

other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

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

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

(ii) 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)).

(14) 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)).

(15) By any supplier of durable medical equipment, including suppliers of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a 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)).

§ 402.109 Statistical sampling.

(a) *Purpose.* HCFA 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 HCFA 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. HCFA 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, HCFA 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 factors listed in paragraph (a) of this section, HCFA 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