

program receiving funds under title V or from an allotment to a State under such title, or any program receiving funds under title XX or from an allotment to a State under such title.

Substantial violation in a substantial number of cases means a pattern of providing care, as defined in this section, that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO.

Urban means a Metropolitan Statistical Area as defined by the Executive Office of Management and Budget.

Vision care professional is a term limited to licensed doctors of medicine who limit their practice to ophthalmology and to doctors of optometry.

Subpart B—Sanctions Under the PRO Program; General Provisions

§ 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are—

- (a) Provided economically and only when, and to the extent, medically necessary;
- (b) Of a quality that meets professionally recognized standards of health care; and
- (c) Supported by evidence of medical necessity and quality in the form and fashion and at such time that the reviewing PRO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements) to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under law, a practitioner or other person may be—

- (a) Excluded from participating in programs under titles V, XVIII, XIX, and XX of the Social Security Act; or
- (b) In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, and XX of the Act, if the violation involved the provision or ordering (or at the medical direction or the prescription of a physician) of health care services that were medically improper or unnecessary, required to

pay an amount not in excess of the cost of the improper or unnecessary services that were furnished or ordered (and 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.

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 documentation 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