

§ 402.109

timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

- (i) The supplier did 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)(23)).

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.109 Statistical sampling.

(a) *Purpose.* CMS or OIG may introduce the results of a statistical sampling study to show the number and amount of claims subject to sanction under this part that the respondent presented or caused to be presented.

(b) *Prima facie evidence.* The results of the statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitute prima facie evidence of the number and amount of claims or requests for payment subject to sanction under § 402.1.

(c) *Burden of proof.* Once CMS or OIG has made a prima facie case, the burden is on the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. CMS or OIG then has the opportunity to rebut this evidence.

§ 402.111 Factors considered in determinations regarding the amount of penalties and assessments.

(a) *Basic factors.* In determining the amount of any penalty or assessment, CMS or OIG takes into account the following:

- (1) The nature of the claim, request for payment, or information given and the circumstances under which it was presented or given.
- (2) The degree of culpability, history of prior offenses, and financial condition of the person submitting the claim or request for payment or giving the information.
- (3) The resources available to the person submitting the claim or request for payment or giving the information.
- (4) Such other matters as justice may require.

(b) *Criteria to be considered.* As guidelines for taking into account the fac-

42 CFR Ch. IV (10–1–23 Edition)

tors listed in paragraph (a) of this section, CMS or OIG considers the following circumstances:

(1) *Aggravating circumstances of the incident.* An aggravating circumstance is any of the following:

- (i) The services or incidents were of several types, occurring over a lengthy period of time.
- (ii) There were many of these services or incidents or the nature and circumstances indicate a pattern of claims or requests for payment for these services or a pattern of incidents.
- (iii) The amount claimed or requested for these services was substantial.

(iv) Before the incident or presentation of any claim or request for payment subject to imposition of a civil money penalty, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services.

(v) There is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care service. (The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance.)

(2) *Mitigating circumstances.* The following circumstances are mitigating circumstances:

(i) All the services or incidents subject to a civil money penalty were few in number and of the same type, occurred within a short period of time, and the total amount claimed or requested for the services was less than \$1,000.

(ii) The claim or request for payment for the service was the result of an unintentional and unrecognized error in the process of presenting claims or requesting payment and the respondent took corrective steps promptly after discovering the error.

(iii) Imposition of the penalty or assessment without reduction would jeopardize the ability of the respondent to continue as a health care provider.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to ensure the achievement of the purposes of this part.

(c) *Effect of aggravating or mitigating circumstances.* In determining the amount of the penalty and assessment to be imposed for every service or incident subject to a determination under § 402.1(c)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment is set at an amount sufficiently below the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment is set at an amount at or sufficiently close to the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(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 is not 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 section limits the authority of CMS or OIG to settle any issue or case as provided by § 402.19 or to compromise any penalty and assessment as provided by § 402.115.

§ 402.113 When a penalty and assessment are collectible.

A civil money penalty and assessment become collectible after the earliest of the following:

(a) Sixty days after the respondent receives CMS's or OIG's notice of proposed determination under § 402.7, if the respondent has not requested a hearing before an ALJ.

(b) Immediately after the respondent abandons or waives his or her appeal right at any administrative level.

(c) Thirty days after the respondent receives the ALJ's decision imposing a civil money penalty or assessment under § 1005.20(d) of this title, if the respondent has not requested a review before the DAB.

(d) If the DAB grants an extension of the period for requesting the DAB's review, the day after the extension expires if the respondent has not requested the review.

(e) Immediately after the ALJ's decision denying a request for a stay of the effective date under § 1005.22(b) of this title.

(f) If the ALJ grants a stay under § 1005.22(b) of this title, immediately after the judicial ruling is completed.

(g) Sixty days after the respondent receives the DAB's decision imposing a civil money penalty if the respondent has not requested a stay of the decision under § 1005.22(b) of this title.

§ 402.115 Collection of penalty or assessment.

(a) Once a determination by HHS has become final, CMS is responsible for the collection of any penalty or assessment.

(b) The General Counsel may compromise a penalty or assessment imposed under this part, after consultation with CMS or OIG, and the Federal government may recover the penalty or assessment 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 United States or a State agency may deduct the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing to the respondent.

(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.