

violate the statute. We believe that the great majority of practitioners and other persons do not engage in such prohibited activities and practices, and that the aggregate economic impact of these provisions should, in effect, be minimal, affecting only those who have engaged in prohibited behavior in violation of statutory intent. As such, these regulations should have no direct effect on the economy or on Federal or State expenditures.

In addition, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601 through 612), the Secretary certifies that this final rulemaking will not have a significant economic impact on a substantial number of small entities. While some sanctions and penalties may have an impact on small entities, we do not anticipate that a substantial number of these small entities would be significantly affected by this rulemaking. Therefore, we have determined, and the Secretary certifies, that this final rule should not have a significant economic impact on a number of small business entities.

List of Subjects in 42 CFR Part 1004

Administrative practice and procedure, Health facilities, Health professions, Medicare, Peer Review Organizations, Penalties, Reporting and recordkeeping requirements.

Part 1004 is revised to read as follows:

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A PEER REVIEW ORGANIZATION

Subpart A—General Provisions

Sec.

1004.1 Scope and definitions.

Subpart B—Sanctions Under the PRO Program; General Provisions

1004.10 Statutory obligations of practitioners and other persons.

1004.20 Sanctions.

Subpart C—PRO Responsibilities

1004.30 Basic responsibilities.

1004.40 Action on identification of a violation.

1004.50 Meeting with a practitioner or other person.

1004.60 PRO finding of a violation.

1004.70 PRO action on final finding of a violation.

1004.80 PRO report to the OIG.

1004.90 Basis for recommended sanction.

Subpart D—OIG Responsibilities

1004.100 Acknowledgement and review of report.

1004.110 Notice of sanction.

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.

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 peer review organizations (PROs) 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 PRO.

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 PRO.

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