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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.

(c) The respondent has no right to appeal a penalty, assessment, or exclusion for which he or she has not requested a hearing.

§ 402.11 Notice to other agencies and other entities.

(a) Whenever a penalty, assessment, or exclusion becomes final, CMS or OIG notifies the following organizations and entities about the action and the reasons for it:

(1) The appropriate State or local medical or professional association.

(2) The appropriate quality improvement organization.

(3) As appropriate, the State agency responsible for the administration of each State health care program (Medicaid, the Maternal and Child Health Services Block Grant Program, and the Social Services Block Grant Program).

(4) The appropriate Medicare carrier or fiscal intermediary.

(5) The appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies).

(6) The long-term care ombudsman.

(b) For exclusions, CMS or OIG also notifies the public and specifies the effective date.

§ 402.13 Penalty, assessment, and exclusion not exclusive.

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

§ 402.15 Collateral estoppel.

(a) When a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 402.1 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

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(b) 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 is barred from denying the essential elements of the criminal offense if the proceedings under this part involve the same transactions.

§ 402.17 Settlement.

CMS or OIG has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time before a final decision by the Secretary. Thereafter, the General Counsel has the exclusive authority.

§ 402.19 Hearings and appeals.

The hearings and appeals procedures set forth in part 1005 of chapter V of this title are available to any person that receives an adverse determination under this part. For an appeal of a civil money penalty, assessment, or exclusion imposed under this part, either CMS or OIG may represent the government in the hearing and appeals process.

§ 402.21 Judicial review.

After exhausting all available administrative remedies, a respondent may seek judicial review of a penalty, assessment, or exclusion that has become final. The respondent may seek review only with respect to a penalty, assessment, or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this title unless the court excuses the failure or neglect to urge the exception in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

Subpart B—Civil Money Penalties and Assessments

§ 402.105 Amount of penalty.

(a) *\$2,000.* Except as provided in paragraphs (b) through (g) of this section, CMS or OIG may impose a penalty of not more than \$2,000 for each service, bill, or refusal to issue a timely refund that is subject to a determination under this part and for each incident

involving the knowing, willful, and repeated failure of an entity furnishing a service to submit a properly completed claim form or to include on the claim form accurate information regarding the availability of other health insurance benefit plans (§ 402.1(c)(21)).

(b) *\$1,000.* CMS or OIG may impose a penalty of not more than \$1,000 for the following:

(1) Per certificate of medical necessity knowingly and willfully distributed to physicians on or after December 31, 1994 that—

(i) Contains information concerning the medical condition of the patient; or

(ii) Fails to include cost information.

(2) Per individual about whom information is requested, for willful or repeated failure of an employer to respond to an intermediary or carrier about coverage of an employee or spouse under the employer's group health plan (§ 402.1(c)(20)).

(c) *\$5,000.* CMS or OIG may impose a penalty of not more than \$5,000 for each violation resulting from the following:

(1) The failure of a Medicare supplemental policy issuer, on a replacement policy, to waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods that were satisfied under a preceding policy (§ 402.1(c)(29)); and

(2) Any issuer of any Medicare supplemental policy denying a policy, conditioning the issuance or effectiveness of the policy, or discriminating in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A). (§ 402.1(c)(29)).

(d) *\$10,000.* (1) CMS or OIG may impose a penalty of not more than \$10,000 for each day that reporting entity ownership arrangements is late (§ 402.1(c)(22)).

(2) CMS or OIG may impose a penalty of not more than \$10,000 for the following violations that occur on or after January 1, 1997:

(i) Knowingly and willfully, and on a repeated basis, billing for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(ii) By any durable medical equipment supplier, knowingly and willfully

charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(iii) By any durable medical equipment supplier, knowingly and willfully, in violation of section 1834(a)(18)(A), failing to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(iv) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(v) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(vi) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(vii) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assigned-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance;

or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(viii) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for practitioners specified in section 1842(b)(18)(B) (§ 402.1(c)(11)).

(ix) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on

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or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§402.1(c)(12)).

(x) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§402.1(c)(13)).

(xi) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least \$500, knowingly and willfully failing to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§402.1(c)(14)).

(xii) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§402.1(c)(15)).

(xiii) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(A) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(B) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv) (§402.1(c)(17)).

(xiv) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§402.1(c)(18)).

(xv) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare bene-

ficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§402.1(c)(23)).

(3) CMS or OIG may impose a penalty of not more than \$10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient therapy or comprehensive rehabilitation services other than on an assignment-related basis.

(4) CMS or OIG may impose a penalty of not more than \$10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient ambulance services other than on an assignment-related basis.

(e) *\$15,000.* CMS or OIG may impose a penalty of not more than \$15,000 if the seller of a Medicare supplemental policy is not the issuer, for each violation described in paragraphs (f)(2) and (f)(3) of this section (§402.1(c)(25) and (c)(26)).

(f) *\$25,000.* CMS or OIG may impose a penalty of not more than \$25,000 for each of the following violations:

(1) Issuance of a Medicare supplemental policy that has not been approved by an approved State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C) of the Act (§402.1(c)(23)).

(2) Sale or issuance after July 30, 1992, of a Medicare supplemental policy that fails to conform with the NAIC or Federal standards established under section 1882(p) of the Act (§402.1(c)(25)).

(3) Failure to make the core group of basic benefits available for sale when selling other Medicare supplemental plans with additional benefits (§402.1(c)(26)).

(4) Failure to provide, before sale of a Medicare supplemental policy, an outline of coverage describing the benefits provided by the policy (§402.1(c)(26)).

(5) Failure of an issuer of a policy to suspend or reinstate a policy, based on the policy holder's request, during entitlement to or upon loss of eligibility for medical assistance (§402.1(c)(27)).

(6) Failure to provide refunds or credits for Medicare supplemental policies as required by section 1882(r)(1)(B) (§ 402.1(c)(28)).

(7) By an issuer of a Medicare supplemental policy—

(i) Substantial failure to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(ii) Imposition of premiums on enrollees in excess of the premiums approved by the State;

(iii) Action to expel an enrollee for reasons other than nonpayment of premiums; or

(iv) Failure to provide each enrollee, at the time of enrollment, with the specific information provided in section 1882(t)(1)(E)(i) or failure to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)) (section 1882(t)(2)).

(g) *\$100.* CMS or OIG may impose a penalty of not more than \$100 for each violation if the person or entity does not furnish an itemized statement to a Medicare beneficiary within 30 days of the beneficiary's request.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001; 72 FR 39752, July 20, 2007; 72 FR 46175, Aug. 17, 2007]

§ 402.107 Amount of assessment.

A person subject to civil money penalties specified in § 402.1(c) may be subject, in addition, to an assessment. An assessment is a monetary payment in lieu of damages sustained by HHS or a State agency.

(a) The assessment may not be more than twice the amount claimed for each service that was a basis for the civil money penalty, except for the violations specified in paragraph (b) of this section that occur before January 1, 1997.

(b) For the violations specified in this paragraph occurring after January 1, 1997, the assessment may not be more than three times the amount claimed for each service that was the basis for a civil money penalty. The violations are the following:

(1) Knowingly and willfully billing, and on a repeated basis, for a clinical diagnostic laboratory test, other than

on an assignment-related basis (§ 402.1(c)(1)).

(2) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(3) By any durable medical equipment supplier, knowingly and willfully failing, in violation of section 1834(a)(18)(A), to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(4) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(5) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(6) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(7) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(i) The supplier does not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(8) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for a person or entity specified in sections 1834(k)(6), 1834(l)(6), or 1842(b)(18)(B) (§ 402.1(c)(11), (c)(31), or (c)(32)).