater than 10%. The Board also finds that PGFMC has not shown the reduction of at least one pattern of life threatening incidence. Therefore, PGFMC is not entitled to a score higher than a level "2".

The Board finds unpersuasive PGFMC's argument that impact should be measured by looking at the entire population benefiting from PGFMC's intervention. While PGFMC's method may represent a valid alternative of measuring impact, PGFMC has not presented any evidence showing why the Agency's method is incorrect, or why it does not produce an accurate measure of impact under PGFMC's CQA system. Without such a showing, the Board will not require the Agency to adjust its method of measuring impact to accommodate PGFMC.

The Board also rejects PGFMC's claim that it documented a 19% impact rate under the Agency's method of computation. PGFMC computed the number of patients impacted upon by extrapolating from sample data. (See, PGFMC November 25, 1981 Memorandum, Attachment B.) PGFMC has presented no evidence to support the sample or to explain why extrapolation is a valid method of determining the number of patients impacted upon. Indeed, we agree with the Agency's assessment that, since CQA provides for a 100% data base, actual figures should be presented. Without documentation of the actual number of patients upon whom PGFMC had an impact the Board finds against PGFMC.

We also find that PGFMC has failed to document the reduction of at least one pattern of life threatening incidence. The two examples submitted by PGFMC show PGFMC intervening on the behalf of an individual patient in detecting and correcting a problem concerning proper medical care. It is unnecessary for us to determine whether the two situations represent life threatening incidence. The criterion required that the PSRO reduce one "pattern" of life threatening incidence. We agree with the Agency's assessment that PGFMC's examples at best represent isolated cases. PGFMC has presented no evidence in the form of follow-up studies which would establish that a pattern of problem medical care existed. Therefore, we find that PGFMC failed to meet this part of the criterion.

IV. Conclusion

Based on the foregoing analysis, the Board has determined that the Record does not support the Agency's determination to terminate PGFMC's grant. PGFMC should have received a base score of 1125 points, 20 points greater than the 1105 points needed to pass the evaluation. PGFMC also passed two of the three parts: Part I with 260 points and Part II with 685 points. PGFMC should have received 180 points for Part III.

/s/ Cecilia Sparks Ford

/s/ Norval D. (John) Settle

/s/ Alexander G. Teitz
Presiding Board Member