

prior to the effective date of 30 CFR part 7 subpart D." This would enable mine operators to continue to safely use blasting units already accepted for use by the Agency. This acceptance could have been granted under an interim criteria issued for a large capacity blasting unit or through an evaluation which determined a particular unit to be as safe for use as an approved unit.

Executive Order 12291 and the Regulatory Flexibility Act

This proposed rule would revise previously issued methane standards to allow mine operators to use any MSHA approved multiple-shot blasting unit without regard to the specific approval part under which it was issued and deletes certain performance requirements which are the same as those required for approval of blasting units by part 7 subpart D. There is no cost impact of this proposed revision on mine operators. The cost impact of the testing and approval requirements has been analyzed in the context of subpart D of part 7 in which the Agency has determined that the rule would not result in a major cost increase or have an incremental effect of \$100 million or more on the economy. Therefore, a regulatory impact analysis is not required. The Agency has also determined that the final rule would not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The proposal does not contain any information collection requirements subject to the Paperwork Reduction Act of 1980.

List of Subjects in 30 CFR Part 57

Mine safety and health, metal and nonmetal mining, safety standards for methane.

Dated: March 26, 1990.

John B. Howerton,

Deputy Assistant Secretary for Mine Safety and Health.

Accordingly, subpart T, part 57, subchapter N, chapter 1, title 30 of the Code of Federal Regulations is proposed to be amended as follows:

PART 57—[AMENDED]

The authority citation for subpart T of part 57 continues to read as follows:

Authority: 30 U.S.C. 811.

2. Section 57.22606 is proposed to be amended by revising paragraphs (a) and (g) to read as follows:

§ 57.22606 Explosive materials and blasting units (III mines).

(a) Mine operators shall notify the appropriate MSHA District Manager of all nonapproved explosive materials to be used prior to their use. Explosive materials used for blasting shall be approved by MSHA under 30 CFR part 15 or nonapproved explosive materials shall be evaluated and determined by the District Manager to be safe for blasting in a potentially gassy environment. The notice shall also include the millisecond-delay interval between successive shots and between the first and last shot in the round.

(g) Blasting units shall be:
(1) Approved by MSHA; or
(2) Accepted by MSHA prior to the effective date of 30 CFR part 7 subpart D.

[FR Doc. 90-7385 Filed 3-30-90; 8:45 am]

BILLING CODE 4510-49-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL-3751-3]

Cancellation Notice of Scheduled Public Hearings Concerning EPA's Tentative Approval of Mississippi's Underground Storage Tank Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of cancellation of public hearings concerning approval of Mississippi's underground storage tank (UST) program.

SUMMARY: The purpose of this notice is to announce the cancellation of two public hearings concerning EPA's approval of Mississippi's UST program. On February 20, 1990, EPA published a tentative decision announcing its intent to grant Mississippi final approval of its program and to hold two public hearings to allow all interested persons to testify on any aspect of Mississippi's underground storage tank program approval application. The two hearings were to be held on April 13, 1990, in the Embassy I Room, Metro Ramada Inn, Ellis Avenue and Interstate 20 West in Jackson, Mississippi, from 10 a.m. to 1 p.m. and from 7 p.m. until the end of testimony or 10 p.m. EPA had reserved the right to cancel these hearings in the event of no significant public interest. Since no public requests to testify on any aspect of Mississippi's UST program application for final approval were

made, EPA is cancelling the previously scheduled public hearings.

Further background on EPA's tentative decision to grant final approval of Mississippi's UST program appears at 55 FR 5861, February 20, 1990. Any further information regarding EPA's final approval of Mississippi's underground storage tank program can be obtained from Mr. John K. Mason, (404) 347-3866, 345 Courtland Street, NE., Atlanta, Georgia 30365.

Dated: March 22, 1990.

Lee A. DeHihns III,

Acting Regional Administrator.

[FR Doc. 90-7452 Filed 3-30-90; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Inspector General

42 CFR Parts 1000, 1001, 1002, 1003, 1004, 1005, 1006, and 1007

RIN 0991-AA47

Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the OIG sanction and civil money penalty provisions established through section 2 and other conforming amendments in Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987, along with certain additional provisions contained in Public Law 99-272, the Consolidated Omnibus Budget Reconciliation Act of 1985 and Public Law 100-360, the Medicare Catastrophic Coverage Act of 1988. Specifically, these regulations are designed to protect program beneficiaries from unfit health care practitioners, and otherwise to improve the anti-fraud provisions of the Department's health care programs under titles V, XVIII, XIX, and XX of the Act.

DATES: To assure consideration, comments must be mailed and delivered to the address provided below by June 1, 1990.

ADDRESSES: Address comments in writing to: Office of Inspector General, Department of Health and Human Services, Attention: LRR-18-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-18-P.

Comments 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) 472-5270.

FOR FURTHER INFORMATION CONTACT:

Joel J. Schaer, Legislation, Regulations and Public Affairs Staff, (202) 472-5270

James Patton, Office of Investigations, (301) 966-9601

Robin Schneider, Office of the General Counsel, (202) 245-6306.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

The Medicare and Medicaid Patient and Program Protection Act (MMPPPA) of 1987, Public Law 100-93, was enacted on August 18, 1987 and became effective on September 1, 1987. This statute recodified and expanded the Secretary's authority to exclude various individuals and entities from receiving payment for services that would otherwise be reimbursable under Medicare (title 18), Medicaid (title 19), the Maternal and Child Health Block Grant Program (title 5) and the Social Services Block Grant (title 20). In addition, new civil money penalty (CMP) authorities, and technical amendments to existing CMP provisions, were established under MMPPPA.

The Medicare and Medicaid Patient and Program Protection Act of 1988

MMPPPA both consolidated many of the Secretary's preexisting exclusion authorities into section 1128 of the Social Security Act (42 U.S.C. 1320a-7), and added significant new grounds for exclusion under those authorities. The Secretary's authority under this section of the Act has been delegated to the Department's Office of Inspector General (OIG). (53 FR 12999, April 20, 1988).

A. Expanded Exclusion Authorities

MMPPPA provides the OIG broad authority to protect the financial integrity of the Department's Medicare and other health care programs, as well as the quality of care provided to the programs' beneficiaries, by giving OIG added authority to control who may obtain payment for services furnished to program beneficiaries. The statute provides an expanded list of activities that can, and in some cases must, serve

as a basis for exclusion from eligibility for such payment. Section 1128 of the Act provides for two types of exclusions—mandatory and permissive. The mandatory exclusions, found in section 1128(a), require that an individual or entity that has been convicted of certain types of crimes be excluded, and that the exclusion be for a period of not less than five years. Under authorities set forth in section 1128(b) of the Act, the OIG has the discretion to determine whether, and for how long, to impose the permissive exclusions.

MMPPPA establishes two categories of permissive exclusions. One category involves the authority to exclude an individual or entity from Medicare and the State health care programs based on an action previously taken by a court, licensing board or other agency. For example, a person who has (1) been convicted of embezzlement, (2) had his or her license to practice medicine revoked, or (3) been debarred from practicing medicine in a Veterans' Administration facility, could also be excluded from Medicare and the State health care programs, as discussed in further detail below. We will refer to these types of exclusions as derivative exclusions because our ability to exclude derives from the fact that another entity has imposed a sanction on the individual or health care entity. The OIG would not be required to re-establish the factual or legal basis for such underlying sanction.

The second broad category of permissive exclusions is based on determinations of misconduct that would originate with determinations made by the OIG. These non-derivative exclusions would require the OIG, if challenged, to make a prima facie showing that the improper behavior did occur. For example, a person could be excluded if he or she (1) rendered poor quality care, (2) submitted bills to the Medicare program substantially in excess of usual charges, (3) failed to provide certain required information, or (4) filed false claims for reimbursement.

B. State Health Care Programs: Exclusions and Waivers

The Act provides for exclusion not only from the Medicare program, but also from "State health care programs," which are defined to include those programs covered under titles 5, 19, 20 of the Social Security Act. The statute makes clear that, in most cases, an individual or entity excluded from Medicare is to be excluded from all of these programs, and the exclusion is to be for the same period of time. The relevant State agency or agencies, when

directed by OIG, must exclude from participation in State health care programs any individual or entity excluded from Medicare by the OIG.

The OIG will consider requests for a waiver from exclusion from one or more of the State health care programs in limited situations. Waiver would be granted only for those programs for which the State agency administering the specific program requests the waiver, and only where the individual or entity is the sole community physician or sole source of specialized services in a community.

These proposed regulations are intended to implement section 2 of MMPPPA and certain conforming amendments found elsewhere in that statute. In addition, certain relevant provisions contained in the Consolidated Omnibus Budget Reconciliation Act of 1985, Public Law 99-272, and the Medicare Catastrophic Coverage Act of 1988, Public Law 100-360, would also be promulgated through this rulemaking. As a result of these statutory changes, various revisions to 42 CFR chapter V are being proposed, as discussed below.

II. Provisions of the Proposed Regulations

Part 1001

The basic structure of the regulations in 42 CFR part 1001 is as follows: for each type of exclusion, the basis (that is, the activity that will justify the exclusion) is set out, and followed by the considerations the OIG will use in determining the period of the exclusion. The general provisions concerning notice and opportunity to respond, requests for hearing, notice to the public, the effect of the exclusion, and requests for reinstatement appear in subsequent subparts. The proposed regulations governing Administrative Law Judge (ALJ) hearings and subsequent appeals to the Secretary appear in 42 CFR part 1005.

A. Mandatory Exclusions

Section 1001.101—The Act makes mandatory the exclusion of any individual or entity that has been convicted of (1) a criminal offense related to the delivery of an item or service under Medicare or a State health care program, or (2) patient abuse or neglect. The exclusion for program-related crimes is essentially a recodification of prior law. Mandatory exclusions under § 1001.101(a) are broadly defined to include offenses relating to performance of management or administrative services relating to

delivery of items or services under the program. These could include, for example, a physician's conviction for filing false Medicare or Medicaid claims, a Medicare carrier claims processor's conviction for accepting bribes relating to payment of claims under a program, or a nursing home administrator convicted of using a Medicaid beneficiary's patient fund account for his or her own use. The exclusion for patient abuse or neglect is intended to apply to all criminal offenses that entail or result in neglect or abuse of patients.

Period of exclusion under § 1001.101—Congress provided that these exclusions are not only mandatory, but must be for a minimum period of five years. We are proposing that the exclusion may be for a longer period if aggravating circumstances exist with respect to the individual or entity. Mitigating circumstances may offset the aggravating circumstances, but the exclusion cannot be for a period less than five years.

Although a person excluded under these provisions is entitled to an ALJ hearing following the imposition of the exclusion, the issues at that hearing will be limited, in view of the derivative nature of the exclusion. The hearing may not be used to collaterally attack the conviction which is serving as the basis of the exclusion. Moreover, if the exclusion is for the five-year statutory minimum, that period may not be challenged.

B. Permissive Exclusions

There are several types of permissive exclusions. As noted in the discussion above, some are derivative in nature and others are not.

1. Derivative Exclusions

(a) *Sections 1001.201, 1001.301 and 1001.401*—Exclusions based on criminal convictions—Sections 1001.201, 1001.301 and 1001.401 would authorize exclusion of individuals and entities that have been convicted of certain types of crimes that are not directly related to delivery of items or services under Medicare or the State health care programs. Section 1001.201 concerns convictions for fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct in two broad contexts: (1) With respect to any program operated or financed by a federal, State or local government agency, and (2) in connection with any health care item or service. Thus, conviction of such crimes in connection with either a government-funded program or a private health insurance program will now subject someone to exclusion from the Medicare

and State health care programs. While some convictions for crimes relating to Medicare or the State health care programs would also fall under this permissive section, the mandatory exclusion authority of § 1001.101 would be used in all cases where it applies. In determining whether a particular type of crime is covered by this section, the OIG would look to the nature of the actual offense, and not merely at its label.

Section 1001.301 involves convictions for obstruction of investigations of program-related crimes. Among the types of convictions covered by this section are perjury, witness tampering and obstruction of justice. This list is not intended to be exhaustive.

Section 1001.401 concerns certain federal and State convictions relating to controlled substances. The criminal offenses enumerated in the statute and the regulations do not include offenses relating solely to possession of controlled substances.

Periods of exclusion under §§ 1001.201, 1001.301, and 1001.401—The OIG is proposing that an exclusion on any of these three bases be for a period of five years as set forth in the regulations. This five-year benchmark is based on several factors. Although Congress did not set a mandatory minimum period for these exclusions, the policies that it articulated in the legislative history supporting the minimum five-year period for mandatory exclusions apply equally to these exclusions. Specifically, the legislative history indicates that:

[A] minimum five-year exclusion is appropriate, given the seriousness of the offenses at issue. The minimum exclusion provides the Secretary with adequate opportunity to determine whether there is a reasonable assurance that the types of offenses for which the individual or entity was excluded have not recurred and are not likely to do so. Moreover, a mandatory five-year exclusion should provide a clear and strong deterrent against the commission of criminal acts.

H.R. Rept. No. 85, Part 1, 100th Cong., 1st Sess. 5-6 (Energy and Commerce Committee) (1987); H.R. Rept. No. 85, Part 2, 100th Cong., 1st Sess. 5 (Ways and Means Committee) (1987); S. Rept. No. 109, 100th Cong., 1st Sess. 5 (Finance Committee) (1987).

The same policies would apply to these three types of exclusions. The types of offenses set out in §§ 1001.201, 1001.301 and 1001.401 are comparable in nature and seriousness to the ones for which Congress prescribed a minimum five-year period. Congress recognized that a five-year period would be appropriate to use to determine whether the offenses are likely to recur, a standard equally applicable to the

permissive exclusions and the mandatory ones. Moreover, the interest in deterrence is equally strong in both contexts. The legislative history also states:

While the Committee expects that most of these [permissive exclusions based on convictions] will result in exclusion, it wishes to give the Secretary the option to avoid exclusion if, in his judgment, exclusion would jeopardize another investigation.

H.R. Rept. No. 85, Part 1, *supra*, at 7; H.R. Rept. No. 85, Part 2, at 6; S. Rept. No. 109, *supra*, at 6.

Accordingly, except in unusual cases, the OIG intends to treat the convictions in §§ 1001.201, 1001.301 and 1001.401 similarly to the convictions set forth in § 1001.101. However, because the five-year period is not made mandatory in the context of permissive exclusions, the OIG would consider whether there are circumstances in the context of a particular case that would warrant either increasing or decreasing the five-year exclusion period.

(b) *Sections 1001.501 and 1001.601*—Actions by licensing boards and other agencies—Section 1001.501 would authorize the exclusion of an individual or entity whose license to provide health care has been revoked, suspended or that has otherwise lost its license. The Social Security Act has always prohibited a physician from providing services on a reimbursable basis in a State where he or she has no license (section 1861(r) of the Act; 42 U.S.C. 1395x(c)). This section carries that prohibition further, and would prohibit, for example, a physician who has lost a license in any State from treating program beneficiaries in every State, even if that physician has a license in another State.

The statute and the regulations refer to licenses that have been "revoked, suspended, * * * or otherwise lost, for reasons bearing on the individual's professional competence, professional performance, or financial integrity." The term "otherwise lost" is intended to cover any situation where the effectiveness of the person's license to provide health care has been interrupted or precluded, regardless of the term used in a particular jurisdiction. The exclusion is not intended normally to apply to losses of license for such infractions as failure to pay dues or improper advertising which, except in an unusual case, would not bear either on the person's ability to properly treat patients or his or her financial integrity. As noted above, however, such a person would still be ineligible for reimbursement in the State that took the

license, based on section 1861(r) of the Act.

Period of exclusion under § 1001.501—The regulations propose that a person who has lost his or her license or who has surrendered it, would be excluded for a period at least as long as that set by the State licensing agency. If surrender, suspension or revocation is for an indefinite period, the OIG would not entertain a request for reinstatement (see discussion below) until such time as the person obtains a valid license from the State where the license was lost. The OIG could also exclude someone for a period longer than the period the licensing board action is effective if the OIG determines that aggravating factors justify a longer exclusion.

Section 1001.601 provides for exclusion of an individual or entity that has been excluded, suspended or otherwise sanctioned by a State health care program or any other Federal program involving the provision of health care. The underlying action must also have been for reasons bearing on the individual's professional competence, professional performance or financial integrity.

Under this section, individuals or entities excluded from any State Medicaid program could be excluded from Medicare. The Department could also exclude from participation in its health care programs any individual or entity that another Federal agency has determined should not be participating in its health care program. For example, if a physician is barred from practicing at Veterans Administration facilities, the OIG could exclude that physician from the Medicare and State health care programs as well. The phrase "or otherwise sanctioned" is intended to cover all actions that limit the ability of a person to participate in the program at issue, regardless of what such a sanction is called. Agencies, for example, use terms such as "debarment," "termination," "suspension" or "exclusion." This section would generally not be used to exclude an individual or entity from the Department's programs based solely on the fact that another agency has imposed a monetary penalty on that individual or entity.

As discussed above, the effect of § 1001.601 would be that a State Medicaid program's decision to exclude someone from that State's program could be translated into a nationwide sanction. The OIG will entertain requests for waiver of the effect of such an exclusion from individual States on a few narrow bases. If such a waiver is granted, it would be effective only in the State or States that requested it.

Period of exclusion under § 1001.601—An exclusion under this section would never be for a period shorter than that imposed by the agency whose action is the basis for this exclusion. In some situations, the OIG may impose a longer exclusion if certain aggravating circumstances exist. If the other agency's action is for an indefinite period, the OIG would not entertain a request for reinstatement until such time as the other agency has let the individual or entity back into its program (see discussion below).

The bases for exclusion discussed above all have in common the fact that they are predicated on the action of another organization, such as the courts or another agency. It is the fact of that action taken by another agency that provides the basis for the exclusion by the OIG. Therefore, the validity of that underlying action may not be challenged in this Department's proceedings. The administrative appeal process is not a forum for collateral attack. If, however, the underlying action is subsequently reversed or vacated *ab initio*, the OIG's action would similarly be vacated.

2. Non-derivative Exclusions

Some of the bases for exclusion are based on factual determinations initially made by the OIG. Several of these non-derivative exclusion authorities are essentially recodifications of pre-existing law while others reflect new authority.

(a) **Section 1001.701—**Section 1001.701(a) would implement section 1128(b)(6)(A) of the Act and, for the most part, represents a recodification of former section 1862(d)(1)(B) of the Act. The general purpose of § 1001.701(a) would be to ensure that the programs are not charged more for covered services than are other payers.

Section 1001.701(b) would implement section 1128(b)(6)(B) of the Act, formerly section 1862(d)(1)(C) of the Act. The statute has been expanded, permitting the exclusion of those who provide unnecessary or substandard care not only to Medicare and State health care program beneficiaries, but to any person. The language of the provision is potentially broad enough to permit the exclusion of individuals and entities that furnish unnecessary services ordered by someone else, where the person actually providing the service would not have any basis for knowing that the service is unnecessary. For example, a pharmacy filling a prescription may not know whether that prescription is either necessary or medically appropriate. Such a pharmacy would not generally be subject to exclusion under this section, however, unless it were in a position to

determine the necessity of the service and in a position to refuse to fill the prescription.

Period of exclusion under § 1001.701—The Department has a very strong interest in ensuring that program beneficiaries receive quality health care. The OIG believes that poor quality care or substantially excessive services are at least as great a threat to the programs and their beneficiaries as the types of behavior that underlie the convictions that serve as a basis for exclusion. Furthermore, where an individual or entity has been determined to be rendering care that does not meet professionally recognized standards, a substantial period of time is necessary to enable the OIG to effectively determine that the care being rendered meets and will continue to meet such standards. The OIG, therefore, proposes to use a five-year exclusion period as a benchmark for exclusions under § 1001.701, with the discretion to alter that period if aggravating or mitigating circumstances exist with respect to the individual or entity involved.

(b) **Section 1001.801—**Section 1001.801 provides for the exclusion of health maintenance organizations (HMOs) and similar types of entities for failure to provide medically necessary items and services where such failure has adversely affected or has a substantial likelihood of adversely affecting program beneficiaries.

Period of exclusion under § 1001.801—The OIG is proposing to use a five-year benchmark in this context for the same reasons discussed above with respect to § 1001.701.

(c) **Sections 1001.901 and 1001.951—**MMPPPA has expanded the bases for exclusion to include any act that is described in sections 1128A or 1128B of the Act. As a result, any activity that would serve as the basis for imposition of a civil money penalty (CMP) under section 1128A may now serve as the basis for an exclusion as well, independent of whether penalties and assessments are also being imposed. In addition, any activity that could be the basis for criminal sanctions may now also serve as the basis for an exclusion, irrespective of whether criminal sanctions are pursued or whether a person is convicted.

Specifically, § 1001.901 provides for exclusion actions based on acts described in section 1128A of the Act (42 U.S.C. 1320a-7a), the CMP law. Section 1001.951 provides for exclusions based on conduct that is also criminal under section 1128B of the Act, a recodification of the criminal provisions formerly contained in sections 1877 and 1909 of

the Act as amended. Exclusion of an individual or entity for committing such an act, however, will not require proof beyond a reasonable doubt as it would if criminal sanctions were being sought. To the contrary, the usual standard of proof in an administrative proceeding, that is, the preponderance of the evidence, would apply. (See *Steadman v. Securities and Exchange Commission*, 450 U.S. 91, 102, *reh'g denied*, 451 U.S. 933 (1981). Also see H.R. Rep. No. 85, part 1, *supra*, at 10; H.R. Rep. No. 85, part 2, *supra*, at 9; S. Rep. No. 109, *supra*, at 10.)

Section 1001.951 not only encompasses what was formerly section 1862(d)(1)(A), the filing of false claims, but also now authorizes an exclusion based on behavior that is described in section 1128B(b) of the Act (formerly sections 1877(b) and 1909(b)), commonly known as the anti-kickback statute. Section 1001.951(b) would make clear that an individual or entity that has offered, paid, solicited or received remuneration as described in section 1128B(b) is subject to exclusion so long as one of the purposes of such remuneration is unlawful under the statute. In other words, liability under the statute could not be avoided by the fact that there may also have been some additional, lawful purpose for the remuneration. Such an arrangement could, however, be raised in a challenge to the length of exclusion proposed by the OIG in accordance with § 1001.952.

This position has been adopted in the context of section 1128B(b) of the Act in the only Court of Appeals decision to address the issue. In *United States v. Greber*, 760 F.2d 68 (3d. Cir.), *cert. denied*, 474 U.S. 988, 106 S.Ct 396 (1985), the Court of Appeals for the Third Circuit stated: "[I]f one purpose of the payment was to induce future referrals, the Medicare statute has been violated." *Id.* at 69. This regulation would specifically follow this interpretation.

The anti-kickback statute contains three statutory exceptions to its broad coverage. In addition, Congress has provided for a rulemaking proceeding to determine the appropriateness of creating additional exceptions or "safe harbors" to coverage of the anti-kickback provision. That rulemaking is being developed separately. (See 54 FR 3088, January 23, 1989). If any new exceptions are promulgated, they will be incorporated as exceptions to the bases for exclusion under this section. When these "safe harbor" regulations take effect, § 1001.951 makes clear that an individual or an entity subject to an exclusion has the burden of demonstrating that the remuneration

that is the subject of the exclusion is specifically exempted by one of these "safe harbor" provisions.

Pending the outcome of that rulemaking, the OIG may exercise its discretion to take action under the language of section 1128B(b). Congress made MMPPPA effective as of September 1, 1987. It simultaneously provided for a two-year timetable for the rulemaking relating to these anti-kickback "safe harbor" provisions, without providing that the use of the exclusion authority relating to kickbacks should await the completion of that rulemaking.

Periods of exclusion under §§ 1001.901 and 1001.951—There is no benchmark being proposed with respect to the length of exclusions taken under §§ 1001.901 and 1001.951. Rather, the proposed regulations list factors that the OIG will consider in setting a length of exclusion. The factors being proposed to determine the length of exclusions under § 1001.901 are similar to those set forth in the CMP law, except that the factor relating to financial condition is not being included because that factor is relevant only to the amount of a penalty or assessment and not to the length of an exclusion.

The rulemaking relating to the anti-kick provisions described above may result in further refinements of the provisions of § 1001.952 concerning the factors that will be considered in determining the length of exclusions based on section 1128B(b) violations.

(d) *Section 1001.1001*—Section 1001.1001 provides for the exclusion of entities when they are owned or controlled by individuals who have been convicted, excluded or have had CMPs or assessments imposed against them. This provision reflects a significant broadening of the authority that the OIG had under former section 1128(b) of the Act to exclude entities under the control or ownership of individuals that had been excluded as a result of convictions of program-related crimes under the former section 1128(a). Under MMPPPA, entities may now be excluded if they are owned or controlled by individuals who have been convicted, had CMPs or assessments imposed against them, or have been excluded from any of the programs under any exclusion authority, including sections 1156 and 1842(j) of the Act. The purpose of this section would be to ensure that the programs do not indirectly reimburse excluded individuals through payments to entities that they control or own or with which they have any significant relationship.

Period of exclusion under § 1001.1001—We are proposing that an

entity excluded under this section be excluded for a period corresponding to the period set for the individual whose relationship with the entity is the basis for the exclusion. If the entity severs its relationship with the individual, it would be eligible to seek reinstatement at such time.

(e) *Sections 1001.1101 and 1001.1201*—Several of the new exclusion authorities relate to the failure to provide certain information to the Department or its agents. The OIG recognizes that these types of actions may not have as severe an impact on the programs and their beneficiaries as do some of the other bases for exclusion set forth above. On the other hand, §§ 1001.1101 and 1001.1201 are based on pre-existing statutory disclosure obligations. The proper administration of the programs depends in large part on the Department having access to information that is required by statute. Balancing these interests, the OIG intends to take its responsibilities under these sections seriously, but in general does not expect to take action based on isolated or unintentional failures to supply information unless such failures have a significant impact on the programs or their beneficiaries.

(f) *Section 1001.1301*—Section 1001.1301 would authorize exclusion for failures to grant immediate access upon reasonable request to certain agency representatives. Congress mandated that the terms "immediate access" and "reasonable request" be defined in regulations. The provision distinguishes between two general types of request for access. The first—proposed in § 1001.1301(a) (1) and (2)—addresses requests by the entities that review compliance by certain types of facilities with their applicable conditions of participation in the programs. Congress recognized that, in most cases, such access will be meaningful only if it is granted at the time the request is made. For example, access to a nursing home by State survey personnel to inspect compliance with on-site nursing services requirements becomes meaningless if the facility has the opportunity before the access is granted to correct a situation that might otherwise violate its condition of participation. Therefore, in the context of this section, we are proposing to define the terms "immediate access" and "reasonable request" to ensure access on the spot. This is intended to be consistent with those rules governing survey agencies that are conducting the surveys.

Section 1001.1301(a) (3) and (4) provides for an exclusion where individuals or entities fail to provide

immediate access to investigators or agents of the OIG or the State Medicaid Fraud Control Units (MFCUs) in conjunction with the investigators' or agents' review of documents related to the control of fraud and abuse in the Department's programs. (The OIG's authority to seek documents is rather broad (42 U.S.C. 3525)). The definition of the phrase "failure to grant immediate access" in this context would mean the failure to produce or make available for inspection and copying requested records, or to provide a compelling reason why such records cannot be produced, within 24 hours. We also propose to define the phrase "reasonable request" as a request in writing presented by a properly identified agent of the OIG or the MFCU. Although the OIG or MFCU must have information to suggest that the individual or entity from whom the documents are being sought has violated a statutory or regulatory requirement, their agents are not obliged to disclose such information except in the context of an exclusion hearing before an ALJ.

These regulations would not require that documents be produced, but only that they be made available for inspection or copying. The requested documents are to be described in writing. Except in unusual situations, we believe that 24 hours should be sufficient time for the individual or entity to determine that the person requesting the documents is a legitimate OIG or MFCU representative, and that authority exists to seek the documents at issue. If the individual or entity does not have control over or access to the requested documents, that would generally constitute a compelling reason why they could not be produced. We believe 24 hours should be sufficient time to make such a determination.

Although the OIG would not in the normal course of action assume that documents are about to be destroyed or altered, where the OIG has reason to believe that this may occur, the OIG must be able to review the documents immediately. Therefore, where the OIG or the MFCU has reason to believe that the destruction or alteration of documents may be occurring, "immediate access upon reasonable request" is proposed to mean on demand.

As a matter of constitutional law, the threat of exclusion from Federal programs as a means of obtaining access to private property is clearly permissible. *Wyman v. James*, 400 U.S. 309, 91 S.Ct. 381 (1971). Even if in some situations where the exercising of OIG's access authority might implicate the

Fourth Amendment and the law of search and seizure, the Government conduct contemplated by § 1001.1301, as proposed, fully comports with constitutional requirements. The test in such circumstances is the reasonableness of the conduct.

With respect to State surveys of facilities, constitutional reasonableness is assured by the comprehensive regulatory scheme under which such surveys are conducted. *Donovan v. Dewey*, 452 U.S. 594, 100 S.Ct. 2534 (1981). Further, the facilities, by virtue of their participation in the Federal programs, have consented to the surveys. (See, for example, *United States v. Brown*, 763 F.2d 984 (1985), cert. denied, 106 S.Ct. 273 (1985).) Consent itself satisfies the reasonableness requirement. *Schneekloth v. Bustamonte*, 412 U.S. 218, 222-23, 93 S.Ct. 2041, 2045 (1973).

With respect to OIG investigations, constitutional reasonableness is assured by the requirement that the OIG possess "information to suggest" a statutory or regulatory violation. The 24-hour period for providing access in ordinary cases is a further indication of reasonableness. However, where it appears that documents may be altered or destroyed, the presence of such "exigent circumstances" is sufficient in terms of reasonableness to justify immediate access. *United States v. Kunkler*, 879 F.2d 187 (9th Cir. 1982); *Pembauer v. City of Cincinnati*, 475 U.S. 469, 106 S.Ct. 1292 (1986). Where there are exigent circumstances, access must be granted at the time it is requested by a properly identified OIG or MFCU agent.

(g) *Section 1001.1401*—Section 1001.1401 provides for the exclusion of a hospital that has failed to comply substantially with a corrective action that has been required under section 1886(f)(2)(B) of the Act. Under that section, the Health Care Financing Administration (HCFA) may require a hospital to adopt corrective action to prevent or correct inappropriate admissions or practice patterns under the prospective payment system. Section 1886(f)(3) of the Act provides procedures for challenging HCFA's determination that there have been inappropriate admissions or practice patterns that warrant the imposition of a corrective action.

Exclusions will be based on HCFA's determination that the hospital has substantially failed to comply with such corrective action, and only issues related to the failure to substantially comply with the corrective action may be appealed in the OIG proceeding. Issues related to the underlying

inappropriate admissions or practice patterns may be contested only in the proceeding under section 1886(f)(3).

(h) *Section 1001.1501*—The exclusion based on the failure to pay back loans and scholarships under proposed § 1001.1501 will be based on a determination by the Public Health Service (PHS) that the individual is in default of a covered obligation. The statute requires the Department to take all reasonable steps available to it to secure repayment of such obligations or loans before it exercises its authority to exclude. The OIG intends to rely on the PHS to take whatever actions it considers reasonable before referring the case to the OIG for an exclusion.

The legislative history suggests that offsets be taken against other money due to the individual from the programs. In addition, the legislative history also reflects that only administrative steps need be taken prior to referral for an exclusion; judicial remedies, such as suits to collect the debt, need not be pursued first.

(i) *Sections 1001.1601 and 1001.1701*—Sections 1001.1601 and 1001.1701 involve exclusions authorized under Public Law 99-272, sections 9307(c)(2) and 9301(b)(2), amending section 1842 (j) and (k) of the Act. These provisions, among other things, provide for exclusions for certain types of billing practices. The exclusions are for a maximum of five years. These sections are largely a recodification of prior regulatory provisions, except that they reflect the amendments contained in Public Law 100-360, the Medicare Catastrophic Coverage Act of 1988, which extended the exclusions to all programs.

C. Notice and Hearing Provisions

There are two different categories of exclusions for the purposes of provisions for notice and hearing: (1) Those where the OIG would provide notice and opportunity to respond prior to imposition of a sanction, and the ALJ hearing to which the excluded party is entitled would occur after the exclusion has taken effect; and (2) those where the statute provides that the exclusion may not take effect until after the ALJ hearing has occurred, unless the health and safety of individuals receiving services warrants otherwise (section 1128(f)(2) of the Act).

For most of the exclusions set forth in part 1001, the individual or entity will have an opportunity to respond in writing to the OIG's proposal to exclude before such exclusion becomes effective. With respect to some of the bases for exclusion, the excluded party would also be permitted to present oral

argument to a representative of the OIG. A full evidentiary hearing before an ALJ would be provided only following the imposition of the exclusion.

These procedures, reflecting established practices, conform not only with the intent of Congress but also with due process. The legislative history makes clear that Congress intended in these cases, with certain exceptions discussed below, that the evidentiary hearings heard by ALJs occur after the exclusion has gone into effect. H.R. Rep. No. 85, part 1, *supra*, at 12-13; H.R. Rep. No. 85, part 2, *supra*, at 13; S. Rep. No. 109, *supra*, at 12-13. Further, it is well-established in a growing list of court decisions that a post-exclusion hearing satisfies the requirements of due process. (See, for example, *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Varandani v. Bowen*, 824 F.2d 304 (4th Cir. 1987); *Koerpel v. Heckler*, 797 F.2d 858 (10th Cir. 1986); *Patchogue Nursing Center v. Bowen*, 797 F.2d 1137 (2d Cir. 1986); *Ram v. Heckler*, 792 F.2d 444 (4th Cir. 1986).)

As set forth in proposed §§ 1001.901 and 1001.951, Congress did provide that, for certain types of exclusions, the individual or entity whose exclusion is proposed is entitled to an ALJ hearing prior to the exclusion being effected, unless the OIG determines that the health or safety of individuals receiving services warrants the exclusion taking effect earlier.

1. Post-Exclusion Hearing Cases

In the cases involving permissive exclusions for which the exclusion may be effected prior to the ALJ hearing, we are proposing that the OIG send a notice to the individual or entity proposed to be excluded (1) indicating OIG's proposed intention to exclude them and the basis for the proposal, and (2) providing them 30 days to respond in writing. In cases where the basis for the proposed exclusion involves complicated factual issues, for example, in §§ 1001.701 or 1001.801, the individual or entity would also be offered the opportunity to meet with an OIG official to argue orally. This is comparable with existing regulations currently in effect.

Following the receipt of written comments, if any, and oral argument where permitted, the OIG would determine whether to impose the sanction. An exclusion would become effective 20 days after the notice of exclusion is sent. The excluded party would then be given the opportunity to request a hearing before an ALJ. As discussed below, we are also proposing to amend the regulations governing those hearings as part of this rulemaking activity in an effort to ensure that the procedures governing hearings in OIG

sanction hearings are as uniform as possible.

Because the exclusions in accordance with the new proposed § 1001.101 are mandatory, and the five-year minimum period is established by statute, the OIG is proposing to send only a notice of exclusion in such instances.

2. Pre-exclusion hearings

For exclusions under proposed §§ 1001.901 and 1001.951, the party would generally be entitled to an ALJ hearing before the exclusion becomes effective. In these types of cases, the party would be given a notice of intent to exclude, similar to the notice currently in use in CMP proceedings, that informs the party of (i) the basis for the exclusion, (ii) the length of the exclusion, and (iii) the right to request a hearing. While the exclusion may not be effected until the ALJ upholds the exclusion, Congress made clear in the legislative history to this statute that the exclusion may be imposed during the pendency of any appeals of the ALJ decision to the Secretary or the courts (S. Rep. 109, *supra*, at 13).

If, in cases under proposed § 1001.901 or 1001.951, the OIG determines that the health and safety of individuals receiving services warrants the exclusion taking effect earlier than after the ALJ decision, the procedures governing post-exclusion hearings would be used.

During the time an individual or entity is excluded, no payment would be made by Medicare or any of the State health care programs for any items or services (i) furnished by the excluded individual or entity, or (ii) if the individual is a physician, ordered under his or her medical direction or prescription. In order to protect Medicare program beneficiaries, HCFA will pay the first otherwise payable claim submitted by a beneficiary enrolled in the Medicare part B program, where the items or services were furnished by an excluded individual or entity. However, HCFA will notify the beneficiary of the exclusion and of the fact that no claims will be paid for services or items furnished 15 days after the notice. An excluded individual or entity is additionally subject to CMPs if it presents, or causes to be presented, a claim for items or services furnished while the exclusion is in effect, regardless of whether HCFA ultimately reimburses the beneficiary.

The statute provides that emergency services furnished by excluded individuals or entities will be payable; the regulations indicate that the emergency nature of such services must be documented by a sworn statement

specifying the nature of the emergency and why the items or services could not have been furnished by a non-excluded individual or entity. In addition, the regulations would make clear that an excluded physician working as an emergency room physician, or in any other capacity where he or she routinely provides emergency health care services, may not be reimbursed for such services.

Appealing an exclusion determination. The OIG's determination to exclude an individual or entity from the program is appealable to an ALJ whether the statute provides for such appeal before or after the exclusion takes effect. The regulations governing the appeals procedures are also being proposed for revision.

Appealable issues are limited to whether (i) there is a basis for liability, and (ii) the period of exclusion is unreasonable. In derivative exclusions—proposed §§ 1001.101 through 1001.601—the ALJ's review of the basis for liability would be limited to determining whether the action was of the type set forth in the statute, that is, for example, whether a conviction entailed or resulted in patient abuse or whether the excluded individual or entity was the one against whom the prior action was taken. The ALJ proceeding would not be a forum for collateral attack of the prior determination; neither substantive nor procedural challenges to the conviction or the licensing action, for example, would be heard. If, on the other hand, such an action is subsequently reversed or vacated on appeal, any exclusion based on such action will be vacated, and the individual or entity reinstated retroactively. If the previous action is modified, but neither reversed nor vacated, the exclusion would not be vacated.

Reinstatement. Although an exclusion would, in most cases, be for a fixed period, that period reflects only that time during which the OIG would not consider a request for reinstatement. Reinstatement is not automatic. Rather, reinstatement is appropriate only where—

“ * * * (A) * * * there is no basis under subsection (a) or (b) [of section 1128 of the Act] or section 1128A for a continuation of the exclusion, and (B) there are reasonable assurances that the types of actions which formed the basis for the original exclusion have not recurred and will not recur.” (Section 1128(g)(2) of the Act.)

An individual or entity may not be reinstated into any of the State health care programs until they are reinstated into the Medicare program. The legislative history of MPPPA makes

clear that the OIG's determination whether reinstatement is appropriate is within its discretion, and is not subject to administrative or judicial review.

Part 1002

42 CFR part 1002 in its current form sets forth the responsibilities of State Medicaid agencies for implementing OIG exclusion and suspension authorities. (Since the enactment of Public Law 100-93, the term "suspension" has been eliminated; what were previously known as suspensions have become one category of exclusions.) As indicated above, the new requirements of Public Law 100-93 would now be incorporated into part 1001, which would require State health care programs, including Medicaid, to exclude those whom the OIG has excluded under Medicare. We believe it is unnecessary, therefore, to repeat these proposed requirements in the revised provisions being set forth in 42 CFR, part 1002.

Instead, the proposed part 1002 would replace the current regulations with provisions pertaining only to State agency-initiated exclusions. These proposed regulations would require State Medicaid agencies to have procedures in place for initiating exclusions of individuals and entities that could be excluded from Medicare under section 1128, 1128A or 1866(b)(2) of the Act. This authority was enacted in Public Law 100-93, and is codified at section 1902(p)(1) of the Act. These new regulatory provisions would place certain minimal requirements on State agencies when they undertake such exclusions—requirements that are substantially consistent with OIG procedures and ensure adequate due process.

Part 1003

The proposed revisions to part 1003, addressing the imposition of civil money penalties, would implement the statutory changes affecting section 1128A of the Social Security Act that were enacted as part of Public Law 100-93. In addition, the regulations at 42 CFR part 1003 would be amended to incorporate a number of statutory revisions made as a result of Public Law 100-203, the Omnibus Budget Reconciliation Act of 1987, Public Law 100-360, the Medicare Catastrophic Coverage Act of 1988, and Public Law 100-485, the Family Support Act of 1988. Finally, we are proposing to remove and recodify specific sections presently contained in part 1003 that set forth the hearing procedures applicable to CMP cases.

Conforming and other technical changes in part 1003 that (1) reflect the transfer of the hearing provisions, (2) substitute the term "exclusion" for "suspension," (3) provide for service of process by any means authorized by Rule 4 of the Federal Rules of Civil Procedure, and (4) extend the time to request a hearing to 60 days, are also being proposed through this rulemaking.

Revisions to the CMP authorities

As enacted, section 3 of Public Law 100-93 revised the language of section 1128A(a) of the Social Security Act, set forth a number of revisions to our existing civil money penalty provisions and provided for three new grounds by which the OIG can levy CMPs.

1. *New CMP provisions.* Under the statute, a penalty, assessment and exclusion may be imposed for claims for physicians services where the individual (1) was not licensed as a physician, (2) was licensed but obtained such license through fraud or misrepresentation, or (3) falsely represented to a patient that he or she was certified in a medical specialty. Additionally, a penalty of up to \$15,000 and an exclusion may be imposed on any person who gives false or misleading information relating to coverage of inpatient hospital services under the Medicare program that could reasonably be expected to influence the decision of when to discharge a person from the hospital. Finally, a penalty and exclusion may be imposed upon a person who requests payment in violation of an agreement not to charge patients for services denied as a result of a determination of an abuse of the prospective payment system.

2. *Technical changes.* Public Law 100-93 amended the notice, effective date, period of exclusion, scope of exclusion, and reinstatement provisions applicable where an exclusion has been imposed in addition to a CMP. These provisions are identical to the exclusion provisions imposed in accordance with section 1128 of the Social Security Act, and are described above in the preamble discussion relating to revisions to part 1001.

The Omnibus Budget Reconciliation Act of 1987 amended section 1128A by revising the standard of knowledge from "knows or has reason to know" to "knows or should know." This change is reflected in these proposed regulations. The Medicare Catastrophic Coverage Act further resulted in the need to incorporate a number of conforming and technical changes into the CMP regulations. All exclusions are now from Medicare and from the State health care programs.

In addition, the statute of limitations applicable to CMP cases has been revised to reflect violations that do not involve claims, and the definition of claim as well as the introductory language in section 1128A was revised. Additional changes to the CMP provisions relating to the provision of services during a period in which the individual was excluded would be revised under these regulations to incorporate all bases for exclusion and to make clear that unassigned claims are covered as well. Finally, the proposed regulations would implement the new section 1128A(1) of the Act which provides that a principal is liable for the acts of his or her agent when functioning within the scope of his or her agency.

Part 1004

In part 1004, Imposition of sanctions on health care practitioners and providers of health care services by a Peer Review Organization, § 1004.130 would be revised and § 1004.100(g) would be deleted in its entirety to be consistent with the proposed establishment of the new part 1005 regulations, as discussed below.

Part 1005

A new and separate part 1005, Appeals of exclusion, civil money penalties and assessments, would be established by revising and recodifying the various hearing procedures set forth in the existing OIG regulations. The new part 1005 would specifically govern administrative law judge (ALJ) hearings and subsequent appeals to the Secretary for all CMP and other OIG sanction cases.

At present, most exclusion proceedings are conducted under procedures set forth under 42 CFR 1001.107, 1001.128 and 1004.128. These sections incorporate by reference all or most of the appeal procedures contained in 42 CFR part 498. In addition, CMP proceedings—and exclusions imposed as a part of a CMP proceeding—are also conducted under procedures set forth in §§ 1003.111 through 1003.132 of the regulations. We are proposing to revise and consolidate these appeals procedures into a new 42 CFR part 1005. This revision and consolidation would serve to substantially simplify the duties of ALJs, attorneys and others who are involved in the administrative adjudication of various OIG cases.

The proposed new hearing regulations are modeled to a significant degree on the hearing and appeal procedures recently adopted by this Department for administrative adjudication of cases

under the Program Fraud Civil Remedies Act (PFCRA) (32 U.S.C. 3801 *et seq.*). The PFCRA regulations were published in final form on April 8, 1988 (53 FR 11656), and were based on the work product of an interagency task force under the direction of the President's Council on Integrity and Efficiency.

The following is a summary of the major elements proposed for inclusion in the new part 1005:

A. Rights of parties; authority of the ALJ

The provisions in §§ 1005.3 and 1005.4 would list the rights of the parties and the authorities of the ALJ not specifically provided in other sections of the regulations.

B. Hearing before an ALJ

The party against whom the OIG has imposed a CMP or exclusion—the "petitioner" in exclusion cases and the "respondent" in CMP cases—may, in writing, request a hearing following receipt of notice of the CMP or exclusion. The requirements for such notice are contained in the respective regulations that apply to each particular CMP or exclusion. If such party fails to file a timely request for a hearing, or thereafter withdraws or abandons his or her request for a hearing, the ALJ is required to dismiss the hearing request. In such a case, the CMP or exclusion would become final with no further appeal permitted.

C. Ex-parte contacts

The provisions in § 1005.5 are designed to ensure the fairness of the hearing by prohibiting ex-parte contacts with the ALJ on matters in issue.

D. Prehearing Conferences

The ALJ is required to schedule at least one prehearing conference. The experience of the OIG has shown that the prehearing conference narrows many of the outstanding issues to be addressed at the hearing and thus helps to expedite the formal hearing process.

E. Discovery

Limited discovery is provided in the form of production for inspection and copying of documents that are relevant and material to the issues before the ALJ. We are specifically proposing that all other forms of discovery, such as depositions and interrogatories, are not authorized. Prehearing discovery is not provided for under the Administrative Procedure Act (APA) and is rarely available in administrative hearings. We believe that full-scale discovery is inappropriate in administrative hearings since full discovery would unduly delay the streamlined administrative process.

These regulations would, however, provide for exchange of relevant and material documents, as well as the exchange of witness lists, prior witness statements and exhibits prior to the hearing, as provided in proposed section 1005.8.

F. Exchange of Witness Lists, Statements and Exhibits

Section 1005.8 would provide for the exchange of certain documents before the hearing, including witness lists, copies of prior statements of witnesses and copies of hearing exhibits. The ALJ would be able to exclude witnesses and documents offered by a party that did not provide such materials before the hearing, except where there is good cause for the failure, or where there is not substantial prejudice to the objecting party. These regulations would provide that the ALJ may recess the hearing for a reasonable time to allow the objecting party the opportunity to prepare and respond to such witnesses or exhibits. This procedure has been followed in the past in CMP cases and has worked successfully.

In addition, any documents exchanged prior to trial would be deemed authentic for purposes of admissibility at the hearing unless a party objected to a particular exhibit before the hearing.

G. Subpoenas

Proposed § 1005.9 would prescribe procedures for the ALJ to issue, and for parties and prospective witnesses to contest, subpoenas to appear at the hearing, as authorized by statute.

H. Motions

The provisions of § 1005.13 set forth requirements for the content of motions and the time allowed for responses.

I. Sanctions

Section 1005.14 would expressly recognize an ALJ's authority to sanction parties and their representatives for failing to comply with an order or procedure, failing to defend an action, or other misconduct. These sanctions are modeled on those of the Merit System Protection Board at 5 CFR 1201.43, and on the regulations implementing PFCRA at 45 CFR 79.29. With respect to CMP cases commenced under section 1128A of the Social Security Act, these sanction authorities are specifically provided for by statute (42 U.S.C. 1320a-7a(c)(4)).

J. The Hearing and Burden of Proof

The burden of proof in ALJ proceedings is being allocated in the following manner. The "burden of proof" has two components—the burden of

going forward and the burden of persuasion. The burden of going forward relates to the obligation to go forward initially with evidence that supports a prima facie case. The burden of going forward then shifts to the other party. In typical administrative litigation, the burden of persuasion relates to the obligation ultimately to convince the trier of fact that it is more likely than not that the position advocated is true. The party with the burden of persuasion loses in the situation where the evidence is in equipoise.

Proposed § 1005.15 would also recognize that the Department has the burden of persuasion in CMP cases with respect to issues of liability and the existence of any factors that might aggravate or increase the amount of penalties and assessments that may be imposed. Conversely, the respondent has the burden of persuasion with respect to affirmative defenses and any mitigating circumstances.

In exclusion cases, which concern the right of the petitioner to continue to participate in Medicare and in the State health care programs, the burden of proof is substantially different. Of course, the OIG would have the burden of going forward with evidence to present a prima facie case to support an exclusion. The burden of going forward then switches to the petitioner who also bears the burden of going forward with respect to affirmative defenses and any mitigating circumstances. The petitioner bears the burden of persuasion with respect to all issues; that is, it is up to the excluded individual or entity to persuade the ALJ that the exclusion is not supportable or that the period of exclusion is unreasonable.

The allocation of the burden of persuasion in exclusion cases is supported by the APA. Specifically, 5 U.S.C. 556(d) states that "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." The courts have interpreted section 556(d) as authorizing a split of the burden of proof; that is, the agency has the burden of going forward with the evidence, but the opposing party may bear the ultimate burden of persuasion. The Supreme Court in *N.L.R.B. v. Transportation Management Corp.*, 462 U.S. 393, 403, n.7 (1983) stated that section 556(d) "determines only the burden of going forward, not the burden of proof." (Also see *Environmental Defense Fund, Inc. v. E.P.A.*, 548 F.2d 998, 1004, n.14 (D.C. Cir. 9176), and *Old Ben Coal Corp. v. Interior Bd. of Mine Op. App.*, 523 F.2d 25, 39-40 (7th Cir. 1975)).

Finally, § 1005.15 would provide that the OIG is not limited at the trial to presentation of items or information that are set forth in the notice letter. As a practical matter in the past, ALJs have traditionally allowed petitioners and respondents to introduce evidence at a hearing that was relevant and material to the issues before the ALJ, irrespective of whether that evidence or issue is referred to in the notice letter. This provision is designed to ensure that the OIG is afforded the same opportunity to introduce items or information, as long as such items or information are relevant and material and otherwise admissible.

K. Witnesses

Under § 1005.16, the ALJ could allow testimony to be admitted in the form of a written statement or deposition so long as the opposing party has a sufficient opportunity to subpoena the person whose statement is being offered. Also, this section would allow an OIG investigator or medical expert to be a witness, in addition to assisting the counsel for the government at counsel table during the hearing. This policy comports with standard practice in federal court under Rule 615 of the Federal Rules of Evidence. Presence of the investigator or medical expert is analogous to the presence of an individual petitioner or respondent, or representative of a corporate respondent, assisting counsel for the petitioner or respondent during the hearing.

L. Evidence

In § 1005.17, paragraphs (a)-(d) are being proposed to comply with Recommendation 86-2 of the Administrative Conference of the United States (1 CFR 305.86-2, 51 FR 25, 641, July 16, 1986). The Federal Rules of Evidence are not, with some exceptions, generally binding on the ALJ. However, the ALJ may apply the Federal Rules of Evidence to exclude unreliable evidence.

M. Post-Hearing Briefs

Section 1005.19 of these proposed regulations would indicate that it is within the ALJ's discretion to order post-hearing briefs, although the parties are entitled to file one if they desire.

N. Initial Decision

The proposed § 1005.20 would provide that not later than 60 days after the filing of final post-hearing briefs, the ALJ shall serve on the parties an initial decision making specific findings of fact and conclusions of law. The initial decision would become final within 60 days unless it is appealed timely.

O. Appeal of Initial Decision

Section 1005.21 would prescribe procedures for any party to appeal the initial decision to the Board by filing a notice of appeal within 45 days, with a possible extension of 15 days. There would be no appeal of an ALJ's interlocutory orders.

P. Stay of Initial Decision

Proposed regulations under § 1005.22 would recodify the provisions formerly located in § 1003.125(f)(5) with respect to a request for a stay of the payment of a CMP or assessment pending review by a U.S. Court of Appeals or the U.S. Supreme Court.

Q. Harmless Error

Section 1005.23 of these proposed regulations would adopt the harmless error rule that applies to civil federal litigation. It is modeled on Rule 61 of the Federal Rules of Civil Procedure.

Part 1006

A new part 1006 would be added to 42 CFR chapter V, and would address the implementation of the OIG's testimonial subpoena authority for investigations of cases under the CMP law. Public Law 100-93 authorized the Secretary to delegate to the Inspector General the authority under section 205(d) of the Act for the purposes of any investigation under section 1128A. Section 205(d) authorizes the issuance of a subpoena requiring the attendance and testimony of witnesses and the production of evidence.

With a delegation signed by the Secretary on April 26, 1988, the OIG has now been given the authority to subpoena witnesses as well as documents in investigations of CMP cases. This encompasses not only investigations involving potential violations set forth in section 1128A, but also in other sections of the Act that incorporate section 1128A(j), such as section 1842(j). As a result of congressional action in recent years, there are currently some 60 bases for monetary penalties relating to the Medicare and Medicaid programs that incorporate section 1128A(j). (The testimonial subpoena authority for CMP investigations is in addition to, and independent of, the OIG's subpoena authority for documents arising from 42 U.S.C. 3525. Part 1006 would neither apply to, nor limit, that authority in any way.)

Specifically, the proposed regulatory provisions in part 1006 would provide for the subpoenaing not only of named individuals, but of unnamed individuals associated with subpoenaed entities. A

subpoenaed entity would be required to name an individual or individuals knowledgeable about the subjects on which information is sought. This procedure is similar to that provided for in Rule 30(b)(6) of the Federal Rules of Civil Procedure.

The taking of subpoenaed testimony, referred to as an investigational inquiry, would take place as provided in proposed § 1006.4. The Administrative Procedure Act provides that a person subpoenaed as a witness is entitled to be accompanied, represented and advised by an attorney (5 U.S.C. 555(b)). Testimony will be taken under oath or affirmation. The proposed regulations provide that any claim of privilege by a witness must be placed on the record by the witness himself or herself. Privileges applicable in investigational inquiries are federally-recognized privileges, as under Rule 501 of the Federal Rules of Evidence.

Since investigational inquiries are non-public investigatory proceedings, a witness' right to retain a copy of the transcript of his or her testimony may be limited for good cause (5 U.S.C. 555(c)). The witness, however, would be entitled to inspect the transcript.

Although the regulations in part 1006 are being set forth in proposed rulemaking, the OIG does not intend to postpone the use of the testimonial subpoena authority in the interim. The OIG will implement this authority in general conformity with these regulations.

Part 1007

Existing regulations addressing the State Medicaid Fraud Control Units, currently set forth in 42 CFR part 1003, subpart C, would be recodified into a new part 1007.

III. Additional Items for Public Comment

In addition to those proposed provisions set forth above, we are seeking public comment on the possible adoption of several other related changes to 42 CFR chapter V.

A. Revising the Definition of "Furnished"

We invite comments on whether the definition of the term "furnished" at 42 CFR 1001.2 should be amended to explicitly encompass medical device manufacturers, drug companies and others who may not participate directly in Medicare or State health care programs ("indirect participants"), but rather provide items or services to providers, practitioners or suppliers who directly participate in these programs ("direct participants"). If the term

"furnished" is defined narrowly, it may limit the effect of an exclusion from the Medicare and State health care programs.

For example, should the definition of "furnished" specifically cover an intraocular lens manufacturer who offers kickbacks to ophthalmologists such that an exclusion under the kickback statute would actually have an effect on the manufacturer? Similarly, should the definition specifically cover a device manufacturer who is convicted of a health care related criminal offense so that the Department could refuse to pay for any item or service provided by that manufacturer to a direct participant? We invite commenters to recommend what modifications are necessary to include indirect participants in the ambit of the definition for "furnished."

B. Defining "Substantially in Excess" and "Usual Charges or Costs"

Proposed § 1001.701(a)(1) provides for the exclusion of individuals or entities that submit, or cause to be submitted, bills or requests for payment containing charges or costs that are "substantially in excess of" the "usual charges or costs" for such items or services. We are considering whether to define in regulations the terms "substantially in excess of" and "usual charges or costs," and we invite comment on whether defining these terms would be useful, and if so, what the appropriate definitions should be.

C. Inclusion of Rule 404(b) of the Federal Rules of Evidence

We are also soliciting comments on whether part 1005, containing the proposed rules for administrative adjudication of all OIG sanction cases, should be amended to specifically recognize and include Rule 404(b) of the Federal Rules of Evidence. Rule 404(b) allows for the introduction of evidence of "other crimes, wrongs or acts" for the purposes of proving knowledge, lack of mistake and existence of a scheme regardless of whether the acts occurred during the statute of limitations period applicable to the counts in issue in the case. We are also soliciting comments on whether it would be appropriate to clarify that proof of "other crimes, wrongs or acts" is an aggravating circumstance in OIG sanction cases.

D. Government-Wide Effect of Exclusions

To protect the interest of the Federal government and to insure proper management and integrity in Federal activities, Executive Orders 12549 and 12689, "Debarment and Suspension," provide that debarment, suspension, or

other exclusion action taken by any Federal agency shall have government-wide effect. Accordingly, with respect to the effect of exclusions taken by this Department, we are proposing that § 1001.1901 will not only apply to participation in Medicare and State health care programs, but may also apply to all Federal nonprocurement health programs. We are soliciting comments on this specific approach as well as on the following alternative approaches for giving government-wide effect to OIG exclusions. Should the regulations provide that:

- Exclusions will apply to all Federal nonprocurement health programs;
- Exclusions may or will apply to all Federal nonprocurement programs;
- Exclusions may or will apply to all Federal procurement and nonprocurement programs?

IV. Regulatory Impact Statement

Introduction

Executive Order 12291 requires us to prepare and publish an initial regulatory impact analysis for any proposed regulation that meets 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 competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601 through 612), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial number of small entities. The analysis is intended to explain what effect the regulatory action by the agency will have on small businesses and other small entities, and to develop lower cost or burden alternatives.

Impact on Providers and Practitioners

We have determined that this rule is not a "major rule" under Executive Order 12291 as it is not likely to meet the criteria for having a significant economic impact. As indicated above, the proposed provisions contained in this rulemaking provide new authorities to the OIG to exclude a person or entity from Medicare and State health care

programs, and to levy civil money penalties and assessments, if they are engaged in a prohibited activity or practice proscribed by statute. These provisions are a result of statutory changes and not this proposed rule, and serve to clarify departmental policy with respect to the imposition of exclusions, CMPs and assessments 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.

Conclusion

For the reasons set forth above, we have determined that no regulatory impact analysis is required for these proposed regulations. In addition, while some penalties and assessments 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, since we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a number of small business entities, we have not prepared a regulatory flexibility analysis.

V. Effect of NPRM on Pending Actions

Until the promulgation of final regulations, the Secretary intends that these proposed regulations shall provide guidance with respect to the imposition and adjudication of OIG sanctions.

List of Subjects

Part 1001

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicare.

Part 1002

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements.

Part 1003

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

Part 1004

Administrative practice and procedure, Health facilities, Health professions, Medicare, Peer Review Organizations (PROs), Penalties, Reporting and recordkeeping requirements.

Part 1005

Administrative practice and procedure, Fraud, Penalties.

Part 1006

Administrative practice and procedure, Fraud, Investigations, Penalties.

Part 1007

Administrative practice and procedure, Fraud, Medicaid, Reporting and recordkeeping requirements.

TITLE 42—PUBLIC HEALTH

42 CFR chapter V would be amended as set forth below:

PART 1000—INTRODUCTION; GENERAL DEFINITIONS

A. Part 1000 would be amended as follows:

1. The authority citation for part 1000 would continue to read as follows:

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

2. In subpart B, the introductory text of § 1000.10 is republished and § 1000.10 would be amended by adding a new definition for the term "beneficiary" to read as follows:

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

* * * * *

Beneficiary means any individual eligible to have benefits paid to him or her, or on his or her behalf, under Medicare or any State health care program.

* * * * *

3. Section 1000.20 would be amended by removing the existing definition for the term "beneficiary."

B. Part 1001 would be revised to read as follows:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS**Subpart A—General Provisions**

Sec.

1001.1 Scope and purpose.

1001.2 Definitions.

Subpart B—Mandatory Exclusions

1001.101 Basis for liability.

1001.102 Length for exclusion.

Subpart C—Permissive Exclusions

1001.201 Conviction related to program or health care fraud.

1001.301 Conviction relating to obstruction of an investigation.

1001.401 Conviction relating to controlled substances.

1001.501 License revocation or suspension.

1001.601 Exclusion or suspension under a Federal or State health care program.

1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

1001.901 Civil money penalty exclusions.

1001.951 Fraud and kickbacks and other prohibited activities.

1001.1001 Exclusion of entities owned or controlled by a sanctioned individual.

1001.1101 Failure to disclose certain information.

1001.1201 Failure to provide payment information.

1001.1301 Failure to grant immediate access.

1001.1401 Violations of PPS corrective action.

1001.1501 Default of health education loan or scholarship obligations.

1001.1601 Violations of the limitations on physician charges.

1001.1701 Billing for services of assistant at surgery during cataract operations.

Subpart D—Waivers and effect of exclusion

1001.1801 Waivers of exclusions.

1001.1901 Effect of exclusion.

Subpart E—Notice and appeals

1001.2001 Notice of proposed exclusion.

1001.2002 Notice of exclusion.

1001.2003 Notice of intent to exclude.

1001.2004 Notice to State agencies.

1001.2005 Notice to State licensing agencies.

1001.2006 Notice to others regarding exclusion.

1001.2007 Appeal of exclusions.

Subpart F—Reinstatement into the programs

1001.3001 Timing and method of request for reinstatement.

1001.3002 Basis for reinstatement.

1001.3003 Approval of request for reinstatement.

1001.3004 Denial of request for reinstatement.

1001.3005 Reversed or vacated decisions.

Authority: Secs. 1102, 1128, 1128B, 1842(j), 1842(k), 1862(d), 1862(e), 1866(b)(2) (D), (E) and (F), and 1871 of the Social Security Act (U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2) (D), (E) and (F), and 1395hh).

Subpart A—General Provisions**§ 1001.1 Scope and purpose.**

The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicare and certain State health care programs. They also state the effect of

exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement in the programs.

§ 1001.2 Definitions.

Controlled substance means:

(a) Drug or other substance, or immediate precursor, included in schedules I, II, III, IV or V of part B of subchapter I in 21 CFR chapter 13, or

(b) As defined by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or dismissed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or nolo contendere by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual, or other person whose care is in issue, recognize as applying to those peers practicing or providing care within a State. Where FDA, HCFA or PHS has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care.

Sole community physician means a physician who is the only physician who provides primary care services within a health manpower shortage area designated by the Public Health Service for primary care. (See 42 CFR part 5 and Appendix A.)

Sole source of essential specialized services in the community means that an individual or entity—

(a) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Public Health Service as a health manpower shortage area for that medical specialty, as listed in 42 CFR part 5, Appendices B through F;

(b) Is a sole community hospital, as defined in § 412.92 of this title;

(c) Is the only source for specialized services in a defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State health care program means:

(a) A State plan approved under title XIX of the Act (Medicaid),

(b) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Block Grant program), or

(c) Any program receiving funds under title XX of the Act or from any allotment to a State under such title (Social Services Block Grant program).

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and § 1002.305 of this chapter.

Subpart B—Mandatory Exclusions

§ 1001.101 Basis for liability.

The OIG shall exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program, or

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients. The conviction need not relate to a patient who is a beneficiary.

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 shall be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, resulted in financial loss to Medicare and the State health care programs of \$1500 or more. (The entire amount of financial loss to such programs will be considered including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made to the programs);

(2) The acts that resulted in the conviction, or similar acts, were

committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had an adverse physical, mental or financial impact on one or more individuals;

(4) The sentence imposed by the court included incarceration;

(5) The convicted individual or entity has a prior criminal, civil or administrative sanction record; or

(6) The individual or entity has at any time been overpaid a total of \$1500 or more by Medicare or State health care programs as a result of improper billings.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than five years. Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of three or fewer misdemeanor offenses, and the entire amount of financial loss to Medicare and the State health care programs due to the acts that resulted in the conviction, and similar acts, is less than \$1500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in others being convicted or excluded from Medicare or any of the State health care programs.

Subpart C—Permissive Exclusions

§ 1001.201 Conviction related to program or health care fraud.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of any health care item or service, or

(2) With respect to any act or omission in a program operated by, or financed in whole or in part by, any Federal State or local government agency.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 5 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and

(b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts, resulted in financial loss of \$1,500 or more to a government program or to one or more other individuals or entities. (The total amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made.);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one or more years;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on individuals or on Medicare or any of the State health care programs;

(iv) The sentence imposed by the court included incarceration; or

(v) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss to a government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than \$1,500;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(iii) The individual's or entity's cooperation with Federal or State officials resulted in others being convicted or excluded from Medicare or any of the State health care programs; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.301 Conviction relating to obstruction of an investigation.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of interference with, or obstruction of, any investigation into a criminal offense described in §§ 1001.101 and 1001.201.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with

this section will be for a period of 5 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The interference with, or obstruction of, the criminal investigation caused the expenditure of significant additional time or resources;

(ii) The interference or obstruction had an adverse, mental, physical or financial impact on patients, witnesses, beneficiaries or on the Medicare or State health care programs;

(iii) The interference or obstruction also affected a civil or administrative investigation;

(iv) The sentence imposed by the court included incarceration; or

(v) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record in the criminal proceedings, including sentencing documents, demonstrates that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in others being convicted or excluded from Medicare or any of the State health care programs; or

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a criminal relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 5 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;

(ii) The acts that resulted in the conviction or similar acts had an adverse physical, mental or financial impact on beneficiaries or the Medicare or State health care programs;

(iii) The sentence imposed by the court included incarceration; or

(iv) The convicted individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for shortening the period of exclusion—

(i) The individual's or entity's cooperation with Federal or State officials resulted in others being convicted or excluded from Medicare or any other of the State health care programs; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance or financial integrity was pending before a State licensing authority.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will never be for a period of time less than the period during which an individual's or entity's license is revoked, suspended or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the revocation, suspension or loss of the individual's or entity's license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more individuals; or

(ii) The individual or entity has a prior criminal, civil or administrative sanction record.

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of

exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with a State licensure authority resulted in the sanctioning of other individuals or entities; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

(4) When an individual or entity has been excluded under this section, the OIG will accept a request for reinstatement in accordance with § 1001.3001 if the individual or entity obtains a valid license in the State where the license was originally revoked, suspended, lost or surrendered.

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under (1) any Federal program involving the provision of health care, or (2) a State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will never be for a period of time less than the period for which the individual or entity is suspended, excluded or otherwise sanctioned under the Federal or State health care program.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The period of exclusion, suspension or other sanction under the Federal or State health care programs does not properly take into account the adverse impact the individual's or entity's action had or could have on Medicare, the State health care programs or the beneficiaries of those programs; or

(ii) The individual or entity has a prior criminal, civil or administrative record.

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies an exclusion longer than the period of suspension, exclusion or other sanction imposed by the Federal or State health care program, may mitigating factors be considered as a basis for reducing the period of exclusion. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with Federal or State officials resulted in the sanctioning of other individuals or entities; or

(ii) Alternative sources of the types of health care items or services furnished by the individual or entity are not available.

(4) The OIG will accept a request for reinstatement in accordance with § 1001.3001 when the individual or entity is reinstated by the Federal or State health care program that originally imposed the suspension, exclusion or other sanction.

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of the usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) *Exceptions.* An individual or entity will not be excluded for—

(1) Bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing items or services in excess of the needs of patients, when the items or services were ordered by a physician, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the physician's order.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 5 years, unless aggravating or mitigating factors listed in paragraphs (c)(2) and (c)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The violations were serious in nature, and occurred over a period of one year or more;

(ii) The violations had a significant adverse physical, mental or financial impact on patients or beneficiaries;

(iii) The individual or entity has a prior criminal, civil or administrative sanction record; or

(iv) The violation resulted in financial loss to Medicare and the State health care programs of \$1,500 or more.

(3) Only the following factors may be considered mitigating and a basis for reducing the period of exclusion—

(i) The violations had no adverse physical, mental or financial impact on individuals, or on Medicare or State health care programs; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

§ 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

(a) *Circumstances for exclusion.* The OIG may exclude an entity—

(1) That is a—

(i) Health maintenance organization, as defined in section 1903(m) of the Act, providing items or services under a State Medicaid Plan;

(ii) Primary care case management system providing services, in accordance with a waiver approved under section 1915(b)(1) of the Act; or

(iii) Health maintenance organization or competitive medical plan providing items or services in accordance with a risk-sharing contract under section 1876 of the Act;

(2) That has failed substantially to provide medically necessary items and services that are required under law or contract to be provided to individuals covered by a plan, waiver or contract; and

(3) Where such failure has adversely affected or has a substantial likelihood of adversely affecting covered individuals.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 5 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The entity failed to provide a large number or a variety of items or services;

(ii) The failures occurred over a lengthy period of time;

(iii) The entity's failure to provide a necessary item or service had or could have had a serious adverse effect; or

(iv) The entity has a criminal, civil or administrative sanction record.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the entity are not available.

§ 1001.901 Civil money penalty exclusions.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

(3) The individual's or entity's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(4) Other matters as justice may require.

§ 1001.951 Fraud and kickbacks and other prohibited activities.

(a) *Circumstance for exclusion.* (1) Except as provided for in paragraph (a)(2)(ii) of this section, the OIG may exclude any individual or entity that it determines has committed an act described in section 1128B of the Act.

(2) With respect to acts described in section 1128B of the Act, the OIG—

(i) May exclude any individual or entity that it determines has knowingly and willfully solicited, received, offered or paid any remuneration in the manner and for the purposes described therein, irrespective of whether the individual or entity may be able to prove that the remuneration was also intended for some other purpose; and

(ii) Will not exclude any individual or entity if that individual or entity can prove that the remuneration that is subject of the exclusion is exempted from serving as the basis for an exclusion.

(b) *Length of exclusion.* (1) The following factors will be considered in determining the length of exclusion in accordance with this section—

(i) The nature and circumstances of the acts and other similar acts;

(ii) The nature and extent of any adverse physical, mental, financial or other impact the conduct had on

beneficiaries or the Medicare or State health programs;

(iii) The excluded individual's or entity's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(iv) Any other facts bearing on the nature and seriousness of the individual's or entity's misconduct.

(2) It shall be considered a mitigating factor if—

(i) The individual had a documented mental, emotional, or physical condition before or during the commission of the prohibited act(s) that reduced the individual's culpability for the acts in question;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the sanctioning of other individuals or entities; or

(iii) Alternative sources of the type of health care items or services provided by the individual or entity are not available.

§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned individual.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any entity in which a person within such entity who:

(i) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2), or (3) of the Act;

(ii) Has had money penalties imposed under section 1128A of the Act; or

(iii) Has been excluded from participation in Medicare or any of the State health care programs—

(A) Has a direct or indirect interest (or any combination thereof) of 5 percent or more in the entity;

(B) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(C) Is an officer or director of the entity, if the entity is organized as a corporation;

(D) Is a partner in the entity, if the entity is organized as a partnership;

(E) Is an agent of the entity; or

(F) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity, or directly or indirectly conducts the day-to-day operations of the entity.

(2) For purposes of this section, the term:

Indirect ownership interest includes an ownership interest through any other entities that ultimately have an

ownership interest in the entity in issue. (For example, an individual has a 10 percent ownership interest in the entity at issue if he or she has a 20 percent ownership interest in a corporation that wholly owns a subsidiary that is a 50 percent owner of the entity in issue.)

Ownership interest includes an interest in:

(i) The capital, the stock or the profits of the entity, or

(ii) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

(b) *Length of exclusion.* (1) Except as provided in § 1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at any time in accordance with the procedures set forth in § 1001.3001(a)(2).

§ 1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the disclosed information;

(3) The entity's prior criminal, civil and administrative sanction record (the lack of any prior record is to be considered neutral);

(4) Any other facts that bear on the nature or seriousness of the conduct;

(5) The availability of alternative sources of the type of health care services provided by the entity; and

(6) The extent to which the entity knew that the disclosures made were not full or accurate.

§ 1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that furnishes items or services for which payment may be made under Medicare or any of the State health care programs and that:

(1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof, or

(2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where information was not provided;

(2) The circumstances under which such information was not provided;

(3) The amount of the payments at issue;

(4) The individual's or entity's criminal, civil or administrative sanction record (the lack of any prior record is to be considered neutral); and

(5) The availability of alternative sources of the type of health care items or services provided by the individual or entity.

§ 1001.1301 Failure to grant immediate access.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

(i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s) (12) and (13) of the Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the requirements of section 1861(p)(4) (A) or (B) of the Act; or

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F)(i) of the Act;

(ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to skilled nursing and intermediate care facilities), 1902(a)(33) and 1903(g) of the Act;

(iii) The OIG for the purposes of reviewing records, documents and other data necessary to the performance of the Inspector General's statutory functions; or

(iv) A State Medicaid fraud control unit for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (a)(1)(ii) of the section, the term—
Failure to grant immediate access means the failure to grant access at the time of a reasonable request;

Reasonable request means a request made by a properly identified agent of the Secretary, of a State survey agency or of another authorized entity, during hours that the facility, agency or institution is open for business.

(3) For purposes of paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the term—

Failure to grant immediate access means:

(i) Except where the OIG or State Medicaid fraud control unit has reason to believe that requested documents are about to be altered or destroyed, the failure to produce or make available for inspection and copying requested records upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request; or

(ii) Where the OIG or State Medicaid fraud control unit has reason to believe that requested documents are about to be altered or destroyed, the failure to provide access to requested records at the time the request is made.

Reasonable request means a request in writing by a properly identified agent of the OIG or a State Medicaid fraud control unit, where there is information to suggest that the individual or entity has violated statutory or regulatory requirements under titles V, XVIII, XIX or XX of the Act.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion.* (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The length of the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(3) The exclusion of an entity may be for a longer period than that established in paragraph (b)(2) of this section based

on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access of Medicare or any of the State health care programs, beneficiaries or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on Medicare or any of the State health care programs, beneficiaries or the public; and

(iv) The entity's prior criminal, civil or administrative sanction record. (The lack of any prior record is to be considered neutral.)

§ 1001.1401 Violations of PPS corrective action.

(a) *Circumstance for exclusion.* The OIG may exclude any hospital that HCFA determines has failed substantially to comply with a corrective action required by HCFA under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion.* The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on Medicare or any of the State health care programs, beneficiaries or the public;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on Medicare or any of the State health care programs, beneficiaries or the public; and

(5) The hospital's prior criminal, civil or administrative sanction record. (The lack of any prior record is to be considered neutral.)

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any individual that the Public Health Service determines—

(i) Is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured in whole or in part by the Secretary; and

(ii) Is not a sole community physician or sole source of essential specialized services in the community.

(2) The OIG must determine that the Public Health Service has taken all reasonable administrative steps to secure repayment of the loans or obligations.

(b) *Length of exclusion.* The individual will be excluded until such time as the Public Health Service notifies the OIG that the default has been cured or the obligations have been

resolved to the PHS's satisfaction. Upon such notice, the OIG will inform the individual of his or her right to request reinstatement.

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) The OIG may exclude a physician whom it determines, for any period beginning on or after January 1, 1987—

(i) Is a non-participating physician under section 1842(h) of the Act;

(ii) Furnished services to a beneficiary; and

(iii) Knowingly and willfully billed for such services actual charges in excess of the maximum allowable actual charges determined in accordance with section 1842(j)(1)(C) of the Act.

(2) An exclusion under this section is limited to the Medicare program.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges;

(iv) The physician's prior criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and

(v) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) *Circumstance for exclusion.* The OIG may exclude a physician whom it determines—

(1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled under part B of the Medicare program for:

(i) Services of an assistant at surgery during a cataract operation, or

(ii) Charges that include a charge for an assistant at surgery during a cataract operation; and

(a) Has not obtained prior approval for the use of such assistant from the appropriate Peer Review Organization (PRO) or Medicare carrier.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in

accordance with this section, the OIG will consider the following factors—

- (i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;
 - (ii) The amount of claims or bills presented;
 - (iii) The circumstances under which the claims or bills were made;
 - (iv) Whether approval for the use of an assistant was requested from the PRO or carrier;
 - (v) The physician's criminal, civil or administrative sanction record (The lack of any prior record is to be considered neutral); and
 - (vi) The availability of alternative sources of the type of health care items or services furnished by the physician.
- (2) The period of exclusion may not exceed 5 years.

Subpart D—Waivers and Effect of Exclusion

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from a State health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b).

(b) A request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(d) In the event a waiver is granted, it is applicable only to the State health care program that requested the waiver.

(e) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

(f) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program.

§ 1001.1901 Effect of exclusion.

(a) Except as otherwise provided, exclusions will be from Medicare and all of the State health care programs. The OIG will exclude the individual or entity from the Medicare program and direct each State agency administering a State health care program to exclude the

individual or entity for the same period. In the case of an individual or entity not eligible to participate in Medicare, the exclusion will still be effective on the date, and for the period, established by the OIG.

(b) Except as otherwise provided in this section, no payment will be made by Medicare or any of the State health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.

(c) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(d) (1) If an enrollee of part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician after the effective date of exclusion, HCFA will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) HCFA will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(e) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare or a State health care program warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(1) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion, and

(2) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of exclusion.

(f)(1) Notwithstanding the other provisions of this section, payment may be made under Medicare or a State health care program for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person

furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(2) Notwithstanding paragraph (f)(1) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

Subpart E—Notice and Appeals

§ 1001.2001 Notice of proposed exclusion.

(a) Except as provided in paragraph (b) of this section and in § 1001.2003, if the OIG proposes to exclude an individual or entity in accordance with Subpart C of this part, it will send written notice of its intent, and the basis for the proposed exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument in response.

(b) If the OIG proposes to exclude an individual or entity in accordance with §§ 1001.701 or 1001.801, it will send written notice of its intent, and the basis for proposed exclusion. Within 30 days of receipt of the notice, which will be deemed to be 5 days from the date on the notice, the individual or entity may submit:

(1) Documentary evidence and written argument against the proposed action, and

(2) A written request to present evidence or argument orally to an OIG official.

(c) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraphs (a) and (b) of this section will so state.

§ 1001.2002 Notice of exclusion.

(a) If the OIG determines that exclusion is warranted after consideration of information received in accordance with § 1001.2001, or in instances of exclusion under subpart B of this part, it will send a written notice of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

(1) The basis for the exclusion;

(2) The length of the exclusion and, where applicable, the factors considered in setting the length;

(3) The effect of the exclusion;

(4) The earliest date on which the OIG will accept a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded individual or entity.

§ 1001.2003 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG intends to exclude an individual in accordance with §§ 1001.901 and 1001.951, it will send written notice of its intent, the basis for the exclusion and its length. If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. Within 60 days, the individual may file a written request for a hearing in accordance with Part 1005 of this chapter. Such request must set forth—

(1) The specific issues or statements in the notice with which the individual or entity disagrees;

(2) The basis for that disagreement;

(3) The defenses on which reliance is intended;

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health and safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter.

(b) (1) If the individual or entity does not make a written request for a hearing as provided for in paragraph (a) of this section, the OIG will send a notice of exclusion as described in § 1001.2002 (b) and (c).

(2) If the individual or entity makes a timely written request for a hearing and the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant an immediate exclusion, an exclusion will not go into effect before an ALJ upholds the determination to exclude.

(c) If the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§ 1001.2001 and 1001.2002.

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with § 1001.1901(d), and, as appropriate, to—

(1) Any entity in which the excluded individual or entity is known to be serving as an employee, administrator, operator, or in which the individual or entity is serving in any other capacity and is receiving payment for providing services (the lack of this notice will not affect HCFA's ability to deny payment for services);

(2) State Medicaid Fraud Control Units;

(3) Peer Review Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;

(5) Medical societies and other professional organizations;

(6) Contractors, health care prepayment plans and other affected agencies and organizations;

(7) The State and Area Agencies on Aging established under title III of the Older Americans Act; and

(8) Any other agencies or organizations as required.

(b) In the case of an exclusion in accordance with § 1001.101 of this chapter and to which it may apply to section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)), HHS will give notice to the Attorney General of the United States of the facts

and circumstances of the exclusion and the length of the exclusion.

§ 1001.2007 Appeal of exclusions.

(a) An individual or entity excluded under this part may file a request for a hearing before an ALJ on the issues of whether:

(1) The basis for the imposition of the sanction exists, and

(2) The length of exclusion is unreasonable.

(b) Except as provided in § 1001.2003, the excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in § 1001.2002 to file a request for such a hearing.

(c) The standard of proof is preponderance of the evidence.

(d) When the exclusion is based on the existence of a conviction, a determination by another government agency or any other prior determination, the basis for the underlying determination is not reviewable and the individual or entity may not collaterally attack the underlying determination, either on substantive or procedural grounds, in this appeal.

(e) The procedures in part 1005 of this chapter will apply to the appeal.

Subpart F—Reinstatement into the Programs

§ 1001.3001 Timing and method of request for reinstatement.

(a) (1) Except as provided in paragraph (a)(2) of this section or in §§ 1001.501(b)(4) and 1001.601(b)(4), an excluded individual or entity (other than those excluded in accordance with § 1001.1001) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion.

(2) An entity under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in § 1001.3002(c) have been met.

(3) Upon receipt of a written request, the OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies and such others as may be necessary to determine whether reinstatement should be granted.

(4) Failure to furnish the required information or authorization will result in the continuation of the exclusion.

(b) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the individual or entity may request reinstatement once the reduced exclusion period expires.

§ 1001.3002 Basis for reinstatement.

(a) Except as provided in paragraph (c) of this section, the OIG will not authorize reinstatement unless—

- (1) The period of exclusion has expired;
 - (2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and
 - (3) There is no additional basis under sections 1128 (a) or (b) or 1128A of the Act for continuation of the exclusion.
- (b) In making the reinstatement determination, the OIG will consider—
- (1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;
 - (2) Conduct of the individual or entity after the date of the notice of exclusion;
 - (3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid or satisfactory arrangements have been made to fulfill these obligations; and
 - (4) Whether HCFA has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations.

(c) An entity excluded in accordance with § 1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity's exclusion—

- (1) Has reduced his or her ownership or control interest in the entity below 5 percent;
- (2) Is no longer an officer, director, agent or managing employee of the entity; or
- (3) Has been reinstated in accordance with paragraph (a) of this section or § 1001.3005.

(d) Reinstatement will not be effective until OIG grants the request and provides notice under § 1001.3003(a)(1). Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in § 1001.3004.

§ 1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, HHS will—

- (1) Give written notice to the excluded individual or entity specifying the date when Medicare participation may resume;
- (2) Notify State agencies that administer the State health care programs that the individual or entity has been reinstated into the Medicare program; and
- (3) To the extent possible, give notice to those agencies, groups, individuals and others that were originally notified of the exclusion.

(b) If the OIG makes a determination to reinstate an individual or entity under Medicare, the State health care program upon notification from the OIG must automatically reinstate the individual or entity under such program, effective on the date of reinstatement under Medicare, unless—

- (1) Reinstatement is not available to such excluded party under State law, or
- (2) A longer exclusion period was established in accordance with the State's own authorities and procedures.

§ 1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to the requesting individual or entity. Within 30 days of the date on the notice, the excluded individual or entity may submit:

- (1) Documentary evidence and written argument against the continued exclusion, or
- (2) A written request to present written evidence and oral argument to an OIG official.

(b) After evaluating any additional evidence submitted by the excluded individual or entity (or at the end of the 30-day period, if none is submitted), the OIG will send written notice either confirming the denial, and indicating that a subsequent request for reinstatement will not be accepted until one year after the date of denial, or consistent with the procedures set forth in § 1001.3003(a).

(c) The decision to deny reinstatement will not be subject to administrative or judicial review.

§ 1001.3005 Reversed or vacated decisions.

(a) An individual or entity will be reinstated into the Medicare program retroactive to the effective date of the exclusion when such exclusion is based on—

- (1) A conviction that is reversed or vacated on appeal; or

(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal.

(b) HCFA will make payment for payable services covered under Medicare that were furnished or performed during the period of exclusion.

(c) The OIG will give notice of a reinstatement under this section in accordance with § 1001.3003(a).

(d) An action taken by OIG under this section will not require any State health care program to reinstate the individual or entity if it has imposed an exclusion under its own authority.

C. Part 1002 would be revised to read as follows:

PART 1002—PROGRAM INTEGRITY—STATE-INITIATED EXCLUSIONS FROM MEDICAID

Subpart A—General Provisions

Sec.

- 1002.1 Scope and purpose.
- 1002.2 General authority.
- 1002.3 Disclosure by providers; information on persons convicted of crimes.
- 1002.100 State plan requirement.

Subpart B—Mandatory Exclusion

- 1002.203 Mandatory exclusion.

Subpart C—Permissive Exclusions

- 1002.210 Permissive exclusions; general authority.
- 1002.211 Effect of exclusion.
- 1002.212 State agency notifications.
- 1002.213 Appeals of exclusions.
- 1002.214 Basis for reinstatement after State agency-initiated exclusion.
- 1002.215 Action on request for reinstatement.

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

- 1002.230 Notification of State or local convictions of crimes against Medicaid.

Authority: Secs. 1102, 1124, 1126, 1128, 1902(a)(4)(A), 1902(a)(30), 1902(a)(39), 1903(a)(6), 1903(b)(3), 1903(i)(2) and 1903(q) of the Social Security Act (42 U.S.C. 1302, 1320a-3, 1320a-5, 1320a-7, 1396(a)(4)(A), 1396a(30), 1396a(39), 1396b(a)(6), 1396b(b)(3), 1396b(i)(2) and 1396b(q)).

Subpart A—General Provisions

§ 1002.1 Scope and purpose.

The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicaid program. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. These regulations also delineate the States'

obligation to inform the OIG of certain Medicaid-related convictions.

§ 1002.2 General authority.

(a) In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare program under sections 1128, 1128A or 1866(b)(2) of the Social Security Act.

(b) Nothing contained in this part should be construed to limiting State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law.

§ 1002.3 Disclosure by providers; information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person described in § 1001.1001(a)(1) of this chapter.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must also promptly notify the Inspector General of any action it takes on the provider's application for participation in the program.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services program.

(2) The Medicaid agency may refuse to enter into, or terminate, a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

§ 1002.100 State plan requirement.

The plan must provide that the requirements of this subpart are met. However, the provisions of these regulations are minimum requirements. The agency may impose broader sanctions if it has the authority to do so under State law.

Subpart B—Mandatory Exclusion

§ 1002.203 Mandatory exclusion.

(a) The State agency, in order to receive FFP, must provide that it will exclude from participation any health maintenance organization (HMO), or entity furnishing services under a waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Could be excluded under § 1001.1001 of this chapter, or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under § 1001.1001 of this chapter.

(b) As used in this section, the term—
Exclude includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

Substantial contractual relationship is one in which the sanctioned individual described in § 1001.1001 of this chapter has direct or indirect business transactions with the organization or entity that, in any fiscal year, amount to more than \$25,000 or 5 percent of the organization's or entity's total operating expenses, whichever is less. Business transactions include, but are not limited to, contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, space or salaried employment.

Subpart C—Permissive Exclusions

§ 1002.210 Permissive exclusions; general authority.

The State agency must have administrative procedures in place that enable it to exclude an individual or entity for any reason for which the Secretary could exclude such individual or entity under parts 489, 1001 or 1003 of this title. The period of such exclusion is at the discretion of the State agency.

§ 1002.211 Effect of exclusion.

(a) *Denial of payment.* Except as provided for in § 1001.1901 (e) and (f) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when a person furnishing such item or service knew, or had reason to know, of the exclusion.

(b) *Denial of FFP.* FFP is not available where the State agency is required to deny payment under paragraph (a) of this section. FFP will be reinstated at such time as the excluded individual or

entity is reinstated in the Medicaid program.

§ 1002.212 State agency notifications.

When the State agency initiates an exclusion under § 1002.210, it must provide to the individual or entity subject to the exclusion notification consistent with that required in Subpart E of Part 1001 of this chapter, and must notify other State agencies, the public, beneficiaries, and others as provided in §§ 1001.2005 and 1001.2006 of this chapter.

§ 1002.213 Appeal of exclusions.

Before imposing an exclusion under § 1002.210, the State agency must give the individual or entity the opportunity to submit documents and written argument against the exclusion. The individual or entity must also be given any additional appeals rights that would otherwise be available under procedures established by the State.

§ 1002.214 Basis for reinstatement after State agency-initiated exclusion.

(a) The provisions of this section and § 1002.215 apply to the reinstatement in the Medicaid program of all individuals or entities excluded in accordance with § 1002.210, if a State affords reinstatement opportunity to those excluded parties.

(b) An individual or entity who has been excluded from Medicaid may be reinstated only by the Medicaid agency that imposed the exclusion.

(c) An individual or entity may submit to the State agency a request for reinstatement at any time after the date specified in the notice of exclusion.

§ 1002.215 Action on request for reinstatement.

(a) The State agency may grant reinstatement only if it is reasonably certain that the types of actions that formed the basis for the original exclusion have not recurred and will not recur. In making this determination, the agency will consider, in addition to any factors set forth in State law—

(1) The conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the agency at the time of the exclusion;

(2) The conduct of the individual or entity after the date of the notice of exclusion; and

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State Health programs, have been paid, or satisfactory arrangements have been made, to fulfill these obligations.

(b) Notice of action on request for reinstatement. (1) If the State agency approves the request for reinstatement, it must give written notice to the excluded party, and to all others who were informed of the exclusion in accordance with § 1002.212, specifying the date on which Medicaid program participation may resume.

(2) If the State agency does not approve the request for reinstatement, it will notify the excluded party of its decision. Any appeal of a denial of reinstatement will be in accordance with State procedures and need not be subject to administrative or judicial review, unless required by State law.

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

§ 1002.230 Notification of State or local convictions of crimes against Medicaid.

(a) The State agency must notify the OIG whenever a State or local court has convicted an individual who is receiving reimbursement under Medicaid of a criminal offense related to participation in the delivery of health care items or services under the Medicaid program.

(b) If the State agency was involved in the investigation or prosecution of the case, it must send notice within 15 days after the conviction.

(c) If the State agency was not so involved, it must give notice within 15 days after it learns of the conviction.

PART 1003—[AMENDED]

D. Part 1003 would be amended to read as follows:

1. The heading of part 1003 would be revised to read as follows:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

2. The authority citation for part 1003 would continue to read as follows:

Authority: Secs. 1102, 1128, 1128A, 1842(j) and 1842(k) of the Social Security Act (42 U.S.C. 1302, 1320a-7, 1320a-7a, 1395u(j) and 1395u(k)).

3. Section 1003.100 would be revised to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128, 1128A, 1842(j) and 1842(k) of the Social Security Act (42 U.S.C. 1320a-7, 1320a-7a, 1395u(j) and 1395u(k)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and assessments against persons who—

(i) Have submitted certain prohibited claims under the Medicare, Medicaid, or the Maternal and Child Health Services or Social Services Block Grant programs;

(ii) Seek payment in violation of the terms of an assignment agreement or a limitation on charges or payments under the Medicare program, or a requirement not to charge in excess of the amount permitted under the Medicaid program; or

(iii) Give false or misleading information that might affect the decision to discharge a Medicare patient from the hospital;

(2) Provides for the exclusion of persons from the Medicare or State health care programs against whom a civil money penalty or assessment has been imposed, and the basis for reinstatement of persons who have been excluded; and

(3) Sets forth the appeal rights of persons subject to a penalty, assessment and exclusion.

4. Section 1003.101 would be amended by removing the definitions *Agent* and *Suspension*; by revising the definitions *Claim*, *Program* and *Request for payment*; and by adding definitions *Exclusion*, *Furnished*, *Social Services Block Grant program* and *State health care program* to read as follows:

§ 1003.101 Definitions.

Claim means an application for payment for an item or service for which payment may be made under the Medicare, Medicaid, Maternal and Child Health Services Block Grant, or Social Services Block Grant programs.

Exclusion means the temporary or permanent barring of a person from participation in the Medicare program or in a State health care program, and that items or services furnished or ordered by such person are not reimbursed under such programs.

Furnished refers to items or services provided directly by, under the direct supervision of, or ordered by a person (either as an employee or in his or her own capacity).

Program means the Medicare, Medicaid, Maternal and Child Health Services Block Grant, and Social Services Block Grant programs.

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

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

5. Section 1003.102 would be amended by revising paragraphs (a), (b) introductory text, (b)(1) introductory text, (b)(1)(ii), (b)(1)(iv), (b)(4), (c)(2), and (c)(3) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent;

(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)); or

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

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(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.

(b) The OIG may impose a penalty against any person whom it determines in accordance with this part—

(1) Has presented or caused to be presented a request for payment in violation of the terms of—

* * * *

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

* * * *

(iv) An agreement in accordance with section 1866(a)(1)(C) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act.

* * * *

(4) Has given to any person, in the case of inpatient hospital services subject to the provisions of section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital.

(c) * * *

(2) In any case in which it is determined that more than one person was responsible for presenting, or causing to be presented, a request for payment or for giving false or misleading information as described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

(3) Under this section, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

6. Section 1001.103 would be revised to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraph (b) 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 of 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).

7. Section 1003.105 would be revised to read as follows:

§ 1003.105 Exclusion from participation in Medicare or a State health care program.

(a) A person subject to a penalty or assessment determined under § 1003.102 may, in addition, be excluded from participation in Medicare for a period of time determined under § 1003.107. The OIG will also direct each appropriate State agency to exclude the person from each State health care program for the same period of time. The OIG may

waive an exclusion from a State health care program upon request of the State agency in accordance with the following provisions—

(1) The OIG will consider an application from a State agency for a waiver if the person is:

(i) The sole community physician, or
(ii) The sole source of essential specialized services in a community.

(2) If a waiver is granted, it is applicable only to the State health care program for which the State agency requested the waiver.

(3) If the State agency subsequently submits evidence that the basis for the waiver no longer exists, the waiver will cease and the person will be excluded from the State health care program for the remainder of the period that such person is excluded from Medicare.

(4) The OIG will notify the State agency whether its request for a waiver has been granted or denied.

(5) The decision to deny a waiver is not subject to administrative or judicial review.

(b) Any exclusion under this section will become effective only after there is a final decision of the Secretary in accordance with §§ 1005.20 or 1005.21 of this chapter, or at any earlier date that the respondent fails, within the time permitted, to exercise his or her right to a hearing under § 1003.109 or administrative review under § 1005.21. The effect of such exclusion will be governed by part 1001 of this chapter.

(c) When the Inspector General proposes to exclude a long-term care facility from the Medicare and Medicaid programs, he or she will at the same time he or she notifies the respondent, notify the appropriate State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the Inspector General's intention to exclude the facility.

8. Section 1003.106 would be amended by revising paragraphs (a), (b) and (c) introductory text to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) In determining the amount of any penalty or assessment, the Department will take into account, in accordance with this section—

(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 of the person submitting the claim or request for payment, or giving the information;

(3) The history of prior offenses of the person submitting the claim or request for payment, or giving the information;

(4) The financial condition of the person presenting the claim or request for payment, or giving the information; and

(5) Such other matters as justice may require.

(b) *Guidelines for determining the amount of the penalty or assessment.* As guidelines for taking into account the factors listed in paragraph (a) of this section, the following circumstances are to be considered—

(1) *Nature and circumstances of the incident.* It should be considered a mitigating circumstance if all the items or services or incidents subject to a determination under § 1003.102 included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or incidents, and the total amount claimed or requested for such items or services was less than \$1,000. It should be considered an aggravating circumstance if—

(i) Such items or services or incidents were of several types, occurred over a lengthy period of time;

(ii) There were many such items or services or incidents (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of incidents);

(iii) The amount claimed or requested for such items or services was substantial; or

(iv) The false or misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission.

(2) *Degree of culpability.* It should be considered a mitigating circumstance if the claim or request for payment for the item or service was the result of an unintentional and unrecognized error in the process respondent followed in presenting claims or requesting payment, and corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if—

(i) The respondent knew the item or service was not provided as claimed or if the respondent knew that the claim was false or fraudulent;

(ii) The respondent knew that the items or services were furnished during a period that he or she had been excluded from participation and that no payment could be made as specified in § 1003.102(a)(3) or because payment would violate the terms of an assignment or an agreement with a State agency or other agreement or limitation on payment under § 1003.102(b); or

(iii) The respondent knew that the information could reasonably be expected to influence the decision of when to discharge a patient from a hospital.

(3) *Prior offenses.* It should be considered an aggravating circumstance if at any time prior to the incident or presentation of any claim or request for payment which included an item or service subject to a determination under § 1003.102, 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 reimbursement for medical services.

(c) As guidelines for determining the amount of the penalty and assessment to be imposed, for every item or service or incident subject to a determination under § 1003.102:

9. Section 1003.107 would be revised to read as follows:

§ 1003.107 Determinations regarding exclusion.

(a) In determining whether to exclude a person and the duration of an exclusion, the Department will take into account the circumstances set forth in § 1003.106(a) and described in § 1003.106(b). Where there are aggravating circumstances as described in § 1003.106(b), the person should be excluded. In the case of an exclusion based on a determination under § 1003.102(b) (2) or (3), the length of the exclusion may not exceed 5 years.

(b) The guidelines set forth in this section are not binding. Moreover, nothing in this section will limit the authority of the Department to settle any issue or case as provided by § 1003.126 or to compromise any exclusion as provided by § 1003.128.

10. Section 1003.109 would be amended by revising paragraphs (a) and (b) to read as follows:

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes to impose a penalty and assessment, or to exclude a respondent from participation in Medicare or a State health care program in accordance with this part, he or she must serve notice of the action by any manner authorized by Rule 4 of the Federal Rules of Civil Procedure. The notice will include—

(1) Reference to the statutory basis for the penalty, assessment and exclusion;

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

(except in cases where the Inspector General is relying upon statistical sampling in accordance with § 1003.133 in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and will also briefly describe the statistical sampling technique utilized by the Inspector General);

(3) The reason why such claims, requests for payment or incidents subject the respondent to a penalty, assessment and exclusion; the amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(4) Any circumstances described in § 1003.106 which were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

(5) Instructions for responding to the notice, including a specific statement of respondent's right to a hearing, of the fact that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and

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

(b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion in accordance with part 1005 of this chapter.

11. Section 1003.110 would be amended by substituting the word "exclusion" in place of the word "suspension" every time it appears; and by revising the citation in the first sentence to read as "§ 1003.109(a)".

12. Sections 1003.111 through 1003.113 would be removed.

13. Section 1003.114 would be revised to read as follows:

§ 1003.114 Collateral estoppel.

(a) Where a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part that—

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

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

§§ 1003.115, 1003—1003.125 [Removed]

14. Sections 1003.115 through 1003.125 would be removed.

15. Section 1003.127 would be revised to read as follows:

§ 1003.127 Judicial review.

Section 1128A(e) of the Act authorizes judicial review of a penalty, assessment or exclusion that has become final. Judicial review may be sought by a respondent only with respect to a penalty, assessment or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this chapter unless the failure or neglect to urge such exception will be excused by the court in accordance with section 1128A(e) because of extraordinary circumstances.

16. Section 1003.128 would be amended by revising paragraphs (a) and (d) to read as follows:

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of HCFA, except in the case of the Maternal and Child Health Services Block Grant program, where the collection will be the responsibility of the Public Health Service, and in the case of the Social Services Block Grant program, where the collection will be the responsibility of the Office of Human Development Services.

(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.

17. Section 1003.129 would be revised to read as follows:

§ 1003.129 Notice to other agencies.

Whenever a penalty, assessment or exclusion become final, the following organizations and entities will be notified about such action and the reasons for it—the appropriate State or local medical or professional association; the appropriate Peer Review Organization; as appropriate,

the State agency responsible or the administration of each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

§§ 1003.130 and 1003.131 [Removed]

18. Sections 1003.130 and 1003.131 would be removed.

19. Section 1003.132 would be revised to read as follows:

§ 1003.132 Limitations.

No action under this part will be entertained unless commenced, in accordance with § 1003.109(a) of this part, within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

§ 1003.133 [Amended]

20. Section 1003.113 would be amended by revising the citation in the introductory clause of the first sentence of paragraph (a) from "§ 1003.114" to "§ 1005.15 of this chapter".

21. New §§ 1003.134 and 1003.135 would be added to read as follows:

§ 1003.134 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of §§ 1001.3001 through 1001.3004 of this chapter.

§ 1003.135 Effect of exclusion.

The effect of an exclusion will be as set forth in § 1001.2005 of this chapter.

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A PEER REVIEW ORGANIZATION

E. Part 1004 would be amended to read as follows:

1. The authority citation for part 1004 would continue to read as follows:

Authority: Secs. 1102 and 1156 of the Social Security Act (42 U.S.C. 1302 and 1320c-5).

§ 1004.100 [Amended]

2. Section 1004.100 would be amended by removing paragraph (g).

3. Section 1004.130 would be revised to read as follows:

§ 1004.130 Appeal rights.

(a) *Right to administrative review.* (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in § 1004.90(e), the following limitations apply—

(i) The period for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed, will not be considered by the OIG.

(3) The OIG's determination continues in effect unless reversed by a hearing.

(b) *Right to judicial review.* Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

F. A new part 1005 would be added to read as follows:

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

Sec.	
1005.1	Definitions.
1005.2	Hearing before an administrative law judge.
1005.3	Rights of parties.
1005.4	Authority of the ALJ.
1005.5	Ex parte contacts.
1005.6	Prehearing conferences.
1005.7	Discovery.
1005.8	Exchange of witness lists, witness statements and exhibits.
1005.9	Subpoenas for attendance at hearing.
1005.10	Fees.
1005.11	Form, filing and service of papers.
1005.12	Computation of time.
1005.13	Motions.
1005.14	Sanctions.
1005.15	The hearing and burden of proof.
1005.16	Witnesses.
1005.17	Evidence.
1005.18	The record.
1005.19	Post-hearing briefs.
1005.20	Initial decision.
1005.21	Appeal to Secretary or delegate.
1005.22	Stay of initial decision.
1005.23	Harmless error.

Authority: Secs. 205(a), 205(b), 1102, 1128, 1128A and 1156 of the Social Security Act (42 U.S.C. 405(a), 405(b), 1302, 1320a-7, 1320a-7a and 1320c-5).

§ 1005.1 Definitions.

Exclusion cases refer to all proceedings arising under parts 1001 and 1004 of this chapter.

Civil money penalty cases refer to all proceedings arising under part 1003 of this title.

§ 1005.2 Hearing before an administrative law judge.

(a) A party sanctioned under any criteria specified in parts 1001, 1003 and 1004 of this chapter may request a hearing before an administrative law judge (ALJ).

(b) In exclusion cases, the parties to the hearing proceeding will consist of the petitioner and the IG. In civil money penalty cases, the parties to the hearing proceeding will consist of the respondent and the IG.

(c) The request for a hearing will be made in writing, signed by the petitioner or respondent or by his or her attorney. The request must be filed within 60 days after the notice letter is received by the petitioner or respondent. For purposes of this section, the date of receipt of the notice letter will be presumed to be 5 days after the date of such notice unless there is a reasonable showing to the contrary.

(d) The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect.

(e) The ALJ will dismiss a hearing request where—

(1) The petitioner's or the respondent's hearing request is not filed in a timely manner;

(2) The petitioner or respondent withdraws his or her request for a hearing; or

(3) The petitioner or respondent abandons his or her request for a hearing.

§ 1005.3 Rights of parties.

(a) Except as otherwise limited by this part, all parties may—

(1) Be accompanied, represented and advised by an attorney;

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

(3) Conduct discovery of documents as permitted by this Part;

(4) Agree to stipulations of fact or law which will be made part of the record;

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

(6) Present and cross-examine witnesses;

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

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

(b) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of section 206 of title II of the Act, which authorizes

the Secretary to specify or limit these fees.

§ 1005.4 Authority of the ALJ.

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

(b) The ALJ has the authority to—

- (1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;
 - (2) Continue or recess the hearing in whole or in part for a reasonable period of time;
 - (3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
 - (4) Administer oaths and affirmations;
 - (5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;
 - (6) Rule on motions and other procedural matters;
 - (7) Regulate the scope and timing of documentary discovery as permitted by this part;
 - (8) Regulate the course of the hearing and the conduct of representatives and parties;
 - (9) Examine witnesses;
 - (10) Receive, rule on, exclude or limit evidence;
 - (11) Upon motion of a party, take official notice of facts;
 - (12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact; and
 - (13) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone.
- (c) The ALJ does not have the authority to—
- (1) Find Federal statutes or regulations invalid, or to enjoin any act of the Secretary;
 - (2) Enter an order in the nature of a directed verdict; or
 - (3) Compel settlement negotiations.

§ 1005.5 Ex parte contacts.

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

§ 1005.6 Prehearing conferences.

(a) The ALJ will schedule at least one prehearing conference, and may schedule additional prehearing

conferences as appropriate, upon reasonable notice to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

- (1) Simplification of the issues;
 - (2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;
 - (3) Stipulations and admissions of fact or as to the contents and authenticity of documents;
 - (4) Whether the parties can agree to submission of the case on a stipulated record;
 - (5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;
 - (6) Limitation of the number of witnesses;
 - (7) Scheduling dates for the exchange of witness lists and of proposed exhibits;
 - (8) Discovery of documents as permitted by this Part;
 - (9) The time and place for the hearing; and
 - (10) Such other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings.
- (c) The ALJ will issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 1005.7 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ.

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

(c) Except as permitted by this part, requests for documents, requests for admissions, written interrogatories, depositions and any other forms of discovery are not authorized.

(d)(1) Within 10 days of service of a request for production of documents, a party may file a motion for a protective order.

(2) The ALJ may grant a motion for a protective order if he or she finds that the discovery sought:

- (i) Is unduly costly or burdensome,
- (ii) Will unduly delay the proceeding, or
- (iii) Seeks privileged information.

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

§ 1005.8 Exchange of witness lists, witness statements and exhibits.

(a) At least 15 days before the hearing, or at such other time as may be ordered by the ALJ, the parties will exchange witness lists, copies of prior written statements of proposed witnesses and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 1005.16.

(b) If a party objects, the ALJ will not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as specified in paragraph (a) of this section unless the ALJ finds good cause for the failure, or that there is no substantial prejudice to the objecting party. The ALJ may recess the hearing for such time to allow the objecting party the opportunity to prepare and respond to such witness or exhibit.

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

§ 1005.9 Subpoena for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of an individual may also require the individual to produce evidence at the hearing in accordance with § 1005.7.

(c) A party seeking a subpoena will file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. Such request will:

- (1) Specify any evidence to be produced,
- (2) Designate the witnesses, and
- (3) Describe the address and location with sufficient particularity to permit such witness to be found.

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

(e) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(f) If the motion requesting issuance of a subpoena is granted, the party seeking

the subpoena will serve it by delivery to the individual named, or by certified mail addressed to such individual at his or her last dwelling place or principal place of business.

(g) The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(h) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in section 205(e) of the Social Security Act (42 U.S.C. 405(e)).

§ 1005.10 Fees.

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

§ 1005.11 Form, filing and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ will include an original and two copies.

(2) Every pleading and paper filed in the proceeding will contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

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

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

(b) *Service.* A party filing a document with the ALJ or the Secretary will, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document will be made by delivering a copy, or placing a copy of the document will be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service will be made upon such attorney in lieu of the party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting

forth the manner of service, will be proof of service.

§ 1005.12 Computation of time.

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

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays and legal holidays observed by the Federal Government will be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 1005.2.

§ 1005.13 Motions.

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

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

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

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

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

§ 1005.14 Sanctions.

(a) The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. Such sanctions will reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(1) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating such refusal as an

admission by deeming the matter, or certain facts, to be established;

(2) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(3) Striking pleadings, in whole or in part;

(4) Staying the proceedings;

(5) Dismissal of the action;

(6) Entering a decision by default; and

(7) Refusing to consider any motion or other action that is not filed in a time manner.

(b) In civil money penalty cases commenced under section 1128A of the Act or under any provision which incorporates section 1128A(c)(4) of the Act, the ALJ may also order the party or attorney who has engaged in any of the acts described in paragraph (a) of this section to pay attorney's fees and other costs caused by the failure or misconduct.

§ 1005.15 The hearing and burden of proof.

(a) The ALJ will conduct a hearing on the record in order to determine whether the petitioner or respondent should be found liable under this part.

(b) *Burden of proof in exclusion cases.* In exclusion cases—

(1) The petitioner bears the burden of going forward with respect to affirmative defenses and any mitigating circumstances;

(2) The IG bears the burden of going forward with respect to all other issues; and

(3) The petitioner bears the burden of persuasion with respect to all issues.

(c) *Burden of proof in civil money penalty cases.* In civil money penalty cases—

(1) The respondent bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances; and

(2) The IG bears the burden of going forward and the burden of persuasion with respect to all other issues.

(d) The burden of persuasion will be judged by a preponderance of the evidence.

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

(f) A hearing under this part is a de novo hearing with respect to those violations of law specified in the notice letter, and is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Additional items or information may be introduced at the hearing, if deemed otherwise admissible by the ALJ.

§ 1005.16 Witnesses.

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

(b) At the discretion of the ALJ, testimony (other than expert testimony) may be admitted in the form of a written statement. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner that allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statement of witnesses proposed to testify at the hearing will be exchanged as provided in § 1005.8.

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

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

(2) Avoid repetition or needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

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

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses. This does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

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

§ 1005.17 Evidence.

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

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

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

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

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

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

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

(h) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the ALJ for good cause shown.

§ 1005.18 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ at a cost not to exceed the actual cost of duplication. No transcription or duplication fee will be charged to the IG.

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

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order any part of the record sealed, or appropriate redactions made to the record.

§ 1005.19 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ will fix the time for filing such briefs which are not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 1005.20 Initial decision.

(a) The ALJ will issue an initial decision, based only on the record, which will contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or vacate the imposition of the exclusion. In exclusion cases where the period of exclusion commenced prior to the hearing, any period of exclusion imposed by the ALJ will be deemed to commence on the date such exclusion originally went into effect.

(c) The ALJ will promptly serve the initial decision on all parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. The decision will be accompanied by a statement describing the right of any party to file a notice of appeal with the Secretary and instructions for how to file such appeal. If the ALJ fails to meet the deadline contained in this paragraph, he or she will notify the parties of the reason for the delay and will set a new deadline.

(d) Unless the initial decision of the ALJ is timely appealed to the Secretary, the initial decision will be final and binding on the parties 60 days after it is issued by the ALJ.

§ 1005.21 Appeal to Secretary or delegate.

(a) Any party may appeal the initial decision of the ALJ to the Secretary, or his or her delegate, by filing a notice of appeal with the Secretary within 30 days of the date of issuance of the initial decision. The Secretary may extend the initial 30 day period for an additional 15 days if a party files with Secretary a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the Secretary, the ALJ will forward the record of the proceeding to the Secretary.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief. The Secretary may permit the parties to file reply briefs.

(d) There is no right to appear personally before the Secretary, or to appeal to the Secretary any interlocutory ruling by the ALJ.

(e) The Secretary will not consider any exception not based on an objection that was raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(f) If any party demonstrates to the satisfaction of the Secretary that additional evidence not presented at such hearing is relevant and material and that there were extraordinary circumstances that account for the failure to present such evidence at such hearing, the Secretary may remand the matter to the ALJ for consideration of such additional evidence.

(g) The Secretary may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty,

assessment or exclusion determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

(i) The Secretary will promptly serve each party to the appeal with a copy of the decision of the Secretary and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired.

(j) After a petitioner or respondent has exhausted all administrative remedies under this part and unless a petition for judicial review is filed as provided by statute, after 60 days following the date on which the Secretary serves the petitioner with a copy of the Secretary's decision, a determination that a petitioner or respondent is found liable is final and is not subject to judicial review.

§ 1005.22 Stay of Initial decision.

(a) In civil money penalty cases, the filing of a respondent's request for review by the Secretary will automatically stay the effective date of the initial decision. After the Secretary renders a decision, the respondent may file with the ALJ a request for stay of the effective date of the final administrative decision pending appeal to the courts, as permitted by statute. Such a request will state the grounds upon which respondent relies in requesting the stay, together with a copy of the notice(s) of appeal filed by respondent seeking review of the final administrative decision. The filing of such a request will automatically act to stay the effective date of the final administrative decision until such time as the ALJ rules upon the request.

(b) The IG may file an opposition to respondent's request for a stay within 10 days of receipt of the request. If the IG fails to file such an opposition within the allotted time, or indicates that he or she has no objection to the request, the ALJ will grant the stay without requiring respondent to give a bond or other security.

(c) In those cases in which the IG opposes respondent's request for a stay, the ALJ may grant respondent's request where justice so requires and to the extent necessary to prevent irreparable harm. An ALJ may grant an opposed request to stay a final decision requiring the payment of money only upon the respondent's giving of a bond or other

adequate security. The ALJ will rule upon an opposed request for stay within 10 days of the receipt of the opposition of the IG. A decision of the ALJ denying respondent's request for a stay will constitute final agency action.

§ 1005.23 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties, including Federal representatives such as Medicare carriers and intermediaries and Peer Review Organizations, is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the Secretary inconsistent with substantial justice. The ALJ and the Secretary at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

G. A new part 1006 would be added to read as follows:

PART 1006—INVESTIGATIONAL INQUIRIES

Sec.

- 1006.1 Scope.
- 1006.2 Contents of subpoena.
- 1006.3 Service and fees.
- 1006.4 Procedures for investigational inquiries.
- 1006.5 Enforcement of a subpoena.

Authority: Secs. 205(d), 205(e), 1102 and 1128A of the Social Security Act (42 U.S.C. 405(d), 405(e), 1302 and 1320a-7a).

§ 1006.1 Scope.

(a) The provisions in this Part govern subpoenas issued by the Inspector General, or his or her delegates, in accordance with sections 205(d) and 1128A(j) of the Act, and require the attendance and testimony of witnesses and the production of any other evidence at an investigational inquiry.

(b) Such subpoenas may be issued in investigations under section 1128A of the Act or under any other section of the Act that incorporates the provisions of section 1128A(j).

(c) Nothing in this Part is intended to apply to or limit the authority of the Inspector General, or his or her delegates, to issue subpoenas for the production of documents in accordance with 5 U.S.C. App. 3 section 6(a)(4).

§ 1006.2 Contents of subpoena.

A subpoena issued under this part will—

(a) State the name of the individual or entity to whom the subpoena is addressed;

(b) State the statutory authority for the subpoena;

(c) Indicate the date, time and place that the investigational inquiry at which the witness is to testify will take place;

(d) Include a reasonably specific description of any documents or items required to be produced; and

(e) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In such event, the named entity will designate one or more individuals who will testify on its behalf, and will state as to each individual so designated that individual's name and address and the matters on which he or she will testify. The individual so designated will testify as to matters known or reasonably available to the entity.

§ 1006.3 Service and fees.

(a) A subpoena under this part will be served by—

(1) Delivering a copy to the individual named in the subpoena;

(2) Delivering a copy to the entity named in the subpoena at its last principal place of business; or

(3) Registered or certified mail addressed to such individual or entity at its last known dwelling place or principal place of business.

(b) A verified return by the individual serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signing return post office receipt, will be proof of service.

(c) Witnesses will be entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Such fees need not be paid at the time the subpoena is served.

§ 1006.4 Procedures for investigational inquiries.

(a) Testimony at investigational inquiries will be taken under oath or affirmation.

(b) Investigational inquiries are non-public investigatory proceedings. Attendance of non-witnesses is within the discretion of the OIG, except that—

(1) A witness is entitled to be accompanied, represented and advised by an attorney; and

(2) Representatives of the OIG and the Office of the General Counsel are entitled to attend and ask questions.

(c) A witness will have an opportunity to clarify his or her answers on the record following the questions by the OIG.

(d) Any claim of privilege must be asserted by the witness on the record.

(e) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to the objection.

(f) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the OIG may seek enforcement of the subpoena under § 1006.5.

(g)(1) The proceedings will be recorded and transcribed.

(2) The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(3)(i) The transcript will be submitted to the witness for signature.

(ii) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the OIG written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(iii) Where, as provided in paragraph (g)(2) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days or receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(iv) The OIG's proposed revisions to the transcript will be attached to the transcript.

(h) Testimony and other evidence obtained in an investigational inquiry may be used by the OIG or DHHS in any of its activities, and may be used or offered into evidence in any administrative or judicial proceeding.

§ 1006.5 Enforcement of a subpoena.

A subpoena to appear at an investigational inquiry is enforceable through the District Court of the United States and the district where the

subpoenaed person is found, resides or transacts business.

H. A new part 1007 would be added to read as follows:

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

Sec.

- 1007.1 Definitions.
- 1007.3 Scope and purpose.
- 1007.5 Basic requirement.
- 1007.7 Organization and location requirements.
- 1007.9 Relationship to, and agreement with, the Medicaid agency.
- 1007.11 Duties and responsibilities of the unit.
- 1007.13 Staff requirements.
- 1007.15 Applications, certification and recertification.
- 1007.17 Annual report.
- 1007.19 Federal financial participation (FFP).
- 1007.21 Other applicable HHS regulations.

Authority: Secs. 1903(a)(6), 1903(b)(3) and 1903(g) of Social Security Act (42 U.S.C. 1396b(a)(6), 1396b(b)(3) and 1396b(q)).

§ 1007.1 Definitions.

As used in this part, unless otherwise indicated by the context:

Employ or employee, as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is on full-time detail or assignment to the unit from another government agency, if the detail or assignment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

Provider means an individual or entity which furnishes items or services for which payment is claimed under Medicaid.

Unit means the State Medicaid fraud control unit.

§ 1007.3 Scope and purpose.

This part implements sections 1903(a)(6), 1903(b)(3), and 1903(g) of the Social Security Act, as amended by the Medicare-Medicaid Anti-fraud and Abuse Amendments (Pub. L. 95-142 of October 25, 1977). The statute authorizes the Secretary to pay a State 90 percent of the costs of establishing and operating a State Medicaid fraud control unit, as defined by the statute, for the purpose of eliminating fraud in the State Medicaid program.

§ 1007.5 Basic requirement.

A State Medicaid fraud control unit must be a single identifiable entity of the State government certified by the Secretary as meeting the requirements of §§ 1007.7 through 1007.13.

§ 1007.7 Organization and location requirements.

Any of the following three alternatives is acceptable:

(a) The unit is located in the office of the State attorney general or another department of State government which has statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the provision or administration of medical assistance under a State plan implementing Title XIX of the Act; or

(b) If there is no State agency with statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures which assure that the unit refers suspected cases of criminal fraud in the State Medicaid program to the appropriate State prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases; or

(c) The unit has a formal working relationship with the office of the State attorney general and has formal procedures for referring to the attorney general suspected criminal violations occurring in the State Medicaid program and for effective coordination of the activities of both entities relating to the detection, investigation and prosecution of those violations. Under this requirement, the office of the State attorney general must agree to assume responsibility for prosecuting alleged criminal violations referred to it by the unit. However, if the attorney general finds that another prosecuting authority has the demonstrated capacity, experience and willingness to prosecute an alleged violation, he or she may refer a case to that prosecuting authority, as long as the Attorney General's Office maintains oversight responsibility for the prosecution and for coordination between the unit and the prosecuting authority.

§ 1007.9 Relationship to, and agreement with, the Medicaid agency.

(a) The unit must be separate and distinct from the Medicaid agency.

(b) No official of the Medicaid agency shall have authority to review the activities of the unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.

(c) The unit shall not receive funds paid under this subpart either from or through the Medicaid agency.

(d) The unit shall enter into an agreement with the Medicaid agency under which the Medicaid agency will

agree to comply with all requirements of § 455.21(a)(2) of this title.

§ 1007.11 Duties and responsibilities of the unit.

(a) The unit shall conduct a statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan.

(b) The unit shall also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities.

(1) If the initial review indicates substantial potential for criminal prosecution, the unit shall investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.

(2) If the initial review does not indicate a substantial potential for criminal prosecution, the unit shall refer the complaints to an appropriate State agency.

(c) If the unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider of medical assistance under the State Medicaid plan, the unit shall either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection.

(d) Where a prosecuting authority other than the unit is to assume responsibility for the prosecution of a case investigated by the unit, the unit shall insure that those responsible for the prosecutive decision and the preparation of the case for trial have the fullest possible opportunity to participate in the investigation from its inception and will provide all necessary assistance to the prosecuting authority throughout all resulting prosecutions.

(e) The unit shall make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and shall cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.

(f) The unit shall safeguard the privacy rights of all individuals and shall provide safeguards to prevent the misuse of information under the unit's control.

§ 1007.13 Staffing requirements.

(a) The unit shall employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner. The staff must include:

(1) One or more attorneys experienced in the investigation or prosecution of civil fraud or criminal cases, who are capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(2) One or more experienced auditors capable of supervising the review of financial records and advising or assisting in the investigation of alleged fraud;

(3) A senior investigator with substantial experience in commercial or financial investigations who is capable of supervising and directing the investigative activities of the unit.

(b) The unit shall employ, or have available to it, professional staff who are knowledgeable about the provision of medical assistance under title XIX and about the operation of health care providers.

§ 1007.15 Applications, certification, and recertification.

(a) *Initial application.* In order to receive FFP under this subpart, the unit must submit to the Secretary, an application approved by the Governor, containing the following information and documentation.

(1) A description of the applicant's organization, structure, and location within State government, and an indication of whether it seeks certification under § 1007.7 (a), (b) or (c);

(2) A statement from the State attorney general that the applicant has authority to carry out the functions and responsibilities set forth in this subpart. If the applicant seeks certification under § 1007.7(b), the statement must also specify either that there is no State agency with the authority to exercise statewide prosecuting authority for the violations with which the unit is concerned, or that, although the State attorney general may have common law authority for statewide criminal prosecutions, he or she has not exercised that authority;

(3) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures required under § 1007.7(b), or the formal working relationship and procedures required under § 1007.7(c);

(4) A copy of the agreement with the Medicaid agency required under § 1007.9;

(5) A statement of the procedures to be followed in carrying out the functions and responsibilities of this subpart;

(6) A projection of the caseload and a proposed budget for the 12-month period for which certification is sought; and

(7) Current and projected staffing, including the names, education, and experience of all senior professional staff already employed and job descriptions, with minimum qualifications, for all professional positions.

(b) *Conditions for, and notification of certification.* (1) The Secretary will approve an application only if he or she has specifically approved the applicant's formal procedures under § 1007.7 (b) or (c) if either of those provisions is applicable, and has specifically certified that the applicant meets the requirements of § 1007.7;

(2) The Secretary will promptly notify the applicant whether the application meets the requirements of this subpart and is approved. If the application is not approved, the applicant may submit an amended application at any time. Approval and certification will be for a period of 1 year.

(c) *Conditions for recertification.* In order to continue receiving payments under this subpart, a unit must submit a reapplication to the Secretary at least 60 days prior to the expiration of the 12-month certification period. A reapplication must:

(1) Advise the Secretary of any changes in the information or documentation required under paragraphs (a) (1) through (5) of this section;

(2) Provide projected caseload and proposed budget for the recertification period; and

(3) Include or incorporate by reference the annual report required under § 1007.17.

(d) *Basis for recertification.* (1) The Secretary will consider the unit's reapplication, the reports required under § 1007.17, and any other reviews or information he or she deems necessary or warranted, and will promptly notify the unit whether he or she has approved the reapplication and recertified the unit.

(2) In reviewing the reapplication, the Secretary will give special attention to whether the unit has used its resources effectively in investigating cases of possible fraud, in preparing cases for prosecution, and in prosecuting cases or cooperating with the prosecuting authorities.

(Approved by the Office of Management and Budget under control number 0990-0162)

§ 1007.17 Annual report.

At least 60 days prior to the expiration of the certification period, the unit shall submit to the Secretary a report covering the last 12 months (the first 9 months of the certification period for the first annual report), and containing the following information:

(a) The number of investigations initiated and the number completed or closed, categorized by type of provider;

(b) The number of cases prosecuted or referred for prosecution; the number of cases finally resolved and their outcomes; and the number of cases investigated but not prosecuted or referred for prosecution because of insufficient evidence;

(c) The number of complaints received regarding abuse and neglect of patients in health care facilities; the number of such complaints investigated by the unit; and the number referred to other identified State agencies;

(d) The number of recovery actions initiated by the unit; the number of recovery actions referred to another agency; the total amount of overpayments identified by the unit; and the total amount of overpayments actually collected by the unit;

(e) The number of recovery actions initiated by the Medicaid agency under its agreement with the unit; and the total amount of overpayments actually collected by the Medicaid agency under this agreement;

(f) Projections for the succeeding 12 months for items listed in paragraphs (a) through (e) of this section;

(g) The costs incurred by the unit;

(h) A narrative that evaluates the unit's performance; describes any specific problems it has had in connection with the procedures and agreements required under this subpart; and discusses any other matters that have impaired its effectiveness.

(Approved by the Office of Management and Budget under control number 0990-0162)

§ 1007.19 Federal financial participation (FFP).

(a) *Rate of FFP.* Subject to the limitation of this section, the Secretary will reimburse each State by an amount equal to 90 percent of the costs incurred by a certified unit which are attributable to carrying out its functions and responsibilities under this subpart.

(b) *Retroactive certification.* The Secretary may grant certification retroactive to the date on which the unit first met all the requirements of the statute and of this subpart. For any quarter with respect to which the unit is

certified, the Secretary will provide reimbursement for the entire quarter.

(c) *Amount of FFP.* FFP for any quarter shall not exceed the higher of \$125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State Medicaid program.

(d) *Costs subject to FFP.* FFP is available under this subpart for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement shall be limited to costs attributable to the specific responsibilities and functions set forth in this subpart in connection with the investigation and prosecution of suspected fraudulent activities and the review of complaints of alleged abuse or neglect of patients in health care facilities. Establishment costs are limited to clearly identifiable costs of personnel that:

(1) Devote full time to the establishment of the unit which does achieve certification; and

(2) Continue as full-time employees after the unit is certified. All establishment costs will be deemed made in the first quarter of certification.

(e) *Costs not subject to FFP.* FFP is not available under this subpart for expenditures attributable to:

(1) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud;

(2) Efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received;

(3) The routine notification of providers that fraudulent claims may be punished under Federal or State law;

(4) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;

(5) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or

(6) Any payment, direct or indirect, from the unit to the Medicaid agency, other than payments for the salaries of employees on detail to the unit.

§ 1007.21 Other applicable HHS regulations.

Except as otherwise provided in this part, the following regulations from 45 CFR subtitle A apply to grants under this subpart:

Subpart C of part 16—Department Grant Appeals Process—Special Provisions Applicable To Reconsideration of Disallowance (note that this applies only to disallowance determinations and not to any other determinations, e.g., over certification or recertification)

Part 74—Administration of Grants

Part 75—Informal Grant Appeals Procedures

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services; Effectuation of title VI of the Civil Rights Act of 1964

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance.

PART 91—NONDISCRIMINATION ON THE BASIS OF AGE IN HHS PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

Dated: May 22, 1989.

R.P. Kusserow,

Inspector General, Department of Health and Human Services.

Approved: November 3, 1989.

Louis W. Sullivan,
Secretary.

[FR Doc. 90-7075 Filed 3-30-90; 8:45 am]

BILLING CODE 4150-04-M

DEPARTMENT OF TRANSPORTATION**Federal Railroad Administration****49 CFR Part 240**

[FRA Docket No. RSOR-9, Notice 3]

RIN 2130-AA51

Qualifications for Locomotive Operators; Change in Schedule for Public Hearings

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Scheduling of additional day for public hearing.

SUMMARY: On December 11, 1989 FRA published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) concerning the establishment of minimum qualifications for locomotive operators. FRA has found it necessary to extend the duration of the public