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Copies of the DEIS have been mailed to Federal agencies and individuals who requested copies of the DEIS in response to the NOI.

The DEIS will be available to the public on the Commission Posting System (CIPS). CIPS is an electronic bulletin board service which provides access to the text of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208-1397 or (800) 856-3920. To access CIPS, set your communications software to 19200, 14400, 12000, 9600, 7200, 4800, 2400, or 1200 bps, full duplex, no parity, 8 data bits and 1 stop bit.

Written comments are welcome on the DEIS. Please take notice that all written comments on specific environmental issues should contain supporting documentation and rationale. Written comments must be filed on or before January 8, 1996, reference Docket Nos. RM95-8-000 and RM94-7-001, and be addressed to:

Office of the Secretary, Federal Energy
Regulatory Commission, 888 First Street
NE., Washington, D.C. 20426.

A copy of any comments should also be sent to:

Mr. William Meroney, DEIS Project Manager,
Office of Economic Policy, 888 First Street
NE., Washington, DC 20426.

In addition, commenters are asked to submit their written comments on a 3½-inch diskette formatted for MS-DOS based computers. In light of our ability to translate MS-DOS based materials, the text need only be submitted in the format and version that it was generated (i.e., MS Word, WordPerfect, ASCII, etc.). It is not necessary to reformat word processor generated text to ASCII. For Macintosh users, it would be helpful to save the documents in Macintosh word processor format and then write them to files on a diskette formatted for MS-DOS machines.

After the comments are reviewed, any significant new issues are investigated, and modifications are made to the DEIS, a final EIS will be published and distributed by the staff. The final EIS will contain the staff's responses to timely comments received on the DEIS.

Lois D. Cashell,
Secretary.

[FR Doc. 95-28846 Filed 11-24-95; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 498

RIN 0960-AE23

Civil Monetary Penalties, Assessments and Recommended Exclusions

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

ACTION: Proposed rule.

SUMMARY: We propose to add new rules that would establish 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. These proposed rules would implement the civil monetary penalty provisions of section 206(b) of the Social Security Independence and Program Improvements Act of 1994.

DATES: To be sure that your comments are considered, we must receive them no later than January 26, 1996.

ADDRESSES: Comments should be submitted in writing to the Inspector General of the Social Security Administration, c/o Commissioner of Social Security, P.O. Box 1585, Baltimore, MD 21235, sent by telefax to (410) 966-2830, sent by E-mail to "regulations@ssa.gov" or delivered to 3-B-1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, between 8:00 a.m. and 4:30 p.m. on regular business days.

The electronic file of this document is available on the Federal Bulletin Board (FBB) at 9 a.m. on the date of publication in the Federal Register. To download the file, modem dial (202) 512-1387. The FBB instructions will explain how to download the file and the fee. This file is in WordPerfect and will remain on the FBB during the comment period.

FOR FURTHER INFORMATION CONTACT: Judith A. Kidwell, Office of the Inspector General, (410) 965-9750 or Glenn Sklar, Office of the General Counsel, (410) 965-6247.

SUPPLEMENTARY INFORMATION:

Background

These proposed rules would implement the civil monetary penalty (CMP) provisions of section 206(b) of the Social Security Independence and Program Improvements Act of 1994,

Public Law (Pub. L.) 103-296, which added section 1129 of the Social Security Act (the Act), effective October 1, 1994. Section 108 of Pub. L. 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.

Section 206 provides expanded authority for SSA to prevent, detect, and terminate fraudulent claims for Old-Age, Survivors, and Disability Insurance (OASDI) benefits and Supplemental Security Income (SSI) benefits. The new CMP provision contained in section 1129 of the Act is intended to deter applicants, beneficiaries, employees, employers, interpreters, physicians, medical providers, recipients, representative payees, representatives, translators, and other individuals and entities from providing false or misleading information, or omitting material information in connection with benefit claims.

Previously, the SSA relied on provisions of the Civil False Claims Act (CFCA) or the Program Fraud Civil Remedies Act (PFCRA) for imposing CMPs against persons who submitted fraudulent claims to SSA. These statutory provisions have been of limited usefulness in imposing CMPs for SSA fraud, inasmuch as the CFCA requires the Department of Justice to initiate civil action in Federal court to impose penalties, and the applicability of PFCRA is restricted to fraudulent action on initial benefit applications in some circumstances. The new CMP and assessment authority provides an alternative censure in cases not acceptable for action under the CFCA or the PFCRA.

Section 1129 of the Act provides that the Commissioner may delegate authority under this section to the Inspector General of the Social Security Administration (IG). On June 28, 1995, the Commissioner delegated to the IG authority under the CMP provisions in section 1129. However, the Commissioner has retained the authority to conduct hearings and to review initial hearing decisions related to the imposition of administrative sanctions.

Provisions of the Proposed Rule

These proposed regulations reflect and implement section 1129 of the Act. Section 1129 provides the Agency with direct authority, after approval by the Department of Justice, to impose a CMP and assessment against any individual, organization, agency, or other entity that knowingly makes or causes to be made a statement or representation of a

material fact for use in determining initial or continuing rights to OASDI or SSI benefit payments when such statement or representation is false, misleading, or omits a material fact. Under section 1129, each offense is subject to a penalty of not more than \$5,000 and an assessment, in lieu of damages, of not more than twice the amount of benefits paid as a result of such statement, representation or omission. In addition, medical providers or physicians who commit an offense described in section 1129 may be subject to exclusion from participation in the Medicare program (title XVIII of the Act). Specifically, section 1129(a)(1) provides that the Commissioner may make a determination, as part of the same proceeding in which penalties and assessments are determined, to recommend that the Secretary of Health and Human Services (Secretary) exclude as provided in section 1128 of the Act, such medical providers or physicians from participating in the Medicare program. Because of policy issues that need to be addressed and coordinated with the Department of Health and Human Services, we are reserving this issue at this time.

The criteria for exclusions of physicians and medical providers are in many instances discretionary and involve policy issues within the Department of Health and Human Services. The SSIPIA amended section 1128 of the Act to provide that fraud under section 1129 of the Act constitutes a basis for exclusion from the Medicare and Medicaid programs by the Secretary.

We are discussing these issues with the Department of Health and Human Services and have decided to reserve the issue of recommended exclusions in the regulations at this time. However, as provided in section 1129 of the Act, we will notify the Secretary upon a final determination to impose a penalty or assessment with respect to a physician or medical provider.

A CMP may be imposed for misrepresentation of a material fact. Section 1129(a)(2) defines a material fact as one which the Agency may consider in evaluating whether an applicant has initial or continuing entitlement to or eligibility for OASDI or SSI benefit payments.

Section 1129(b) provides that after a violation has occurred, the IG has six years to initiate a proceeding, in accordance with Rule 4 of the Federal Rules of Civil Procedure, to determine whether to impose a CMP or assessment. Department of Justice authorization must be obtained before

such a proceeding may be initiated. The IG must give the respondent written notice and an opportunity for the determination to be made on the record after a hearing at which the respondent is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses. Persons who have previously been convicted of a Federal or State crime charging fraud or false statement(s) are estopped from denying the elements of the criminal offense.

The IG will determine the amount or scope of the penalty and assessment after considering, as provided in section 1129(c), the nature of the statements or representations and the circumstances under which they occurred, the degree of culpability, the history of prior offenses, the financial condition of the person who committed the offense, and other matters as justice may require.

These proposed rules would implement the notice requirements of section 1129(b) by providing in § 498.109 that, if the IG proposes to impose a penalty or assessment in accordance with this part, the IG must send written notice to the respondent of the IG's intent to take such action. Under the proposed rules, the notice will describe the statutory basis for the penalty or assessment. The notice will also provide instructions for responding and will explain the respondent's hearing rights. The IG's detailed CMP hearings and appeal procedures will be published in the Federal Register in the near future, and will be located at 20 C.F.R. § 498.200 et seq.

These proposed CMP regulations have been modeled after longstanding regulations in 42 C.F.R. part 1003 which implement similar statutory CMP provisions for false claims in the Medicare and Medicaid programs.

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 proposed regulations impose no new reporting or recordkeeping requirements requiring OMB clearance.

Regulatory Flexibility Act

We have determined that no regulatory impact analysis is required for these proposed 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 proposed regulations would 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.

Effect of NPRM on Pending Actions

Until the promulgation of final regulations, the IG intends that these proposed regulations shall provide guidance with respect to the imposition and adjudication of the CMPs and assessments.

(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; 96.006, Supplemental Security Income Program)

List of Subjects in 20 CFR part 498

Administrative practice and procedure, Fraud, Penalties.

Approved: October 10, 1995.

June Gibbs Brown,
Inspector General.

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

PART 498—CIVIL MONETARY PENALTIES, ASSESSMENTS AND RECOMMENDED EXCLUSIONS

1–2. 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).

3. Section 498.100 is amended by revising paragraphs (a), (b) introductory text, and (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

* * * * *

4. 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.

* * * * *

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

* * * * *

5. 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 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.

* * * * *

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

* * * * *

§ 498.103 Amount of penalty.

(a) Under section § 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.

* * * * *

7. 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.

8. Section 498.106 is amended by 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 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.

* * * * *

9. Section 498.108 is revised to read as follows:

§ 498.108 Penalty and assessment not exclusive.

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

10. 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 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, any penalty and assessment, as applicable, becomes final.

11. 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.

12. 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.

13. 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.

14. Section 498.128 is amended by revising 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 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 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 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 when finally determined, or the amount agreed upon in compromise, may also be deducted from:

- (i) 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; or
 - (ii) A tax refund to which a person is entitled to after notice to the Secretary of the Treasury under 31 U.S.C. 3720A; or
 - (iii) 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 Act; or
 - (iv) 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 under this part.

15. 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 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.

16. 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 only—

(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 812**

[Docket No. 95N-0342]

Export Requirements for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations for investigational devices to streamline requirements for persons seeking to export unapproved medical devices. The proposed rule would establish that FDA approval of an investigational device exemption application (IDE) constitutes an agency determination that the export of the unapproved device is not contrary to the public health or safety. The proposed rule would also consider a country as approving importation of an unapproved device if the country has notified FDA that it approves of the importation of unapproved devices with an approved IDE into their countries. Thus, for devices with an FDA-approved IDE, the proposal would eliminate the need for FDA to make independent determinations either that exportation is not contrary to the public health or safety or that an importing country approves the importation of a specific device. The proposed rule is intended to codify and to simplify export requirements for certain unapproved devices pursuant to the President's and Vice-President's "National Performance Review," as reflected in the April 1995 report titled, "Reinventing Drug & Medical Device Regulations." The agency is also requesting comments on other ways of improving the export process for medical devices.

DATES: Written comments by February 12, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

SUPPLEMENTARY INFORMATION:**I. Introduction**

Section 801(e)(1) (21 U.S.C. 381(e)(1)) of the Federal Food, Drug, and Cosmetic Act (the act) states, in part, that a device intended for export shall not be deemed to be adulterated or misbranded if it: (1) meets the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in domestic commerce. Section 801(e)(1) of the act does not apply, however, to any device that does not comply with an applicable requirement under sections 514 (21 U.S.C. 360d) (performance standards) or 515 (21 U.S.C. 360e) (premarket approval) of the act, a device which, under section 520(g) of the act (21 U.S.C. 360j(g)), is exempt from sections 514 and 515 of the act, or to a banned device, unless, in addition to the requirements in section 801(e)(1), the agency "has determined that exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export." (See section 801(e)(2) of the act.) This statutory scheme requires parties to submit requests to FDA for exportation of certain unapproved devices and also requires FDA to approve such requests if the requirements in section 801(e) of the act are met.

To enable FDA to determine whether the exportation of a particular device is not contrary to the public health or safety, FDA generally asks that the person seeking to export the device submit, along with the export request, information or data regarding the device's safety. However, if the device is the subject of an IDE approved by FDA and will be marketed or used in clinical trials for the same intended use in the foreign country, FDA does not require submission of safety data with the export request because those safety data are already contained in the IDE.

To determine whether a foreign country has approved importation of a