§ 466.1 Definitions.

As used in this part, unless the context indicates otherwise:
Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) to order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a PRO of the medical necessity and appropriateness of a patient’s admission to a specific facility.

Continued stay review means PRO review that is performed after admission review and during a patient’s hospitalization to determine the medical necessity and appropriateness of continuing the patient’s stay at a hospital level of care.

Criteria means predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a PRO validates that DRG assignments are based on the correct diagnostic and procedural information.

Elective, when applied to admission or to a health care service, means an admission or a service that can be delayed without substantial risk to the health of the individual.

Five percent or more owner means a person (including, where appropriate, a corporation) who:
(a) Has an ownership interest of 5 percent or more;
(b) Has an indirect ownership interest equal to 5 percent or more;
(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or
(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or facility means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Health care practitioners other than physicians means those health professionals who do not hold a doctor of medicine or doctor of osteopathy degree, who meet all applicable State or Federal requirements for practice of their professions, and who are in active practice.

Hospital means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)-(g) of the Act, other than a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts.

Initial denial determination means an initial negative decision by a PRO, regarding the medical necessity, quality, or appropriateness of health care services furnished, or proposed to be furnished, to a patient.

Major clinical area means medicine, surgery, pediatrics, obstetrics and gynecology, or psychiatry.

Major procedure means a diagnostic or therapeutic procedure which involves a surgical or anesthetic risk or requires highly trained personnel or special facilities or equipment.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the PRO area.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Peer review means review by health care practitioners of services ordered or furnished by other practitioners in the same professional field.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient’s admission for payment purposes.

Preadmission review means review prior to a patient’s admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

Profile means aggregated data in formats that display patterns of health care services over a defined period of time.

Profile analysis means review and analysis of profiles to identify and consider patterns of health care services.

Quality review study means an assessment conducted by or for a PRO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Regional norms, criteria, and standards means norms, criteria, and standards that apply to a geographic division which is larger than a PRO area.

Retrospective review means review that is conducted after services are provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.
§ 466.70 Review responsibility means (1) the re-
sponsibility of the PRO to perform re-
view functions prescribed under Part B
of Title XI of the Act and the Social
Security Amendments of 1983 (Pub. L.
No. 98-21) and the regulations of this
part; (2) the responsibility to fulfill the
terms and meet the objectives set forth
in the negotiated contract between
HCFA and the PRO; and (3) the author-
ity of a PRO to make conclusive initial
denial determinations regarding the
medical necessity and appropriateness
of health care and changes as a result
of DRG validations.

§ 466.71 PRO review requirements.
(a) Scope of PRO review. In its review,
the PRO must determine (in accord-
ance with the terms of its contract)—
(1) Whether the services are or were
reasonable and medically necessary for
the diagnosis and treatment of illness
or injury or to improve functioning of
a malformed body member, or (with re-
spect to pneumococcal vaccine) for pre-
vention of illness or (in the case of hos-
pice care) for the palliation and man-
agement of terminal illness;
(2) Whether the quality of the serv-
ices meets professionally recognized
standards of health care;
(3) Whether those services furnished
or proposed to be furnished on an inpa-
tient basis could, consistent with the
provisions of appropriate medical care,
be effectively furnished more economi-
cally on an outpatient basis or in an
inpatient health care facility of a dif-
ferent type;
(4) Through DRG validation, the va-
validity of diagnostic and procedural in-
formation supplied by the hospital;

Subpart B [Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

Source: 50 FR 15330, Apr. 17, 1985, unless otherwise noted.

General Provisions

§ 466.70 Statutory bases and applica-
bility.
(a) Statutory basis. Sections 1154,
1866(a)(1)(F) and 1886(f)(2) of the Act re-
quire that a PRO review those services
furnished by physicians, other health care professionals, providers and sup-
pliers as specified in its contract with
the Secretary. Section 1154(a)(4) of the
Act requires PROs, or, in certain cir-
cumstances, non-PRO entities, to per-
form quality of care reviews of services
furnished under risk-basis contracts by
health maintenance organizations
(HMOs) and competitive medical plans
(CMPs) that are covered under subpart
C of part 417 of this chapter.

(b) Applicability. The regulations in
this subpart apply to review conducted
by a PRO and its subcontractors. Sec-
tion 466.72 of this part also applies, for
purposes of quality of care reviews
under section 1154(a)(4) of the Act, to
non-PRO entities that enter into con-
tracts to perform reviews of services
furnished under risk-basis contracts by
HMOs and CMPs under subpart C of
part 417 of this chapter.

[52 FR 37457, Oct. 7, 1987]