

drug applications when a manufacturer has waived its opportunity for a hearing.

EFFECTIVE DATE: June 3, 1991.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION:

Currently, the Director and Deputy Director, CBER, are authorized to issue a notice of license revocation when requested by the manufacturer (21 CFR 5.67(c)). This new delegation of authority will also authorize them to issue a notice of license revocation when a manufacturer has waived the opportunity for a hearing under § 601.7(a) (21 CFR 601.7(a)) by failing to respond to a notice of opportunity for a hearing (see 21 CFR 314.200(a)(2), referenced in § 601.7(a)). Currently, this authority is held by the Commissioner or his designee.

Therefore, the agency is adding new paragraph (d) to § 5.67 *Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.*

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such a position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354-360f, 361, 362, 1701-1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b-263n, 264, 265, 300a-300a-5, 300aa-1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591.

2. Section 5.67 is amended by adding new paragraph (d) to read as follows:

§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.

(d) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

Dated: May 29, 1991.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

Prescriptions; Requirements Clarification

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This final rule amends 21 CFR 1306.05 and 1306.13 to clarify the requirements of prescriptions for controlled substances, and to extend the partial filling of Schedule II prescriptions to patients in hospice or home-care that have a medical diagnosis documenting a terminal illness. The proposal regarding the use of medication order sheets for filling prescriptions for patients in Long Term Care Facilities under the provisions of 21 CFR 1306.11 is not adopted at this time and will be the subject of a separate proposed Federal Register announcement which will allow a period for additional comments.

EFFECTIVE DATE: July 3, 1991.

FOR FURTHER INFORMATION CONTACT: Chief, State and Industry Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 (202) 307-7297.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was published in the Federal Register on March 16, 1989 (54 FR 11006) to amend 21 CFR 1306.02, 1306.05, 1306.11, and 1306.13 to clarify the issuance of controlled substance prescriptions and to facilitate the requirements for Schedule II prescriptions for patients in a Long Term Care Facility (LTCF) and the terminally ill. The proposed rulemaking provided an opportunity for interested parties to

submit comments in writing on or before April 17, 1989. The comment period was extended until May 25, 1989 by a notice published in the Federal Register on April 25, 1989 (54 FR 17769).

Section 1306.02 Definitions

Several comments were received concerning the definition of the term "terminally ill" as used by the Health Care Financing Administration (HCFA) in title 42 CFR 418.3, as an individual who has a medical prognosis that the life expectancy is six months or less. Nine of the comments objected to the six-month limitation as being too restrictive since predicting an individual's life expectancy is difficult and often uncertain. Upon consideration of the comments, DEA has eliminated this definition and has, instead, incorporated into the final regulations the phrase "a patient with a medical diagnosis documenting a terminal illness".

Section 1306.05 Manner of Issuance of Prescriptions

Two comments expressed concern over allowing a secretary or agent of the physician to prepare the prescriptions for the signature of the physician. This provision has always been permitted and is not affected by the proposed changes to § 1306.05. It has been DEA's position that a secretary or agent of the physician may prepare the prescription. However, it is the physician's responsibility before signing the prescription to ensure that the prescription is properly prepared.

Two comments objected to the requirement to specify the quantity prescribed on prescriptions for LTCF patients, especially in those states which do not require a quantity of prescribed drugs for LTCF residents or for hospice or home-care patients. DEA has considered these comments and finds that the quantity prescribed has always been a requirement of the regulations. For example, 21 CFR 1304.24 requires dispensers of controlled substances to maintain records including the number of units dispensed. And, 21 CFR 1306.22(b)(1) requires computerized prescription records to provide on-line retrieval of original prescription order information including the drug name, strength, dosage form and quantity prescribed. The purpose of this change is to make "quantity prescribed" a part of 21 CFR 1306.05, "Manner of issuance of prescriptions."

One comment questioned the requirement for "directions for use" on the prescription and inquired whether the phrase "take as directed" would

satisfy the requirement. DEA considers the "directions for use" to be essential to drug therapy and on a prescription it serves as a means of communicating to the patient and pharmacist the recommended dosage. The use of the phrase "take as directed," while not desirable complies with the regulatory requirement. The most communicative form of directions include the number of dosage units to be taken in a specified time period.

Section 1306.11 Requirement for Prescription (Schedule II)

Seven comments were received addressing the proposed use of the physician's medication order sheet for LTCF patients in lieu of a signed written prescription from the physician. While some supportive comments were received, most of the comments indicated that the proposed changes did not adequately address the realities of LTCF operations, especially the difficulty in obtaining a written prescription from the prescribing physician prior to the need to administer a schedule II controlled substance. DEA has considered these comments and has concluded a second proposal will be published in the *Federal Register*. This announcement will propose to amend the use of emergency provisions under 21 CFR 1306.11, taking into consideration the unique situation between pharmacies and LTCF patients.

Section 1306.13 Partial Filling of Prescriptions (Schedule II)

A large majority of comments supported the proposed allowance of partial filling of Schedule II controlled substances for hospice and home care patients that have a terminally ill medical diagnosis. However, they objected to the 15-day limitation on partial dispensing under those circumstances and for LTCF patients and would prefer to have the amount to be partially dispensed left to the discretion of the pharmacist and the patient. Some also commented that the 15-day limitation would add unnecessary visits to the pharmacy and would actually increase patient cost. The intent of this proposal was not to place any restriction on partial filling of Schedule II prescriptions for LTCF patients, but to reduce the quantity of controlled substances which may be in the home or in the hospice of terminally ill patients. In considering the comments, DEA finds that by encouraging the use of partial filling, the objective of reducing large quantities of drugs from being stored where the patient resides stands to be achieved.

Therefore, the 15-day limitation has been deleted from the final rule.

Four comments were received which sought to broaden partial filling to include not only LTCF and terminally ill patients, but also patients with severe intractable pain regardless of diagnosis. DEA finds no merit in broadening the partial filling of Schedule II controlled substances beyond LTCFs and terminally ill patients and considers the issue of intractable pain to be separate and apart from prescribing to the terminally ill. A partial filling to other than an LTCF or terminally ill patient constitutes a violation of the Controlled Substances Act. DEA has further amended the regulation by requiring the pharmacist to record on the prescription whether the patient is terminally ill or is an LTCF patient. This will differentiate those prescriptions which are authorized for partial filling from the pharmacy's regular prescriptions.

One comment addressed partial filling and whether a new prescription is required when the physician changes only the initial directions for use, e.g., a prescription is authorized for 200 Percodan to be taken four times a day, and a week later the physician changes the directions for use to six tablets a day. This would not require a new prescription. The pharmacist merely is required to amend the directions for use on the original prescription and continue dispensing under that prescription until the 200 tablet quantity is reached. The pharmacist may not dispense beyond the original quantity prescribed without a new prescription.

Several comments were received objecting to the language of 21 CFR 1306.13(c) as being vague, confusing, unnecessary, and causing an additional recordkeeping burden on the pharmacist. Two comments suggested that this section be deleted since there is an initial procedure of review to assure that the schedule of use of the controlled substance is consistent with the prescribing practitioner's directions. The purpose of this section was to cause the pharmacist to check with the patient or with the LTCF prior to automatically dispensing another partial refill to ensure that the quantities previously dispensed have been administered and that there is justification for the continued use of the controlled substance. DEA has considered the comments and has rephrased the regulation to clarify its intent by deleting the proposed § 1306.13(c) and incorporating into § 1306.13(b) a requirement for the pharmacist to confirm that additional partial fillings are necessary prior to dispensing to a

LTCF patient or to a terminally ill hospice or home-care patient.

General Comments

The amendments will not require any additional paperwork or recordkeeping burden beyond normal business practices and are intended to clarify the present requirements and to extend partial filling of Schedule II controlled substances to hospice and homecare for the terminally ill.

The Deputy Assistant Administrator, Office of Diversion control, hereby certifies that this final rule will not have significant impact upon entities whose interest must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. The changes will not impose any additional regulatory requirements. They will revise the method by which certain Schedule II controlled substance prescriptions are handled and will allow a smaller quantity of controlled substances to be dispensed to authorized patients. The final rule is not a major rule for the purposes of Executive Order (E.O.) 12291 of February 17, 1981. Pursuant to section 3(c)(3) and 3(e)(2)(C) of E.O. 12291, this final rule has been submitted for review to the Office of Management and Budget.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that the final rule does not have sufficient federalism implications to warrant the preparation of Federalism Assessment.

List of Subject in 21 CFR Part 1306

Drug Enforcement Administration, Drug traffic control, Prescription drugs.

For reasons set out above, 21 CFR part 1306 is amended as follows:

PART 1306—[AMENDED]

1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b) unless otherwise noted.

2. Section 1306.05 is amended by revising paragraph (a) to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. A practitioner may sign a

prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

3. Section 1306.13 is amended by revising paragraph (b) and the introductory text of paragraph (c) and paragraph (c)(1) to read as follows:

§ 1306.13 Partial filling of prescriptions.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contract the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days

from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in § 1306.13(b).

Dated: March 11, 1991.

Gene R. Haislip,

Deputy Assistant Administrator, Drug Enforcement Administration.

[FR Doc. 91-12730 Filed 5-31-91; 8:45 am]

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UNITED STATES INFORMATION AGENCY

22 CFR Part 521

Implementation of the Program Fraud Civil Remedies Act

AGENCY: United States Information Agency.

ACTION: Final regulations.

SUMMARY: The U.S. Information Agency is promulgating as a final rule regulations to implement the Program Fraud Civil Remedies Act of 1986. These final regulations establish administrative procedures for imposing the statutorily authorized civil penalties and assessments against any person who makes, submits, or presents or causes to be made, submitted or presented a false, fictitious or fraudulent claim or written statement to the U.S. Information Agency.

EFFECTIVE DATE: May 16, 1991.

FOR FURTHER INFORMATION CONTACT: Richard S. Werksman, Assistant General Counsel, Office of the General Counsel, room 700, United States Information Agency, 301 4th Street, SW., Washington, DC 20547, (202) 619-6975.

SUPPLEMENTARY INFORMATION: The Program Fraud Civil Remedies Act established a new administrative remedy for imposing civil penalties and assessments against any person who

makes a false claim or false written statement to the Federal Government in an amount less than \$150,000. This remedy applies to any person who knowingly submits or causes to be submitted a false claim or statement to the Federal Government. The statute requires Federal agencies to follow certain procedures to recover penalties and assessments against persons who file false claims or statements. It provides for designated investigative and reviewing officials, an administrative hearing process, and an agency appeal procedure with limited judicial review. The President's Council on Integrity and Efficiency developed draft model regulations in order to promote uniformity in implementing the new procedure. These regulations are based on the Council's draft.

The U.S. Information Agency published a notice of proposed rulemaking on this subject in the Federal Register on February 6, 1991 [56 FR 4761]. No comments were received, and the final rule contains no changes from the proposed rule.

Consistent with the statute's requirements, the U.S. Information Agency's final regulations provide that the Office of Inspector General will act as the Investigating Official; the Office of General Counsel will act as the Reviewing Official; an administrative law judge will be the Presiding Official; and the Director of the U.S. Information Agency will act as the Authority Head on appeals.

The new administrative process should serve to deter the submission of false claims and statements and provide USIA with an effective remedy against persons submitting such false claims to the Agency.

The final rule will have no direct effect on the economy, or on Federal or State expenditures, and thus does not constitute a "major rule" within the meaning of section 1(b) of Executive Order 12291. As a result, we have concluded that an initial regulatory impact analysis is not required. Nor do the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b) apply. The final rules contain no information collection or recordkeeping requirements as defined by the Paperwork Reduction Act of 1978, and fall within the exceptions to coverage.

Lists of Subjects in 22 CFR Part 521

Administrative practice and procedure, Claims, Fraud, Penalties.

Accordingly, Title 22 CFR Chapter V, is amended to add Part 521 to read as follows:

PART 521—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL REMEDIES ACT

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- 521.1 Basis and Purpose.
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 - 521.19 Prehearing conferences.
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 - 521.21 Discovery.
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 - 521.24 Protective order.
 - 521.25 Fees.
 - 521.26 Form, filing and service of papers.
 - 521.27 Computation of time.
 - 521.28 Motions.
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 - 521.30 The hearing and burden of proof.
 - 521.31 Determining the amount of penalties and assessments.
 - 521.32 Location of hearing.
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 - 521.42 Judicial review.
 - 521.43 Collection of civil penalties and assessments.
 - 521.44 Right to administrative offset.
 - 521.45 Deposit in Treasury of United States.
 - 521.46 Compromise or settlement.
 - 521.47 Limitations.

Authority: 22 U.S.C. 2658; 31 U.S.C. 3801-3812.

§ 521.1 Basis and purpose.

(a) *Basis.* This part implements the Program Fraud Civil Remedies Act of 1986, Public Law 99-509, sections 6101-6104, 100 Stat. 1874 (October 21, 1986), codified at 31 U.S.C. 3801-3812. The Act requires each authority head to promulgate regulations necessary to implement the provisions of the statute (31 U.S.C. 3809).

(b) *Purpose.*

(1) This part establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to the United States Information Agency or to its agents, and

(2) Specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

(c) *Special considerations abroad.*

Where a party, witness or material evidence in a proceeding under these regulations is located abroad, the investigating official, reviewing official or ALJ, as the case may be, may adjust the provisions below for service, filing of documents, time limitations, and related matters to meet special problems arising out of that location.

§ 521.2 Definitions.

ALJ means an Administrative Law Judge in USIA appointed pursuant to 5 U.S.C. 3105 or detailed to USIA pursuant to 5 U.S.C. 3344.

Benefit means, in the context of "statement," anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee.

Claim means any request, demand, or submission—

(1) Made to USIA for property, services or money (including money representing grants, loans, insurance or benefits);

(2) Made to a recipient of property, services or money from USIA, or to a party to a contract with USIA—

(i) For property or services if the United States—

(A) Provided such property or services;

(B) Provided any portion of the funds for the purchase of such property or services; or

(C) Will reimburse such recipient or party for the purchase of such property or services; or

(ii) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

(A) Provided any portion of the money requested or demanded; or

(B) Will reimburse such recipient or party for any portion of the money paid on such request or demand; or

(3) Made to USIA which has the effect of decreasing an obligation to pay or account for property, services, or money.

Complaint means the administrative complaint served by the reviewing official on the defendant under § 521.7.

Defendant means any person alleged in a complaint under § 521.7 to be liable for a civil penalty or assessment under § 521.3.

Director means Director of the United States Information Agency.

Government means the United States Government.

Individual means a natural person.

Initial decision means the written decision of the ALJ required by § 521.10 or § 521.37, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Investigating Official means the Inspector General for USIA or an officer or employee of the Office of Inspector General designated by the Inspector General and serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

Knows or has reason to know means that a person, with respect to a claim or statement—

(1) Has the actual knowledge that the claim or statement is false, fictitious, or fraudulent;

(2) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or

(3) Acts in reckless disregard of the truth or falsity of the claim or statement.

Makes, wherever it appears, shall include the terms *presents*, *submits* and *causes to be made*, *presented*, or *submitted*. As the context requires, *making* or *made* shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association, or private organization and includes the plural of that term.

Representative means an attorney who is a member in good standing of the bar of any State, Territory, or possession of the United States or the District of Columbia or the Commonwealth of Puerto Rico.

Reviewing official means the General Counsel of USIA or his designee who is:

USIA means the United States Information Agency.

(1) Not subject to supervision by, or required to report to, the investigating official;

(2) Not employed in the organizational unit of USIA in which the investigating official is employed; and

(3) Is serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made—

(1) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or

(2) With respect to (including relating to eligibility for)—

- (i) A contract with, or a bid or proposal for a contract with; or
- (ii) A grant, loan, or benefit from, USIA, or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit.

USIA means the United States Information Agency.

§ 521.3 Basis for civil penalties and assessments.

(a) Claims.

(1) Any person who makes claim that the person knows or has reason to know—

- (i) Is false, fictitious, or fraudulent;
- (ii) Includes or is supported by any written statement which asserts a material fact which is false, fictitious, or fraudulent;
- (iii) Includes or is supported by any written statement that—
 - (A) Omits a material fact;
 - (B) Is false, fictitious, or fraudulent as a result of such omission; and
 - (C) Is a statement in which the person making such statement has a duty to include such material fact; or
 - (iv) Is for payment for the provision of property or services which the person has not provided as claimed; shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such claim.

(2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to USIA, a recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of USIA or such recipient or party.

(4) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(5) If the Government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under

paragraph (a)(1) of this section shall also be subject to an assessment of not more than twice the amount of such claim or that portion thereof that is determined to be in violation of paragraph (a)(1) of this section. Such assessment shall be in lieu of damages sustained by the Government because of such claim.

(b) Statement.

(1) Any person who makes, a written statement that—

(i) The person knows or has reason to know—

- (A) Asserts a material fact which is false, fictitious, or fraudulent; or
- (B) Is false, fictitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such statement; and

(ii) Contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such statement.

(2) Each written representation, certification, or affirmation constitutes a separate statement.

(3) A statement shall be considered made to USIA when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of USIA.

(c) No proof of specific intent to defraud is required to establish liability under this section.

(d) In any case in which it is determined that more than one person is liable for making a claim or statement under this section, each such person may be held liable for a civil penalty under this section.

(e) In any case in which it is determined that more than one person is liable for making a claim under this section on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severally against any combination of such persons.

§ 521.4 Investigation.

(a) If an investigating official concludes that a subpoena pursuant to the authority conferred by 31 U.S.C. 3804(a) is warranted—

(1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued, and shall identify the records or documents sought;

(2) The investigating official may

designate a person to act on his or her behalf to receive the documents sought; and

(3) The person receiving such subpoena shall be required to tender to the investigating official or the person designated to receive the documents a certification that the documents sought have been produced, or that such documents are not available and the reasons therefore, or that such documents, suitably identified, have been withheld based upon the assertion of an identified privilege.

(b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall submit a report containing the findings and conclusions of such investigation to the reviewing official.

(c) Nothing in this section shall preclude or limit an investigating official's discretion to refer allegations directly to the Department of Justice for suit under the False Claims Act or other civil relief, or to defer or postpone a report or referral to the reviewing official to avoid interference with a criminal investigation or prosecution.

(d) Nothing in this section modifies any responsibility of an investigating official to report violations of criminal law to the Attorney General.

§ 521.5 Review by the reviewing official.

(a) If, based on the report of the investigating official under § 521.4(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under § 521.3 of this part, the reviewing official shall transmit to the Attorney General a written notice of the reviewing official's intention to issue a complaint under § 521.7.

(b) Such notice shall include—

(1) A statement of the reviewing official's reasons for issuing a complaint;

(2) A statement specifying the evidence that supports the allegations of liability;

(3) A description of the claims or statements upon which the allegations of liability are based;

(4) An estimate of the amount of money or the value of property, services, or other benefits requested or demanded in violation of § 521.3 of this part;

(5) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and

(6) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

§ 521.6 Prerequisites for issuing a complaint.

(a) The reviewing official may issue a complaint under § 521.7 only if:

(1) The Department of Justice approves the issuance of a complaint in a written statement described in 31 U.S.C. 3803(b)(1); and

(2) In the case of allegations of liability under § 521.3(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in paragraph (b) of this section), the amount of money or the value of property or services demanded or requested in violation of § 521.3(a) does not exceed \$150,000.

(b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official's authority to join in a single complaint against a person's claims that are unrelated or were not submitted simultaneously, regardless of the amount of money, or the value of property or services, demanded or requested.

§ 521.7 Complaint.

(a) On or after the date the Department of Justice approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1), the reviewing official may serve a complaint on the defendant, as provided in § 521.8.

(b) The complaint shall state:

(1) Allegations of liability against the defendant including the statutory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;

(2) The maximum amount of penalties and assessments for which the defendant may be held liable;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the defendant's right to request a hearing by filing an answer and to be represented by a representative; and

(4) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the maximum amount of penalties and assessment without right to appeal, as provided in § 521.10.

(c) At the same time the reviewing official serves the complaint, he or she

shall serve the defendant with a copy of these regulations.

§ 521.8 Service of complaint.

(a) Service of a complaint must be made by certified or registered mail or by delivery in any manner authorized by rule 4(d) of the Federal Rules of Civil Procedure. Service is complete upon receipt.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:

(1) Affidavit of the individual serving the complaint by delivery;

(2) A United States Postal Service return receipt card acknowledging receipt; or

(3) Written acknowledgment of receipt by the defendant or the defendant's representative.

(4) In case of service abroad authenticated in accordance with the Convention on the Service Abroad of Judicial and Extra Judicial Documents in Civil or Commercial Matters.

§ 521.9 Answer.

(a) The defendant may request a hearing by filing an answer with the reviewing official within 30 days of service of the complaint. An answer shall be deemed to be a request for a hearing.

(b) In the answer, the defendant:

(1) Shall admit or deny each of the allegations of liability made in the complaint;

(2) Shall state any defense on which the defendant intends to rely;

(3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and

(4) Shall state the name, address, and telephone number of the person authorized by the defendant to act as defendant's representative, if any.

(c) If the defendant is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the defendant may, before the expiration of 30 days from service of the complaint, file with the reviewing official a general answer denying liability and requesting a hearing, and a request for an extension of time within which to file an answer meeting the requirements of paragraph (b) of this section. The reviewing official shall file promptly with the ALJ the complaint, the general answer denying liability, and the request for an extension of time as provided in § 521.11. For good cause shown, the ALJ may grant the defendant up to 30 additional days within which to file an

answer meeting the requirements of paragraph (b) of this section.

§ 521.10 Default upon failure to file an answer.

(a) If the defendant does not file an answer within the time prescribed in § 521.9(a), the reviewing official may refer the complaint to the ALJ.

(b) Upon the referral of the complaint, the ALJ shall promptly serve on defendant in the manner prescribed in § 521.8, a notice that an initial decision will be issued under this section.

(c) If the defendant fails to answer, the ALJ shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under § 521.3, the ALJ shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.

(d) Except as otherwise provided in this section, by failing to file a timely answer, the defendant waives any right to further review of the penalties and assessments imposed under paragraph (c) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(e) If, before such an initial decision becomes final, the defendant files a motion with the ALJ seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing an answer, the initial decision shall be stayed pending the ALJ's decision on the motion.

(f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file a timely answer, the ALJ shall withdraw the initial decision in paragraph (c) of this section, if such a decision has been issued, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the ALJ denying defendant's motion under paragraph (e) of this section is not subject to reconsideration under § 521.38.

(h) The defendant may appeal to the Director the decision denying a motion to reopen by filing a notice of appeal with the Director within 15 days after the ALJ denies the motion. The timely filing of a notice of appeal shall stay the initial decision until the Director decides the issue.

(i) If the defendant files a timely notice of appeal with the Director, the ALJ shall forward the record of the proceeding to the Director.

(j) The Director shall decide expeditiously whether extraordinary circumstances excuse the defendant's failure to file a timely answer based solely on the record before the ALJ.

(k) If the Director decides that extraordinary circumstances excused the defendant's failure to file a timely answer, the Director shall remand the case to the ALJ with instructions to grant the defendant an opportunity to answer.

(l) If the Director decides that the defendant's failure to file a timely answer is not excused, the Director shall reinstate the initial decision of the ALJ, which shall become final and binding upon the parties 30 days after the Director issues such decision.

§ 521.11 Referral of complaint and answer to the ALJ.

Upon receipt of an answer, the reviewing official shall file the complaint and answer with the ALJ.

§ 521.12 Notice of hearing.

(a) When the ALJ receives the complaint and answer, the ALJ shall promptly serve a notice of hearing upon the defendant in the manner prescribed by § 521.8. At the same time, the ALJ shall send a copy of such notice to the representative for the Government.

(b) Such notice shall include:

- (1) The tentative time and place, and the nature of the hearing;
- (2) The legal authority and jurisdiction under which the hearing is to be held;
- (3) The matters of fact and law to be asserted;
- (4) A description of the procedures for the conduct of the hearing;
- (5) The name, address, and telephone number of the representative of the Government and of the defendant, if any; and
- (6) Such other matters as the ALJ deems appropriate.

§ 521.13 Parties to the hearing.

(a) The parties to the hearing shall be the defendant and USIA.

(b) Pursuant to 31 U.S.C. 3730(c)(5), a private plaintiff under the False Claims Act may participate in these proceedings to the extent authorized by the provisions of that Act.

§ 521.14 Separation of functions.

(a) The investigating official, the reviewing official, and any employee or agent of USIA who takes part in investigating, preparing, or presenting a particular case may not, in such case or a factually related case:

- (1) Participate in the hearing as the ALJ;
- (2) Participate or advise in the initial decision or the review of the initial decision by the Director, except as a witness or representative in public proceedings; or
- (3) Make the collection of penalties and assessments under 31 U.S.C. 3806.

(b) The ALJ shall not be responsible to, or subject to, the supervision or direction of the investigating official or the reviewing official.

(c) Except as provided in paragraph (a) of this section, the representative for the Government may be employed anywhere in USIA, including in the offices of either the investigating official or the reviewing official.

§ 521.15 Ex Parte contacts.

No party or person (except employees of the ALJ's office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 521.16 Disqualification of reviewing official or ALJ.

(a) A reviewing official or ALJ in a particular case may disqualify himself or herself at any time.

(b) A party may file with the ALJ a motion for disqualification of a reviewing official or ALJ. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.

(c) Such motion and affidavit shall be filed promptly upon the party's discovery of reasons requiring disqualification, or such objections shall be deemed waived.

(d) Such affidavit shall state specific facts that support the party's belief that personal bias or other reason for disqualification exists and the time and circumstances of the party's discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.

(e) Upon the filing of such a motion and affidavit, the ALJ shall proceed no further in the case until he or she resolves the matter of disqualification in accordance with paragraph (f) of this section.

(f)(1) If the ALJ determines that the reviewing official is disqualified, the ALJ shall dismiss the complaint without prejudice.

(2) If the ALJ disqualifies himself or herself, the case shall be reassigned promptly to another ALJ.

(3) If the ALJ denies a motion to disqualify, the Director may determine the matter only as part of his or her review of the initial decision upon appeal, if any.

§ 521.17 Rights of parties.

Except as otherwise limited by this part, all parties may:

(a) Be accompanied, represented, and advised by a representative;

(b) Participate in any conference held by the ALJ;

(c) Conduct discovery;

(d) Agree to stipulations of fact or law, which shall be made part of the record;

(e) Present evidence relevant to the issues at the hearing;

(f) Present and cross-examine witnesses;

(g) Present oral arguments at the hearing as permitted by the ALJ; and

(h) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

§ 521.18 Authority of the ALJ.

(a) The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The ALJ may:

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas to be served within the United States requiring the attendance of witnesses and the production of documents at depositions or at hearings. Subpoenas to be served outside the jurisdiction of the United States shall state on their face the authority therefore;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and time of discovery;

(8) Regulate the course of the hearing and the conduct of representatives and parties;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and

(14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.

(c) The ALJ does not have the authority to find treaties and other

international agreements or Federal Statutes or regulations invalid.

§ 521.19 Prehearing conferences.

(a) The ALJ may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The ALJ may use prehearing conferences to discuss the following:

- (1) Simplification of the issues;
- (2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;
- (3) Stipulations and admissions of fact or as to the contents and authenticity of documents;
- (4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery;

(9) The time and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The ALJ shall issue an order containing all matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 521.20 Disclosure of documents.

(a) Upon written request to the reviewing official, the defendant may review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under § 521.4(b) are based, unless such documents are subject to a privilege under Federal law. Upon payment of fees for duplication, the defendant may obtain copies of such documents.

(b) Upon written request to the reviewing official, the defendant also may obtain a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.

(c) The notice sent to the Attorney General from the reviewing official as described in § 521.5 is not discoverable under any circumstances.

(d) The defendant may file a motion to compel disclosure of the document subject to the provisions of this section. Such a motion may only be filed with the ALJ following the filing of an answer pursuant to § 521.9.

§ 521.21 Discovery.

(a) The following types of discovery are authorized:

- (1) Requests for production of documents for inspection and copying;
- (2) Requests for admissions of the authenticity of any relevant document or the truth of any relevant fact;
- (3) Written interrogatories; and
- (4) Depositions.

(b) For the purpose of this section and § 521.22 and § 521.23, the term "documents" includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless mutually agreed to by the parties, discovery is available only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.

(d) *Motions for Discovery.*

(1) A party seeking discovery may file a motion with the ALJ. Such a motion shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.

(2) Within ten days of service a party may file an opposition to the motion and/or a motion for protective order as provided § 521.24.

(3) The ALJ may grant a motion for discovery only if the ALJ finds that the discovery sought:

- (i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;
- (ii) Is not unduly costly or burdensome;
- (iii) Will not unduly delay the proceeding; and
- (iv) Does not seek privileged information.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

(5) The ALJ may grant discovery subject to a protective order under § 521.24.

(e) *Deposition.*

(1) If a motion for deposition is granted, the ALJ shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and

place at which the deposition will be held.

(2) The party seeking to depose shall serve the subpoena in the manner prescribed in § 521.8.

(3) The deponent may file with the ALJ a motion to quash the subpoena or a motion for a protective order within ten days of service.

(4) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition which it shall make available to all other parties for inspection and copying.

(f) Each party shall bear its own costs of discovery.

§ 521.22 Exchange of witness lists, statements and exhibits.

(a) At least 15 days before the hearing or at such other time as may be ordered by the ALJ, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 521.33(b). At the time the above documents are exchanged, any party that intends to rely on the transcript of deposition testimony in lieu of live testimony at the hearing, if permitted by the ALJ, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects, the ALJ shall not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above, unless the ALJ finds good cause for the failure or that there is no prejudice to the objecting party.

(c) Unless another party objects within the time set by the ALJ, documents exchanged in accordance with paragraph (a) of this section shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 521.23 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the ALJ issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 15 days before the date fixed for the hearing unless otherwise allowed by the ALJ for good cause shown. Such

request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed in § 521.8. A subpoena on a party or upon an individual under the control of a party may be served by first class mail.

(f) A party or individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within ten days after service or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§ 521.24 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or, with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

- (1) That the discovery not be had;
- (2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;
- (3) That the discovery may be had only through a method of discovery other than that requested;
- (4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;
- (5) That discovery be conducted with no one present except persons designated by the ALJ;
- (6) That the contents of discovery or evidence be sealed;
- (7) That a deposition after being sealed be opened only by order of the ALJ;

(8) That a trade secret or other confidential research, development, commercial information, or facts pertaining to any criminal investigation, proceeding or other administrative investigation not be disclosed or be disclosed only in a designated way; or

(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the ALJ.

§ 521.25 Fees.

The party requesting a subpoena shall pay the cost of the fee and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in the United States District Court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of USIA, a check for witness fees and mileage need not accompany the subpoena.

§ 521.26 Form, filing and service of papers.

(a) Form.

(1) Documents filed with the ALJ shall include an original and two copies.

(2) Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the ALJ, and a designation of the paper (e.g., motion to quash subpoena), and shall be in English or accompanied by an English translation.

(3) Every pleading and paper shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed. Date of mailing may be established by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.

(b) Service.

A party filing a document with the ALJ shall, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document other than those required to be served as prescribed in § 521.8, shall be made by delivering a copy or by placing a copy of the document in the United States mail, postage prepaid, and addressed to the party's last known address. When a party is represented by a representative, service shall be made upon such representative in lieu of the actual party.

(c) Proof of Service.

A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, shall be proof of service.

§ 521.27 Computation of time.

(a) In computing any period of time under this part or in an order issued hereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government shall be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional five days will be added to the time permitted for any response.

§ 521.28 Motions.

(a) Any application to the ALJ for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ shall make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 521.29 Sanctions.

(a) The ALJ may sanction a person, including any party or representative for:

(1) Failing to comply with an order, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party's control, or a request for admission, the ALJ may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.

(e) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

§ 521.30 The hearing and burden of proof.

(a) The ALJ shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under § 521.3, and if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.

(b) USIA shall prove defendant's liability and any aggravating factors by a preponderance of the evidence.

(c) The defendant shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the ALJ for good cause shown.

§ 521.31 Determining the amount of penalties and assessments.

(a) In determining an appropriate amount of civil penalties and assessments, the ALJ and the Director, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, ordinarily double damages and a significant civil penalty should be imposed.

(b) Although not exhaustive, the following factors are among those that may influence the ALJ and the Director in determining the amount of penalties and assessments to impose with respect to the misconduct (i.e., the false, fictitious, or fraudulent claims or statements) charged in the complaint:

(1) The number of false, fictitious, or fraudulent claims or statements;

(2) The time period over which such claims or statements were made;

(3) The degree of the defendant's culpability with respect to the misconduct;

(4) The amount of money or the value of the property, services, or benefit falsely claimed;

(5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the costs of investigation;

(6) The relationship of the amount imposed as civil penalties to the amount of the Government's loss;

(7) The potential or actual impact of the misconduct upon national defense, public health or safety, or public confidence in the management of Government programs and operations, including particularly the impact on the intended beneficiaries of such programs;

(8) Whether the defendant has engaged in a pattern of the same or similar misconduct;

(9) Whether the defendant attempted to conceal the misconduct;

(10) The degree to which the defendant has involved others in the misconduct or in concealing it;

(11) Where the misconduct of employees of agents is imputed to the defendant, the extent to which the defendant's practices fostered or attempted to preclude such misconduct;

(12) Whether the defendant cooperated in or obstructed an investigation of the misconduct;

(13) Whether the defendant assisted in identifying and prosecuting other wrongdoers;

(14) The complexity of the program or transaction, and the degree of the defendant's sophistication with respect to it, including the extent of defendant's prior participation in the program or in similar transactions;

(15) Whether the defendant has been found, in any criminal, civil, or administrative proceeding, to have engaged in similar misconduct or to have dealt dishonestly with the Government of the United States or of a State, directly or indirectly; and

(16) The need to deter the defendant and others from engaging in the same or similar misconduct.

(c) Nothing in this section shall be construed to limit the ALJ or the Director from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 521.32 Location of hearing.

(a) The hearing may be held:

(1) In any judicial district of the United States in which the defendant resides or transacts business;

(2) In any judicial district of the United States in which the claim or statement in issue was made; or

(3) In such other place as may be agreed upon by the defendant and the ALJ.

(b) Each party shall have the opportunity to present arguments with respect to the location of the hearing.

(c) The hearing shall be held at the place and at the time ordered by the ALJ.

§ 521.33 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in § 521.22(a).

(c) The ALJ shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ shall permit the parties to conduct such cross-examination as may be required for a full and true disclosure of the facts.

(e) At the discretion of the ALJ, a witness may be cross-examined on matters relevant to the proceeding without regard to the scope of his or her direct examination. To the extent permitted by the ALJ, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the ALJ shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This rule does not authorize exclusion of:

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party appearing for the entity pro se or

designated by the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by the Government engaged in assisting the representative for the Government.

§ 521.34 Evidence.

(a) The ALJ shall determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ shall not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence, where appropriate (e.g., to exclude unreliable evidence).

(c) The ALJ shall exclude irrelevant and immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by consideration of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ pursuant to § 521.24.

§ 521.35 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Director.

(c) The record of the hearing may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ pursuant to § 521.24.

§ 521.36 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ shall fix the time for filing briefs, at a time not exceeding 60 days from the date the parties receive the transcript of

the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 521.37 Initial decision.

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the claims or statements identified in the complaint, or any portion thereof, violate § 521.3;

(2) If the person is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering any mitigating or aggravating factors that he or she finds in the case, such as those described in § 521.31.

(c) The ALJ shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired. The ALJ shall at the same time serve all parties with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration with the ALJ or a notice of appeal with the Director. If the ALJ fails to meet the deadline contained in this paragraph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.

(d) Unless the initial decision of the ALJ is timely appealed to the Director, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the Director and shall be final and binding on the parties 30 days after it is issued by the ALJ.

§ 521.38 Reconsideration of initial decision.

(a) Except as provided in paragraph (d) of this section, any party may file a motion for reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be five days from the date of mailing in the absence of contrary proof.

(b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.

(c) Responses to such motions shall be allowed only upon request of the ALJ.

(d) No party may file a motion for reconsideration of an initial decision

that has been revised in response to a previous motion for reconsideration.

(e) The ALJ may dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.

(f) If the ALJ denies a motion for reconsideration, the initial decision shall constitute the final decision of the Director and shall be final and binding on the parties 30 days after the ALJ denies the motion, unless the initial decision is timely appealed to the Director in accordance with § 521.39.

(g) If the ALJ issues a revised initial decision, that decision shall constitute the final decision of the Director and shall be final and binding on the parties 30 days after it is issued, unless it is timely appealed to the Director in accordance with § 521.39.

§ 521.39 Appeal to the USIA Director.

(a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a civil penalty or assessment may appeal such decision to the USIA Director by filing a notice of appeal with the USIA Director in accordance with this section.

(b)(1) No notice of appeal may be filed until the time period for filing a motion for reconsideration under § 521.38 has expired.

(2) If a motion for reconsideration is timely filed, a notice of appeal may be filed within 30 days after the ALJ denies the motion or issues a revised initial decision, whichever applies.

(3) If no motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ issues the initial decision.

(4) The Director may extend the initial 30-day period for an additional 30 days if the defendant files with the Director a request for an extension within the initial 30-day period and shows good cause.

(c) If the defendant files a timely notice of appeal with the Director, and the time for filing motions for reconsideration under § 521.38 has expired, the ALJ shall forward the record of the proceeding to the Director.

(d) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decisions and reasons supporting the exceptions.

(e) The representative for the Government may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.

(f) There is no right to appear personally before the Director.

(g) There is no right to appeal any interlocutory ruling by the ALJ.

(h) In reviewing the initial decision, the Director shall not consider any objection that was not raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(i) If any party demonstrates to the satisfaction of the Director that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure to present such evidence at such hearing, the Director shall remand the matter to the ALJ for consideration of such additional evidence.

(j) The Director may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment determined by the ALJ in an initial decision.

(k) The Director shall promptly serve each party to the appeal with a copy of her/his decision and a statement describing the right of any person determined to be liable for a penalty or assessment to seek judicial review.

(l) Unless a petition for review is filed as provided in 31 U.S.C. 3805 after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the Director serves the defendant with a copy of her/his decision, a determination that a defendant is liable under § 521.3 is final and is not subject to judicial review.

§ 521.40 Stays ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the Director a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the Director shall stay the process immediately. The Director may order the process resumed only upon receipt of the written authorization of the Attorney General.

§ 521.41 Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the Director.

(b) No administrative stay is available following a final decision of the Director.

§ 521.42 Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the Director imposing penalties or assessments

under this part and specifies the procedures for such.

§ 521.43 Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 521.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under § 521.42 or § 521.43, or any amount agreed upon in a compromise or settlement under § 521.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under the subsection against a refund of an overpayment of Federal taxes, then or later owing by the United States to the defendant.

§ 521.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 521.46 Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The Director has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during pendency of any review under § 521.42 or during the pendency of any action to collect penalties and assessments under § 521.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 521.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the Director, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the Director, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

§ 521.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 521.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 521.10(b) shall be deemed notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

Dated: May 21, 1991.

Henry E. Catto,

Director, U.S. Information Agency.

[FR Doc. 91-12948 Filed 5-31-91; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 700, 840, and 842

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Compliance With Court Order

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of suspension.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the United States Department of the Interior (DOI) is suspending certain portions of its permanent program regulations which: (1) Provide that a regulatory authority may terminate regulatory jurisdiction under the Surface Mining Control and Reclamation Act of 1977 (the Act) for reclaimed sites of completed surface coal mining and reclamation operations and coal exploration operations; and (2) allow for a reduced inspection frequency for "abandoned sites." OSM is taking these actions as a result of a recent District Court decision which remands these rules to the Secretary of the DOI because the court has found these rules contrary to the language and intent of the Act.

EFFECTIVE DATE: July 3, 1991.

FOR FURTHER INFORMATION CONTACT: George M. Stone, Jr., Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue NW., Washington, DC 20240; telephone (202) 208-2550 (Commercial) or 268-2550 (FTS).

SUPPLEMENTARY INFORMATION:

I. Background.

II. Discussion of Rules Suspended.

III. Procedural Matters.