

(c) *Regulations.* (1) The general regulations contained in 33 C.F.R. 165.23 apply.

(2) All persons shall comply with the instructions of the Coast Guard Captain of the Port or the designated on scene patrol personnel. U.S. Coast Guard patrol personnel include commissioned, warrant and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel via siren, radio, flashing light, or other means, the operator of the vessel shall proceed as directed.

(3) In accordance with the general regulations in section 165.23 of this part, entry or movement within this zone is prohibited unless authorized by the Captain of the Port, Portland, ME.

Dated: November 24, 1998.

R.A. Nash,

Commander, U.S. Coast Guard, Captain of the Port, Portland, Maine.

[FR Doc. 98-33080 Filed 12-11-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, and 402

[HCFA-6135-FC]

Medicare and Medicaid Program; Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This rule establishes procedures for imposing civil money penalties, assessments, and exclusions for certain violations of the Medicare and Medicaid programs. The regulations also provide for hearings and appeals when those penalties, assessments, and exclusions are imposed. These procedures are based on the procedures that the Office of the Inspector General has promulgated for the civil money penalties, assessments, and exclusions. These regulations are designed to protect program beneficiaries from unfit health care practitioners and to otherwise improve antifraud provisions under the Medicare and Medicaid Acts.

DATES: These regulations are effective on January 13, 1999. Comments must be received by February 12, 1999.

FOR FURTHER INFORMATION CONTACT: Joel Cohen, (410) 786-3349

ADDRESSES: Mail written comments (1 original and 3 copies) to the following

address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-6135-FC, PO Box 26676, Baltimore, MD 21207-0519.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850

Comments may also be submitted electronically to the following e-mail address: HCFA6135FC@hcfa.gov. For e-mail comment procedures, see the beginning of **SUPPLEMENTARY INFORMATION**. For further information on ordering copies of the **Federal Register** containing this document and on electronic access, see the beginning of **SUPPLEMENTARY INFORMATION**.

Electronically submitted comments will be available for public inspection at the Independence Avenue address below.

SUPPLEMENTARY INFORMATION:

E-Mail, Comments, Procedures, Availability of Copies, and Electronic Access

E-mail comments must include the full name and address of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-0047-P and the specific section or sections of the proposed rule. Both electronic and written comments received by the time and date indicated above will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890). Electronic and legible written comments will also be posted, along with this proposed rule, at the following web site: <http://aspe.os.dhhs.gov/admsimp/>.

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I. Background

In 1981, the Congress added section 1128A to the Social Security Act (the Act) (section 2105 of Pub.L. 97-35) to authorize the Secretary of Health and Human Services to impose civil money penalties and assessments on certain health care facilities, health care practitioners, and other suppliers under the Medicare and Medicaid programs. Civil money penalties and assessments provide an alternative enforcement tool for agencies to establish compliance with legal and program standards and are in addition to potential criminal proceedings.

Since 1981, the Congress has significantly increased both the number and the types of circumstances under which the Secretary may impose civil money penalties. Some of the civil money penalty authorities address fraud, misrepresentation, or falsification while others address noncompliance with programmatic or regulations requirements. The Secretary has delegated the authority for these provisions to either the Office of Inspector General (OIG) or HCFA (58 FR 52967, October 20, 1994). Under this delegation of authority, the OIG has the authority to impose civil money penalties and prosecute cases involving civil money penalties and assessments that were delegated to HCFA if HCFA and the OIG jointly determine it to be

in the interest of economy, efficiency, or effective coordination of activities.

On October 31, 1994, the Social Security Amendments of 1994 (Pub. L. 103-432) were enacted. This law repealed several statutory provisions providing for civil money penalties and established additional civil money penalty provisions. On August 21, 1996, the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) was enacted. This law provides for higher maximum civil money penalties (\$10,000 instead of \$2,000) for certain of the violations and also increased the assessments that can be imposed for those violations.

Most of the specific statutory provisions authorizing civil money penalties also permit the Secretary of Health and Human Services (or his or her designee) to impose an assessment in addition to the civil money penalty. An assessment is an additional monetary payment in lieu of damages sustained by HHS or a State agency. The maximum amount of the assessment varies according to the civil money penalty (from \$1,000 to \$25,000) and is not more than three times the amount claimed for each service upon which the civil money penalty was based. Also, for many statutory violations, the Secretary of Health and Human Services or his or her designee may exclude the individual or entity violating the statute from participating in a Federal health care program for certain specific periods of time. A Federal health care program is defined in section 1128B of the Act (42 U.S.C. 1320(a)-7b) as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code); or * * * any State health care program as defined in section 1128(h) of the Social Security Act."

The regulations currently governing civil money penalties, assessments, and civil money penalty-related exclusions are contained in 42 CFR part 1003. Procedures for hearings and appeals of civil money penalties, assessments, and exclusions are in 42 CFR part 1005.

II. Regulations Revisions

This final rule with comment period duplicates in substance 42 CFR part 1003 for most of the civil money penalties and related assessments that have been delegated to HCFA. Other rules concerning civil money penalties and assessment authorities that have been delegated to HCFA, such as those imposed for violations by long term care

facilities and clinical laboratories, have already been codified in the Code of Federal Regulations. Civil money penalties and assessments that were added by the Balanced Budget Act of 1997 (BBA), Pub. L. 105-33 (August 5, 1997) and that are delegated to HCFA in the future will be added to the Code of Federal Regulations through another **Federal Register** document, as will the specific rules concerning the exclusions that HCFA is authorized to impose.

Although we are not addressing the civil money penalties and assessments added by the BBA in this regulation, it is important to recognize the impact of the BBA on certain provisions of this regulation. Section 4507 of the BBA permits a physician or practitioner to enter into private contracts with Medicare beneficiaries for services furnished on or after January 1, 1998. If a physician or practitioner enters into a private contract, he or she has "opted out" of the Medicare program for two years for all covered items or services furnished to Medicare beneficiaries. A beneficiary who enters into a private contract agrees to waive the right to Medicare payment for services rendered by the physician or practitioner and to pay the physician or practitioner without regard to any limits that would otherwise apply to what the physician or practitioner could charge. We are clarifying here that physicians and practitioners who enter into valid private contracts will not be subject to civil money penalties and assessments under this regulation unless they knowingly and willfully violate the terms of the private agreement. In particular, physicians and practitioners will not be subject to penalties and assessments pursuant to section 1834(c)(4) of the Social Security Act, which provides for sanctions against physicians who charge in excess of the limiting charge, or section 1848(g)(4) of the Act, which imposes sanctions on physicians and practitioners who violate the mandatory submission of claims requirement of the statute.

The civil money penalties to which this rule pertains include those that apply to Medicare payments or billings as "assignment" violations; violations involving the failure to provide information or improperly providing information; violations of charge or service limits; and violations of Medigap and Medicare Select requirements.

This rule adds a new part to chapter IV of title 42 of the Code of Federal Regulations. This new part is part 402 and is entitled Civil Money Penalties, Assessments and Exclusions. We are dividing the part into three subparts for

the present: Subpart A-General Requirements; Subpart B-Civil Money Penalties and Assessments; and Subpart C-Exclusions (which is reserved for future use).

Subpart A contains the statutory authorities for most of the civil money penalties, assessments, and exclusions that the Secretary has delegated to HCFA. The remainder of the subpart contains the general requirements and procedures that are common to the imposition of civil money penalties, assessments, and exclusions. These procedures are based on the OIG regulations in 42 CFR part 1003.

Under the Secretary's delegation, some authorities will be enforced by the Office of Inspector General, even though similar penalties, applicable under other statutes, are delegated to HCFA. For instance, two of the statutory citations that subject violators to potential sanctions (section 1842(p)(3)(A) and 1848(g)(1)(B)) authorize HCFA to impose various penalties for abusive practices involving bills or requests for payment that are *not* made on an assignment-related basis. We note that the OIG has the comparable authority under section 1128A of the Act to impose civil money penalties for those abusive practices in cases where payment is requested on an assignment-related basis. Although the OIG penalties are not listed in this section, we want to make clear that individuals involved in abusive billing practices are subject to penalties, whether or not the claim is submitted on an assignment-related basis.

Subpart B includes procedures specific to the imposition of civil money penalties and assessments. These rules are also based on those the OIG uses in 42 CFR part 1003.

Our regulations are based on those in part 1003 but are organized somewhat differently in order to be able to, in the future, include all our rules regarding exclusions in more detail. The organization will also make the regulations easier to understand and to find. The organizational changes are not substantive; they change neither the procedures nor the extent of the regulations' applicability.

Although the OIG regulations generally refer to the OIG as the government entity implementing a given function, our new regulations will refer to "HCFA or OIG" as the government agent.

Another purely technical departure from the OIG regulations is our inclusion of a description of all the statutory citations. HCFA is revising its rules to include a description of all pertinent statutory citations in a

particular section, rather than using a long list of citations (by number only) in the "Authority" paragraph that currently appears in each part or subpart in title 42 of the Code of Federal Regulations. The descriptions, of course, also include the new authorities that are not in the existing OIG rules. We also make several editorial changes and clarifying changes designed to make the language clearer to the public.

The regulations provisions in this rule do not revise any procedures or rights currently available to any person on whom we may impose a civil money penalty, assessment, or exclusion. The procedures we will follow also remain the same.

III. Impact Analysis

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all health care providers and suppliers of services (except some individual physicians) are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

As indicated above, the provisions in this final rule with comment period provide HCFA (and the OIG) with regulations to implement the statutory authorities to levy civil money penalties and assessments against providers and physicians and other suppliers of services. The civil money penalties to which this rule pertains include those that apply to Medicare payments or billings as "assignment" violations; violations involving the failure to provide information or the improper provision of information; violations of charge or service limits; and violations of Medigap and Medicare Select requirements. Most of these authorities rested solely with the OIG until October 1994; there are also a few new authorities, which are included in the new part 402. These new authorities do not materially expand or increase the overall impact of civil money penalty

oversight activities. This final rule basically transfers the existing civil money penalty functional responsibility (along with the new authorities) for assuring compliance with programmatic and/or regulations violations (versus fraud, misrepresentation, and falsification types of violations, which remain with the OIG) from the OIG to HCFA. It is expected that no significant economic impact will be imposed on a substantial number of small business entities as a result of this action.

For this reason, any new economic effect of these regulations should be minimal, affecting only those that have engaged in prohibited behavior contained in the authorities put in place on or after October 31, 1994; the economic effect of the already existing authorities is not new and is also minimal because of the relatively few violators involved. We believe the majority of the persons and entities subject to these regulations do not commit the violations discussed in these regulations. Those providers, physicians, and suppliers that are not currently in compliance with existing and new authorities will be subject to more vigorous enforcement of these provisions of the CMP oversight activity and may experience a significant economic impact as a result of such violations. However, the population subject to such actions is reasonably believed to be a very minor portion of the total population of providers, physicians and other suppliers. Moreover, small rural hospitals are not expected to be appreciably affected by this final rule. In addition, there are minimal costs and savings to the government.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble and will respond to the

comments in the preamble to any subsequent **Federal Register** document.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite prior public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

It would be contrary to the public interest to delay the publication of these rules pending completion of the usual notice and comment procedures. The delay would be contrary to the public interest because HCFA would not be able to utilize fully civil money penalties and assessments as tools to encourage compliance with certain provisions of the Medicare Act as the Congress intended. These provisions are designed to discourage entities from engaging in fraudulent and abusive behavior. According to the General Accounting Office's report, *Vulnerable Payers Lose Billions to Fraud and Abuse* (GAO/HRD-92-69), costs of health care fraud and abuse are estimated to be ten percent of our total health care spending. The Medicare trust funds and the public are significantly harmed by these abusive practices, and we find that further delaying the use of these sanctions pending the end of a public comment period would be contrary to the public's interest.

We also believe it is unnecessary to delay publication of these final rules pending completion of a notice and comment period. We are adopting the OIG's procedures and policies as our own and are not revising the rights of persons to whom the provisions pertain. Over the years, the Department of Health and Human Services has published the substance of the OIG's regulations in proposed rules that solicited comment and responded to those comments in final rules (55 FR 12205, April 2, 1990; 57 FR 3298, January 29, 1992). The procedures in this rule do not differ significantly from the OIG rules and we believe it is redundant to, in effect, propose rules that are already contained in the Code of Federal Regulations.

Finally, a delay of publication of the final rule is unnecessary because all of

the specific civil money penalties are required by the current statute. Thus, the one significant addition to the OIG rules, the addition of the new authorities, is not discretionary and we would not be able to change these authorities in the regulations in response to public comment.

Accordingly, we find good cause for waiving the prior notice-and-comment procedure as unnecessary and contrary to the public interest.

List of Subjects in 42 CFR Part 402

Administrative practice and procedure, Health facilities, Health professions, Medicaid, Medicare, Penalties.

42 CFR chapter IV is amended as set forth below:

PART 400—[AMENDED]

A. Part 400 is amended as follows:

1. The authority citation continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

2. Section 400.200 is amended by adding, in alphabetical order, a definition for "DAB" to read as follows:

§ 400.200 General definitions.

* * * * *

DAB stands for Departmental Appeals Board.

* * * * *

B. A new part 402 is added to read as follows:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

Secs.

402.1 Basis and scope.

402.3 Definitions.

402.5 Right to a hearing before the final determination.

402.7 Notice of proposed determination.

402.9 Failure to request a hearing.

402.11 Notice to other agencies and other entities.

402.13 Penalty, assessment, and exclusion not exclusive.

402.15 Collateral estoppel.

402.17 Settlement.

402.19 Hearings and appeals.

402.21 Judicial review.

Subpart B—Penalties and Assessments

Secs.

402.105 Amount of penalty.

402.107 Amount of assessment.

402.109 Statistical sampling.

402.111 Factor consideration determinations regarding the amount of penalties and assessments.

402.113 When a penalty and assessment are collectible.

402.115 Collection of assessment and penalty.

Subpart C—Exclusions [Reserved]

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 402.1 Basis and scope.

(a) *Basis.* This part is based on the sections of the Act that are specified in paragraph (c) of this section.

(b) *Scope.* This part—

(1) Provides for the imposition of civil money penalties, assessments, and exclusions against persons that violate the provisions of the Act specified in paragraph (c), (d), or (e) of this section; and

(2) Sets forth the appeal rights of persons subject to penalties, assessments, or exclusion and the procedures for reinstatement following exclusion.

(c) *Civil money penalties.* HCFA or OIG may impose civil money penalties against any person or other entity specified in paragraphs (c)(1) through (c)(30) of this section under the identified section of the Act. The authorities that also permit imposition of an assessment or exclusion are noted in the applicable paragraphs.

(1) Sections 1833(h)(5)(D) and 1842(j)(2)—Any person that knowingly and willfully, and on a repeated basis, bills for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also include an assessment and cause exclusion.)

(2) Section 1833(i)(6)—Any person that knowingly and willfully presents, or causes to be presented, a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.

(3) Section 1833(q)(2)(B)—Any entity that knowingly and willfully fails to provide information about a referring physician, including the physician's name and unique physician identification number for the referring physician, when seeking payment on an unassigned basis. (This violation, if it occurs in repeated cases, may also cause an exclusion.)

(4) Sections 1834(a)(11)(A) and 1842(j)(2)—Any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be

made (except for maintenance and servicing) as provided in section 1834(a)(7)(A). (This violation may also include an assessment and cause exclusion.)

(5) Sections 1834(a)(18)(B) and 1842(j)(2)—Any nonparticipating durable medical equipment supplier that knowingly and willfully, in violation of section 1834(a)(18)(A), fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also include an assessment and cause exclusion.)

(6) Sections 1834(b)(5)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services. (This violation may also include an assessment and cause exclusion.)

(7) Sections 1834(c)(4)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(4)(B), for mammography screening. (This violation may also include an assessment and cause exclusion.)

(8) Sections 1834(h)(3) and 1842(j)(2)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also include an assessment and cause exclusion.)

(9) Section 1834(j)(2)(A)(iii)—Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully distributes a certificate of medical necessity in violation of section 1834(j)(2)(A)(i) or fails to provide the information required under section 1834(j)(2)(A)(ii).

(10) Sections 1834(j)(4) and 1842(j)(2)—

(i) Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15); or

(C) The service is determined not to be medically necessary or reasonable.

(ii) These violations may also include an assessment and cause exclusion.

(11) Sections 1842(b)(18)(B) and 1842(j)(2)—Any practitioner specified in section 1842(b)(18)(C) (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists) or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(12) Sections 1842(k) and 1842(j)(2)—Any physician who knowingly and willfully presents, or causes to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15). (This violation may also include an assessment and cause exclusion.)

(13) Sections 1842(l)(3) and 1842(j)(2)—Any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A). (This violation may also include an assessment and cause exclusion.)

(14) Sections 1842(m)(3) and 1842(j)(2)—(i) Any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least \$500, who knowingly and willfully fails to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program.

(ii) This violation may also include an assessment and cause exclusion.

(15) Sections 1842(n)(3) and 1842(j)(2)—Any physician who knowingly and willfully, in repeated cases, bills one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B). (This violation may also include an assessment and cause exclusion.)

(16) Section 1842(p)(3)(A)—Any physician who knowingly and willfully fails promptly to provide the appropriate diagnosis code or codes upon request by HCFA or a carrier on any request for payment or bill not submitted on an assignment-related basis for any service furnished by the physician. (This violation, if it occurs in repeated cases, may also cause exclusion.)

(17) Sections 1848(g)(1)(B) and 1842(j)(2)—

(i) Any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis, that—

(A) Knowingly and willfully bills or collects in excess of the limiting charge (as defined in section 1848(g)(2)) on a repeated basis; or

(B) Fails to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv).

(ii) These violations may also include an assessment and cause exclusion.

(18) Section 1848(g)(3)(B) and 1842(j)(2)—Any person that knowingly and willfully bills for State plan approved physicians' services, as defined in section 1848(j)(3), on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may also include an assessment and cause exclusion.)

(19) Section 1848(g)(4)(B)(ii), 1842(p)(3), and 1842(j)(2)(A)—

(i) Any physician, supplier, or other person (except any person that has been excluded from the Medicare program) that, for services furnished after September 1, 1990, knowingly and willfully—

(A) Fails to submit a claim on a standard claim form for services provided for which payment is made under Part B on a reasonable charge or fee schedule basis; or

(B) Imposes a charge for completing and submitting the standard claims form.

(ii) These violations, if they occur in repeated cases, may also cause exclusion.

(20) Section 1862(b)(5)(C)—Any employer (other than a Federal or other governmental agency) that, before October 1, 1998, willfully or repeatedly fails to provide timely and accurate information requested relating to an employee's group health insurance coverage.

(21) Section 1862(b)(6)(B)—Any entity that knowingly, willfully, and repeatedly—

(i) Fails to complete a claim form relating to the availability of other health benefit plans in accordance with section 1862(b)(6)(A); or

(ii) Provides inaccurate information relating to the availability of other health benefit plans on the claim form.

(22) Section 1877(g)(5)—Any person that fails to report information required by HHS under section 1877(f) concerning ownership, investment, and compensation arrangements. (This violation may also include an assessment and cause exclusion.)

(23) Sections 1879(h), 1834(a)(18), and 1842(j)(2)—

(i) Any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15) of the Act; or

(C) The service is determined not to be payable under section 1834(a)(17)(b) because of unsolicited telephone contacts.

(ii) These violations may also include an assessment and cause exclusion.

(24) Section 1882(a)(2)—Any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C). (This violation may also include an assessment and cause exclusion.)

(25) Section 1882(p)(8)—Any person that sells or issues Medicare supplemental policies, on or after July 30, 1992, that fail to conform to the NAIC or Federal standards established under section 1882(p). (This violation may also include an assessment and cause exclusion.)

(26) Section 1882(p)(9)(C)—

(i) Any person that sells a Medicare supplemental policy and—

(A) Fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits; or

(B) Fails to provide the individual, before the sale of the policy, an outline of coverage describing the benefits provided by the policy.

(ii) These violations may also include an assessment and cause exclusion.

(27) Section 1882(q)(5)(C)—

(i) Any person that fails to—

(A) Suspend a Medicare supplemental policy at the policyholder's request, if

the policyholder applies for and is determined eligible for medical assistance, and the policyholder provides notice within 90 days of the eligibility determination; or

(B) Automatically reinstate the policy as of the date of termination of medical assistance if the policyholder loses eligibility for medical assistance and the policyholder provides notice within 90 days of loss of eligibility.

(ii) These violations may also include an assessment and cause exclusion.

(28) Section 1882(r)(6)(A)—Any person that fails to provide refunds or credits as required by section 1882(r)(1)(B). (This violation may also include an assessment and cause exclusion.)

(29) Section 1882(s)(3)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Does not waive any time periods applicable to preexisting conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare supplemental policy; or

(B) Denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A).

(ii) These violations may also include an assessment and cause exclusion.

(30) Section 1882(t)(2)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Fails substantially to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(B) Imposes premiums on enrollees in excess of the premiums approved by the State;

(C) Acts to expel an enrollee for reasons other than nonpayment of premiums; or

(D) Does not provide each enrollee at the time of enrollment with the specific information provided in section 1882(t)(1)(E)(i) or fails to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)).

(ii) These violations may also include an assessment and cause exclusion.

(d) *Assessments.* HCFA or OIG may impose assessments in addition to civil money penalties for violations of the following statutory sections:

(1) Section 1833: Paragraph (h)(5)(D).

(2) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), and (j)(4).

(3) Section 1842: Paragraphs (k), (l)(3), (m)(3), and (n)(3).

(4) Section 1848: Paragraph (g)(1)(B).

(5) Section 1877: Paragraph (g)(5).

(6) Section 1879: Paragraph (h).

(7) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), and (t)(2).

(e) *Exclusions.* (1) HCFA or OIG may exclude any person from participation in the Medicare program on the basis of any of the following violations of the statute:

(i) Section 1833: Paragraphs (h)(5)(D) and, in repeated cases, (q)(2)(B).

(ii) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), and (j)(4).

(iii) Section 1842: Paragraphs (b)(18)(B), (k), (l)(3), (m)(3), (n)(3), and, in repeated cases, (p)(3)(B).

(iv) Section 1848: Paragraphs (g)(1)(B), (g)(3)(B), and, in repeated cases, (g)(4)(B)(ii).

(v) Section 1877: Paragraph (g)(5).

(vi) Section 1879: Paragraph (h).

(vii) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), and (t)(2).

(2) HCFA or OIG must exclude from participation in the Medicare program any of the following, under the identified section of the Act:

(i) Section 1834(a)(17)(C)—Any supplier of durable medical equipment and supplies that are covered under section 1834(a)(13) that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of covered services in violation of section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts as described under section 1834(a)(17)(A).

(ii) Section 1834(h)(3)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of prosthetic devices, orthotics, or prosthetics in the same manner as in the violation under section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts in the same manner as described in section 1834(a)(17)(C).

(f) *Responsible persons.* (1) If HCFA or OIG determines that more than one person is responsible for any of the violations described in paragraph (c) or paragraph (d) of this section, it may impose a civil money penalty or a civil money penalty and assessment against any one of those persons or jointly and severally against two or more of those persons. However, the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person were responsible.

(2) A principal is liable for penalties and assessments for the actions of his or

her agent acting within the scope of the agency.

(g) *Time limits.* Neither HCFA nor OIG initiates an action to impose a civil money penalty, assessment, or proceeding to exclude a person from participation in the Medicare program unless it begins the action within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

§ 402.3 Definitions.

For purposes of this part:

Assessment means the amount described in § 402.107 and includes the plural of that term.

Assignment-related basis means that the claim submitted by a physician, supplier or other person is paid on the basis of an assignment, whereby the physician, supplier or other person agrees to accept the Medicare payment as payment in full for the services furnished to the beneficiary and is precluded from charging the beneficiary more than the deductible and coinsurance based upon the approved Medicare fee amount. Additional obligations, including obligations to make refunds in certain circumstances, are established at section 1842(b)(3) of the Act.

Claim means an application for payment for a service for which the Medicare or Medicaid program may pay.

Covered means that a service is described as reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. A service is not covered if it is specifically identified as excluded from Medicare Part B coverage or is not a defined Medicare Part B benefit.

Exclusion means the temporary or permanent barring of a person or other entity from participation in the Medicare or State health care program and that services furnished or ordered by that person are not paid for under either program.

General Counsel means the General Counsel of HHS or his or her designees.

Knowingly or knowingly and willfully means that a person, with respect to information—

(1) Has actual knowledge of the information;

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

(3) Acts in reckless disregard of the truth or falsity of the information; and

(4) No proof of specific intent is required.

Medicare supplemental policy means a policy guaranteeing that a health plan will pay a policyholder's coinsurance and deductible and will cover other

limitations on payment imposed under title XVIII of the Act and will provide additional health plan or non-Medicare coverage for services up to a predefined benefit limit.

NAIC stands for the National Association of Insurance Commissioners.

Nonparticipating describes a physician, supplier, or other person (excluding any provider of services) that, at the time of furnishing the services to Medicare Part B beneficiaries, is not a participating physician or supplier.

Participating describes a physician or supplier (excluding any provider of services) that, before the beginning of any given year, enters into an agreement with HHS that provides that the physician or supplier will accept payment under the Medicare program on an assignment-related basis for all services furnished to Medicare Part B beneficiaries.

Penalty means the amount described in § 402.105 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physicians' services means the following Medicare covered professional services:

(1) Surgery, consultation, home, office and institutional calls, and other professional services performed by physicians.

(2) Services and supplies furnished "incident to" a physician's professional services.

(3) Outpatient physical and occupational therapy services.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding clinical diagnostic laboratory tests).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens prepared by a physician.

Radiologist service means radiology services performed only by, or under the direction of, a physician who is certified, or eligible to be certified, by the American Board of Radiology or for whom radiology services account for at least 50 percent of the total amount of charges made under part B of title XVIII of the Act.

Request for payment means an application submitted by a person to any person for payment for a service.

Respondent means the person upon which HCFA or OIG has imposed, or proposes to impose, a civil money penalty, assessment, or exclusion.

Service includes—

(1) Any item, device, medical supply, or service claimed to have been

furnished to a patient and listed in an itemized claim for program payment; or

(2) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Timely basis means that the adjustment to a bill or a refund is considered "on a timely basis" if the physician, supplier, or other person makes the adjustment or refund to the appropriate party no later than 30 days after the date the physician, supplier, or other person is notified by the Medicare Part B contractor of the violation and the requirement to refund any excess collections.

§ 402.5 Right to a hearing before the final determination.

HCFA or OIG does not make a determination adverse to any person under this part until the person has been given a written notice and opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

§ 402.7 Notice of proposed determination.

(a) If HCFA or OIG proposes a penalty and, as applicable, an assessment, or proposes to exclude a respondent from participation in Medicare in accordance with this part, it sends the respondent written notice of its intent by certified mail, return receipt requested. The notice includes the following information:

(1) Reference to the statutory basis or bases for the penalty, assessment, exclusion, or any combination, as applicable.

(2)(i) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment, and exclusion are proposed; or

(ii) If HCFA or OIG is relying upon statistical sampling to project the number and types of claims or requests for payment and the dollar amount, a description of the claims and requests for payment comprising the sample and a brief description of the statistical sampling technique HCFA or OIG used.

(3) The reason why the claims, requests for payment, or incidents are subject to a penalty and assessment.

(4) The amount of the proposed penalty and of any proposed assessment.

(5) Any mitigating or aggravating circumstances that HCFA or OIG considered when it determined the amount of the proposed penalty and any applicable assessment.

(6) Information concerning response to the notice, including—

(i) A specific statement of the respondent's right to a hearing; and

(ii) A statement that failure to request a hearing within 60 days renders the proposed determination final and permits the imposition of the proposed penalty and any assessment.

(iii) A statement that the debt may be collected through an administrative offset.

(7) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

§ 402.9 Failure to request a hearing.

(a) If the respondent does not request a hearing within 60 days of receipt of the notice of proposed determination specified in § 402.7, any civil money penalty, assessment, or exclusion becomes final and HCFA or OIG may impose the proposed penalty, assessment, or exclusion, or any less severe penalty, assessment, or suspension.

(b) HCFA or OIG notifies the respondent by certified mail, return receipt requested, of any penalty, assessment, or exclusion that has been imposed and of the means by which the respondent may satisfy the judgment.

(c) The respondent has no right to appeal a penalty, assessment, or exclusion for which he or she has not requested a hearing.

§ 402.11 Notice to other agencies and other entities.

(a) Whenever a penalty, assessment, or exclusion becomes final, HCFA or OIG notifies the following organizations and entities about the action and the reasons for it:

(1) The appropriate State or local medical or professional association.

(2) The appropriate peer review organization.

(3) As appropriate, the State agency responsible for the administration of each State health care program (Medicaid, the Maternal and Child Health Services Block Grant Program, and the Social Services Block Grant Program).

(4) The appropriate Medicare carrier or fiscal intermediary.

(5) The appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies).

(6) The long-term care ombudsman.

(b) For exclusions, HCFA or OIG also notifies the public and specifies the effective date.

§ 402.13 Penalty, assessment, and exclusion not exclusive.

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

§ 402.15 Collateral estoppel.

(a) When a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 402.1 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

(b) A person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements is barred from denying the essential elements of the criminal offense if the proceedings under this part involve the same transactions.

§ 402.17 Settlement.

HCFA or OIG has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time before a final decision by the Secretary. Thereafter, the General Counsel has the exclusive authority.

§ 402.19 Hearings and appeals.

The hearings and appeals procedures set forth in part 1005 of chapter V of this title are available to any person that receives an adverse determination under this part. For an appeal of a civil money penalty, assessment, or exclusion imposed under this part, either HCFA or OIG may represent the government in the hearing and appeals process.

§ 402.21 Judicial review.

After exhausting all available administrative remedies, a respondent may seek judicial review of a penalty, assessment, or exclusion that has become final. The respondent may seek review only with respect to a penalty, assessment, or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this title unless the court excuses the failure or neglect to urge the exception in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

Subpart B—Civil Money Penalties and Assessments

§ 402.105 Amount of penalty.

(a) *\$2,000.* Except as provided in paragraphs (b) through (f) of this section, HCFA or OIG may impose a penalty of not more than \$2,000 for each service, bill, or refusal to issue a timely refund that is subject to a determination under this part and for each incident involving the knowing, willful, and repeated failure of an entity furnishing a service to submit a properly completed claim form or to include on the claim form accurate information regarding the availability of other health insurance benefit plans (§ 402.1(c)(21)).

(b) *\$1,000.* HCFA or OIG may impose a penalty of not more than \$1,000 for the following:

(1) Per certificate of medical necessity knowingly and willfully distributed to physicians on or after December 31, 1994 that—

(i) Contains information concerning the medical condition of the patient; or
(ii) Fails to include cost information.

(2) Per individual about whom information is requested, for willful or repeated failure of an employer to respond to an intermediary or carrier about coverage of an employee or spouse under the employer's group health plan (§ 402.1(c)(20)).

(c) *\$5,000.* HCFA or OIG may impose a penalty of not more than \$5,000 for each violation resulting from the following:

(1) The failure of a Medicare supplemental policy issuer, on a replacement policy, to waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods that were satisfied under a preceding policy (§ 402.1(c)(29)); and

(2) Any issuer of any Medicare supplemental policy denying a policy, conditioning the issuance or effectiveness of the policy, or discriminating in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A). (§ 402.1(c)(29)).

(d) *\$10,000.* (1) HCFA or OIG may impose a penalty of not more than \$10,000 for each day that reporting entity ownership arrangements is late (§ 402.1(c)(22)).

(2) HCFA or OIG may impose a penalty of not more than \$10,000 for the following violations that occur on or after January 1, 1997:

(i) Knowingly and willfully, and on a repeated basis, billing for a clinical diagnostic laboratory test, other than on

an assignment-related basis (§ 402.1(c)(1)).

(ii) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(iii) By any durable medical equipment supplier, knowingly and willfully, in violation of section 1834(a)(18)(A), failing to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(iv) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(v) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(vi) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 402.1(c)(8)).

(vii) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assigned-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(viii) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for practitioners specified in section 1842(b)(18)(B) (§ 402.1(c)(11)).

(xix) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(x) By any nonparticipating physician who does not accept payment on an

assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(xi) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least \$500, knowingly and willfully failing to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(xii) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(xiii) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(A) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(B) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv) (§ 402.1(c)(17)).

(xiv) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(xv) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

(e) \$15,000. HCFA or OIG may impose a penalty of not more than \$15,000 if the seller of a Medicare supplemental policy is not the issuer, for each violation described in paragraphs (f)(2)

and (f)(3) of this section (§ 402.1 (c)(25) and (c)(26)).

(f) \$25,000. HCFA or OIG may impose a penalty of not more than \$25,000 for each of the following violations:

(1) Issuance of a Medicare supplemental policy that has not been approved by an approved State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C) of the Act (§ 402.1(c)(23)).

(2) Sale or issuance after July 30, 1992, of a Medicare supplemental policy that fails to conform with the NAIC or Federal standards established under section 1882(p) of the Act (§ 402.1(c)(25)).

(3) Failure to make the core group of basic benefits available for sale when selling other Medicare supplemental plans with additional benefits (§ 402.1(c)(26)).

(4) Failure to provide, before sale of a Medicare supplemental policy, an outline of coverage describing the benefits provided by the policy (§ 402.1(c)(26)).

(5) Failure of an issuer of a policy to suspend or reinstate a policy, based on the policy holder's request, during entitlement to or upon loss of eligibility for medical assistance (§ 402.1(c)(27)).

(6) Failure to provide refunds or credits for Medicare supplemental policies as required by section 1882(r)(1)(B) (§ 402.1(c)(28)).

(7) By an issuer of a Medicare supplemental policy—

(i) Substantial failure to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(ii) Imposition of premiums on enrollees in excess of the premiums approved by the State;

(iii) Action to expel an enrollee for reasons other than nonpayment of premiums; or

(iv) Failure to provide each enrollee, at the time of enrollment, with the specific information provided in section 1882(t)(1)(E)(i) or failure to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii) (section 1882(t)(2)).

§ 402.107 Amount of assessment.

A person subject to civil money penalties specified in § 402.1(c) may be subject, in addition, to an assessment. An assessment is a monetary payment in lieu of damages sustained by HHS or a State agency.

(a) The assessment may not be more than twice the amount claimed for each

service that was a basis for the civil money penalty, except for the violations specified in paragraph (b) of this section that occur before January 1, 1997.

(b) For the violations specified in this paragraph occurring after January 1, 1997, the assessment may not be more than three times the amount claimed for each service that was the basis for a civil money penalty. The violations are the following:

(1) Knowingly and willfully billing, and on a repeated basis, for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(2) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(3) By any durable medical equipment supplier, knowingly and willfully failing, in violation of section 1834(a)(18)(A), to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(4) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(5) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(6) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(7) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(i) The supplier does not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(8) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for practitioners specified in section 1842(b)(18)(B) (§ 402.1(c)(11)).

(9) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(10) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(11) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least \$500, knowingly and willfully failing to—

(i) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(ii) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(12) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(13) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(i) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(ii) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A) (iii) or (iv) (§ 402.1(c)(17)).

(14) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(15) By any supplier of durable medical equipment, including suppliers of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries

for services billed on an assignment-related basis if—

(i) The supplier did not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

§ 402.109 Statistical sampling.

(a) *Purpose.* HCFA or OIG may introduce the results of a statistical sampling study to show the number and amount of claims subject to sanction under this part that the respondent presented or caused to be presented.

(b) *Prima facie evidence.* The results of the statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitute prima facie evidence of the number and amount of claims or requests for payment subject to sanction under § 402.1.

(c) *Burden of proof.* Once HCFA or OIG has made a prima facie case, the burden is on the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. HCFA or OIG then has the opportunity to rebut this evidence.

§ 402.111 Factors considered in determinations regarding the amount of penalties and assessments.

(a) *Basic factors.* In determining the amount of any penalty or assessment, HCFA or OIG takes into account the following:

(1) The nature of the claim, request for payment, or information given and the circumstances under which it was presented or given.

(2) The degree of culpability, history of prior offenses, and financial condition of the person submitting the claim or request for payment or giving the information.

(3) The resources available to the person submitting the claim or request for payment or giving the information.

(4) Such other matters as justice may require.

(b) *Criteria to be considered.* As guidelines for taking into account the factors listed in paragraph (a) of this section, HCFA or OIG considers the following circumstances:

(1) *Aggravating circumstances of the incident.* An aggravating circumstance is any of the following:

(i) The services or incidents were of several types, occurring over a lengthy period of time.

(ii) There were many of these services or incidents or the nature and

circumstances indicate a pattern of claims or requests for payment for these services or a pattern of incidents.

(iii) The amount claimed or requested for these services was substantial.

(iv) Before the incident or presentation of any claim or request for payment subject to imposition of a civil money penalty, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services.

(v) There is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care service. (The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance.)

(2) *Mitigating circumstances.* The following circumstances are mitigating circumstances:

(i) All the services or incidents subject to a civil money penalty were few in number and of the same type, occurred within a short period of time, and the total amount claimed or requested for the services was less than \$1,000.

(ii) The claim or request for payment for the service was the result of an unintentional and unrecognized error in the process of presenting claims or requesting payment and the respondent took corrective steps promptly after discovering the error.

(iii) Imposition of the penalty or assessment without reduction would jeopardize the ability of the respondent to continue as a health care provider.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to ensure the achievement of the purposes of this part.

(c) *Effect of aggravating or mitigating circumstances.* In determining the amount of the penalty and assessment to be imposed for every service or incident subject to a determination under § 402.1(c)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment is set at an amount sufficiently below the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate

amount of the penalty and assessment is set at an amount at or sufficiently close to the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this section limits the authority of HCFA or OIG to settle any issue or case as provided by § 402.19 or to compromise any penalty and assessment as provided by § 402.115.

§ 402.113 When a penalty and assessment are collectible.

A civil money penalty and assessment become collectible after the earliest of the following:

(a) Sixty days after the respondent receives HCFA's or OIG's notice of proposed determination under § 402.7, if the respondent has not requested a hearing before an ALJ.

(b) Immediately after the respondent abandons or waives his or her appeal right at any administrative level.

(c) Thirty days after the respondent receives the ALJ's decision imposing a civil money penalty or assessment under § 1005.20(d) of this title, if the respondent has not requested a review before the DAB.

(d) If the DAB grants an extension of the period for requesting the DAB's review, the day after the extension expires if the respondent has not requested the review.

(e) Immediately after the ALJ's decision denying a request for a stay of the effective date under § 1005.22(b) of this title.

(f) If the ALJ grants a stay under § 1005.22(b) of this title, immediately after the judicial ruling is completed.

(g) Sixty days after the respondent receives the DAB's decision imposing a civil money penalty if the respondent has not requested a stay of the decision under § 1005.22(b) of this title.

§ 402.115 Collection of penalty or assessment.

(a) Once a determination by HHS has become final, HCFA is responsible for the collection of any penalty or assessment.

(b) The General Counsel may compromise a penalty or assessment

imposed under this part, after consultation with HCFA or OIG, and the Federal government may recover the penalty or assessment in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The United States or a State agency may deduct the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

Subpart C—Exclusions [Reserved]

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)

Dated: July 7, 1998.

Nancy-Ann Min De Parle,

Administrator, Health Care Financing Administration.

[FR Doc. 98-33010 Filed 12-11-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 401

[USCG-1998-4874]

Great lakes Pilotage Rates

AGENCY: Coast Guard, DOT.

ACTION: Notice of annual review findings; request for comments.

SUMMARY: The Coast Guard conducted a review of Great Lakes pilotage rates. Based on the results of this review, the Coast Guard concluded that no changes were necessary to the Great Lakes pilotage rates for the 1998 navigation season. The Coast Guard is interested in comments on the 1998 Rate Review.

DATES: Comments must reach the Docket Management Facility on or before February 12, 1999.

ADDRESSES: You may mail your comments to the Docket Management Facility, (USCG-1998-4874), U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington DC 20590-0001, or deliver

them to room PL-401 on the Plaza level of the Nassif Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

The Docket Management Facility maintains the public docket for this notice. Comments, and documents as indicated in this notice, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: For questions on this notice, contact John Bennett, Office of Great Lakes Pilotage, 400 7th Street SW., Suite 5421, Washington, DC 20590, (202) 366-8986. For questions on viewing or submitting material to the docket, contact Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202-366-9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to submit written data, views, or arguments on the findings presented in this notice. Persons submitting comments should include their names and addresses, identify this notice (USCG-1998-4874) and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing to the Docket Management Facility at the address under **ADDRESSES**. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period.

Background and Purpose

On May 9, 1996, the Department of Transportation (DOT) published a final rule entitled "Great Lakes Pilotage Rate Methodology" in the **Federal Register** (61 FR 21081). This rule established the DOT's procedures and methodology for determining Great Lakes pilotage rates.

The regulations governing Great Lakes pilotage rates (46 CFR Part 404) require