

(33) Sections 1834(l)(6) and 1842(j)(2)—Any supplier of ambulance services who knowingly and willfully bills or collects for any services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(34) Section 1806(b)(2)(B)—Any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.

(35) Section 1128G (b) (1) and (2)—Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately, or completely report a payment or other transfer of value or an ownership or investment interest to CMS, as required under part 403, subpart I, of this chapter.

(d) *Assessments.* CMS or OIG may impose assessments in addition to civil money penalties for violations of the following statutory sections:

(1) Section 1833: Paragraph (h)(5)(D).

(2) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(3) Section 1842: Paragraphs (k), (l)(3), (m)(3), and (n)(3).

(4) Section 1848: Paragraph (g)(1)(B).

(5) Section 1877: Paragraph (g)(5).

(6) Section 1879: Paragraph (h).

(7) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), and (t)(2).

(e) *Exclusions.* (1) CMS or OIG may exclude any person from participation in the Medicare program on the basis of any of the following violations of the statute:

(i) Section 1833: Paragraphs (h)(5)(D) and, in repeated cases, (q)(2)(B).

(ii) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(iii) Section 1842: Paragraphs (b)(18)(B), (k), (l)(3), (m)(3), (n)(3), and, in repeated cases, (p)(3)(B).

(iv) Section 1848: Paragraphs (g)(1)(B), (g)(3)(B), and, in repeated cases, (g)(4)(B)(ii).

(v) Section 1877: Paragraph (g)(5).

(vi) Section 1879: Paragraph (h).

(vii) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(4), and (t)(2).

(2) CMS or OIG must exclude from participation in the Medicare program any of the following, under the identified section of the Act:

(i) Section 1834(a)(17)(C)—Any supplier of durable medical equipment and supplies that are covered under section 1834(a)(13) that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of covered services in violation of section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts as described under section 1834(a)(17)(A).

(ii) Section 1834(h)(3)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of prosthetic devices, orthotics, or prosthetics in the same manner as in the violation under section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts in the same manner as described in section 1834(a)(17)(C).

(f) *Responsible persons.* (1) If CMS or OIG determines that more than one person is responsible for any of the violations described in paragraph (c) or paragraph (d) of this section, it may impose a civil money penalty or a civil money penalty and assessment against any one of those persons or jointly and severally against two or more of those persons. However, the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person were responsible.

(2) A principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(g) *Time limits.* Neither CMS nor OIG initiates an action to impose a civil money penalty, assessment, or proceeding to exclude a person from participation in the Medicare program unless it begins the action within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001; 78 FR 9520, Feb. 8, 2013; 88 FR 70372, Oct. 11, 2023]

#### § 402.3 Definitions.

For purposes of this part:

### § 402.3

### 42 CFR Ch. IV (10–1–24 Edition)

*Assessment* means the amount described in § 402.107 and includes the plural of that term.

*Assignment-related basis* means that the claim submitted by a physician, supplier or other person is paid on the basis of an assignment, whereby the physician, supplier or other person agrees to accept the Medicare payment as payment in full for the services furnished to the beneficiary and is precluded from charging the beneficiary more than the deductible and coinsurance based upon the approved Medicare fee amount. Additional obligations, including obligations to make refunds in certain circumstances, are established at section 1842(b)(3) of the Act.

*Claim* means an application for payment for a service for which the Medicare or Medicaid program may pay.

*Covered* means that a service is described as reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. A service is not covered if it is specifically identified as excluded from Medicare Part B coverage or is not a defined Medicare Part B benefit.

*Exclusion* means the temporary or permanent barring of a person or other entity from participation in the Medicare or State health care program and that services furnished or ordered by that person are not paid for under either program.

*General Counsel* means the General Counsel of HHS or his or her designees.

*Initiating agency* means whichever agency (CMS or the OIG) initiates the interaction with the person.

*Knowingly or knowingly and willfully* means that a person, with respect to information—

- (1) Has actual knowledge of the information;
- (2) Acts in deliberate ignorance of the truth or falsity of the information; or
- (3) Acts in reckless disregard of the truth or falsity of the information; and
- (4) No proof of specific intent is required.

*Medicare supplemental policy* means a policy guaranteeing that a health plan will pay a policyholder's coinsurance and deductible and will cover other limitations on payment imposed under title XVIII of the Act and will provide

additional health plan or non-Medicare coverage for services up to a predefined benefit limit.

*NAIC* stands for the National Association of Insurance Commissioners.

*Nonparticipating* describes a physician, supplier, or other person (excluding any provider of services) that, at the time of furnishing the services to Medicare Part B beneficiaries, is not a participating physician or supplier.

*Participating* describes a physician or supplier (excluding any provider of services) that, before the beginning of any given year, enters into an agreement with HHS that provides that the physician or supplier will accept payment under the Medicare program on an assignment-related basis for all services furnished to Medicare Part B beneficiaries.

*Penalty* means the amount described in § 402.105 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.

*Physicians' services* means the following Medicare covered professional services:

- (1) Surgery, consultation, home, office and institutional calls, and other professional services performed by physicians.
- (2) Services and supplies furnished "incident to" a physician's professional services.
- (3) Outpatient physical and occupational therapy services.
- (4) Diagnostic x-ray tests and other diagnostic tests (excluding clinical diagnostic laboratory tests).
- (5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.
- (6) Antigens prepared by a physician.

*Radiologist service* means radiology services performed only by, or under the direction of, a physician who is certified, or eligible to be certified, by the American Board of Radiology or for whom radiology services account for at least 50 percent of the total amount of charges made under part B of title XVIII of the Act.

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

*Respondent* means the person upon which CMS or OIG has imposed, or proposes to impose, a civil money penalty, assessment, or exclusion.

*Service* includes—

(1) Any item, device, medical supply, or service claimed to have been furnished to a patient and listed in an itemized claim for program payment; or

(2) 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.

*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.

*Timely basis* means that the adjustment to a bill or a refund is considered “on a timely basis” if the physician, supplier, or other person makes the adjustment or refund to the appropriate party no later than 30 days after the date the physician, supplier, or other person is notified by the Medicare Part B contractor of the violation and the requirement to refund any excess collections.

[63 FR 68690, Dec. 14, 1998, as amended at 72 FR 39752, July 20, 2007]

#### **§ 402.5 Right to a hearing before the final determination.**

CMS or OIG does not make a determination adverse to any person under this part until the person has been given a written notice and opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

#### **§ 402.7 Notice of proposed determination.**

(a) If CMS or OIG proposes a penalty and, as applicable, an assessment, or proposes to exclude a respondent from participation in Medicare in accordance with this part, it sends the respondent written notice of its intent by certified mail, return receipt requested. The notice includes the following information:

(1) Reference to the statutory basis or bases for the penalty, assessment,

exclusion, or any combination, as applicable.

(2)(i) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment, and exclusion are proposed; or

(ii) If CMS or OIG is relying upon statistical sampling to project the number and types of claims or requests for payment and the dollar amount, a description of the claims and requests for payment comprising the sample and a brief description of the statistical sampling technique CMS or OIG used.

(3) The reason why the claims, requests for payment, or incidents are subject to a penalty and assessment.

(4) The amount of the proposed penalty and of any proposed assessment.

(5) Any mitigating or aggravating circumstances that CMS or OIG considered when it determined the amount of the proposed penalty and any applicable assessment.

(6) Information concerning response 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 renders the proposed determination final and permits the imposition of the proposed penalty and any assessment.

(iii) A statement that the debt may be collected through an administrative offset.

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

#### **§ 402.9 Failure to request a hearing.**

(a) If the respondent does not request a hearing within 60 days of receipt of the notice of proposed determination specified in § 402.7, any civil money penalty, assessment, or exclusion becomes final and CMS or OIG may impose the proposed penalty, assessment, or exclusion, or any less severe penalty, assessment, or suspension.

(b) CMS or OIG notifies the respondent by certified mail, return receipt requested, of any penalty, assessment, or exclusion that has been imposed and of the means by which the respondent may satisfy the judgment.