requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or food/feed additive regulations or raising tolerance or food/feed additive regulation levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Parts 180

Environmental Protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 1, 1993.

Stephanie R. Irene

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By amending § 180.418 in the table therein, by adding and alphabetically inserting the following raw agricultural commodities, to read as follows:

§ 180.418 Cypermethrin; tolerances for residues.

* * * * *

Commodity	Parts per million
* * * * *	
Cabbage	2.0
* * * * *	
Onions, bulb	0.10
* * * * *	

[FR Doc. 93-25617 Filed 10-19-93; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Parts 180, 185, and 186

[PP 8F2034, 7F2013, 4F2993, 2F2623, 4F3046, 6F3453, and 6F3318/P569; FRL-4638-7]

RIN 2070-AC18

Pesticide Tolerances for Permethrin, Cypermethrin, Fenvalerate/Esfenvalerate, Tralomethrin, Bifenthrin, Cyfluthrin and Lambda-Cyhalothrin; Extension of Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to extend tolerances for the residues of seven synthetic pyrethroids—permethrin, cypermethrin, fenvalerate/esfenvalerate, tralomethrin, bifenthrin, cyfluthrin, and lambda-cyhalothrin (collectively referred to as the synthetic pyrethroids)—in or on certain raw agricultural commodities. This proposal to extend the effective date for tolerances for maximum permissible levels of residues of these synthetic pyrethroids in or on these commodities was requested by FMC Corp. (FMC), Zeneca Ag Products, E. I. DuPont de Nemours and Co., Inc., Hoechst-Roussel Agri-Vet Co., and Miles, Inc. (collectively called the industry's Pyrethroid Working Group (PWG)).

DATES: Written comments, identified by the document control number [PP 8F2034, 7F2013, 4F2993, 2F2623, 4F3046, 6F3453, and 6F3318/P569], must be received on or before November 19, 1993.

ADDRESSES: Written comments, identified by the document control number, may be submitted to: Public Response Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1128 at the Virginia address given above, from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 202, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703-305-6100.

SUPPLEMENTARY INFORMATION: Beginning in 1985 the Agency issued Data Call-In Notices (DCI) for chemical-specific aquatic field (mesocosm) data and other aquatic toxicological data to maintain existing registrations and support new registration of synthetic pyrethroid insecticides on cotton. Because laboratory data indicate synthetic pyrethroids are extremely toxic to fish and other aquatic organisms the field data was required to allow the Agency to better understand the potential risk and exposure to the aquatic environment and enable it to complete an ecological risk assessment. In addition, since laboratory tests indicated similar aquatic toxicity among the pyrethroids, for regulatory purposes the Agency decided to treat all synthetic pyrethroids registered for use on cotton as a class. Thus the registrations were made conditional because of the common lack of specific aquatic toxicological hazard data, and the tolerances on cotton and other affected commodities were made temporary until the conditions of registration were fulfilled.

In November 1990, the Agency and the PWG in collaboration with the National Cotton Council agreed to interim risk reduction measures designed to reduce the potential for exposure of aquatic habitats of concern to synthetic pyrethroids applied to cotton. The interim risk reduction measures included user surveys to assess current pyrethroid use practices on cotton, label changes aimed at reducing the aquatic environmental exposure to pyrethroids, and a program of data generation to evaluate the effectiveness of the risk reduction measures. The data and other information required by this joint agreement have been submitted to the Agency and are under review.

As part of this agreement the Agency extended the conditional registration for the seven synthetic pyrethroids on cotton and related commodities to November 15, 1992. This expiration date was subsequently extended to November 15, 1993, to allow the Agency sufficient time to review the data. By

November 15, 1993, the Agency intends to complete review of all data submitted under the data generation program and other information and to make FIFRA section 3 (c)(5) or other appropriate regulatory decisions for the cotton use of the synthetic pyrethroids.

To be consistent with the extensions issued for the conditional registrations the Agency is proposing to amend/extend the tolerances for the seven synthetic pyrethroids on cotton. The Agency has determined that amending/extending the tolerances will protect the human health. Therefore, extensions for the tolerances on cotton and other affected crops are proposed as set forth below.

The data submitted in support of these tolerances and other relevant material have been reviewed. The toxicological and metabolism data and analytical methods for enforcement purposes considered in support of these tolerances are discussed in detail in related documents published in the Federal Registers of April 25, 1979 (44 FR 24287—permethrin), January 31, 1979 (44 FR 6098—fenvalerate), September 18, 1985 (50 FR 37581—tralomethrin), February 21, 1985 (50 FR 7172—cypermethrin), January 25, 1988 (53 FR 1923—cyfluthrin), August 15, 1988 (53 FR 30676—befentrhin), and May 24, 1988 (53 FR 18558—lambda cyhalothrin).

Residues remaining in or on the above raw agricultural commodity after expiration of these tolerances will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the conditional registrations.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 8F2034, 7F2013, 4F2993, 2F2623, 4F3046, 6F3453, and 6F3318/P569]. All written comments filed in response to this petition will be available in the Public Response Section, at the address given above from 9 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or food/feed additive regulations or raising tolerance or food/feed additive regulation levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Parts 180, 185, and 186

Environmental protection, Administrative practice and procedure, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 27, 1993.

Stephanie R. Irene,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that chapter I of title 40 of the Code of Federal Regulations be amdned as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346 and 371.

b. In § 180.378, by revising the introductory text of paragraph (a), to read as follows:

§ 180.378 Permethrin; tolerances for residues.

(a) Tolerances, to expire on November 15, 1994, are established for residues of the insecticide permethrin [(3-pheoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] in or on the following raw agricultural commodities:

* * * * *

c. In § 180.379 by amending the table in paragraph (a) by adding a footnote to the entry for cottonseed as follows:

§ 180.379 Cyano(3-phenoxyphenyl)methyl-4-chloro-α-(1-methylethyl) benzeneacetate; tolerances for residues.

(a)* * *

Commodity	Parts per million
* * * * *	
Cottonseed	0.2[1]
* * * * *	

[1]The tolerance for cottonseed expires on November 15, 1994.

* * * * *

§ 180.418 [Amended]

d. By amending § 180.418 *Cypermethrin; tolerances for residues* in the introductory text by changing "July 1, 1993," to read "November 15, 1994."

e. In § 180.422, by revising the introductory text to read as follows:

§ 180.422 Tralomethrin; tolerances for residues.

Tolerances, to expire on November 15, 1994, are established for the combined residues of the insecticide tralomethrin ((*S*)-alpha-cyano-3-phenoxybenzyl (1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate; CAS Reg. No. 66841-25-6) and its metabolites (*S*)-alpha-cyano-3-phenoxybenzyl (1*R*,3*R*)-3(2,2,-dibromovinyl)2,2-dimethylcyclopropanecarboxylate and (*S*)-alpha-cyano-3-phenoxybenzyl (1*S*, 3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate calculated as the parent in or on the following raw agricultural commodities:

* * * * *

f. In § 180.436, by amending the table therein by adding a footnote to the entry for cottonseed as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

* * * * *

Commodity	Parts per million
* * * * *	
Cottonseed	1.0[1]
* * * * *	

[1]The tolerance for cottonseed expires on November 15, 1994.

g. In § 180.438, the section designation "(a)" is removed, the introductory text is revised, and the table is amended by adding a footnote to the entry for cottonseed as follows:

§ 180.438 [1 α-(S*),3 α (Z)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate; tolerances for residues.

Tolerances are established for the combined residues of the insecticide [1 α-(S*),3 α (Z)]-(±)-cyano(3-

phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethycyclopropanecarboxylate, in or on the following raw agricultural commodities:

Commodity	Parts per million
* * * * *	
Cottonseed	0.05[1]
* * * * *	

[1]The tolerance for cottonseed expires on November 15, 1994.

* * * * *

h. In § 180.442 by revising the introductory text, to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

Tolerances, to expire on November 15, 1994, are established for residues of the pyrethroid bifentrhin (2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the following commodities:

* * * * *

Part 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

AUTHORITY: 21 U.S.C. 348.

b. In § 185.1250, by revising paragraph (a) to read as folllows:

§ 185.1250 Cyfluthrin.

(a) A tolerance, to expire on November 15, 1994, of 2.0 parts per million is established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS Reg. No. 69359-37-5) in cottonseed oil resulting from appliction of the insecticide to cottonseed.

* * * * *

c. In § 185.5450, by revising the introductory text to read as follows:

§ 185.5450 Tralomethrin.

Tolerances, to expire on November 15, 1994, are established for the combined residues of the insecticide tralomethrin [(*S*)-alpha-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl] cyclopropanecarboxylate; CAS Reg. No. 66841-25-6]) and its metabolites (*S*)-alpha-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-alpha-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate calculated as the parent in or on the following food commodities when present as a result of application of the insecticide to the growing crops:

* * * * *

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 348

b. In § 186.1250, by revising paragraph (a), to read as follows:

§ 186.1250 Cyfluthrin.

(a) A tolerance, to expire on November 15, 1994, of 2.0 parts per million is established for residues of the insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS Reg. No. 68359-37-5) in cottonseed hulls resulting from application of the insecticide to cottonseed.

* * * * *

[FR Doc. 93-25638 Filed 10-19-93; 8:45 am]
BILLING CODE 8580-50-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1003

RIN 0991-AA65

Civil Money Penalties for Prohibited Referrals to Entities Providing Clinical Laboratory Services and for Prohibited Arrangements and Schemes

AGENCY: Office of Inspector General, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement sections 1877(g)(3) and 1877(g)(4) of the Social Security Act. Section 1877(g)(3) authorizes the imposition of civil money penalties and an exclusion against any person who presents, or causes to be represented, a bill or claim for a service unlawfully referred under section 1877(a)(1)(A), or has not refunded amounts inappropriately collected for a prohibited referral. In addition, in accordance with section 1877(g)(4) of the Act, the OIG is authorized to impose civil money penalties and an exclusion in cases where a physician or entity enters into an arrangement or scheme, a principal purpose of which the physician or entity knows, or should have known, is to assure referrals which, if they were made directly to the entity, would violate the prohibition on referrals described in section 1877(a) of the Act.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 20, 1993.

ADDRESSES: Address comments to: Office of Inspector General, Department of Health and Human Services, Attention: LRR-30-P, room 5246, 330 Independence Avenue, SW., Washington, DC 20201.

If you prefer, you may deliver your comments to room 5551, 330 Independence Avenue, SW., Washington, DC. In commenting, Please refer to file code LRR-30-P. Comments received timely will be available for public inspection, beginning approximately two weeks after publication, in room 5551, 330 Independence Avenue, SW., Washington, DC on Monday through Friday of each week from 9 a.m. to 5 p.m., (202) 619-3270.

FOR FURTHER INFORMATION CONTACT: Stuart E. Wright, Legislation and Regulations Staff (202) 619-3270.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, Congress has provided the Department of Health and Human Services with increasing civil money penalty (CMP) authorities to ensure compliance with statutory provisions. The original CMP authorities were specifically designed to provide penalties for fraudulent and abusive practices, such as submission of false claims, involving the Medicare and Medicaid programs. The authority for levying CMPs was further expanded in recent years to address issues involving quality of care, other reimbursement issues, and other State health care programs.

Several statutory provisions have been recently enacted by the Congress governing relationships between health care providers and those health care professionals who are (1) owners of the providers or (2) compensated in some way by the providers. In particular, criminal penalties are provided for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration intended to induce the furnishing of items or services covered by Medicare or State health care programs (including Medicaid, and any State program receiving funds under titles V or XX of the Act). Offenses are classified as felonies and are punishable by fines of

up to $25,000 or imprisonment for up to 5 years, or both. (See section 1128B(b) of the Act, 42 U.S.C. 1320a–7b(b), as amended by section 4 of the Medicare and Medicaid Patient Program Protection Act of 1987 (Pub. L. 100–93, enacted August 18, 1987).)

For purposes of section 1128B(b) of the Act, remuneration includes kickbacks, bribes, rebates, and any other exchanges of value made directly or indirectly, overtly or covertly, in cash or in kind. Prohibited conduct includes not only remuneration intended to induce referrals of patients, but also remuneration intended to induce the purchasing, leasing, ordering, or arranging for or recommending any good, facility, service, or item paid by the Medicare or State health care provider.

II. Prohibition on Physician Referrals for Laboratory Service

In a May 1989 report to the Congress entitled "Financial Relationships Between Physicians and Health Care Businesses," the OIG found that Medicare patients of referring physicians who own or invest in independent clinical laboratories received 45 percent more clinical laboratory services than all Medicare patients in general. Section 6204 of Public Law 101–239, the Omnibus Budget Reconciliation Act (OBRA) of 1989, added a new section 1877, "Limitations on Certain Physician Referrals," to the Act. In addition, section 4207(e) of Public Law 101–508, the Omnibus Budget Reconciliation Act of 1990, amended certain provisions of section 6204 of Public Law 101–239 (by clarifying certain definitions and reporting requirements relating to physician ownership and referral). To provide readers of this proposed rule with complete information, we are broadly describing the requirements of section 1877 of the Act. For specific details on prohibited referral arrangements under section 1877, we refer the reader to the HCFA proposed rule (57 FR 8588) published in the Federal Register on March 11, 1992.

1. General Prohibition

With certain exceptions, section 1877(a)(1)(A) prohibits a physician from making a referral to an entity for the furnishing of clinical laboratory services, for which Medicare would otherwise pay, if the physician (or a member of the physician's immediate family) has a financial relationship with that entity (as described in section 1877(a)(2)). Further, section 1877(a)(1)(B) prohibits an entity from presenting, or accusing to be presented, a Medicare claim or a bill to any individual, third party payor, or other entity, for clinical laboratory services unlawfully referred under section 1877(a)(1)(A).

For purposes of this general prohibition, section 1877(h)(7) defines "referral" as follows:

- The request by a physician for an item or service which payment may be made under Medicare Part B, including a request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician), or
- The request or establishment of a plan of care by a physician when the plan includes furnishing clinical laboratory service. However, section 1877(h)(7)(C) provides an exception to this definition for a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if the services are furnished by (or under the supervision of) the pathologist pursuant to a consultation requested by another physician. These provisions of the law are effective for referrals made after December 31, 1991. Congress provided for general exceptions to the referral prohibitions for specified circumstances and other exceptions limited to specific types of ownership and compensation arrangements.

2. Financial Relationships

Section 1877(a)(2) describes a financial relationship between a physician (or an immediate family member of a physician) and an entity as being an ownership or investment interest in the entity, or a compensation arrangement (as defined in section 1877(h)(1)(A)) between the physician (or immediate family member) and an entity. An ownership or investment interest may be established "through equity, debt, or other means." A person with a financial relationship with an entity is an "investor." Section 1877(h)(5) defines an "interested investor" as an investor who is a physician in a position to make or influence referrals or business to the entity (or who is an immediate family member of such an investor). A "disinterested investor" is defined as an investor other than an "interested investor."

For purposes of this provision, section 1877(h)(1)(A) defines a "compensation arrangement" as an arrangement involving any remuneration between a physician (or an immediate family member) an entity. Section 1877(h)(1)(B) defines "remuneration" to include any remuneration directly or indirectly, overtly or covertly, in cash or in kind.

In addition to setting forth this prohibition against physician referrals to entities providing clinical laboratory services in which they have a financial interest, the statute also provides for the imposition of CMPs and exclusions against any person who (1) presents, or causes to be presented, a bill or claim for a clinical laboratory service that the person knows, or should have known, was unlawfully referred by a physician [1], or (2) has not refunded amounts inappropriately collected for a prohibited referral. In addition, in accordance with section 1877(g)(4) of the Act, the OIG is authorized to impose CMPs and exclusions in cases where a physician or entity enters into an arrangement or scheme, a principal purpose of which the physician or entity knows, or should have known, is to assure referrals which, if they were made directly, would violate the prohibition on referrals described in section 1877(a) of the Act.

III. Summary of the Proposed Rule

With enactment of section 6204 of Public Law 101–239, Congress has broadened the Department's existing authorities by specifically providing new CMPs for billing for prohibited clinical laboratory services and for certain prohibited arrangements and schemes. Authority for imposing these new CMPs will be delegated to the Office of Inspector General.

Sanctions for Improper Claims

Section 1877(g)(3) of the Social Security Act authorizes the imposition of CMPs and exclusions for any person who presents, or causes to be presented, a bill or claim for a service that the person knows, or should have known (1) was provided in accordance with a prohibited referral, or (2) was not properly refunded in accordance with section 1877(g)(2).

Section 1877(g)(3) provides that the CMP be no more than $15,000 for each such service. The Secretary is authorized to make a determination during the same proceeding to exclude the person from Medicare participation and to direct the appropriate State health care program. (In addition, in accordance with section 1128A of the Act, any person subject to a CMP determination in accordance with

[1] Physicians should be aware that under sections 1877(g)(3) and (g)(4), they, as well as the clinical laboratories to which they have made prohibited referrals, may be subject to civil money penalties, assessments, and exclusions from government health care programs, for causing the submission of claims for services resulting from those referrals.

section 1877(g)(3) may also be subject to an assessment of not more than twice the amount claimed for each item or service which was the basis for the penalty. The assessment is in lieu of damages sustained by the Department or a State agency because of that claim.)

In determining the amount of the penalty or assessment for each violation, we would apply the following 5 existing criteria set forth in § 1003.106(a) of the regulations: (1) The nature of the claim or request for payment and the circumstances under which it was presented; (2) the degree of culpability of the person submitting the claim or request for payment; (3) the history of prior offenses of the person submitting the claims or request for payment; (4) the financial condition of the person presenting the claim or request for payment; and (5) such other matters as justice may require. In addition, with respect to the failure to make a timely refund, we are proposing a sixth criterion to be applied that would consider the timeliness and completeness of the refund made.

Sanctions for Circumvention Schemes

In addition, section 1877(g)(4) of the Act authorizes the imposition of CMPs and exclusions in cases where a physician or entity enters into an arrangement or scheme, a principle purpose of which the physician or entity knows, or should have known, is to assure referrals which, if they were made directly, would violate the prohibition on referrals described in section 1877(a) of the Act. An example of such a circumvention scheme is a cross referral arrangement whereby the physician owners of "Y" refer to "X." We request comments regarding other arrangements that should be specifically described in this regulation that have a principal purpose of circumventing section 1877.

The statute limits the CMP to not more than $100,000 for each such arrangement or scheme. In accordance with section 1128A of the Act, an assessment equal to twice the amount billed for the service may also be imposed. The Secretary is authorized to make a determination in the same proceeding to exclude the person from Medicare participation and to direct the appropriate State agency to exclude the person from participation in any State health care program.

In determining the amount of the penalty or assessment for each violation of § 1003.102(b)(9), we are proposing to apply six criteria—the 5 existing criteria set forth in § 1003.106(a) and a new criterion (§ 1003.106(a)(1)(vi)) that would look at the amount of ownership interests involved. The OIG specifically welcomes public comments on these criteria and on recommendations for applying other mitigating and aggravating factors in assessing CMPs under this statutory provision.

Violators of these provisions would be subject to the same notification, effectuation, and appeals procedures as CMP violations under section 1128A(a) of the Social Security Act which are set forth at 42 CFR part 1003.

IV. Regulatory Impact Statement

Executive Order 12291

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for regulations that meet one of the Executive Order criteria for a "major rule," that is, that would be likely to result in (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individuals, industries, Federal, State, or local government agencies or geographic regions; or (3) significant adverse effects on completion, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

As indicated above, the provisions contained in this rulemaking provide new authorities to the OIG to levy civil money penalties against persons or entities that file claims for services furnished on the basis of prohibited referrals or who engage in prohibited circumvention schemes as proscribed by statute. These provisions are a result of statutory changes and serve to clarify departmental policy with respect to the imposition of CMPs upon persons and entities who violate the statute. We believe that the great majority of providers and practitioners do not engage in such prohibited activities and practices discussed in these regulations, and that the aggregate economic impact of these provisions should, in effect, be minimal, affecting only those who have engaged in prohibited behavior in violation of statutory intent. As such, this rule should have no direct effect on the economy or on Federal or State expenditures.

Regulatory Flexibility Analysis

Consistent with the Regulatory Flexibility Act of 1980, Public Law 96–354 (5 U.S.C. 601 through 612), we are to prepare and publish a regulatory flexibility analysis unless the Secretary certifies that a regulation would not have a significant economic impact on a substantial number of small business entities. The analysis is intended to explain what effect that regulatory action will have on small business and other small entities, and to develop lower cost or burden alternatives.

We have determined that no regulatory impact analysis is required for these proposed regulations. In addition, while some penalties the Department could impose as a result of these regulations might have an impact on small entities, we do not anticipate that a substantial number of these small entities will be significantly affected by this rulemaking. Therefore, we have concluded that a regulatory flexibility analysis is not required for this rulemaking.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1980, Pub. L. 96–511, all Departments are required to submit to the Office of Management and Budget for review and approval any reporting or recordkeeping requirements contained in both proposed and final rules. We have determined that the penalty provisions contained in this rulemaking do not contain such information collection requirements and will not increase the Federal paperwork burden on the public and private sectors.

V. Response to Comments

Because of the number of comments we receive on proposed regulations, we cannot acknowledge or respond to these comments individually. However, in preparing the final rule, we will consider all comments received in response to these penalty provisions and respond to them in the preamble to the document.

List of Subjects in 42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties.

TITLE 42—PUBLIC HEALTH

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR part 1003 would be amended as set forth below:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

1. The authority citation for part 1003 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1302a–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395nn(g), 1131(c) and 11137(b)(2).

2. Section 1003.100 would be amended by revising paragraph (a) and

paragraph (b)(1) (iv) and (v); and by adding a new paragraph (b)(1) (vi)–(ix) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1140, 1842(j), 1842(k), and 1877(g) of the Social Security Act, and sections 421(c) and 427(b)(2) of Public Law 99–660 (42 1320a–7(c), 1320a–7a, 1320, 11131(c) and 11137(b)(2)).

(b) * * *

(1) * * *

(iv) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60;

(v) Misuse certain Medicare and Social Security program words, letters, symbols and emblems;

(vi) Have submitted certain prohibited claims under the Medicare or State health care programs;

(vii) Present or cause to be presented, a bill or claim for a clinical laboratory service that they know, or should know, was furnished in accordance with a referral prohibited under § 411.353 of this chapter;

(viii) Have collected amounts that they know or should know were billed in violations of § 411.353 of this chapter and have not refunded the amounts collected on a timely basis; or

(ix) Is a physician or entity that enters into an arrangement or scheme that the physician or entity knows, or should know, has as a principal purpose the assuring of referrals by a physician to a particular entity which, if made directly, would violate the provisions of § 411.353 of this chapter;

* * * * *

3. Section 1003.102 would be amended by revising paragraphs (a)(3), (a)(4) introductory text, and (a)(4)(iii); and by adding new paragraphs (a)(5), (b)(8) and (b)(9) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

(a) * * *

(3) An item or service furnished during a period in which the person was excluded from participation in the program to which the claim was made in accordance with a determination made under sections 1128 (42 U.S.C. 1320a–7), 1128A (42 U.S.C. 1320a–7a), 1156 (42 U.S.C. 1320c–5), 1160(b) as in effect on September 2, 1982 (42 U.S.C. 1320c–9(b)), 1842(j)(2) (42 U.S.C. 1395u(j)), 1862(d) as in effect on August 18, 1987 (42 U.S.C. 1395y(d)), or 1866(b) (42 U.S.C. 1395cc(b));

(4) A physician's service (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

* * * * *

(iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified; or

(5) Payment which such person knows, or should know, may not be made under § 411.353 of this chapter.

(b) * * *

(8) Has not refunded on a timely basis amounts collected as the result of billing an individual, third party payer or other entity for a clinical laboratory service that was provided in accordance with a prohibited referral as described in § 411.353 of this chapter;

(9) Is a physician or entity that enters into—

(i) A cross referral arrangement, for example, whereby the physician owners of entity "X" refer to entity "Y," and the physician owners of entity "Y" refer to entity "X" in violation of § 411.353 of this chapter,

(ii) Any other arrangement or scheme that the physician or entity know, or should know, has a principal purpose of circumventing the prohibitions of § 411.353 of this chapter.

* * * * *

4. Section 1003.103 would be amended by revising paragraphs (a) and (b) to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b), (c) and (d) of this section, the OIG may impose a penalty of not more than $2,000 for each item or service that is subject to a determination under § 1003.102.

(b) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.102(b)(4), or for each item or service that is subject to a determination under § 1003.102(a)(4) or § 1003.102(b)(8). The OIG may impose a penalty of not more than $100,000 for an arrangement or scheme that is subject to a determination under § 1003.102(b)(9).

* * * * *

5. Section 1003.106 would be amended by revising paragraph (a)(1) introductory text and paragraph (a)(1)(v); and by adding new paragraphs (a)(1) (vi) and (vii) to read as follows:

§ 1003. 106 Determination regarding the amount of the penalty and assessment.

(a)(1) In determining the amount of any penalty or assessment in accordance with § 1003.102(a), (b)(1) to (b)(4), (b)(8) and (b)(9), the Department will take into account—

* * * * *

(v) The completeness and timeliness of the refund with respect to § 1003.102(b)(8);

(vi) The amount of financial interest involved with respect to § 1003.102(b)(9); and

(vii) Such other matters as justice may require.

* * * * *

Dated: July 12, 1993.

Bryan B. Mitchell,

Principal Deputy Inspector General.

Approved: August 26, 1993.

Donna E. Shalala,

Secretary.

[FR Doc. 93–25681 Filed 10–19–93; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 571 and 572

[Docket No. 92–28; Notice 3]

RIN No. 2127–AB85

Federal Motor Vehicle Safety Standards; Head Impact Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Reopening of comment period; notice of public meeting.

SUMMARY: This notice reopens the comment period for a notice of proposed rulemaking, published February 8, 1993, regarding measures to prevent or reduce injury when a vehicle occupant's head strikes upper interior components during a crash. These components include pillars, side rails, headers, and the roof. The initial comment period closed April 9, 1993. NHTSA is reopening the comment period because the agency's examination of the initial public comments and subsequent submissions by commenters reveals that there is need for further public examination of the issues raised by the comments. To that end, NHTSA is reopening the comment period until December 1, 1993. In addition, the agency is conducting a public meeting to further facilitate the comment process.

DATES: *Public meeting:* A public meeting to receive oral comments concerning the