including claims for services rendered by excluded individuals employed by or otherwise under contract with such person, under one or more Federal health care programs;

(xv) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act;

(xvi) Violate the provisions of part 73 of this title, implementing section 351A(b) and (c) of the Public Health Service Act, with respect to the possession and use within the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins in use, or transfer of listed biological agents and toxins; or

(xvii) Violate the provisions of part 403, subpart H of this title, implementing the Medicare prescription drug discount card and transitional assistance program, by misleading or defrauding program beneficiaries, by overcharging a discount program enrollee, or by misusing transitional assistance funds.

(2) Provides for the exclusion of persons from the Medicare or State health care programs against whom a civil money penalty or assessment has been imposed, and the basis for reinstatement of persons who have been excluded; and

(3) Sets forth the appeal rights of persons subject to a penalty, assessment and exclusion.

[65 FR 24414, Apr. 26, 2000, as amended at 67 FR 11935, Mar. 18, 2002; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§ 1003.101 Definitions.

For purposes of this part:

Act means the Social Security Act.

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient or has placed the patient unnecessarily in a high-risk situation.

ALJ means an Administrative Law Judge.

Assessment means the amount described in §1003.104, and includes the plural of that term.

Claim means an application for payment for an item or service to a Federal health care program (as defined in section 1128B(f) of the Act).

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

Contracting organization means a public or private entity, including of a health maintenance organization (HMO), competitive medical plan, or health insuring organization (HIO) which meets the requirements of section 1876(b) of the Act or is subject to the requirements in section 1903(m)(2)(A) of the Act and which has contracted with the Department or a State to furnish services to Medicare beneficiaries or Medicaid recipients.

Department means the Department of Health and Human Services.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization that contracts with the Department under title XVIII or title XIX of the Act.

Exclusion means the temporary or permanent barring of a person from participation in a Federal health care program (as defined in section 1128B(f) of the Act).

Inspector General means the Inspector General of the Department or his or her designees.

Item or service includes—

(a) Any item, device, medical supply or service provided to a patient (i) which is listed in an itemized claim for program payment or a request for payment, or (ii) for which payment is included in other Federal or State health care reimbursement methods, such as a prospective payment system; and

(b) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medicaid means the program of grants to the States for medical assistance authorized under title XIX of the Act.

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician's, dentist's or other health care

practitioner's provision of, or failure to provide health care services, and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

Medicare means the program of health insurance for the aged and disabled authorized under Title XVIII of the Act.

Participating hospital means (1) a hospital or (2) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in §1003.103 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physician incentive plan means any compensation arrangement between a contracting organization and a physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

Preventive care, for purposes of the definition of the term Remuneration as set forth in this section and the preventive care exception to section 231(h) of HIPAA, means any service that—

(1) Is a prenatal service or a postnatal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services,* and

(2) Is reimbursable in whole or in part by Medicare or an applicable State health care program.

Remuneration, as set forth in §1003.102(b)(13) of this part, is consistent with the definition contained in section 1128A(i)(6) of the Act, and includes the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term ''remuneration'' does not include—

(1) The waiver of coinsurance and deductible amounts by a person, if the waiver is not offered as part of any advertisement or solicitation; the person does not routinely waive coinsurance or deductible amounts; and the person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection efforts;

(2) Any permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary;

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented; or

(4) Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include—

(i) Cash or instruments convertible to cash; or

(ii) An incentive the value of which is disproportionally large in relationship to the value of the preventive care service (*i.e.,* either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

Request for payment means an application submitted by a person to any person for payment for an item or service.

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department seeking assistance and includes a physician on call for the care of such individual.

Secretary means the Secretary of the Department or his or her designees.

Select agents and toxins means agents and toxins that are listed by the HHS Secretary as having the potential to pose a severe threat to public health and safety, in accordance with section

351A(a)(1) of the Public Health Service Act.

Should know or *should have known* means that a person, with respect to information—

(1) Acts in deliberate ignorance of the truth or falsity of the information; or

(2) Acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

Timely basis means, in accordance with §1003.102(b)(9) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

Transitional assistance means the subsidy funds that Medicare beneficiaries enrolled in the prescription drug discount card and transitional assistance program may apply toward the cost of covered discount card drugs in the manner described in §403.808(d) of this title.

[51 FR 34777, Sept. 30, 1986, as amended at 56 FR 28492, June 21, 1991; 57 FR 3345, Jan. 29, 1992; 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 61 FR 13449, Mar. 27, 1996; 65 FR 24415, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 66 FR 39452, July 31, 2001; 67 FR 11935, Mar. 18, 2002; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has knowingly presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that is part of a pattern or practice of claims based on codes that the person knows or should know will result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent, including a claim for any item or service furnished by an excluded individual employed by or otherwise under contract with that person;

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was made;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified;

(5) A payment that such person knows, or should know, may not be made under §411.353 of this title; or

(6) An item or service that a person knows or should know is medically unnecessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(1) Has knowingly presented or caused to be presented a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;