

§ 1004.30

unnecessary, required to pay an amount of up to \$10,000 for each instance in which improper or unnecessary services were furnished or ordered (or prescribed, if appropriate). The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

[62 FR 23143, Apr. 29, 1997]

Subpart C—PRO Responsibilities

§ 1004.30 Basic responsibilities.

(a) The PRO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 1004.10.

(b) When the PRO identifies situations where an obligation specified in § 1004.10 is violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§ 1004.40 and 1004.60.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section and, if appropriate, the opportunity to enter into and complete a corrective action plan (CAP) if the PRO finds that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of admissions; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The PRO report to the OIG must comply with the provisions of § 1004.80.

(e) If a practitioner or other person relocates to another PRO area prior to a finding of a violation or sanction recommendation, and the originating PRO—

(1) Is able to make a finding, the originating PRO must, as appropriate, close the case or forward a sanction recommendation to the OIG; or

(2) Cannot make a finding, the originating PRO must forward all docu-

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mentation regarding the case to the PRO with jurisdiction, and notify the practitioner or other person of this action.

(f) The PRO must deny payment for services or items furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by an excluded practitioner or other person when the PRO identifies the services or items. It must report the findings to the Health Care Financing Administration.

§ 1004.40 Action on identification of a violation.

When a PRO identifies a violation, it must—

(a) Indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases; and

(b) Send the practitioner or other person written notice of the identification of a violation containing the following information—

(1) The obligation(s) involved;

(2) The situation, circumstances or activity that resulted in a violation;

(3) The authority and responsibility of the PRO to report violations of any obligation under section 1156(a) of the Act;

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate;

(5) The sanction that the PRO could recommend to the OIG;

(6) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice additional information or a written request for a meeting with the PRO to review and discuss the finding, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary. The notice will also state that if a meeting is requested—

(i) It will be held within 30 days of receipt by the PRO of the request, but may be extended for good cause;

(ii) The practitioner or other person may have an attorney present; and

(iii) The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner

or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person's behalf; and

(7) A copy of the material used by the PRO in arriving at its finding except for PRO deliberations, as set forth in §476.139 of this part.

§ 1004.50 Meeting with a practitioner or other person.

If the practitioner or other person requests a meeting with the PRO—

(a) The PRO panel that meets with the practitioner or other person must consist of a minimum of 3 physicians;

(b) No physician member of the PRO panel may be in direct economic competition with the practitioner or other person being considered for sanction;

(c) The PRO must ensure that no physician member of the PRO panel has a substantial bias for or against the practitioner or other person being considered for sanction;

(d) At least one member of the PRO panel meeting with the practitioner or other person should practice in a similar area, e.g., urban or rural, and at least one member of the panel must be in the same specialty (both requirements could be met by a single individual);

(e) If the practitioner or other person has an attorney present, that attorney will be permitted to make opening and closing remarks, ask clarifying questions and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person behalf;

(f) The physician who recommends to the PRO that a practitioner or other person be sanctioned may not vote on that recommendation at the meeting;

(g) The PRO may allow the practitioner or other person 5 working days after the meeting to provide the PRO additional relevant information that may affect its finding; and

(h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§ 1004.60 PRO finding of a violation.

(a) On the basis of any additional information received, the PRO will af-

firm or modify its finding. If the PRO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the PRO. If the finding has been resolved to the PRO's satisfaction, the PRO may modify its initial finding or recommendation or close the case.

(b) The PRO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in §1004.70.

(c) At least one member of the PRO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g. urban or rural, and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the PRO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or other person being recommended for sanction.

§ 1004.70 PRO action on final finding of a violation.

If the finding is not resolved to the PRO's satisfaction as specified in §1004.60(a), the PRO must—

(a) Submit its report and recommendation to the OIG;

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to the OIG, advising that—

(1) The PRO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified in §1004.100(e), the