

## § 402.5

*Respondent* means the person upon which HCFA 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.

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

HCFA 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 HCFA 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.

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(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 HCFA 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 HCFA 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 HCFA 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 HCFA or OIG may impose the proposed penalty, assessment, or exclusion, or any less severe penalty, assessment, or suspension.

(b) HCFA 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.