

PART 422—ORGANIZATION AND PROCEDURES**Subpart B—[Amended]**

1. The authority citation for subpart B of part 422 continues to read as follows:

Authority: Secs. 205, 232, 702(a)(5), 1131, and 1143 of the Social Security Act (42 U.S.C. 405, 432, 902(a)(5), 1320b-1 and 1320b-13.)

2. Section 422.125 is amended by revising paragraphs (a) and (b) to read as follows:

§ 422.125 Statements of earnings; resolving earnings discrepancies.

(a) *Obtaining a statement of earnings and estimated benefits.* An individual may obtain a statement of the earnings on his earnings record and an estimate of social security benefits potentially payable on his record either by writing, calling, or visiting any social security office, or by waiting until we send him one under the procedure described in § 404.812 of this chapter. An individual may request this statement by completing the proper form or by otherwise providing the information the Social Security Administration requires, as explained in § 404.810(b) of this chapter.

(b) *Statement of earnings and estimated benefits.* Upon receipt of such a request or as required by section 1143(c) of the Social Security Act, the Social Security Administration will provide the individual, without charge, a statement of earnings and benefit estimates or an earnings statement. See §§ 404.811 through 404.812 of this chapter concerning the information contained in these statements.

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20 CFR Part 498

RIN 0960-AE23

Civil Monetary Penalties, Assessments and Recommended Exclusions

AGENCY: Office of the Inspector General (OIG), SSA.

ACTION: Final rule.

SUMMARY: This final rule establishes procedures to impose civil monetary penalties and assessments against certain Old-Age, Survivors, and Disability Insurance beneficiaries, Supplemental Security Income recipients, third parties, physicians, medical providers, and other individuals and entities who make false statements or representations for use in

determining any right to or amount of title II or title XVI benefits under the Social Security Act. This final rule implements the civil monetary penalty provisions of section 206(b) of the Social Security Independence and Program Improvements Act of 1994.

EFFECTIVE DATE: This final rule is effective May 24, 1996.

FOR FURTHER INFORMATION CONTACT : Judith A. Kidwell, Office of the Inspector General, (410) 965-9750.

SUPPLEMENTARY INFORMATION:**Background**

We published a notice of proposed rulemaking (NPRM) in the Federal Register on November 27, 1995, (60 FR 58305) which proposed to establish procedures to implement the civil monetary penalty (CMP) provisions of section 206(b) of the Social Security Independence and Program Improvements Act of 1994, Public Law 103-296, which added section 1129 of the Social Security Act (the Act), effective October 1, 1994. Section 108 of Public Law 103-296 made additional conforming amendments to section 1129, effective March 31, 1995, to reflect the Social Security Administration's (SSA) new status as an independent agency.

The 60-day public comment period closed on January 26, 1996. We received comments on the NPRM from only one commenter, a disability law center. The comments, our responses, and the final rule, with several technical changes we have made, are discussed below.

Since we have made only technical changes, we are adopting the regulations as proposed.

Public Comments on the Proposed Regulations

The commenter was concerned that the regulations were overly broad and that there were unaddressed problems at the SSA which would increase the likelihood of an overbroad application of these rules to claimants and their representatives. The substantive comments made by the commenter and our responses are summarized below.

Comment: The commenter raised concerns that the proposed regulations were overbroad in defining when a person has made or caused to be made a statement, representation, or omission of material fact, inasmuch as the basis and purpose statement in § 498.100 does not include an intent requirement.

Response: Section 498.100 has been developed to briefly catalog the general types of penalty and assessment authorities that will be in part 498. This section is not intended to include the

legally operative language to impose a penalty or assessment. Such language can be found in §§ 498.101 through 498.132.

Comment: The commenter expressed a concern that the definition of material fact at § 498.101 is not limited to facts that might have made a difference in the eligibility decision.

Response: The definition of "material fact" which appears in the NPRM is taken verbatim from section 1129(a)(2) of the Act.

Comment: Although the commenter acknowledged that § 498.102 contains elements of intent, it raised a concern that the basis for imposition of CMPs does not adequately link misstatements and omissions to an intent to fraudulently obtain benefits.

Response: Section 498.102 carefully tracks the language of section 1129(a)(1) of the Act. In order to impose a penalty or assessment under § 498.102, the OIG must determine that an individual knew or should have known that his or her statement or representation was false or misleading or omitted a material fact, or that the individual made the false or misleading statement with knowing disregard for the truth.

Comment: The commenter recited an example of an experience to illustrate problems it perceived with this rule. The commenter also expressed concerns that: (1) The vast majority of claimants do not understand eligibility and reporting requirements; (2) because of staff reductions, access to SSA staff for information is limited; (3) the ability of SSA staff to completely and accurately relate program requirements varies widely; (4) SSA pamphlets are difficult for persons with learning disabilities and limited education or English skills; and (5) SSA record keeping is such that it is not unusual for records to be lost.

Response: Many of these comments are more appropriately directed to the administration of SSA programs and are not within the scope of this rule. However, we would like to point out that section 1129 of the Act is directed toward those persons who defraud the SSA's programs or receive benefits or payments to which they are not entitled, and that steps have been taken to address due process concerns and ensure that innocent persons are not penalized.

As required by section 1129 of the Act, the respondent will be notified of a proposed penalty in a manner authorized by Rule 4 of the Federal Rules of Civil Procedure. Additionally, except with respect to affirmative defenses and mitigating circumstances, the burden of persuasion is on the Government in CMP cases. Finally, the

SSA plans to go beyond the requirements of the statute to ensure due process with respect to the CMP process. The statute requires only that a person be given "an 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." The SSA intends to enter into an agreement with the Departmental Appeals Board (DAB) of the U.S. Department of Health and Human Services to conduct the hearings in these cases because of the DAB's expertise with CMP cases involving Medicare and Medicaid fraud over a period of more than 10 years. SSA plans to include an appeal to the appellate division of the DAB in the administrative review process which will provide an additional opportunity for the respondent to address legal issues before being required to litigate in federal court.

Comment: The commenter expressed concerns that the imposition of CMP magnifies the dilemma of the sometimes competing duties of zealous representation, client confidentiality, and candor towards the tribunal. The commenter opines that the rule will: (1) Interfere with the obligation of advocates to determine the relevance or evidentiary value of information being considered for admission for the record; (2) require representatives to determine what is a material fact and what is opinion; and (3) magnify the dilemma of competing duties of representation, client confidentiality and candor towards the tribunal.

Response: As acknowledged by the commenter, attorneys and paralegals supervised by attorneys are bound by federal and state codes of professional conduct. We do not believe that "zealous representation" would ever include knowingly assisting in presenting or supplying false information to the SSA in order to obtain benefits or payments for a client.

Comment: The commenter indicated that representatives should not be required to submit potentially prejudicial reports or face CMP without the availability of an enforceable subpoena for the report writer.

Response: The Inspector General (IG) has the authority under the Inspector General Act of 1978, as amended, to obtain such information through the issuance of subpoenas during a fraud investigation involving the SSA's programs or operations. Additional subpoena authority exists at sections 205(d) and 1129(i) of the Act.

Comment: The commenter expressed concerns that § 498.109 does not allow

for a showing of good cause for a late request for a hearing, and suggested that the OIG should send a second notice by certified mail.

Response: The SSA's proposed hearing regulations which will be published in the Federal Register in the near future will give the administrative law judge the authority to grant a late request for a hearing upon a showing of good cause. We have revised § 498.109 of this final rule to reflect this good cause exception.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and have determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they are not subject to OMB review.

Paperwork Reduction Act

These regulations impose no new reporting or record keeping requirements requiring OMB clearance.

Regulatory Flexibility Act

We have determined that no regulatory impact analysis is required for these final regulations. While the penalties and assessments which the IG could impose as a result of section 1129 of the Act and these regulations might have a slight impact on small entities, we do not anticipate that a substantial number of these small entities will be significantly affected by this rulemaking. Based on our determination, the IG certifies that these regulations will not have a significant economic impact on a substantial number of small business entities. Any impact on small businesses would primarily be a result of the legislation rather than these regulations. Therefore, we have not prepared a regulatory flexibility analysis.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; and 96.006, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 498

Administrative practice and procedure, Fraud, and Penalties.

Approved: April 16, 1996.

David C. Williams,
Inspector General.

For the reasons set out in the preamble, part 498 of chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

PART 498—CIVIL MONETARY PENALTIES, ASSESSMENTS AND RECOMMENDED EXCLUSIONS

1. The authority citation for part 498 is revised to read as follows:

Authority: Secs. 702(a)(5), 1129, and 1140 of the Social Security Act (42 U.S.C. 902(a)(5), 1320a-8, and 1320b-10).

2. Section 498.100 is amended by revising paragraphs (a) and (b) introductory text and adding paragraph (b)(1) to read as follows:

§ 498.100 Basis and purpose.

(a) *Basis.* This part implements sections 1129 and 1140 of the Social Security Act (42 U.S.C. 1320a-8 and 1320b-10).

(b) *Purpose.* This part provides for the imposition of civil monetary penalties and assessments, as applicable, against persons who—

(1) Make or cause to be made false statements or representations, or omissions of material fact for use in determining any right to or amount of benefits under title II or benefits or payments under title XVI of the Social Security Act; or

* * * * *

3. Section 498.101 is amended by adding the following definitions and revising the definition of "Respondent" to read as follows:

§ 498.101 Definitions.

* * * * *

Assessment means the amount described in § 498.104, and includes the plural of that term.

* * * * *

Material fact means a fact which the Commissioner of Social Security may consider in evaluating whether an applicant is entitled to benefits under title II or eligible for benefits or payments under title XVI of the Social Security Act.

* * * * *

Respondent means the person upon whom the Commissioner or the Inspector General has imposed, or intends to impose, a penalty and assessment, as applicable.

* * * * *

4. Section 498.102 is amended by revising the section heading and adding paragraph (a) to read as follows:

§ 498.102 Basis for civil monetary penalties and assessments.

(a) The Office of the Inspector General may impose a penalty and assessment, as applicable, against any person whom it determines in accordance with this part—

(1) Has made, or caused to be made, a statement or representation of a

material fact for use in determining any initial or continuing right to or amount of:

- (i) Monthly insurance benefits under title II of the Social Security Act; or
- (ii) Benefits or payments under title XVI of the Social Security Act; and
- (2)(i) Knew, or should have known, that the statement or representation—
 - (A) Was false or misleading; or
 - (B) Omitted a material fact; or
 - (ii) Made such statement with knowing disregard for the truth.

* * * * *

5. Section 498.103 is amended by adding paragraph (a) to read as follows:

* * * * *

§ 498.103 Amount of penalty.

(a) Under § 498.102(a), the Office of the Inspector General may impose a penalty of not more than \$5,000 for each false statement or representation.

* * * * *

6. Section 498.104 is added to read as follows:

§ 498.104 Amount of assessment.

A person subject to a penalty determined under § 498.102(a) may be subject, in addition, to an assessment of not more than twice the amount of benefits or payments paid as a result of the statement or representation which was the basis for the penalty. An assessment is in lieu of damages sustained by the United States because of such statement or representation.

7. Section 498.106 is amended by revising the section heading and adding paragraph (a) to read as follows:

§ 498.106 Determinations regarding the amount or scope of penalties and assessments.

(a) In determining the amount or scope of any penalty and assessment, as applicable, in accordance with §§ 498.103(a) and 498.104, the Office of the Inspector General will take into account:

- (1) The nature of the statements and representations referred to in § 498.102(a) and the circumstances under which they occurred;
- (2) The degree of culpability of the person committing the offense;
- (3) The history of prior offenses of the person committing the offense;
- (4) The financial condition of the person committing the offense; and
- (5) Such other matters as justice may require.

* * * * *

8. Section 498.108 is revised to read as follows:

§ 498.108 Penalty and assessment not exclusive.

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

9. Section 498.109 is revised to read as follows:

§ 498.109 Notice of proposed determination.

(a) If the Office of the Inspector General seeks to impose a penalty and assessment, as applicable, it will serve written notice of the intent to take such action. The notice will include:

(1) Reference to the statutory basis for the proposed penalty and assessment, as applicable;

(2) A description of the false statements, representations, and incidents, as applicable, with respect to which the penalty and assessment, as applicable, are proposed;

(3) The amount of the proposed penalty and assessment, as applicable;

(4) Any circumstances described in § 498.106 that were considered when determining the amount of the proposed penalty and assessment, as applicable; and

(5) Instructions for responding to the notice, including

- (i) A specific statement of respondent's right to a hearing; and
- (ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty and assessment, as applicable, without right of appeal.

(b) Any person upon whom the Office of the Inspector General has proposed the imposition of a penalty and assessment, as applicable, may request a hearing on such proposed penalty and assessment.

(c) If the respondent fails to exercise the respondent's right to a hearing within the time permitted under this section, and does not demonstrate good cause for such failure before an administrative law judge, any penalty and assessment, as applicable, becomes final.

10. Section 498.110 is revised to read as follows:

§ 498.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 498.109(a), the Office of the Inspector General may seek the proposed penalty and assessment, as applicable, or any less severe penalty and assessment. The Office of the Inspector General shall notify the respondent by certified mail, return receipt requested, of any penalty and assessment, as applicable, that has been imposed and of the means by

which the respondent may satisfy the amount owed.

11. Section 498.114 is added to read as follows:

§ 498.114 Collateral estoppel.

In a proceeding under section 1129 of the Social Security Act that—

(a) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal or State crime charging fraud or false statements; and

(b) Involves the same transactions as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

12. Section 498.127 is revised to read as follows:

§ 498.127 Judicial review.

Sections 1129 and 1140 of the Social Security Act authorize judicial review of any penalty and assessment, as applicable, that has become final. Judicial review may be sought by a

respondent only in regard to a penalty and assessment, as applicable, with respect to which the respondent requested a hearing, unless the failure or neglect to urge such objection is excused by the court because of extraordinary circumstances.

13. Section 498.128 is amended by revising the section heading, paragraph (a), and adding paragraphs (b), (d), and (e) to read as follows:

§ 498.128 Collection of penalty and assessment.

(a) Once a determination has become final, collection of any penalty and assessment, as applicable, will be the responsibility of the Commissioner or his or her designee.

(b) In cases brought under section 1129 of the Social Security Act, a penalty and assessment, as applicable, imposed under this part may be compromised by the Commissioner or his or her designee, and may be recovered in a civil action brought in the United States District Court for the district where the statement or representation referred to in § 498.102(a) was made, or where the respondent resides.

* * * * *

(d) As specifically provided under the Social Security Act, in cases brought under section 1129 of the Social Security Act, the amount of a penalty and assessment, as applicable, when finally determined, or the amount agreed upon in compromise, may also be deducted from:

- (1) Monthly title II or title XVI payments, notwithstanding section 207 of the Social Security Act as made

applicable to title XVI by section 1631(d)(1) of the Social Security Act;
 (2) A tax refund to which a person is entitled to after notice to the Secretary of the Treasury under 31 U.S.C. § 3720A;

(3) By authorities provided under the Debt Collection Act of 1982, as amended, 31 U.S.C. 3711, to the extent applicable to debts arising under the Social Security Act; or

(4) Any combination of the foregoing.
 (e) Matters that were raised or that could have been raised in a hearing before an administrative law judge or in an appeal to the United States Court of Appeals under sections 1129 or 1140 of the Social Security Act may not be raised as a defense in a civil action by the United States to collect a penalty and assessment, as applicable, under this part.

14. Section 498.129 is added to read as follows:

§ 498.129 Notice to other agencies.

As provided in section 1129 of the Social Security Act, when a determination to impose a penalty and assessment, as applicable, with respect to a physician or medical provider becomes final, the Office of the Inspector General will notify the Secretary of the final determination and the reasons therefore.

15. Section 498.132 is revised to read as follows:

§ 498.132 Limitations.

The Office of the Inspector General may initiate a proceeding in accordance with § 498.109(a) to determine whether to impose a penalty and assessment, as applicable—

(a) In cases brought under section 1129 of the Social Security Act, after receiving authorization from the Attorney General pursuant to procedures agreed upon by the Inspector General and the Attorney General; and

(b) Within 6 years from the date on which the violation was committed.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for 33 approved new animal drug applications (NADA's) from American Cyanamid Co. to Hoffmann-La Roche, Inc. In addition, the agency is amending its regulations to correct some errors. This action is being taken to clarify and improve the accuracy of the animal drug regulations.

EFFECTIVE DATE: April 24, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: American Cyanamid Co., Berdan Ave., Wayne, NJ 07470, has informed FDA that it has transferred ownership of, and all rights and interests in, the following approved NADA's to Hoffmann-La Roche, Inc., Nutley, NJ 07110-1199.

NADA no.	Ingredients
33-950	Sulfamerazine.
35-688	Chlortetracycline Calcium Complex, Penicillin G Procaine, Sulfamethazine
35-805	Chlortetracycline Hydrochloride, Sulfamethazine.
36-361	Chlortetracycline Calcium Complex, Amprolium, Ethopabate, Sodium Sulfate.
41-647	Sulfamethazine, Chlortetracycline Calcium Complex.
41-648	Sulfamethazine, Chlortetracycline Calcium Complex.
41-649	Sulfamethazine, Chlortetracycline Calcium Complex.
41-650	Sulfamethazine, Chlortetracycline Calcium Complex.
41-651	Sulfamethazine, Chlortetracycline Calcium Complex.
41-652	Sulfamethazine, Chlortetracycline Calcium Complex.
41-653	Sulfamethazine, Chlortetracycline Calcium Complex.
41-654	Sulfamethazine, Chlortetracycline Calcium Complex.
46-920	Bacitracin zinc.
48-486	Robenidine Hydrochloride.
48-761	Chlortetracycline Calcium Complex.
48-762	Chlortetracycline Calcium Complex.
48-763	Chlortetracycline Calcium Complex.
55-040	Chlortetracycline Hydrochloride.

NADA no.	Ingredients
92-507	Chlortetracycline Calcium Complex, Robenidine Hydrochloride.
93-372	Chlortetracycline Hydrochloride.
95-546	Robenidine Hydrochloride, Roxarsone.
96-933	Bacitracin zinc, Robenidine Hydrochloride.
97-085	Robenidine Hydrochloride, Bacitracin MD.
105-758	Bacitracin zinc, Amprolium, Ethopabate, Roxarsone.
114-794	Bacitracin zinc, Amprolium, Ethopabate.
121-553	Monensin Sodium, Chlortetracycline Hydrochloride.
123-154	Monensin Sodium, Bacitracin ZN, Roxarsone.
136-484	Bacitracin zinc, Carbasone.
139-075	Maduramicin ammonium.
139-190	Bacitracin zinc, Salinomycin, Sodium Roxarsone.
139-235	Bacitracin zinc, Salinomycin, Sodium Roxarsone.
140-859	Chlortetracycline Calcium Complex, Salinomycin Sodium.
140-867	Chlortetracycline Calcium Complex, Roxarsone, Salinomycin Sodium.

Accordingly, the agency is amending the regulations in part 558 (21 CFR part 558) to reflect the change of sponsor. FDA is also correcting some errors that have been incorporated into the agency's codified regulations. The errors in the regulations are as follows:

In § 558.95(b)(1)(xiii)(b) the reference to the limitations cited in (e)(1)(vii)(b) is incorrect; the correct cite is "paragraph (b)(1)(vii)(b) of this section". In § 558.355(b)(9) the cited reference "paragraphs (f)(1)(xv), (xvi), and (xvii)" incorrectly listed the sponsor, "(xvii)" should refer to sponsor 012799. The agency is correcting this error by removing "(xvii)" from § 558.355(b)(9) and adding sponsor 012799 to § 558.355(b)(10).

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows: