(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid, or satisfactory arrangements have been made, that fulfill these obligations.

(b) Notice of action on request for reinstatement. (1) If the State agency approves the request for reinstatement, it must give written notice to the excluded party, and to all others who were informed of the exclusion in accordance with §1002.212, specifying the date on which Medicaid program participation may resume.

(2) If the State agency does not approve the request for reinstatement, it will notify the excluded party of its decision. Any appeal of a denial of reinstatement will be in accordance with State procedures and need not be subject to administrative or judicial review, unless required by State law.

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

§ 1002.230 Notification of State or local convictions of crimes against Medicaid.

(a) The State agency must notify the OIG whenever a State or local court has convicted an individual who is receiving reimbursement under Medicaid of a criminal offense related to participation in the delivery of health care items or services under the Medicaid program, except where the State Medicaid Fraud Control Unit (MFCU) has so notified the OIG.

(b) If the State agency was involved in the investigation or prosecution of the case, it must send notice within 15 days after the conviction.

(c) If the State agency was not so involved, it must give notice within 15 days after it learns of the conviction.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

Subpart A—General Provisions

Sec.

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

Subpart E—CMPs and Exclusions for EMTALA Violations

Subpart F—CMPs for Section 1140 Violations

Subpart G [Reserved]

AUTHORITY: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

SOURCE: 51 FR 34777, Sept. 30, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 1003.100 Basis and purpose.

(a) *Basis*. This part implements sections 1128(c), 1128A, 1140, 1819(b)(3)(B), 1819(g)(2)(A), 1857(g)(2)(A), 1860D–12(b)(3)(E), 1860D–31(i)(3), 1862(b)(3)(C), 1867(d)(1), 1876(i)(6), 1877(g), 1882(d), 1891(c)(1); 1903(m)(5), 1919(b)(3)(B), 1919(g)(2)(A), 1927(b)(3)(B), 1927(b)(3)(C), and 1929(i)(3) of the Social Security Act; sections 421(c) and 427(b)(2) of Public Law 99–660; and section 201(i) of Public Law 107–188 (42 U.S.C. 1320a–7(c), 1320a–7a, 1320b–10, 1395i–3(b)(3)(B), 1395i–3(g)(2)(A), 1395w–27(g)(2)(A), 1395w–112(b)(3)(E), 1395w–141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm(i)(6), 1395nn(g), 1395ss(d), 1395bbb(c)(1), 1396b(m)(5), 1396r(b)(3)(B), 1396r(g)(2)(A), 1396r–8(b)(3)(B), 1396r–8(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a(i)).

(b) *Purpose*. This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments and exclusions against persons who have committed an act or omission that violates one or more provisions of this part and

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

[81 FR 88354, Dec. 7, 2016]

§ 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 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.

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 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).

(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.

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.

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.

[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. Redesignated and amended at 81 FR 88355, Dec. 7, 2016; 81 FR 88409, Dec. 7, 2016]

§1003.120 Liability for penalties and assessments.

(a) In any case in which it is determined that more than one person was responsible for a violation described in this part, each such person may be held liable for the penalty prescribed by this part.

(b) In any case in which it is determined that more than one person was responsible for a violation described in this part, an assessment may be imposed, when authorized, against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(c) Under this part, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of his or her agency. This provision does not limit the underlying liability of the agent.

[81 FR 88356, Dec. 7, 2016]

§1003.130 Assessments.

The assessment in this part is in lieu of damages sustained by the Department or a State agency because of the violation.

[81 FR 88356, Dec. 7, 2016]

§ 1003.140 Determinations regarding the amount of penalties and assessments and the period of exclusion.

(a) Except as otherwise provided in this part, in determining the amount of any penalty or assessment or the period of exclusion in accordance with this part, the OIG will consider the following factors—

(1) The nature and circumstances of the violation;

(2) The degree of culpability of the person against whom a civil money penalty, assessment, or exclusion is proposed. It should be considered an aggravating circumstance if the respondent had actual knowledge where a lower level of knowledge was required to establish liability (*e.g.,* for a provision that establishes liability if the respondent ''knew or should have known'' a claim was false or fraudulent, it will be an aggravating circumstance if the respondent knew the claim was false or fraudulent). It should be a mitigating circumstance if the person took appropriate and timely corrective action in response to the violation. For purposes of this part, corrective action must include disclosing the violation to the OIG through the Self-Disclosure Protocol and fully cooperating with the OIG's review and resolution of such disclosure, or in cases of physician self-referral law violations, disclosing the violation to CMS through the Self-Referral Disclosure Protocol;

(3) The history of prior offenses. Aggravating circumstances include, if at any time prior to the violation, the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or in connection with the delivery of a health care item or service;

(4) Other wrongful conduct. Aggravating circumstances include proof that the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to a government program or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance; and

(5) Such other matters as justice may require. Other circumstances of an aggravating or mitigating nature should be considered if, in the interests of justice, they require either a reduction or an increase in the penalty, assessment, or period of exclusion to achieve the purposes of this part.

(b)(1) After determining the amount of any penalty and assessment in accordance with this part, the OIG considers the ability of the person to pay the proposed civil money penalty or assessment. The person shall provide, in a time and manner requested by the OIG, sufficient financial documentation, including, but not limited to, audited financial statements, tax returns, and financial disclosure statements, deemed necessary by the OIG to determine the person's ability to pay the penalty or assessment.

(2) If the person requests a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review is that which the person provided to the OIG during the administrative process, unless the ALJ finds that extraordinary circumstances prevented the person from providing the financial documentation to the OIG in the time and manner requested by the OIG prior to the hearing request.

(c) In determining the amount of any penalty and assessment to be imposed

under this part the following circumstances are also to be considered—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by this part to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum permitted by this part to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should not be less than double the approximate amount of damages and costs (as defined by paragraph (e)(2) of this section) sustained by the United States, or any State, as a result of the violation.

(4) The presence of any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors is present.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including, but not limited to, the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this part limits the authority of the Department or the OIG to settle any issue or case as provided by §1003.1530 or to compromise any exclusion and any penalty and assessment as provided by §1003.1550.

(4) Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties, assessments, or other sanctions prescribed by law.

[81 FR 88356, Dec. 7, 2016]

§ 1003.150 Delegation of authority.

The OIG is delegated authority from the Secretary to impose civil money penalties and, as applicable, assessments and exclusions against any person who has violated one or more provisions of this part. The delegation of authority includes all powers to impose and compromise civil monetary penalties, assessments, and exclusion under section 1128A of the Act.

[81 FR 88356, Dec. 7, 2016]

§ 1003.160 Waiver of exclusion.

(a) The OIG will consider a request from the administrator of a Federal health care program for a waiver of an exclusion imposed under this part as set forth in paragraph (b) of this section. The request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) If the OIG subsequently obtains information that the basis for a waiver no longer exists, the waiver will cease and the person will be fully excluded from the Federal health care programs for the remainder of the exclusion period, measured from the time the full exclusion would have been imposed if the waiver had not been granted.

(c) The OIG will notify the administrator of the Federal health care program whether his or her request for a waiver has been granted or denied.

(d) If a waiver is granted, it applies only to the program(s) for which waiver is requested.

(e) The decision to grant, deny, or rescind a waiver is not subject to administrative or judicial review.

[81 FR 88356, Dec. 7, 2016]

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

SOURCE: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

§ 1003.200 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, assessment, and an exclusion against any person who it determines has

knowingly presented, or caused to be presented, a claim that was for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that was part of a pattern or practice of claims based on codes that the person knew, or should have known, would 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;

(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 presented;

(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 by a medical specialty board when he or she was not so certified; or

(5) An item or service that a person knew, or should have known was not medically necessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty; an exclusion; and, where authorized, an assessment against any person who it determines—

(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;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1) of the Act; or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act;

(2) Has knowingly given, or caused to be given, to any person, in the case of inpatient hospital services subject to section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital;

(3) Is an individual who is excluded from participating in a Federal health care program under section 1128 or 1128A of the Act, and who—

(i) Knows, or should know, of the action constituting the basis for the exclusion and retains a direct or indirect ownership or control interest of 5 percent or more in an entity that participates in a Federal health care program or

(ii) Is an officer or a managing employee (as defined in section 1126(b) of the Act) of such entity;

(4) Arranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in Federal health care programs for the provision of items or services for which payment may be made under such a program;

(5) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under a Federal health care program if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act or violates the requirements for such an arrangement;

(6) Orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program, in the case when the person knows, or should know, that a claim for such medical or other item or service will be made under such a program;

(7) Knowingly makes, or causes to be made, any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of

services or a supplier under a Federal health care program, including contracting organizations, and entities that apply to participate as providers of services or suppliers in such contracting organizations;

(8) Knows of an overpayment and does not report and return the overpayment in accordance with section 1128J(d) of the Act;

(9) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(10) Fails to grant timely access to records, documents, and other material or data in any medium (including electronically stored information and any tangible thing), upon reasonable request, to the OIG, for the purpose of audits, investigations, evaluations, or other OIG statutory functions. Such failure to grant timely access means:

(i) Except when the OIG reasonably believes that the requested material is about to be altered or destroyed, the failure to produce or make available for inspection and copying the requested material upon reasonable request or to provide a compelling reason why they cannot be produced, by the deadline specified in the OIG's written request, and

(ii) When the OIG has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.

(c) The OIG may impose a penalty against any person who it determines, in accordance with this part, is a physician and who executes a document falsely by certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements in section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(d) The OIG may impose a penalty against any person who it determines knowingly certifies, or causes another individual to certify, a material and false statement in a resident assessment pursuant to sections 1819(b)(3)(B) and 1919(b)(3)(B).

§ 1003.210 Amount of penalties and assessments.

(a) *Penalties.*[1] (1) Except as provided in this section, the OIG may impose a penalty of not more than $10,000 for each individual violation that is subject to a determination under this subpart.

(2) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.200(b)(2).

(3) The OIG may impose a penalty of not more than $10,000 per day for each day that the prohibited relationship described in § 1003.200(b)(3) occurs.

(4) For each individual violation of § 1003.200(b)(4), the OIG may impose a penalty of not more than $10,000 for each separately billable or non-separately-billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity.

(5) The OIG may impose a penalty of not more than $2,000 for each bill or request for payment for items and services furnished to a hospital patient in violation of § 1003.200(b)(5).

(6) The OIG may impose a penalty of not more than $50,000 for each false statement, omission, or misrepresentation of a material fact in violation of § 1003.200(b)(7).

(7) The OIG may impose a penalty of not more than $50,000 for each false record or statement in violation of § 1003.200(b)(9).

(8) The OIG may impose a penalty of not more than $10,000 for each item or service related to an overpayment that is not reported and returned in accordance with section 1128J(d) of the Act in violation of § 1003.200(b)(8).

(9) The OIG may impose a penalty of not more than $15,000 for each day of failure to grant timely access in violation of § 1003.200(b)(10).

[1] The penalty amounts in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

(10) For each false certification in violation of §1003.200(c), the OIG may impose a penalty of not more than the greater of—

(i) $5,000; or

(ii) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a physician, as prohibited by section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(11) For each false certification in violation of §1003.200(d), the OIG may impose a penalty of not more than—

(i) $1,000 with respect to an individual who willfully and knowingly falsely certifies a material and false statement in a resident assessment; and

(ii) $5,000 with respect to an individual who willfully and knowingly causes another individual to falsely certify a material and false statement in a resident assessment.

(b) *Assessments.* (1) Except for violations of §1003.200(b)(4), (5), and (7), and §1003.200(c) and (d), the OIG may impose an assessment for each individual violation of §1003.200, of not more than 3 times the amount claimed for each item or service.

(2) For violations of §1003.200(b)(4), the OIG may impose an assessment of not more than 3 times—

(i) The amount claimed for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity or

(ii) The total costs (including salary, benefits, taxes, and other money or items of value) related to the excluded individual or entity incurred by the person that employs, contracts with, or otherwise arranges for an excluded individual or entity to provide, furnish, order, or prescribe a non-separately-billable item or service.

(3) For violations of §1003.200(b)(7), the OIG may impose an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement, omission, or misrepresentation of material fact.

§1003.220 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in §1003.140—

(a) It should be considered a mitigating circumstance if all the items or services or violations included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or violations, and the total amount claimed or requested for such items or services was less than $5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items or services or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services, or the amount of the overpayment was $50,000 or more;

(4) The violation resulted, or could have resulted, in patient harm, premature discharge, or a need for additional services or subsequent hospital admission; or

(5) The amount or type of financial, ownership, or control interest or the degree of responsibility a person has in an entity was substantial with respect to an action brought under §1003.200(b)(3).

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

SOURCE: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

§1003.300 Basis for civil money penalties, assessments, and exclusions.

The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines in accordance with this part—

(a) Has not refunded on a timely basis, as defined in §1003.110, amounts

collected as a result of billing an individual, third party payer, or other entity for a designated health service furnished pursuant to a prohibited referral as described in 42 CFR 411.353.

(b) Is a physician or other person who enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person that, if the physician directly made referrals to such person, would be in violation of the prohibitions of 42 CFR 411.353.

(c) Has knowingly presented, or caused to be presented, a claim that is for a payment that such person knows, or should know, may not be made under 42 CFR 411.353;

(d) Has violated section 1128B(b) of the Act by unlawfully offering, paying, soliciting, or receiving remuneration to induce or in return for the referral of business paid for, in whole or in part, by Medicare, Medicaid, or other Federal health care programs.

§ 1003.310 Amount of penalties and assessments.

(a) *Penalties.*[2] The OIG may impose a penalty of not more than—

(1) $15,000 for each claim or bill for a designated health service, as defined in § 411.351 of this title, that is subject to a determination under § 1003.300(a) or (c);

(2) $100,000 for each arrangement or scheme that is subject to a determination under § 1003.300(b); and

(3) $50,000 for each offer, payment, solicitation, or receipt of remuneration that is subject to a determination under § 1003.300(d).

(b) *Assessments.* The OIG may impose an assessment of not more than 3 times—

(1) The amount claimed for each designated health service that is subject to a determination under § 1003.300(a), (b), or (c).

(2) The total remuneration offered, paid, solicited, or received that is subject to a determination under § 1003.300(d). Calculation of the total remuneration for purposes of an assessment shall be without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose.

§ 1003.320 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in § 1003.140:

(a) It should be considered a mitigating circumstance if all the items, services, or violations included in the action brought under this part were of the same type and occurred within a short period of time; there were few such items, services, or violations; and the total amount claimed or requested for such items or services was less than $5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items, services, or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services or the amount of the remuneration was $50,000 or more; or

(4) The violation resulted, or could have resulted, in harm to the patient, a premature discharge, or a need for additional services or subsequent hospital admission.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

SOURCE: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

§ 1003.400 Basis for civil money penalties and assessments.

(a) *All contracting organizations.* The OIG may impose a penalty against any contracting organization that—

(1) Fails substantially to provide an enrollee with medically necessary items and services that are required (under the Act, applicable regulations, or contract with the Department or a

[2] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

State) to be provided to such enrollee and the failure adversely affects (or has the substantial likelihood of adversely affecting) the enrollee;

(2) Imposes a premium on an enrollee in excess of the amounts permitted under the Act;

(3) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by beneficiaries whose medical condition or history indicates a need for substantial future medical services, except as permitted by the Act;

(4) Misrepresents or falsifies information furnished to a person under sections 1857, 1860D–12, 1876, or 1903(m) of the Act;

(5) Misrepresents or falsifies information furnished to the Secretary or a State, as applicable, under sections 1857, 1860D–12, 1876, or 1903(m) of the Act;

(6) Fails to comply with the requirements of 42 CFR 417.479(d) through (i) for Medicare and 42 CFR 417.479(d) through (g) and (i) for Medicaid regarding certain prohibited incentive payments to physicians; or

(7) Fails to comply with applicable requirements of the Act regarding prompt payment of claims.

(b) *All Medicare contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1857, 1860D–12, or 1876 of the Act that—

(1) Acts to expel or to refuse to reenroll a beneficiary in violation of the Act; or

(2) Employs or contracts with a person excluded, under section 1128 or 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services, or employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded person.

(c) *Medicare Advantage and Part D contracting organizations.* The OIG may impose a penalty, and for § 1003.400(c)(4) or (5), an assessment, against a contracting organization with a contract under section 1857 or 1860D–12 of the Act that:

(1) Enrolls an individual without the individual's (or his or her designee's) prior consent, except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1) of the Act;

(2) Transfers an enrollee from one plan to another without the individual's (or his or her designee's) prior consent;

(3) Transfers an enrollee solely for the purpose of earning a commission;

(4) Fails to comply with marketing restrictions described in subsection (h) or (j) of section 1851 of the Act or applicable implementing regulations or guidance; or

(5) Employs or contracts with any person who engages in the conduct described in paragraphs (a) through (c) of this section.

(d) *Medicare Advantage contracting organizations.* The OIG may impose a penalty against a contracting organization with a contract under section 1857 of the Act that fails to comply with the requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii) of the Act.

(e) *Medicaid contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1903(m) of the Act that acts to discriminate among individuals in violation of the Act, including expulsion or refusal to reenroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals with the contracting organization whose medical condition or history indicates a need for substantial future medical services.

§ 1003.410 Amount of penalties and assessments for Contracting Organization.

(a) *Penalties.*[3] (1) The OIG may impose a penalty of up to $25,000 for each individual violation under § 1001.400, except as provided in this section.

(2) The OIG may impose a penalty of up to $100,000 for each individual violation under § 1003.400(a)(3), (a)(5), or (e).

(b) *Additional penalties.* In addition to the penalties described in paragraph (a) of this section, the OIG may impose—

[3] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(1) An additional penalty equal to double the amount of excess premium charged by the contracting organization for each individual violation of §1003.400(a)(2). The excess premium amount will be deducted from the penalty and returned to the enrollee.

(2) An additional $15,000[4] penalty for each individual expelled or not enrolled in violation of §1003.400(a)(3) or (e).

(c) *Assessments.* The OIG may impose an assessment against a contracting organization with a contract under section 1857 or 1860D–12 of the Act (Medicare Advantage or Part D) of not more than the amount claimed in violation of §1003.400(a)(4) or (a)(5) on the basis of the misrepresentation or falsified information involved.

(d) The OIG may impose a penalty or, when applicable, an assessment, against a contracting organization with a contract under section 1857 or 1860D–12 of the Act (Medicare Advantage or Part D) if any of its employees, agents, or contracting providers or suppliers engages in any of the conduct described in §1003.400(a) through (d).

§1003.420 Determinations regarding the amount of penalties and assessments.

In considering the factors listed in §1003.140, aggravating circumstances include—

(a) Such violations were of several types or occurred over a lengthy period of time;

(b) There were many such violations (or the nature and circumstances indicate a pattern of incidents);

(c) The amount of money, remuneration, damages, or tainted claims involved in the violation was $15,000 or more; or

(d) Patient harm, premature discharge, or a need for additional services or subsequent hospital admission resulted, or could have resulted, from the incident; and

(e) The contracting organization knowingly or routinely engaged in any prohibited practice that acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization.

Subpart E—CMPs and Exclusions for EMTALA Violations

SOURCE: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

§1003.500 Basis for civil money penalties and exclusions.

(a) The OIG may impose a penalty against any participating hospital with an emergency department or specialized capabilities or facilities for each negligent violation of section 1867 of the Act or §489.24 (other than §489.24(j)) of this title.

(b) The OIG may impose a penalty against any responsible physician for each—

(1) Negligent violation of section 1867 of the Act;

(2) Certification signed under section 1867(c)(l)(A) of the Act if the physician knew, or should have known, that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(3) Misrepresentation made concerning an individual's condition or other information, including a hospital's obligations under section 1867 of the Act.

(c) The OIG may, in lieu of or in addition to any penalty available under this subpart, exclude any responsible physician who commits a gross and flagrant, or repeated, violation of this subpart from participation in Federal health care programs.

(d) For purposes of this subpart, a ''gross and flagrant violation'' is a violation that presents an imminent danger to the health, safety, or well-being of the individual who seeks examination and treatment or places that individual unnecessarily in a high-risk situation.

§1003.510 Amount of penalties.

The OIG may impose[5]—

(a) Against each participating hospital, a penalty of not more than

[4] This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[5] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

$50,000 for each individual violation, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000 for each violation, and

(b) Against each responsible physician, a penalty of not more than $50,000 for each individual violation.

§ 1003.520 Determinations regarding the amount of penalties and the period of exclusion.

In considering the factors listed in § 1003.140,

(a) It should be considered a mitigating circumstance if a hospital took appropriate and timely corrective action in response to the violation. For purposes of this subpart, corrective action must be completed prior to CMS initiating an investigation of the hospital for violations of section 1867 of the Act and must include disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

(b) Aggravating circumstances include:

(1) Requesting proof of insurance, prior authorization, or a monetary payment prior to appropriately screening or initiating stabilizing treatment for an emergency medical condition, or requesting a monetary payment prior to stabilizing an emergency medical condition;

(2) Patient harm, or risk of patient harm, resulted from the incident; or

(3) The individual presented to the hospital with a request for examination or treatment of a medical condition that was an emergency medical condition, as defined by § 489.24(b) of this title.

Subpart F—CMPs for Section 1140 Violations

SOURCE: 81 FR 88357, Dec. 7, 2016, unless otherwise noted.

§ 1003.600 Basis for civil money penalties.

(a) The OIG may impose a penalty against any person who it determines in accordance with this part has used the words, letters, symbols, or emblems as defined in paragraph (b) of this section in such a manner that such person knew, or should have known, would convey, or in a manner that reasonably could be interpreted or construed as conveying, the false impression that an advertisement, a solicitation, or other item was authorized, approved, or endorsed by the Department or CMS or that such person or organization has some connection with or authorization from the Department or CMS.

(b) Civil money penalties may be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department, or its programs, for misuse of—

(1) The words ''Department of Health and Human Services,'' ''Health and Human Services,'' ''Centers for Medicare & Medicaid Services,'' ''Medicare,'' or ''Medicaid'' or any other combination or variations of such words;

(2) The letters ''DHHS,'' ''HHS,'' or ''CMS,'' or any other combination or variation of such letters; or

(3) A symbol or an emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under Title II, or envelopes or other stationery used by the Department or CMS) or any other combination or variation of such symbols or emblems.

(c) Civil money penalties will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that uses any symbol or emblem or any words or letters that specifically identify that agency or instrumentality of the State or political subdivision.

§ 1003.610 Amount of penalties.

(a) The OIG may impose a penalty of not more than[6]—

(1) $5,000 for each individual violation resulting from the misuse of Departmental, CMS, or Medicare or Medicaid program words, letters, symbols, or emblems as described in § 1003.600(a) relating to printed media;

[6] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(2) $5,000 for each individual violation in the case of such misuse related to an electronic communication, Web page, or telemarketing solicitation;

(3) $25,000 for each individual violation in the case of such misuse related to a broadcast or telecast.

(b) For purposes of this paragraph, a violation is defined as—

(1) In the case of a direct mailing solicitation or advertisement, each separate piece of mail that contains one or more words, letters, symbols, or emblems related to a determination under §1003.600(a);

(2) In the case of a printed solicitation or advertisement, each reproduction, reprinting, or distribution of such item related to a determination under §1003.600(a);

(3) In the case of a broadcast or telecast, each airing of a single commercial or solicitation related to a determination under §1003.600(a);

(4) In the case of an electronic communication, each dissemination, viewing, or accessing of the electronic communication that contains one or more words, letters, symbols, or emblems related to a determination under §1003.600(a);

(5) In the case of a Web page accessed by a computer or other electronic means, each instance in which the Web page was viewed or accessed and that Web page contains one or more words, letters, symbols, or emblems related to a determination under §1003.600(a); and

(6) In the case of a telemarketing solicitation, each individual unsolicited telephone call regarding an item or service under Medicare or Medicaid related to a determination under §1003.600(a).

§1003.620 Determinations regarding the amount of penalties.

(a) In considering the factors listed in §1003.140, the following circumstances are to be considered—

(1) The nature and objective of the advertisement, solicitation, or other communication and the degree to which it had the capacity to deceive members of the public;

(2) The frequency and scope of the violation and whether a specific segment of the population was targeted; and

(3) The prior history of the individual, organization, or entity in its willingness or refusal to comply with a formal or informal request to correct violations.

(b) The use of a disclaimer of affiliation with the United States Government, the Department, or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with §1003.600(a).

Subpart G [Reserved]

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

SOURCE: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

§1003.800 Basis for civil money penalties.

The OIG may impose a penalty against any person (including an insurance company) who it determines—

(a) Fails to report information concerning—

(1) A payment made under an insurance policy, self-insurance, or otherwise for the benefit of a physician, dentist, or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist, or other practitioner in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60 or

(2) An adverse action required to be reported under section 1128E, as established by section 221 of Public Law 104–191.

(b) Improperly discloses, uses, or permits access to information reported in accordance with Part B of Title IV of Public Law 99–660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with Part B of Title IV in response to a subpoena or a discovery request is considered an improper disclosure in violation of section 427 of Public Law 99–660. However, disclosure or release by an entity of original documents or underlying records from

which the reported information is obtained or derived is not considered an improper disclosure in violation of section 427 of Public Law 99–660.)

§ 1003.810 Amount of penalties.

The OIG may impose a penalty of not more than [7]—

(a) $11,000 for each payment for which there was a failure to report required information in accordance with § 1003.800(a)(1) or for each improper disclosure, use, or access to information in accordance with a determination under § 1003.800(b); and

(b) $25,000 against a health plan for each failure to report information on an adverse action required to be reported in accordance with section 1128E of the Act and § 1003.800(a)(2).

§ 1003.820 Determinations regarding the amount of penalties.

In determining the amount of any penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart I—CMPs for Select Agent Program Violations

SOURCE: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

§ 1003.900 Basis for civil money penalties.

The OIG may impose a penalty against any person who it determines in accordance with this part is involved in the possession or use in the United States, receipt from outside the United States or transfer within the United States, of select agents and toxins in violation of sections 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73.

§ 1003.910 Amount of penalties.

For each individual violation of section 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73, the OIG may impose a penalty of not more than $250,000 in the case of an individual, and not more than $500,000 in the case of any other person.[8]

§ 1003.920 Determinations regarding the amount of penalties.

In considering the factors listed in § 1003.140, aggravating circumstances include:

(a) The Responsible Official participated in or knew, or should have known, of the violation;

(b) The violation was a contributing factor to an unauthorized individual's access to or possession of a select agent or toxin, an individual's exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from the person's physical location as identified on the person's certificate of registration; or

(c) The person previously received an observation, finding, or other statement of deficiency from the Department or the Department of Agriculture for the same or substantially similar conduct.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

SOURCE: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

§ 1003.1000 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines offers or transfers remuneration (as defined in § 1003.110) to any individual eligible for benefits under Medicare or a State health care program that such person knows, or should know, is likely to influence such individual to order or to receive from a particular provider, practitioner, or supplier, any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(b) The OIG may impose a penalty against any person who it determines offered any financial or other incentive for an individual entitled to benefits

[7] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[8] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

under Medicare not to enroll, or to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A) of the Act.

§ 1003.1010 Amount of penalties and assessments.

The OIG may impose a penalty of not more than[9]—

(a) $10,000 for each item or service for which payment may be made, in whole or in part, under Medicare or a State health care program, ordered by or received from a particular provider, practitioner, or supplier for a beneficiary who was offered or received remuneration in violation of §1003.1000(a) that was likely to influence the beneficiary to order or receive the item or service from the provider, practitioner, or supplier, and an assessment of not more than 3 times the amount claimed for each such item or service and

(b) $5,000 for each individual violation of §1003.1000(b).

§ 1003.1020 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In determining the amount of any penalty or assessment or the period of exclusion under this subpart, the OIG will consider the factors listed in §1003.140, as well as the amount of remuneration or the amount or nature of any other incentive.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

SOURCE: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

§ 1003.1100 Basis for civil money penalties.

The OIG may impose a penalty against any person who—

(a) Knowingly and willfully makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact with respect to—

(1) The compliance of any policy with the standards and requirements for Medicare supplemental policies set forth in section 1882(c) of the Act or in promulgating regulations, or

(2) The use of the emblem designed by the Secretary under section 1882(a) of the Act for use as an indication that a policy has received the Secretary's certification;

(b) Falsely assumes or pretends to be acting, or misrepresents in any way that he or she is acting, under the authority of or in association with Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands, or obtains money, paper, documents, or anything of value;

(c) Knowingly, directly, or through his or her agent, mails or causes to be mailed any matter for the advertising, solicitation, or offer for sale of a Medicare supplemental policy, or the delivery of such a policy, in or into any State in which such policy has not been approved by the State commissioner or superintendent of insurance;

(d) Issues or sells to any individual entitled to benefits under Part A or enrolled under Part B of Medicare—

(1) A health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under Medicare or Medicaid,

(2) A health insurance policy (other than a Medicare supplemental policy) with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law,

(3) In the case of an individual not electing a Part C plan, a Medicare supplemental policy with knowledge that the individual is entitled to benefits under another Medicare supplemental policy, or

(4) In the case of an individual electing a Part C plan, a Medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Part C plan or under another Medicare supplemental policy;

[9] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(e) Issues or sells a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III)) to any individual entitled to benefits under Medicare Part A or enrolled under Medicare Part B who is applying for a health insurance policy and fails to furnish the appropriate disclosure statement described in section 1882(d)(3)(A)(vii); or

(f) Issues or sells a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Medicare Part B without obtaining the written statement or the written acknowledgment described in section 1882(d)(3)(B) of the Act.

§ 1003.1110 Amount of penalties.

The OIG may impose a penalty of not more than [10]—

(a) $5,000 for each individual violation of § 1003.1100(a), (b), or (c).

(b) $25,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is also the issuer of the policy; and

(c) $15,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is not the issuer of the policy.

§ 1003.1120 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart L—CMPs for Drug Price Reporting

SOURCE: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

§ 1003.1200 Basis for civil money penalties.

The OIG may impose a penalty against—

(a) Any wholesaler, manufacturer, or direct seller of a covered outpatient drug that—

(1) Refuses a request for information by, or

(2) Knowingly provides false information to, the Secretary about charges or prices in connection with a survey being conducted pursuant to section 1927(b)(3)(B) of the Act; and

(b) Any manufacturer with an agreement under section 1927 of the Act that—

(1) Fails to provide any information required by section 1927(b)(3)(A) of the Act by the deadlines specified therein, or

(2) Knowingly provides any item information required by section 1927(b)(3)(A) or (B) of the Act that is false.

§ 1003.1210 Amount of penalties.

The OIG may impose a penalty of not more than [11]—

(a) $100,000 for each individual violation of § 1003.1200(a) or § 1003.1200(b)(2); and

(b) $10,000 for each day that such information has not been provided in violation of § 1003.1200(b)(1).

§ 1003.1220 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

SOURCE: 81 FR 88362, Dec. 7, 2016, unless otherwise noted.

§ 1003.1300 Basis for civil money penalties.

The OIG may impose a penalty against any individual who notifies, or causes to be notified, a skilled nursing facility, nursing facility, home health agency, a community care setting, of the time or date on which a survey pursuant to sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), or 1929(i) of the Act is scheduled to be conducted.

[10] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[11] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

§ 1003.1310 Amount of penalties.

The OIG may impose a penalty of not more than $2,000 for each individual violation of § 1003.1300.[12]

§ 1003.1320 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart N [Reserved]

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

SOURCE: 81 FR 88364, Dec. 7, 2016, unless otherwise noted.

§ 1003.1500 Notice of proposed determination.

(a) If the OIG proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in all Federal health care programs, as applicable, in accordance with this part, the OIG must serve on the respondent, in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure, written notice of the OIG's intent to impose a penalty, an assessment, and an exclusion, as applicable. The notice will include—

(1) Reference to the statutory basis for the penalty, assessment, and exclusion;

(2) A description of the violation for which the penalty, assessment, and exclusion are proposed (except in cases in which the OIG is relying upon statistical sampling in accordance with § 1003.1580, in which case the notice shall describe those claims and requests for payment constituting the sample upon which the OIG is relying and will briefly describe the statistical sampling technique used by the OIG);

(3) The reason why such violation subjects the respondent to a penalty, an assessment, and an exclusion,

(4) The amount of the proposed penalty and assessment, and the length of the period of proposed exclusion (where applicable);

(5) Any factors and circumstances described in this part that were considered when determining the amount of the proposed penalty and assessment and the length of the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of the respondent's right to a hearing and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment, and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the respondent's provider agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the OIG has proposed the imposition of a penalty, an assessment, or an exclusion may appeal such proposed penalty, assessment, or exclusion to the Departmental Appeals Board in accordance with 42 CFR 1005.2. The provisions of 42 CFR part 1005 govern such appeals.

(c) If the respondent fails, within the time period permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

§ 1003.1510 Failure to request a hearing.

If the respondent does not request a hearing within 60 days after the notice prescribed by § 1003.1500(a) is received, as determined by 42 CFR 1005.2(c), by the respondent, the OIG may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, or exclusion. The OIG shall notify the respondent in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of any penalty, assessment, and exclusion that have been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, an assessment, or an exclusion with respect to which he

[12] This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

or she has not made a timely request for a hearing under 42 CFR 1005.2.

§ 1003.1520 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability for acts that violate this part has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part, a person is estopped from denying the essential elements of the criminal offense if the proceeding—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action.

§ 1003.1530 Settlement.

The OIG has exclusive authority to settle any issues or case without consent of the ALJ.

§ 1003.1540 Judicial review.

(a) Section 1128A(e) of the Act authorizes judicial review of a penalty, an assessment, or an exclusion that has become final. The only matters subject to judicial review are those that the respondent raised pursuant to 42 CFR 1005.21, unless the court finds that extraordinary circumstances existed that prevented the respondent from raising the issue in the underlying administrative appeal.

(b) A respondent must exhaust all administrative appeal procedures established by the Secretary or required by law before a respondent may bring an action in Federal court, as provided in section 1128A(e) of the Act, concerning any penalty, assessment, or exclusion imposed pursuant to this part.

(c) Administrative remedies are exhausted when a decision becomes final in accordance with 42 CFR 1005.21(j).

§ 1003.1550 Collection of penalties and assessments.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the case of the Maternal and Child Health Services Block Grant Program, in which the collection will be the responsibility of the Public Health Service (PHS); in the case of the Social Services Block Grant program, in which the collection will be the responsibility of the Administration for Children and Families; and in the case of violations of subpart I, collection will be the responsibility of the Program Support Center (PSC).

(b) A penalty or an assessment imposed under this part may be compromised by the OIG and may be recovered in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The amount of penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States Government or a State agency to the person against whom the penalty or assessment has been assessed.

(d) Matters that were raised, or that could have been raised, in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 1003.1560 Notice to other agencies.

(a) Whenever a penalty, an assessment, or an exclusion becomes final, the following organizations and entities will be notified about such action and the reasons for it: The appropriate State or local medical or professional association; the appropriate quality improvement organization; as appropriate, the State agency that administers each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term-care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

(b) When the OIG proposes to exclude a nursing facility under this part, the OIG will, at the same time the facility is notified, notify the appropriate

State licensing authority, the State Office of Aging, the long-term-care ombudsman, and the State Medicaid agency of the OIG's intention to exclude the facility.

§ 1003.1570 Limitations.

No action under this part will be entertained unless commenced, in accordance with §1003.1500(a), within 6 years from the date on which the violation occurred.

§ 1003.1580 Statistical sampling.

(a) In meeting the burden of proof in 42 CFR 1005.15, the OIG may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment, as described in this part, that were presented, or caused to be presented, by the respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment, as described in this part.

(b) Once the OIG has made a prima facie case, as described in paragraph (a) of this section, the burden of production shall shift to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The OIG will then be given the opportunity to rebut this evidence.

§ 1003.1590 Effect of exclusion.

The effect of an exclusion will be as set forth in 42 CFR 1001.1901.

§ 1003.1600 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of 42 CFR 1001.3001 through 1001.3004.

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

Subpart A—General Provisions

Subpart B—Sanctions Under the QIO Program; General Provisions

Subpart C—QIO Responsibilities

Subpart D—OIG Responsibilities

Subpart E—Effect and Duration of Exclusion

Subpart F—Appeals

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