

## **Title 42: Public Health**

### **Part 1003. Civil Money Penalties, Assessments and Exclusions.**

#### **Subpart A – General Provisions.**

#### **42 C.F.R. § 1003.110 Definitions.**

For purposes of this part:

*Assessment* means the amounts described in this part and includes the plural of that term.

*Claim* means an application for payment for an item or service under a Federal health care program.

*Contracting organization* means a public or private entity, including a health maintenance organization, Medicare Advantage organization, Prescription Drug Plan sponsor, or other organization that has contracted with the Department or a State to furnish, or otherwise pay for, items and services to Medicare or Medicaid beneficiaries pursuant to sections 1857, 1860D-12, 1876(b), or 1903(m) of the Act.

*Enrollee* means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization.

*Items and services or items or services* includes without limitation, any item, device, drug, biological, supply, or service (including management or administrative services), including, but not limited to, those that are listed in an itemized claim for program payment or a request for payment; for which payment is included in any Federal or State health care program reimbursement method, such as a prospective payment system or managed care system; or that are, in the case of a claim based on costs, required to be entered in a cost report, books of account, or other documents supporting the claim (whether or not actually entered).

*Knowingly* means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required.

*Material* means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

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

*Non-separately-billable item or service* means an item or service that is a component of, or otherwise contributes to the provision of, an item or a service, but is not itself a separately billable item or service.

*Overpayment* means any funds that a person receives or retains under Medicare or Medicaid to which the person, after applicable reconciliation, is not entitled under such program.

*Participating hospital* means either a hospital or a critical access 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 this part 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 or 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 post-natal 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.

*Reasonable request*, with respect to §1003.200(b)(10), means a written request, signed by a designated representative of the OIG and made by a properly identified agent of the OIG during reasonable business hours. The request will include: A statement of the authority for the request, the person's rights in responding to the request, the definition of "reasonable request" and "failure to grant timely access" under part 1003, the deadline by which the OIG requests access, and the amount of the civil money penalty or assessment that could be imposed and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

*Remuneration*, for the purposes of §1003.1000(a) of this part, is consistent with the definition in section 1128A(i)(6) of the Act and includes the waiver of copayment, 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;

(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 disproportionately 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).

(5) A reduction in the copayment amount for covered OPD services under section 1833(t)(8)(B) of the Act;

(6) Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—

(i) Being unlikely to interfere with, or skew, clinical decision making;

(ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and

(iii) Not raising patient safety or quality-of-care concerns;

(7) The offer or transfer of items or services for free or less than fair market value by a person if—

(i) The items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) The items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a State health care program (as defined in section 1128(h) of the Act);

(8) The offer or transfer of items or services for free or less than fair market value by a person, if—

(i) The items or services are not offered as part of any advertisement or solicitation;

(ii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a State health care program (as defined in section 1128(h) of the Act);

(iii) There is a reasonable connection between the items or services and the medical care of the individual; and

(iv) The person provides the items or services after determining in good faith that the individual is in financial need;

(9) Waivers by a Part D Plan sponsor (as that term is defined in 42 CFR 423.4) of any copayment for the first fill of a covered Part D drug (as defined in section 1860D-2(e)) that is a generic drug (as defined in 42 CFR 423.4) or an authorized generic drug (as defined in 21 CFR 314.3) for individuals enrolled in the Part D plan (as that term is defined in 42 CFR 423.4), as long as such waivers are included in the benefit design package submitted to CMS. This exception is applicable to coverage years beginning on or after January 1, 2018.

(10) The provision of telehealth technologies by a provider of services or a renal dialysis facility (as such terms are defined for purposes of title XVIII of the Act) to an individual with end stage renal disease who is receiving home dialysis for which payment is being made under part B of such title, if-

(i) The telehealth technologies are furnished to the individual by the provider of services or the renal dialysis facility that is currently providing the in-home dialysis, telehealth visits, or other end stage renal disease care to the patient;

(ii) The telehealth technologies are not offered as part of any advertisement or solicitation;

(iii) The telehealth technologies contribute substantially to the provision of telehealth services related to the individual's end stage renal disease, is not of excessive value, and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes; and

(iv) The provider of services or a renal dialysis facility does not bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the telehealth technologies as a bad debt for payment purposes under a Federal health care program, or otherwise shift the burden of the value of the telehealth technologies onto a Federal health care program, other payors, or individuals.

*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 Official* means the individual designated pursuant to 42 CFR part 73 to serve as the Responsible Official for the person holding a certificate of registration to possess, use, or transfer select agents or toxins.

*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 requesting examination or treatment, including any physician who is on-call for the care of such individual and fails or refuses to appear within a reasonable time at such hospital to provide services relating to the examination, treatment, or transfer of such individual. *Responsible physician* also includes a physician who is responsible for the examination or treatment of individuals at hospitals with specialized capabilities or facilities, as provided under section 1867(g) of the Act, including any physician who is on-call for the care of such individuals and refuses to accept an appropriate transfer or fails or refuses to appear within a reasonable time to provide services related to the examination or treatment of such individuals.

*Select agents and toxins* is defined consistent with the definition of "select agent and/or toxin" and "overlap select agent and/or toxin" as set forth in 42 CFR part 73.

*Separately billable item or service* means an item or service for which an identifiable payment may be made under a Federal health care program, e.g., an itemized claim or a payment under a prospective payment system or other reimbursement methodology.

*Should know, or should have known*, means that a person, with respect to information, either acts in deliberate ignorance of the truth or falsity of the information or 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 Act.

[Telehealth technologies, for purposes of the definition of the term "remuneration" as set forth in this section and the telehealth technologies exception to section 50302\(c\) of the Bipartisan Budget Act of 2018, which adds an exception as new section 1128A\(i\)\(6\)\(J\) of the Act, means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management-paid for by Medicare Part B-between a patient and the remote healthcare provider. Telephones, facsimile machines, and electronic mail systems are not telehealth technologies.](#)

*Timely basis* means, in accordance with §1003.300(a) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.