

§ 1004.1

42 CFR Ch. V (10–1–03 Edition)

**Subpart E—Effect and Duration of Exclusion**

- 1004.120 Effect of an exclusion on program payments and services.
- 1004.130 Reinstatement after exclusion.

**Subpart F—Appeals**

- 1004.140 Appeal rights.
  - AUTHORITY: 42 U.S.C. 1302 and 1320c-5.
  - SOURCE: 60 FR 63640, Dec. 12, 1995, unless otherwise noted.

**Subpart A—General Provisions**

**§ 1004.1 Scope and definitions.**

(a) *Scope.* This part implements section 1156 of the Act by—

- (1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;
- (2) Establishing criteria and procedures for the reports required from quality improvement organizations (QIOs) when there is failure to meet those obligations;
- (3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and
- (4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions.* As used in this part, unless the context indicates otherwise—

*Dentist* is limited to licensed doctors of dental surgery or dental medicine.

*Economically* means the services are provided at the least expensive, medically appropriate type of setting or level of care available.

*Exclusion* means that items and services furnished or ordered (or at the medical direction or on the prescription of a physician) by a specified health care practitioner, provider or other person during a specified period are not reimbursed under titles V, XVIII, XIX, or XX of the Social Security Act and all other Federal non-procurement programs.

*Gross and flagrant violation* means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

*Health care service or services* means services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs.

*Health professional shortage area (HPSA)* means an area designated by the Secretary and defined in 42 CFR 5.2.

*Metropolitan Statistical Area* means an area as defined by the Executive Office of Management and Budget.

*Obligation* means any of the obligations specified at section 1156(a) of the Act.

*Other person* means a hospital or other health care facility, an organization or an agency that provides health care services or which payment may be made (in whole or in part) under the Medicare or State health care programs.

*Pattern or care* means that the care under question has been demonstrated in more than three instances, each of which involved different admissions.

*Pharmacy professional* is a term limited to individuals who are licensed or registered to provide pharmaceutical services.

*Podiatric professional* is a term limited to licensed doctors of podiatric medicine.

*Practice area* means the location where over 50 percent of the practitioner's or other person's patients are seen.

*Practitioner* means a physician or other health care professional licensed under State law to practice his or her profession.

*Primary medical care professional* is a term limited to:

- (i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or

- (ii) Those facilities where care and treatment is provided to patients with health problems other than mental disorders.

*Pro area* means the geographic area subject to review by a particular QIO.

*Provider* means a hospital or other health care facility, agency, or organization.

*Psychiatric professional* is a term limited to licensed doctors of medicine who limit their practice to psychiatry or to those facilities where care and treatment is limited to patients with mental disorders.

*Rural* means any area outside an urban area.

*Rural health professional shortage area* means any health professional shortage area located outside a Metropolitan Statistical Area.

*Sanction* means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a QIO.

*Serious risk* includes situations that may involve the risk of unnecessary treatment, prolonged treatment, lack of treatment, incorrect treatment, medical complication, premature discharge, physiological or anatomical impairment, disability, or death.

*State health care program* means a State plan approved under title XIX, any 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 QIO.

*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 QIO 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 QIO 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 the 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 for a period of no less than 1 year; 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 of health care services (or services furnished at the medical direction or on the prescription of a physician) that were medically improper or 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—QIO Responsibilities

#### § 1004.30 Basic responsibilities.

(a) The QIO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other