requestor would be adequate to justify the action requested.

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

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

**List of Subjects in 40 CFR Parts 180**

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

Dated: January 23, 1992.

**Douglas D. Campt,**

*Director, Office of Pesticide Programs.*

Therefore, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

## PART 180—[AMENDED]

1. In part 180:

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

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

b. By adding new § 180.458, to read as follows:

**§ 180.458 Clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one); tolerances for residues.**

Interim tolerances that expire on January 31, 1994 are established for the combined residues of the herbicide clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety in or on the following raw agricultural commodities.

| Commodity | Parts per million |
|---|---|
| Cattle, fat | 0.2 |
| Cattle, meat | 0.2 |
| Cattle, mbyp | 0.2 |
| Cottonseed | 1.0 |
| Eggs | 0.2 |
| Goats, fat | 0.2 |
| Goats, meat | 0.2 |
| Goats, mbyp | 0.2 |
| Hogs, fat | 0.2 |
| Hogs, meat | 0.2 |
| Hogs, mbyp | 0.2 |
| Horses, fat | 0.2 |
| Horses, meat | 0.2 |
| Horses, mbyp | 0.2 |
| Milk | 0.05 |
| Poultry, fat | 0.2 |
| Poultry, meat | 0.2 |
| Poultry, mbyp | 0.2 |
| Sheep, fat | 0.2 |
| Sheep, meat | 0.2 |
| Sheep, mbyp | 0.2 |
| Soybeans | 10.0 |

## PART 186—[AMENDED]

2. In part 186:

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

**Authority:** 21 U.S.C. 348.

b. By adding new § 186.1075, to read as follows:

**§ 186.1075 Clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one); tolerances for residues.**

Interim tolerances that expire on January 31, 1994 are established for residues of the herbicide clethodim ((E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)-propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety in or on the following feeds.

| Feed | Parts per million |
|---|---|
| Cottonseed meal | 2.0 |
| Soybean soapstock | 15.0 |

[FR Doc. 92-2165 Filed 1-28-92; 8:45 am]

BILLING CODE 6560-50-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### 42 CFR Parts 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 Inspector General, HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements the OIG sanction and civil money penalty provisions established through section 2 and other conforming amendments in the Medicare and Medicaid Patient and Program Protection Act of 1987, along with certain additional provisions contained in the Consolidated Omnibus Budget Reconciliation Act of 1985, the Omnibus Budget Reconciliation Act (OBRA) of 1987, the Medicare Catastrophic Coverage Act of 1988, OBRA of 1989, and OBRA of 1990. 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 Social Security Act.

**EFFECTIVE DATE:** These regulations are effective on January 29, 1992.

**FOR FURTHER INFORMATION CONTACT:**

Joel J. Schaer, Legislation and Regulations Staff, (202) 619-3270.

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

Robin Schneider, Office of the General Counsel, (202) 619-1306.

**SUPPLEMENTARY INFORMATION:**

### I. Statutory Background

The Medicare and Medicaid Patient and Program Protection Act (MMPPPA) of 1987, Public Law 100-93, enacted on August 18, 1987 and effective on September 1, 1987, 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.

MMPPPA both consolidated many of the Secretary's pre-existing exclusion authorities into section 1128 of the Social Security Act, 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 gives the OIG added authority to control who may obtain payment for services furnished to program beneficiaries. Section 1128 of the Act provides for both mandatory and permissive exclusions. The mandatory exclusions (section 1128(a) of

the Act) 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: (1) Derivative exclusions, i.e., ones involving 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; and (2) non-derivative exclusions, based on determinations of misconduct that originate with the OIG. For derivative exclusions, the OIG would not be required to re-establish the factual or legal basis for such underlying sanction; for non-derivative exclusions, the OIG would be required, if the case is appealed to an administrative law judge (ALJ), to make a prima facie showing that the improper behavior did occur.

*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, including those programs covered under titles V, XIX, and XX of the 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 OIG is to consider requests for a waiver from exclusion from one or more of the State health care programs in limited situations.

**II. Provisions of the Proposed Regulations**

Proposed regulations intended to implement section 2 of MMPPPA and certain conforming amendments found elsewhere in that statute were published in the **Federal Register** on April 2, 1990 (55 FR 12205) for public comment and consideration. 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, were also contained in that proposed rulemaking. Set forth below is a brief summary of that rulemaking and the proposed revisions to 42 CFR chapter V.

*Part 1001*

The basic structure of the proposed regulations in this part set forth for each type of exclusion the basis or activity that would justify the exclusion, and the considerations the OIG would use in determining the period of exclusion.

The proposed regulations set forth mandatory exclusions for any individual or entity that was 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. In accordance with the statute, there is to be a minimum 5 year exclusion. The regulations proposed that the exclusion could be for a longer period if aggravating circumstances existed with respect to the individual or entity.

The proposed regulations also addressed two categories of permissive exclusions to be set forth in part 1001. The first category—derivative exclusions—was designed to address exclusions based on an action previously taken by a court, licensing board or other agency. These include convictions for certain types of fraud, theft, embezzlement, breach of fiduciary responsibility, financial misconduct, obstruction of investigations and certain types of offenses related to controlled substances. While Congress did not set a mandatory minimum period for these types of exclusions, we proposed that exclusions derived from such prior convictions be for a period of 5 years, with some flexibility to decrease or increase the period.

The second category of permissive exclusions—non-derivative exclusions—is to be based on OIG-initiated determinations of misconduct. Several of these non-derivative exclusions were essentially recodifications of the existing regulations, while others reflected the newly enacted authorities. With respect to the non-derivative exclusions, the proposed regulations were designed to:

- Permit the exclusion of those individuals and entities who provide unnecessary or substandard care not only to Medicare and State health care program beneficiaries, but to any person. We proposed to use a 5-year exclusion period as a benchmark for these exclusions. Similarly, the regulations proposed a 5-year exclusion period for health maintenance organizations and similar entities subject to exclusion 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.
- Expand the bases for exclusion to include any act that is described in sections 1128A or 1128B of the Social Security Act. No benchmark was set in the proposed regulations for the exclusion period; a list of factors that the OIG would consider in setting the length of an exclusion was included.
- Provide 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. The rulemaking proposed that an entity excluded under this provision be excluded for a period corresponding to the exclusion period established for the individual whose relationship with the entity was the basis for the exclusion.
- Address new exclusion authorities relating to the failure to provide information to the Department or its agents. Exclusions were set forth for failure to grant immediate access upon reasonable requests to certain agency representatives. In the context of this provision, we proposed to define "immediate access" and "reasonable request" to ensure access on the spot in certain defined circumstances. Exclusions were also proposed where individuals or entities failed 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. Except in unusual situations, we proposed 24 hours to be a sufficient period to gain access to the information.
- Provide for the exclusion of a hospital that has failed to comply substantially with a corrective action plan that has been required under section 1886(f)(2)(B) of the Act. The rulemaking proposed that exclusions would be based on the Health Care Financing Administration's (HCFA's) determination that the hospital substantially failed to comply with such corrective action.
- Provide exclusions based on a determination by the Public Health Service (PHS) that an individual failed to pay back covered obligations and loans.

*Part 1002*

Since the new requirements of Public Law 100-93 are being incorporated into part 1001 (which would require State health care programs, including Medicaid, to exclude those whom the OIG has excluded under Medicare), the proposed new part 1002 was designed to set forth provisions pertaining only to State agency-initiated exclusions. The rulemaking proposed 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 CMPs, were designed to implement the statutory changes affecting section 1128A of the Act, and incorporate a number of statutory revisions made as a result of Public Laws 100–203, 100–360 and 100–485.

*Parts 1004 and 1005*

Revisions to part 1004 were proposed consistent with the proposed establishment of the new part 1005. Through the revising and recodification of existing regulations, a new part 1005 was proposed to address various OIG hearing procedures. Specifically, proposed part 1005 was designed to govern ALJ hearings and subsequent appeals to the Secretary for all OIG sanction cases.

*Part 1006*

A new part 1006 was proposed to address the implementation of the OIG's testimonial subpoena authority for investigations of cases under the CMP law.

*Part 1007*

Regulations addressing State MFCUs, previously set forth in part 1002, subpart C, were proposed to be recodified into a new part 1007.

In response to the proposed rulemaking, we received a total of 61 timely-filed public comments from various provider groups, medical facilities, professional and business organizations and associations, medical societies, State and local government entities, private practitioners and concerned citizens. The comments included both general concerns regarding the impact of these regulations, and specific comments on those areas about which we requested public input. A summary of the comments received and our responses to those comments follows.

**III. General Comments on the Proposed Rule**

*A. Definition of "Furnished"*

In the proposed rule, we invited comments on whether the definition of the term "furnished" set forth in § 1001.2 should be revised to explicitly encompass health care manufacturers and other entities who do not receive payments for items or services directly from Medicare or State health care programs, but rather supply items or services to providers, practitioners or suppliers who *do* receive payments from these programs. We explained that if the term "furnished" is defined narrowly, it may inappropriately limit the effect of an exclusion from Medicare and State health care programs.

We received numerous comments on this issue—some supporting and some challenging our authority to revise the definition of "furnished." While we believe that the statute permits us to include entities that "furnish" items covered by the Medicare program but do not receive program payment directly, we have decided not to provide for this in regulations. Because the effect of exclusion is denial of payment for items or services furnished by an excluded individual or entity, it would be difficult to administer exclusions against entities which the Secretary does not directly reimburse. Thus, for the present time, to the extent that manufacturers, suppliers and distributors do not receive payment directly from the Medicare and State health care programs for the items they supply, these regulations will not affect them.

This clarification is in no way intended to limit our exclusion authority under section 1128(b)(8) of the Act. When this statutory provision is applicable, we can assure that no payment is made for items or services furnished by sanctioned persons whether or not they directly receive payments from Medicare and State health care programs, since we can exclude the entities they manage or control which *do* receive such payments.

In this final rule, we are retaining the definition of "furnished" currently found in § 1001.2 of the regulations with one modification, and placing the definition in § 1001.2 under General Definitions. We have deleted the parenthetical statement in the existing definition which we believe is unnecessary in light of the changes made in section 1862(e) of the Act and reflected in § 1001.1901 of these regulations. These provisions, which explicitly incorporate the concept that payment may not be made for items and services provided under the direction of or by prescription of an excluded individual, render the parenthetical statement redundant.

*B. Constitutionality of Administrative Exclusions Based on Criminal Convictions*

*Comment:* Several comments expressed concern that exclusions imposed by the Federal Government based upon prior Federal or State criminal convictions may constitute a second "punishment" for a single offense in violation of the double jeopardy clause of the Fifth Amendment of the Constitution.

*Response:* Exclusions based upon criminal convictions do not constitute an impermissible second punishment under the double jeopardy clause. Exclusions are civil sanctions, not criminal. Only in rare cases will a civil sanction imposed after a criminal sanction violate the double jeopardy clause, and even in those rare cases, only where the sanction may not fairly be characterized as remedial, but only as a deterrent or retribution (see *United States* v. *Halper*, 109 S.Ct. 1892, 1902 (1989)). Thus, under *Halper*, whether a civil sanction constitutes punishment depends in large part upon the goal served by the sanction—if the second civil sanction can be said to serve a remedial purpose, its imposition does not violate the double jeopardy clause (*Halper*, 109 S.Ct. at 1902).

The primary purpose of an exclusionary sanction is remedial, not punitive. When the OIG imposes an exclusion under section 1128 of the Act, it is simply carrying out Congress' intent to protect the Medicare and Medicaid programs from individuals or entities who have already been tried and convicted of a criminal offense (see *Dewayne Franzen* v. *The Inspector General*, Departmental Appeals Board (DAB) decision, Docket No. 90–37 (June 13, 1990), page 11). Further, Congress has made clear that the Department's exclusionary authority was expanded by MMPPPA in 1987 to provide HHS with sufficient authority to better protect the integrity of the Medicare and Medicaid programs and program beneficiaries from providers who have pled guilty to criminal charges. (see Report of Committee on Energy and Commerce, reprinted in 1986 U.S. Cong. and Ad. News, pg. 3665; and 133 Cong. Rec. S 10537 (daily ed. July 23, 1987)). Thus, exclusions serve a remedial purpose and therefore do not constitute a second punishment under *Halper*.

Consistent with the above, courts have held that exclusions do not amount to a second punishment under *Halper*, since "the Inspector General's goals are clearly remedial and include protecting beneficiaries, maintaining program integrity, fostering public confidence in the program, etc." (see *Greene* v. *Sullivan*, No. CIV–3–89–758 (E.D. Tenn. Feb. 8, 1990), page 3; *Matter of David Cooper, R.Ph.*, ALJ Decision, Docket No. C–51 (July 24, 1990); *Matter of Joyce Faye Hughey)*, ALJ Decision, Docket No. C–201 (August 9, 1990)). In a number of these cases, exclusions have been compared to professional license revocations for criminal convictions, "which have the function of protecting the public" (see *DeWayne Franzen* v.

*The Inspector General, Id.* at page 11; *Greene* v. *Sullivan, Id.* at 3). Further, it has been held that remedial sanctions that involve the revocation of a privilege voluntarily granted are civil in nature and do not invoke the double jeopardy clause (see *Helvering* v. *Mitchell,* 303 U.S. 399 (1938)). Thus, Medicare and Medicaid exclusions do not amount to "punishment" for purposes of the double jeopardy clause.

Further, even assuming, that exclusions were penal in nature, the double jeopardy clause would not be implicated where the Federal government imposes an exclusion based upon a *State* conviction. Under the "dual sovereignty doctrine," double jeopardy does not attach to a subsequent Federal prosecution based on facts which led to a State conviction (see *United States* v. *Anthony,* 727 F. Supp. 792 (E.D.N.Y. 1989); *Abbate* v. *United States,* 359 U.S. 187 (1959); *Chapman* v. *United States Department of Health and Human Services,* 821 F.2d 523 (10th Cir. 1987); and *United States* v. *Lanza,* 260 U.S. 377, 382 (1922)). Under this doctrine, States are considered to be a "separate sovereign" from the Federal government, because a State's power to prosecute is derived from its own inherent sovereignty, and not from the powers of the Federal government (see *United States* v. *Wheeler,* 435 U.S. 313, 320 (1978)). Thus, under the dual sovereignty doctrine, exclusions based upon prior State convictions do not violate the double jeopardy clause. In light of the foregoing, we do not agree with the comments on the question of the constitutionality of our exclusion authorities.

## IV. Specific Comments on the Proposed Regulations

### *A. Part 1001, Subpart A—Definitions*

1. Professionally Recognized Standards of Health Care

*Comment:* A few commenters expressed the view that the proposed definition of "professionally recognized standards of health care" inadequately defines the term, that is, it does not (i) adopt traditional malpractice standards, (ii) define "peer," and (iii) take into account differences of opinion among physicians regarding practice standards. Some commenters also felt that the definition should specifically recognize and make allowances for variations in regional or local community standards of care, that is, different standards for rural and urban areas.

*Response:* We recognize that the proposed definition of "professionally recognized standards of health care" does not provide a litmus test which can be easily applied in every case. It would be very difficult to formulate a wholly objective standard in the area of medical practice, where a certain amount of subjectivity in judgment is inevitable. The OIG relies upon the Utilization and Quality Control Peer Review Organizations (PROs) and the Medicare carriers to determine on a case-by-case basis whether the quality of items or services provided has failed to meet professionally recognized standards of health care. (PROs are also required to take interventions other than sanctions for confirmed quality problems.) We do not feel that it is necessary to define the term "peer," but would note that the dictionary defines a peer as one's "equal," and our assessment of who qualifies as a "professional peer" would be consistent with that definition and with the view expressed by Congress in enacting the PRO statute that licensed physicians "practicing in the area" are peers (see House Conf. Rpt. 97-760).

**Note:** HCFA published a final rule on February 27, 1984 (49 FR 7202) which defined a PRO area to be a State.

With respect to the request that the regulations specifically provide for variations in standards for individual localities and service areas, we have decided not to modify the definition. However, while the definition will continue to provide that the standards will be state or national ones, that does not mean that those health care facilities with minimal technical capability and expertise will be evaluated as if they were high-tech facilities. The quality of the care provided will be assessed in light of all of the surrounding circumstances, including the capabilities of the facility. For example, in a facility with limited technical equipment or expertise, we would assess whether a patient who required more sophisticated treatment than was available at that facility should have been transferred to another facility, and whether professionally recognized standards were met in determining whether transfer was appropriate and that appropriate care was rendered to facilitate the transfer.

*Comment:* One commenter pointed out that the definition of "professionally recognized standards of health care" is too narrowly drafted and should be modified to encompass "professional peers of the individual and entity." This commenter also raised a number of related questions about the interpretations and use of this definition in evaluating the quality of care provided by nursing homes where, according to the commenter, the standards governing the industry are primarily regulatory, not peer-based. The commenter asked, for example, whether this definition meant to encompass citations for "substandard care" issued against nursing homes under State and Federal survey and certification guidelines. The commenter states that citations by regulatory agencies which require corrective actions on the part of nursing homes are extremely common and do not normally result in exclusion. The commenter further suggested that nursing homes could be deterred from seeking voluntary accreditation from the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) if failure on the part of an accredited nursing home to meet any of JCAHO's standards, which differ in some respects from state and federal regulatory standards, could be taken as failure to meet "professionally recognized" standards.

*Response:* We agree that the definition should be modified to include the word "entity," and we have amended the regulations accordingly. With respect to the commenter's concerns about the application of this definition to nursing homes and the potential liability of nursing homes under § 1001.701 of these regulations, the following explanation may be helpful. The Inspector General has the legal authority to exclude all kinds of health care providers, including nursing homes, if they fail to furnish items or services which meet "professionally recognized standards of health care." However, in the case of nursing homes, we anticipate that problems related to quality of care would ordinarily be investigated by HCFA which could, if necessary, take action under its authority to terminate provider agreements. We would expect that the vast majority of citations against nursing homes for violations of quality of care would be handled by the State survey and certification agencies or by HCFA, and the Inspector General would not normally be involved. When the OIG chooses to investigate quality of care problems in a nursing home, hospital, laboratory, or other entity, however, it first needs to determine whether the entity has failed to comply with professionally recognized standards of health care. In making such a determination, the OIG would look to Federal and State statutory and regulatory standards and to those standards established by voluntary accrediting organizations such as JCAHO. (The OIG would look to these standards to determine whether the

entity in question was accredited by such an organization.) Previous citations against the entity for violation of any of these established standards, if serious and substantial, could be evidence that the entity has violated professionally recognized standards of health care. However, consistent with our practice in developing cases under section 1128(b)(6)(B) of the Act, the OIG would normally not propose an exclusion based on an isolated instance, but would look for a pattern of poor quality care which might be evidenced by a series of citations by standard-setting agencies and monitoring organizations. The OIG's exclusion authority under section 1128(b)(6)(B) of the Act is a permissive authority, and before the Inspector General decides to exercise it, the OIG would do an independent evaluation of the care provided by the entity rather than rely solely on prior citations. (For further discussion of OIG's practice in such cases, see comment and response section in section IV.C.2. of this preamble regarding § 1001.701.)

*Comment:* One commenter objected to what it termed a "conclusive presumption" set forth in this definition, that is, when the Food and Drug Administration (FDA), PHS or HCFA have declared a treatment modality not to be safe and effective, those who employ it will be deemed not to meet professionally recognized standards of health care. The commenter suggested that this might unfairly restrict practitioners from using a treatment modality which has been declared not safe and effective for one purpose, even though the practitioner might want to use it for a different purpose about which FDA, PHS and HCFA have taken no position.

*Response:* We disagree with the comment and have retained this portion of the definition intact. If a practitioner can show that none of the specified agencies found the treatment modality in question to be unsafe or ineffective for the purpose for which the practitioner used it, the usage of the treatment modality would not cause the practitioner to be deemed to have violated professionally recognized standards of health care.

2. Convicted

*Comment:* Several commenters questioned the use of the word "dismissed" in paragraph (a)(2) of the definition of "convicted" as an unwarranted diversion from the statutory definition, and because dismissal of charges typically occurs either before judgment or upon acquittal, not subsequent to a conviction. These commenters also objected to defining a judgment as a conviction when a post-trial motion is pending, since the motion could result in the overturning of the judgment.

*Response:* We agree that the term "dismissed" was not the appropriate term, and have changed the regulatory language to "otherwise removed" to clarify that this is meant to apply only to actions that are equivalent in effect to expungement, but called something different. With respect to applying the definition even when a post-trial motion is pending, we disagree with the comment. Just as Congress did not intend to tie our hands postponing exclusions while appeals are pending, we are similarly not constrained to delay exclusions while post-trial motions are pending. Any post-trial motion which is resolved quickly will, as a practical matter, be resolved prior to any exclusion, since there is some lag time before the OIG is made aware of convictions and can take action to impose an exclusion. If the post-trial motion is not able to be resolved quickly, then the exclusion will be imposed, but the individual or entity will be retroactively reinstated if the motion results in the conviction being vacated or reversed. (See § 1001.3005 of these regulations for further discussion.)

3. Entity

*Comment:* Several commenters requested that we add a definition of the term "entity" to the regulations that would limit the scope of the term to the "actual offender" who holds the provider number, and would specifically exclude from the definition a parent corporation when one of its subsidiary facilities (such as a laboratory, nursing home, or dialysis center) is excluded.

*Response:* We have decided not to define "entity" in these regulations. In our view, the OIG has the discretion to exclude any offender, and the corporate structure of an entity or group of entities will be one factor to consider when determining who or what the offender is. Depending upon the nature of the offense and the scope of involvement by various parties, the OIG could elect to exclude the parent corporation, the subsidiary, or both. Even if the offense itself was committed by just one of the facilities owned by a parent corporation, if the parent corporation was convicted of the offense along with its subsidiary, and if it was aware of the practices of its subsidiary, or encouraged them, the OIG might elect to exclude both the parent and the subsidiary. However, absent some evidence of involvement or knowledge on the parent of the parent corporation, the OIG would normally exclude only the offending facility rather than an entire chain of facilities. (See discussion of § 1001.1001 below in section IV.C.2. of this preamble.) Of course, with respect to all of the OIG's derivative exclusion authorities (§§ 1001.101, 1001.201, 1001.301, 1001.401, 1001.501, 1001.601, 1001.1401, and 1001.1501), the OIG has authority to exclude *only* those entities against whom action has previously been taken by a court, licensing board, or other agency.

4. Sole Community Physician

*Comment:* Some commenters suggested that the proposed definition was unnecessarily limited to designated health manpower shortage areas, and failed to address the specific need for access by Medicare and Medicaid beneficiaries to providers and practitioners who will accept such beneficiaries.

*Response:* We agree with these comments. Accordingly, we have revised the definition to eliminate the health manpower shortage area limitation, and to ensure that even if other physicians or providers in the community provide the same services as an excluded physician or provider, if the excluded party is the only one practicing in a recognized service area who participates in either Medicare or Medicaid, that individual will meet the terms of the definition and be eligible for waiver on those grounds.

For purposes of both this definition and the definition of "sole source of essential specialized services in the community," the OIG will look at the services offered by providers and physicians in a recognized service area to determine whether other individuals or entities are providing the same services. The OIG will consider any relevant information regarding the scope of the service area, which in some cases may be comprised of an entire town and in other cases may only consist of a small community within a much larger city. In determining what constitutes the service area, the OIG will give a great weight to objective measures where available, such as a breakdown by zip code area of patients served or a demonstration of geographic boundaries that self-define a service area. Where the service area is in dispute, the OIG will also seek advice from the State health agency in making its final determination.

5. Criminal Offense Related to the Delivery of an Item or Service

*Comment:* One commenter requested that we define by regulation the phrase

"criminal offense related to the delivery of an item or service" as used in § 1001.101 of these regulations. The commenter expressed the view that the phrase, which serves as the basis for mandatory exclusions, is too ambiguous, particularly in light of the mandatory 5-year exclusion.

*Response:* We have decided not to define this term. This term has served as the basis for exclusions from Medicare and Medicaid for many years and the absence of a definition of the term has not posed any serious problems. The OIG assesses each conviction on a case-by-case basis to determine whether it falls within the ambit of the statutory language—that is, whether it is related to the delivery of an item or service under one of the programs—and each of those determinations is quite fact-specific. We believe that it will continue to be more effective to make these determinations on a case-by-case basis than to attempt to define the phrase further.

*B. Part 1001, Subpart B—Mandatory Exclusions*

*Comment:* Some commenters believe that mandatory minimum five-year exclusions may violate the Eighth Amendment bar against cruel and unusual punishment because they may be disproportionate to the underlying crimes committed.

*Response:* We do not agree. Exclusions, whether mandatory or permissive, do not invoke the Eighth Amendment prohibition against "excessive bail, excessive fines, and cruel and unusual punishment." As discussed earlier in this preamble, it is well-established that exclusions are remedial sanctions that serve a remedial purpose. The Eighth Amendment applies only to criminal punishments and not to civil sanctions (see *Ingraham* v. *Wright*, 430 U.S. 651 (1977); *Bell* v. *Wolfish*, 441 U.S. 520, 99 S. Ct. 1861 (1979); *Stamp* v. *Commissioner of Internal Revenue*. 579 F.Supp. 168, 171 (N.D. Ill. 1984); *Popow* v. *City of Margate*, 476 F.Supp. 1237 (1979)). Further, at least one court has held that civil sanctions disqualifying individuals from receiving certain benefits based on prior convictions do not violate the Eighth Amendment, even when they apply automatically to all offenders without regard to the circumstances of the offense (see *Blout* v. *Smith*, 440 F.Supp. 528 (M.D. Pa. 1977)). Finally, in enacting section 1128(a) of the Act, Congress has required the OIG to exclude individuals or entities convicted of certain offenses for at least five years, and § 1001.101 merely implements that provision. For all of the foregoing reasons, the OIG is not accepting this comment.

*Comment:* One commenter expressed concern that the language of § 1001.101 gives the OIG independent authority to review criminal convictions to determine whether such convictions resulted in patient abuse or neglect. This commenter believes that a body such as a licensing board or a peer review organization, rather than the OIG, should conduct a medical-type review to determine whether a conviction entailed patient abuse or neglect.

*Response:* Section 1001.101 simply parrots the language of section 1128(a)(2) of the Act. As is evidenced by its legislative history, Congress intended for section 1128(a)(2) to give the Secretary the authority to protect Medicare and the State health care program beneficiaries from individuals or entities that have already been tried and convicted of offenses "which the *Secretary* concludes entailed or resulted in neglect or abuse of other patients * * *." (emphasis added) (see S. Rep. No. 100–109, 100th cong., 1st Sess. 6). Thus, whether or not an individual or entity has been convicted of a criminal offense "relating to neglect or abuse of patients in connection with the delivery of a health care item or service" is a legal determination to be made by the Secretary based on the facts underlying the conviction. Further, the offense that is the basis for the exclusion need not be couched in terms of patient abuse or neglect. For example, an individual convicted of embezzling a nursing home's funds may be excluded if the OIG determines that the offense resulted in the abuse or neglect of patients, i.e., that as a result of the offense, the facility was underfinanced to the point that the residents could not be properly cared for. Further, it is clear from the language of the statute and its legislative history that the OIG may exclude an individual convicted of an offense related to patient abuse or neglect irrespective of whether the individual intended to harm patients.

*Comment:* Several commenters were confused as to what offenses are included in the phrase "criminal offenses related to the neglect or abuse of a patient" within the meaning of § 1001.101, and requested that we define the phrase or give examples. These commenters said their confusion was compounded by additional language in § 1001.101 requiring an exclusion where a conviction "entailed, or resulted in, neglect or abuse of patients."

*Response:* Section 1128(a)(2) of the Act authorizes the Secretary to exclude "any individual or entity that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service." Section 1001.101 states that an offense "related to the neglect or abuse of patients" includes "any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients." This language is the same language used by Congress in the legislative history of section 1128(a)(2) of the Act. We have chosen to put this language in the regulation because we believe it makes it clear that it is in the OIG's discretion to determine whether a conviction is related to patient abuse or neglect, as discussed above. We also believe that Congress used this language in the legislative history to expand upon the types of offenses it meant to include in enacting section 1128(a)(2).

We have chosen not to define which offenses "relate to" or "entail or result in" neglect or abuse of patients. Since a determination as to whether an offense related to patient abuse or neglect is fact-intensive, we feel it is most appropriate for the OIG to exercise its authority to make such determinations on a case-by-case basis.

*C. Part 1001, Subpart C—Permissive Exclusions*

1. General Comments

*Comment:* Commenters indicated that the regulations should include a list of factors that the OIG will use in determining whether to impose a permissive exclusion.

*Response:* Our experience has shown that situations which could result in the imposition of a permissive exclusion are extremely varied and must be evaluated on a case-by-case basis. Some of these factors include controlled substance abuse history, criminal history, and prior experience with the programs. However, the statute vests the Secretary with complete discretion, and does not require us to set forth the precise criteria which will be used in determining whether to impose a permissive exclusion.

*Comment:* Several commenters stated that, prior to imposing a permissive exclusion, the OIG should have to prove that allowing continued program participation would harm beneficiaries.

*Response:* The purpose of these permissive authorities is to protect Federal and State health care programs and their beneficiaries. The OIG always considers whether continued participation presents a risk to the programs or their beneficiaries in deciding whether an exclusion is

warranted. However, this determination is within the OIG's discretion. Further, it is not necessary for the OIG to prove that allowing continued program participation would harm beneficiaries since that is not the only basis for the imposition of an exclusion.

*Comment:* A number of commenters stated that §§ 1001.201, 1001.301, 1001.401, 1001.701 and 1001.801 should not include a 5-year "benchmark" length for an exclusion. In contrast to the mandatory exclusions, where Congress expressly set forth a minimum 5-year term, Congress did not set a minimum exclusion length for the permissive authorities. The commenters argued that Congress indicated that these kinds of offenses should not be treated as harshly as the mandatories since Congress did not require the Secretary to exclude providers in these circumstances.

*Response:* Upon careful consideration of the comments and further research, we have decided that a 3-year benchmark for permissive exclusions is more appropriate than the proposed 5-year benchmark. A 3-year benchmark is consistent with the period established by regulation for government-wide debarments and suspensions from nonprocurement contracts, grants and the like, including those debarments and suspensions imposed by HHS (see 45 CFR 76.320). (It is also consistent with longstanding regulations governing the period of debarments in the government procurement context (see 48 CFR 9.406-4)).

Periods of debarment and suspension from HHS programs under 45 CFR 76.320 are determined much the way exclusion periods for permissive exclusions will be determined under these final regulations. Section 76.320 provides the "[d]ebarment shall be for a period commensurate with the seriousness of the cause(s). Generally, a debarment should not exceed three years. Where circumstances warrant, a longer period of debarment may be imposed * * *." Similarly, the 3-year benchmark concept established in these exclusion regulations requires the Secretary to evaluate the seriousness of the violation upon which the exclusion is based by considering whether there are mitigating or aggravating circumstances which should serve to shorten or lengthen the exclusion period and permitting the Secretary to adjust the period accordingly. In practice, this means that no permissive exclusion period will exceed 3 years unless aggravating circumstances exist to justify a longer exclusion period.

Both the 3-year benchmark and the process for adjusting it are consistent with the methods already in use by the Department for determining debarment and suspension periods, and we believe that it is reasonable for our regulations to take the same approach. We have, therefore, modified these regulations accordingly.

*Comment:* Some commenters expressed the opinion that the OIG will never use these authorities to exclude a hospital, thus making the regulations applicable only to certain types of providers.

*Response:* A hospital can and will be excluded if the circumstances warrant that exclusion. However, the OIG must consider all the circumstances in determining whether an exclusion is appropriate in any case, including cases involving hospitals. Certain factors, such as access of program beneficiaries to services, may weigh against imposing an exclusion on hospitals but may be less significant in evaluating possible exclusions of other types of providers.

*Comment:* A number of commenters indicated that exclusions which relate to Medicare billing violations should be withdrawn because Medicare billing rules are so complex.

*Response:* It is the obligation of anyone doing business with the Medicare program to understand relevant Medicare rules of reimbursement. However, these authorities are permissive, and OIG does not intend to impose exclusions in cases involving isolated, legitimate confusion with the Medicare rules.

2. Permissive Exclusions

• *Section 1001.201*

Section 1001.201 implements the OIG's authority to exclude an individual or entity convicted of, among other things, a criminal offense in connection with the delivery of any health care item or service. We have clarified that this authority allows the OIG to exclude a person who was convicted of an offense involving the performance of management or administrative services relating to the delivery of such items or services.

*Comment:* Commenters indicated that the regulations should state that the OIG may exclude anyone who enters a pre-trial diversion program, regardless of whether there was an admission of guilt.

*Response:* The statute permits the imposition of an exclusion on any individual or entity that has been "convicted." Section 1128(i) of the Act contains a broad definition of "convicted," and we are bound by this definition. (See discussion regarding § 1001.102 in section IV.C.1. of this preamble.) "Pre-trial diversion" is defined differently in different States. If a "pre-trial diversion program" satisfies the statutory definition of "convicted", then a party who enters into a pre-trial diversion program may be excluded.

• *Section 1001.301*

No comments specific to this provision were received.

• *Section 1001.401*

This section permits the OIG to exclude anyone who has been convicted of a criminal offense relating to a controlled substance. We have modified this regulation to clarify that the operative definition of the term "controlled substance" will be the definition that applies to the law that forms the basis for the conviction. For example, if an individual is convicted of a Federal offense, the operative definition would be the definition of a controlled substance under Federal law. If the individual was convicted, for example, of a criminal offense under New York State law, the determination of whether the conviction related to a controlled substance will be determined by whether the substance is defined as controlled under the New York criminal code.

*Comment:* Some commenters stated that the regulations should be expanded to permit the OIG to exclude someone for illegal possession of a controlled substance.

*Response:* Section 1128(b)(3) of the Act sets forth the types of convictions relating to controlled substances that may serve as the grounds for an exclusion. Since section 1128(b)(3) of the Act does not state that the OIG may exclude someone based on a conviction for possession, expanding the regulation as suggested is beyond the scope of our statutory authority.

• *Sections 1001.501 and 1001.601*

These regulations implement sections 1128 (b)(4) and (b)(5) of the Act. Both of these authorities permit exclusion of an individual or entity on the basis of the actions of another agency, e.g.; where a State medical society revoked a practitioner's license, or where a provider was suspended from a State health care program. We consider these agencies to be "derivative agencies," since we derive the right to impose an exclusion from their actions. We have modified § 1001.501 to provide that exclusions may be imposed for periods of time shorter than the period for which the license was lost and to allow for early reinstatement, in cases where another State, fully apprised of the circumstances surrounding the loss of

the license, grants the practitioner a new license or takes no significant adverse action as to a current license. We have also revised § 1001.501 to state that loss of a license includes the loss of the right to apply for or renew a license, as provided in section 6411(d) of the Omnibus Budget Reconciliation Act of 1989. We have modified § 1001.601 to provide that exclusions will be for a period of 3 years unless specified aggravating or mitigating factors form a basis for lengthening or shortening that period. We have also clarified § 1001.601 to state that the OIG will normally not consider a request for reinstatement until the period of exclusion imposed by the OIG has expired. Once the OIG has reinstated the party, the Federal or State health care program that originally imposed the sanction will be free to reinstate the party.

*Comment:* Commenters stated that the regulations provide that the OIG may impose an exclusion for a longer length of time than the penalty imposed by the derivative agency. One commenter argued that it is inappropriate to allow for an exclusion to be longer than that imposed by the original sanctioning body, especially since a provider cannot collaterally attack the basis for the first action.

*Response:* We anticipate that in the vast majority of cases, the length of the exclusion imposed by the OIG will parallel the length of time imposed by the original sanctioning body. However, there may be circumstances where the OIG finds that the derivative body did not adequately consider the potential harm that the individual's or entity's actions could have on Medicare or the State health care programs. In those cases, the OIG must have the discretion to extend an exclusion so as to adequately protect the programs and their beneficiaries. Section 1128(c) of the Act, which governs the length of exclusions, does not restrict exclusions imposed under sections 1128 (b)(4) or (b)(5) to the length imposed by the derivative body.

*Comment:* Several commenters stated that §§ 1001.501 and 1001.601 should provide that someone who suffers a license revocation, exclusion, or other action covered by these provisions will automatically be excluded from Medicare and the State health care program.

*Response.* In contrast to the mandatory exclusions, Congress vested the Secretary with the discretion and the responsibility to determine whether it is appropriate, based on the particular circumstances, to exclude the sanctioned individual or entity from Medicare and the State health care programs. To treat these exclusions as automatic, i.e., as mandatory exclusions, would be inconsistent with that authority.

*Comment:* A number of commenters indicated that § 1001.501 should allow for an exclusion where restrictions are imposed that curtail use but do not result in the license being lost entirely, such as prohibiting a physician from performing surgery except under supervision.

*Response:* Section 1128(b)(4) of the Act specifies that someone may be excluded because a license has been suspended, revoked, surrendered or otherwise lost. We do not have the statutory authority to expand this regulation as suggested by this comment.

*Comment:* Commenters pointed out that it is not necessary to provide for an exclusion where someone has surrendered his or her license since the individual or entity would automatically be precluded from rendering services.

*Response:* An individual or entity may lose a license in one State, but that alone would not preclude that individual or entity from rendering services in another State, if licensed there. An exclusion from Medicare or Medicaid, for example, would have nationwide applicability, so that individual or entity could not receive payment from Medicare or Medicaid for rendering services to any program beneficiary, regardless of where that beneficiary is located.

*Comment:* One commenter stated that an individual or entity that surrenders a license should not have to go through the procedures of requesting reinstatement if and when the license is regained.

*Response:* In granting the Secretary the authority to exclude based on surrender of a license, Congress recognized that licenses are often surrendered because of serious underlying problems. Surrender does not mean that the basis for the loss of the license is any less serious than if the license was revoked. Consequently, we do not believe that cases of surrender should be treated any differently than other cases where a license was lost.

*Comment:* Several commenters indicated that in cases of surrender, the regulations exceed congressional intent by allowing for exclusion where someone surrenders a license for a minor infraction while not allowing the practitioner to challenge the reasonableness of the disciplinary action. Congressional intent shows that the critical factor in determining whether to exclude someone is not merely surrender, but whether the practitioner intended to evade scrutiny by surrender. These commenters felt that the regulations should set forth the factors that will be used to determine whether exclusion in surrender cases is appropriate.

*Response:* These regulations consistent with the statute, do not permit exclusion in all cases of surrender, but only in those cases where surrender occurs while a disciplinary proceeding concerning professional competence, professional performance or financial integrity is pending. Thus, exclusions will not be imposed in cases where licenses are surrendered for violations which do not fall in these categories. To the extent a ministerial violation arguably fall within these categories—for example, one could argue that failure to pay annual dues relates to financial integrity—the OIG will exercise its discretion as to whether an exclusion is appropriate. We decline to include a list of factors to be considered in determining whether to impose an exclusion in licensure cases as this will vary depending on the unique circumstances of a particular case.

*Comment:* One commenter stated that exclusions should not be imposed in cases where a license is lost until the practitioner has the opportunity for judicial review of the underlying action which caused the loss of license.

*Response:* We disagree. The regulations are consistent with statutory authority. Often, judicial review occurs a substantial period of time after the original action. Since an independent body has made a determination regarding this practitioner, we believe it is preferable to give controlling weight to the derivative body's conclusions and exclude the practitioner, to protect the program and beneficiaries, consistent with the purposes of the exclusion authorities.

*Comment:* According to some comments received, the definition of "or otherwise sanctioned" that was included in the preamble to the proposed regulations should be incorporated in § 1001.601.

*Response:* We agree and have included a definition of this term in the regulations to explain that it includes any actions that limits the ability of a person to participate in the program at issue. We have also clarified that this includes situations where an individual or entity voluntarily withdraws from program participation solely to avoid a formal sanction, for example, by agreeing to withdraw in order to avoid prosecution or exclusion.

*Comment:* Commenters stated that the OIG should not exclude an individual or entity under § 1001.601 when the original sanctioning agency did not itself exclude the individual or entity. These commenters indicated that the regulations wrongly assume that the basis of the derivative sanction was serious when in reality a provider may choose not to contest a minor sanction simply to avoid further confrontation.

*Response:* We have clarified the scope of § 1001.601 by incorporating in the regulations a definition for the term "or otherwise sanctioned" to cover all actions that limit the ability of a person to participate in the program. This definition will ensure that OIG exclusions will be based only on prior sanctions that were significant in nature.

*Comment:* A number of individuals indicated that the terms "professional competence," "professional performance" and "financial integrity" are too vague. Commenters questioned whether these terms would include, for example, a deficiency in a facility's conditions of participation.

*Response:* We decline to further define these terms, and believe that whether someone's professional competence, professional performance or financial integrity are implicated must be determined based on all the circumstances. However, the fact that this authority can only be used in cases where someone's program participation has been curtailed militates against the concern that someone would be excluded for insignificant violations. In addition, this authority is permissive, and the OIG can and will exercise its discretion in determining whether a particular violation warrants the severe penalty of exclusion.

*Comment:* Commenters felt that the OIG should consult with a sanctioning agency before imposing an exclusion, rather than providing notice after the fact.

*Response:* By its delegated statutory authority, the OIG has full discretion to decide whether to impose a permissive exclusion, and need not consult with third parties including the original sanctioning bodies. However, we would note that in specific cases, the OIG may decide to contact the original sanctioning body to obtain relevant information or guidance in deciding whether to impose an exclusion.

● *Section 1001.701*

*Comment:* Several commenters pointed out that the proposed regulatory language in § 1001.701(a)(1) did not comport with the statutory language which specifies that the point of reference is "such individual's or entity's usual charges or costs."

*Response:* We agree with these concerns, and have amended the regulatory provision accordingly.

*Comment:* A number of commenters suggested that the exception in § 1001.701(b)(2), permitting the furnishing of items or services in excess of the needs of individuals under certain circumstances when such items or services were ordered by a physician, is too narrow and should be expanded to include those situations where the item or service was ordered by a health care professional other than a physician, such as a nurse practitioner or a clinical psychologist.

*Response:* We agree, and have amended the regulation to include a physician or other authorized individual.

*Comment:* One commenter pointed out that although current regulations specify the sources of information that the OIG will look to in making a determination that items or services provided were in excess of the needs of individuals or of a quality that fails to meet professionally recognized standards of health care (§ 1001.101(b)), the proposed rule did not include such a provision. This commenter suggested that the final regulations should contain a similar list of information sources.

*Response:* We agree. This provision was inadvertently omitted from both §§ 1001.701 and 1001.801 of the proposed regulations. We have added provisions specifying sources of information to both sections in this final rule.

*Comment:* A number of commenters asked that we define the phrase "substantially in excess of the patient's needs," and one commenter suggested that we adopt a definition from the Home Health Agency manual. Along the same line, some commenters suggested that we amend the regulations to state that liability under this section requires a pattern of abuse, or a showing of repetitive violations. One commenter expressed the view that § 1001.701(a)(2) should never be a basis for exclusion since no standards exist for determining whether care is substandard or unnecessary.

*Response:* Section 1001.701(a)(2) implements section 1128(b)(6)(B) of the Act, which is a recodification of an authority which the Department has had for many years (section 1862(d)(1)(C) of the Act). We have initiated a number of cases under this authority and can therefore speak from some experience. In our opinion, it is unnecessary to define the phrase "substantially in excess of the patient's needs" or to limit by regulations the OIG's discretion to initiate cases that are not based on a pattern of violations. Before we initiate a case under this authority, the Inspector General makes a determination of liability based on all of the facts available. This determination is always made on the basis of expert medical opinion, usually that of medical reviewers from the Medicare carrier or from the local PRO, and followed up by a review by one of our own medical officers. In fact, cases under this section almost always originate with Medicare carriers or other medical sources who refer the case to the OIG. Thus, on a case-by-case basis, we are in a position to determine whether the care provided was substantially in excess of the needs of the patient.

As evidenced by the legislative history to this section, Congress did not intend that the OIG automatically exclude an individual or entity where the violation was "an isolated or inadvertent instance," but to seek corrective action in such cases. Consistent with this intent, we would rarely propose an exclusion for an isolated and inadvertent instance.

However, if only one or two life-threatening violations were brought to our attention and we determined that imposition of an exclusion under § 1001.701 was the most appropriate remedy, we believe that it is consistent with the intent of the statute for the OIG to retain the discretion under these regulations to initiate an exclusion action, even absent a full-fledged pattern of abuse.

*Comment:* A number of commenters sought specific clarification of the scope of § 1001.701(a)(2). Their concern related to whether entities such as nursing homes and home health agencies would violate this section if they provided an increased level of services to a patient at the specific request of the patient and at the patient's own expense, e.g., private duty nurses, extra home health services not reimbursable by Medicare, or private rooms.

*Response:* Section 1001.701(a)(1) is not intended to subject to liability those who furnish an increased level of care to a patient who has been informed that such care is not medically necessary and that neither Medicare nor a State health care program will reimburse such services, but who chooses to purchase such services at his or her own expense. For purposes of determining liability under this provision, such services would not be viewed as "substantially in excess of the patient's needs."

*Comment:* Some commenters requested clarification of the breadth of the exception set forth § 1001.701(c)(2). Specifically, they expressed concern

about liability of laboratories and of suppliers for items or services that are provided and later determined to be unnecessary or excessive.

*Response:* In general, the exception in paragraph (c)(2) of this section will protect such laboratories and suppliers from liability. However, we are aware that some suppliers have conspired with physicians to obtain certificates of necessity for items or services in order to defraud the Medicare program. If, as in that sort of situation, a supplier was in a position to know that the items or services were not necessary, § 1001.701(c)(2) would provide no protection from liability. With respect to laboratories, although the exception would normally protect a laboratory from being subject to exclusion for providing unnecessary tests ordered by a physician or other authorized individual, we want to make clear that this does not mean that the laboratory is entitled to be paid by Medicare or State health care programs for such tests. Notwithstanding the paragraph (b)(2) exception, payments made to laboratories for services later deemed to be unnecessary may constitute overpayments under HCFA regulations.

*Comment:* In the preamble to the proposed rule, we requested comments on whether to define by regulations the terms "substantially in excess" and "usual costs or charges" which are used in § 1001.701(a). That provision authorizes the exclusion of individuals and 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 received a number of comments in response to our request, many from the clinical laboratory industry. While most commenters agreed that definitions would be helpful, none were able to suggest feasible ones. One commenter suggested that any definition should take account of the fact that it costs laboratories more to deal with Medicare than to deal with physicians, and should permit Medicare to be charged more. Another commenter suggested that we consider such factors as the geographic area in which the provider operates (cost of overhead) and whether there is a scarcity of practitioners in the area in determining whether to permit higher charges. One commenter felt that the OIG should have to prove intent to overbill Medicare in order to show liability under this provision. Two commenters noted that third-party payors other than Medicare normally allow the highest costs for laboratory services, and suggested that the appropriate comparison in charges is between Medicare and other third-party payors, not between Medicare and physicians. One commenter objected to the application of this provision to laboratories at all.

*Response:* Upon review of all the comments and further consideration of this issue, we have decided not to define the terms "substantially in excess" and "usual charges or costs" at this time. We recognize that it would be helpful to the public to have some additional guidance on what standards the OIG intends to apply in cases brought under § 1001.701(a)(1). However, in light of the many different factors and variables that may exist in the wide variety of cases which could be investigated under this provision, we have determined that it is not feasible to define the terms by regulation. Instead, the OIG will continue to evaluate the billing patterns of individuals and entities, including clinical laboratories, on a case-by-case basis.

- *Section 1001.801*

*Comment:* According to some commenters, it was unclear what would be considered a "substantial" failure to provide medically necessary items or services. These commenters indicated that health maintenance organizations (HMOs) should not be sanctioned for denials because an enrollee did not seek required prior approval or where the HMO denies coverage for services provided by a non-plan provider where the HMO determines the services did not meet "emergency" standards, or where medical judgment to not provide the services is made in accordance with the HMO's standard operating policies. A commenter questioned whether this would apply if there was a delay in providing routine services.

*Response:* In determining whether an exclusion should be imposed, legitimate reasons for denying services will be considered. However, HMOs may use "procedures" as a pretext justification, and it is the OIG's responsibility to evaluate all circumstances to determine whether the HMO properly or improperly failed to provide medically necessary items or services.

*Comment:* Some commenters believed that the OIG lacks the expertise to determine whether there is a substantial failure to provide medically necessary items or services, and stated that the OIG's decision should be based on medical review by the carrier or the PRO. The comments indicated that the OIG should defer to HCFA and the States, which are primarily responsible for regulation of HMOs, in determining whether an exclusion is appropriate.

*Response:* We have included in the final regulations the sources on which the OIG's decision to exclude under this authority will be based. These are PROs, State or local licensing or certification authorities, fiscal agents or contractors, private insurance companies, State or local professional societies or other sources deemed appropriate by the OIG. Although the OIG may consider the views of HCFA or a State, or any other entity, the OIG has the delegated authority to impose an exclusion under these circumstances and it is the OIG that must ultimately evaluate the facts to determine if an exclusion is appropriate.

*Comment:* One commenter asked whether an HMO could be excluded if an independent contractor failed to provide medically necessary services.

*Response:* Section 1128(b)(6)(C) of the Social Security Act provides that an HMO can be excluded under these circumstances. As a practical matter, we intend to use this authority only where the HMO had sufficient responsibility for this act, e.g., if problems concerning a physician's professional competence had been brought to the attention of the HMO, but it failed to take any appropriate action. Since the HMOs are selecting the service providers, and beneficiaries place their trust in the HMO's ability to select qualified providers, the HMOs must and should take responsibility for their selection. This provision will help assure that this occurs.

*Comment:* A commenter pointed out that these regulations should state that an exclusion may occur for failure to provide medically necessary services to any persons regardless of whether those persons are covered by Medicare or Medicaid.

*Response:* Section 1128(b)(6)(C) of the Act provides that this exclusion only applies to a failure to provide medically necessary items or services to individuals who are covered under a Medicaid plan, or a waiver under the Medicaid program under section 1915(b)(1) of the Act, or to individuals covered under a risk-sharing contract under section 1876 of the Act. Thus, it would be beyond our statutory authority to expand this regulation as suggested.

- *Section 1001.901*

*Comment:* Commenters believed that the statute does not authorize an exclusion where a CMP is not imposed or where a CMP proceeding is not commenced.

*Response:* Imposition of a CMP is not a predicate to imposing an exclusion under this authority; rather, exclusion is an alternative remedy, to be used instead of or in conjunction with a CMP or criminal proceeding depending on the circumstances. The legislative history to section 1128(b)(7) of the Act states that "[t]he Secretary could exercise this authority to exclude an individual or entity without the necessity of imposing a civil money penalty or obtaining a criminal penalty or obtaining a criminal conviction." (House Report No. 100-85, 100th Cong., 1st sess., 9.)

*Comment:* Some commenters indicated that if someone successfully defended against imposition of a CMP, those same defenses should apply to bar the imposition of an exclusion.

*Response:* We agree. If a respondent successfully defends against imposition of a CMP, we would not then impose an exclusion under § 1001.901 based on the conduct at issue in the CMP case.

*Comment:* One commenter felt that a CMP, rather than an exclusion, should be imposed for a first offense, since a CMP gives the programs a chance to see if corrective action will be taken.

*Response:* We reject this comment since the OIG has the right and responsibility to exercise its discretion in all cases, including first offenses, to determine whether an exclusion is appropriate.

- *Section 1001.951*

*Comment:* One commenter urged that the Inspector General recommend that the exemption under section 1128B of the Act for payments to employees be revoked because outsiders cannot compete for the services employees of referring physicians provide.

*Response:* This issue was addressed at length in the preamble to the OIG "safe harbor" regulations. (See 56 FR 35952, July 29, 1991.)

*Comment:* One commenter questioned whether violations of the anti-kickback statute would depend on the kind of health care provider involved in the remuneration scheme.

*Response:* By its term, section 1128B of the Act applies to "whoever" engages in a kickback. The term "whoever" means any individual or entity, regardless of the kind of items or services they provide.

*Comment:* One commenter proposed that consideration of "[a]ny other facts bearing on the nature and seriousness of the individual's or entity's misconduct" for purposes of determining the period of exclusion was too vague to be evenly applied and, therefore, should be deleted throughout the regulations.

*Response:* The purpose of such a "catch-all" provision is to afford the decisionmaker some leeway to consider certain highly relevant facts which relate to that particular exclusion. Exactly what these facts might be, other than the fact that they must relate to the "nature and seriousness" of the excluded party's conduct, depends entirely on the particular circumstances of the case. We believe that justice is best served if such leeway is afforded the decisionmaker.

*Comment:* One commenter suggested that the financial condition of the excluded party should be considered when determining the length of exclusion under §§ 1001.901 and 1001.951.

*Response:* As we stated in the proposed rule, financial condition is relevant only to the *amount* of a penalty or assessment and not to the *length* of an exclusion. For further discussion, see section IV.D. of this preamble.

*Comment:* One commenter inquired as to the reason why the aggravating and mitigating factors present in other exclusion authorities were not incorporated in this authority.

*Response:* Generally, aggravating and mitigating factors are applied to situations where there is either a benchmark period of exclusion or some other specific period of time that would otherwise set the exclusion period. Here, as with § 1001.901, there are no such periods so that it is appropriate to look only at factors that would help determine an appropriate period of exclusion given the particular facts of each case.

*Comment:* Many commenters objected to § 1001.951(a)(2)(i) which provides that any individual or entity that has offered, paid, solicited or received remuneration as described in section 1128B(b) of the Act is subject to exclusion so long as *one* of the purposes of such remuneration is unlawful under the statute—the so-called "one-purpose" rule. That is, liability could not be avoided by the fact that there may also have been some additional, lawful purpose for the remuneration. Some commenters also asserted that the one-purpose rule is unfairly broad because it would include activities that are nonabusive or beneficial to the Medicare program.

*Response:* The focus of the inquiry is whether an individual or entity has deliberately and intentionally paid or received remuneration to induce the referral of program-related business. We believe it, if the OIG has demonstrated this conduct, the statute does not require the OIG to further prove that the illegal purpose was the primary factor motivating the conduct. We believe that this broad interpretation of the statute is supported by the courts (see *United States* v. *Greber*, 760 F.2d 68 (3d Cir.) *cert. denied*, 474 U.S. 988 (1985); *United States* v. *Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F. 2d 20 (1st Cir. 1989); and *United States* v. *Kats*, 871 f.2d 105 (9th Cir. 1989)).

With respect to conduct that may technically constitute a violation but that should nevertheless be protected, Congress, in recognition of the broad reach of the anti-kickback statute, provided for the development of "safe harbors." These regulations describe various business and payment practices that, although they violate the anti-kickback statute, will not be treated as criminal offenses under section 1128B(b) of the Act and will not serve as a basis for a program exclusion under section 1128(b)(7) of the Act. (See section 14 of Public Law 100-93.) For further discussion on the reach of the anti-kickback statute, we recommend that individuals refer to the "safe harbor" regulations (56 FR 35952, July 29, 1991).

*Comment:* One commenter recommended that we include in § 1001.951 a provision that proof that a lawful purpose existed for an otherwise unlawful kickback could provide a basis for decreasing the length of exclusion.

*Response:* Although we suggested in the preamble of the proposed rule that there are circumstances where a lawful purpose for the remuneration may lead to a reduction in the proposed period of exclusion, in most cases we believe that it would not and should not. Consequently, we believe that such arguments are best considered under § 1001.951(b)(iv) which provides for consideration of "[a]ny other facts bearing on the nature and seriousness of the individual's or entity's misconduct."

- *Section 1001.1001*

This section permits the exclusion of entities that are owned or controlled by an individual who has been criminally convicted, has had CMPs imposed on him or her, or who has been excluded from Medicare or a State health care program.

*Comment:* One commenter suggested that this provision violates the due process requirements because there is no rational relationship between the acts of the individual and the entity. One commenter expressed concern that an entity could be excluded when it did not even know that an individual was sanctioned. Another commenter stated that the entity should have an opportunity to cure the problem prior to exclusion, and one commenter

questioned whether an entity could do this based on §§ 1001.3002(c) (1) and (2), which provide that an entity will be reinstated when it shows that it has terminated its relationship with the sanctioned individual. Another commenter argued that if the individual has not been excluded from Medicare or the State health care programs, that the entity should not be excluded either.

*Response:* In accordance with section 1128(b)(8) of the Act, the Secretary is authorized to exclude any entity in which a person with an ownership or controlling interest, or an officer, director, agent or managing employee, has been sanctioned for certain program-related offenses. The regulations merely implement the OIG's authority in accordance with section 1128(b)(8). The purpose of this provision is 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. Further, section 1128(b)(8) of the Act should encourage entities to scrutinize the background of individuals with whom they plan to embark on a significant relationship before they hire the individual or grant him or her a controlling interest. Thus, excluding an employer who has a significant relationship with any individual who has been sanctioned for program-related offenses is rationally related to the goal of protecting the Medicare and Medicaid programs.

Moreover, in these cases, the OIG will always issue a letter prior to imposing the exclusion that notifies an entity of the OIG's intention to exclude it because of its relationship with a sanctioned individual. This letter states that the entity may supply the OIG with any mitigating information. Thus, the entity is always given an opportunity to cure the situation, such as by terminating its relationship with the sanctioned individual, and notifying the OIG of that fact before the OIG makes a final decision as to whether to exclude the entity.

If an entity, after receiving the OIG's notice of intent to exclude under § 1001.2001, can prove that it has terminated or modified its relationship with the sanctioned individual in accordance with the conditions of §§ 1001.1001(c) (1) or (2), that individual would not be excluded by the OIG. Similarly, the OIG will reinstate an entity as soon as it determines that the sanctioned individual no longer has the proscribed relationship with the entity (§§ 1001.3001(c) (1) and (2)). Thus, it would be extremely unlikely that the OIG would exclude an entity which, when notified of its problematic relationship with a sanctioned individual, promptly severed it.

*Comment:* Commenters expressed concern about how the term "entity" would apply to a corporation with many subsidiaries. In a case where one subsidiary had a relationship with a sanctioned individual, commenters questioned whether only the subsidiary would be excluded, or whether all parent and related corporations could be excluded. Commenters argued that this broad interpretation would simply lead to unnecessary restructuring of entire organizations to insulate the entire entity. Commenters further recommended that the exclusion be limited to the corporate site involved, or that the OIG should have to prove that the entire entity actively encouraged or knowingly tolerated the offending behavior.

*Response:* The statute contemplates excluding an entity that has a substantial relationship with a sanctioned individual. While it may often be possible to target only one offending subsidiary or site for exclusion, we believe that there are situations where an entire corporate entity may be found to have a substantial relationship with one individual who deals primarily with one of its subsidiaries. In deciding whether to exclude an entire corporate network or one isolated subsidiary, we intend to evaluate the nature and extent of the relationship and determine what parties were actually at fault for engaging in a relationship with a sanctioned individual, as well as which entities the sanctioned individual actually controls. The OIG will always consider whether the interests of the programs and their beneficiaries are furthered by excluding an entire corporate network.

*Comment:* The statute and regulations provide for the exclusion of an entity whose agent is a sanctioned individual. Commenters expressed concern as to whether "agent" includes even low-level employees or independent contractors and argued that, to trigger an exclusion, the "agent" should have a substantial relationship with the entity.

*Response:* We agree that the term "agent" is vague and therefore have included in the final regulations a definition of "agent" essentially modeled after a definition set forth in HCFA regulations (42 CFR 455.100) which implement section 1126 of the Act, which is referenced in section 1128(b)(8)(A)(ii) of the Act. We are defining "agent" as anyone who has the express or implied authority to obligate or act on behalf of an entity. We intend for this to apply to agency relationships where the agent has, or is able to have, a significant role in the entity. For example, this definition includes a situation where an excluded individual transferred control of an entity to his or her spouse, but still, in fact, acts on behalf of the entity or exercises some control over the entity. In such a case, the excluded individual would be an agent because he or she would have, at a minimum, the implied authority to act on behalf of the entity. Of course, it is not necessary to prove that someone is an agent if that person falls into another category of enumerated relationships. Thus, in the example cited above, if a State has community property laws, it may be possible to exclude the entity because the excluded spouse still has a legal ownership interest in the business, regardless of whether that spouse meets the definition of "agent."

*Comment:* Some commenters stated that this provision is overly broad and should be restricted to only those cases where the sanctioned individual exercises control over the day-to-day operations of the entity.

*Response:* We disagree with this comment. The regulations are a proper interpretation of statutory authority, and the legislative history establishes that Congress thought ownership alone, or one of the other relationships alone, was enough of a substantial relationship to warrant exclusion. (House Report 100–85, *supra* at 10.)

*Comment:* One commenter expressed concern that an entity could be excluded because of its relationship with an individual who had to pay a minimal monetary penalty, and suggested that the regulations set forth a minimum penalty that would have to have been imposed before the entity could be excluded.

*Response:* We take into account the amount of the penalty in determining whether an exclusion is appropriate. However, we believe the most important factor to consider in determining whether to exclude an entity because of its relationship with a sanctioned individual is the circumstances surrounding, rather than merely the amount of, the penalty.

*Comment:* One commenter questioned whether prohibitions on the various ownership or control relationships set forth in proposed paragraphs (a)(1)(iii)(A)–(F) of § 1001.1001 apply only to individuals who were excluded, or to all sanctioned individuals who were criminally convicted or subject to a CMP, as defined in proposed §§ 1001.1001(a)(1) (i) through (iii).

*Response:* We have revised the final regulations to make it clear that entities may be excluded for having any of the specified relationships with any sanctioned individual as defined in §§ 1001.1001(a)(1) (i) through (iii). We are also adding the word "ownership" to the first factor in this list of relationships. That term was inadvertently omitted from the proposed regulations and is consistent with section 1124(a)(3) of the Act.

*Comment:* One commenter questioned our definition of "indirect ownership interest." The commenter stated that since the proposed regulations provide that indirect ownership interest includes an ownership interest through any other entities, use of the term "includes" suggests that the term "indirect ownership interest" covers other relationships that are not specified in the regulations. In addition, the commenter questioned the example given in the proposed regulation that stated that 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. The commenter argued that the indirect owner may have no control over the actions of the target entity, and stated that it is unclear how ownership would be calculated in a situation which is more complex.

*Response:* We have modified the final regulations to replace the word "includes" with "means." The example used in the proposed rule was merely illustrative to show that an entity may be excluded if a sanctioned individual has even an indirect ownership relationship, which is consistent with the statute. We recognize that complex situations will require an analysis of the extent of the ownership interest, but this must be determined on a case-by-case basis.

• *Sections 1001.1101 and 1001.1201*

These provisions implement sections 1128(b) (9), (10) and (11) of the Act which permit the exclusion of an individual or entity that fails to disclose certain information, including payment information.

*Comment:* One commenter argued that exclusions should be imposed only after the subject individual or entity has an opportunity for a hearing before an ALJ.

*Response:* We do not believe that due process requires a hearing before an ALJ before an exclusion under these regulations is imposed, for the reasons discussed in section IV.F.1. of this preamble. However, § 1001.2001 provides that, prior to exclusion, an individual will receive notice of intent to exclude describing the payment or other information that was not disclosed as requested by the Department, and gives the individual 30 days to comply with the request before the exclusion is implemented. In this way, exclusions will not be imposed for inadvertent failures to comply with statutory or regulatory disclosure requirements, since the subject individual or entity will have an opportunity to cure the problem prior to imposition of exclusion.

*Comment:* One commenter contended that the regulations give no criteria as to what constitutes a failure to provide information, and that there is no requirement that the request for the information be reasonable, relevant, or that specific information requested be identified. The commenter argued that these regulations violate constitutional rights, and that the regulations should state that the exclusion is applicable only if there is some probable cause or reasonable basis for the disclosure through the OIG's subpoena power.

*Response:* These regulations provide for exclusion where information is not provided which is already required by statute or regulation, or information which is necessary to determine appropriate program reimbursement. The successful operation of the programs is based, in large part, on the government having access to information. As noted above, an individual will have 30 days to respond before an exclusion is imposed.

*Comment:* Several commenters expressed concern that an individual or entity would be excluded for declining to provide the information for legitimate reasons, such as the physician-patient privilege.

*Response:* Much of the information required to be provided in §§ 1001.1101 and 1001.1201 relates to ownership interests or significant business transactions which will not implicate patient records. Moreover, to the extent that patient records are sought, the Federal government's interest in such records supercedes State confidentiality privileges, as discussed later in this preamble. With respect to § 1001.1201, the information being requested is limited to that necessary to determine whether payments should be made and the amount thereof, information that is fundamental to the proper administration of the programs. However, as stated above, an individual will have 30 days to comply prior to imposition of an exclusion (§ 1001.2001(a)). If an individual or entity believes it is unable to provide the requested information, whether on the basis of privilege or other reason, it should notify the OIG of that fact during this 30 day period, and the OIG will consider this information in determining whether an exclusion is appropriate.

*Comment:* One commenter expressed concern that excluding an individual in accordance with § 1001.1101 for giving a government representative incorrect information is an extraordinary punishment when the individual was unaware that the information was incorrect. Another commenter suggested that the regulations should include a statement made in the preamble to the proposed regulations that the OIG does not intend to take action based on isolated or unintentional failures unless such failures have a significant impact on the program or beneficiaries.

*Response:* As stated in the preamble to the proposed regulations, the proper administration of the programs depends upon the Department having access to information that is required by statute. However, the OIG 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. We believe it is unnecessary to include a statement in the regulations as to the circumstances when the exclusion would be imposed, because it is within the OIG's discretion to determine what failures will have a significant impact on the program or beneficiaries, and when an exclusion is appropriate.

• *Section 1001.1301*

This authority permits the exclusion of individuals or entities who fail, when a proper request has been made, to grant immediate access to the Secretary, State survey agency or other entity for the purpose of conducting surveys and other reviews, or who fail to grant immediate access to the OIG or State MFCUs for the purpose of reviewing documents to determine if a statutory or regulatory violation has occurred.

*Comment:* Commenters contended that the searches authorized by the regulations are unconstitutional. They argued that warrants should be required, and that the regulations should require that the OIG and MFCUs have probable cause to believe that there is a violation of statutory or regulatory requirements, rather than "information to suggest" a violation.

*Response:* This Department can request through appropriate channels that a search warrant be obtained. In granting survey agencies, the OIG and MFCUs the authority to gain immediate access to documents or to an institution

by threatening exclusion, Congress plainly intended to grant these entities broader and additional authority that is not subject to the restrictions suggested in the comments. Administrative warrantless searches have been upheld by the Supreme Court (see *New York* v. *Burger*, 482 U.S. 691 (1987); *United States* v. *Biswell*, 406 U.S. 311 (1972)). In *Burger*, the Court set forth the three criteria that must be met in order for such searches to be constitutional: (1) There must be a substantial government interest that informs the regulatory scheme in accordance with the inspection made; (2) the warrantless searches must be necessary to further that scheme; and (3) the statutory scheme must provide an adequate substitute for a warrant. To meet this third criterion, the statutory scheme must be sufficiently comprehensive and defined so that the subject cannot help but know that his or her property will be subject to periodic inspections undertaken for specific purposes, and the statutory scheme must limit the discretion of the government inspectors in terms of time, place and scope. We believe each of these criteria is met through the statute and implementing regulations that are published today.

First, the government interest in the administration of its health care programs is obvious. The government must be able to protect the health and welfare of the beneficiaries of its programs, and must be able to assure that government payments are lawful and appropriate. Quality of care is critical to every program beneficiary, and proper government reimbursement is essential given the escalation of health care costs in our nation and the need for the proper distribution of limited public funds.

Second, warrantless searches are necessary to further the statutory schemes of Medicare and State health care programs. With regard to searches by survey facilities, it is critical that the programs have the ability to evaluate conditions of these facilities to be certain that appropriate care is given. With regard to searches by the OIG and MFCUs, these searches are limited to review of documents necessary to determine if good care is being provided and if government payments are proper. In all of these situations, the process of getting a warrant might alert health care providers of the investigation, and thwart the investigation's goals.

Third, the statutory schemes of Medicare, Medicaid and other programs covered by these regulations are sufficiently comprehensive such that providers can reasonably expect administrative searches, and the restrictions on the discretion of those seeking immediate access in terms of time, place and scope are also reasonable. With regard to searches by survey agencies, all facilities subject to such searches have, by their participation, consented to such surveys, and should reasonably be aware that surveys are part of the statutory scheme. We agree that it is reasonable to limit the scope of a survey to ordinary business hours, but facilities such as hospitals and nursing facilities are open, and are caring for beneficiaries, 24 hours a day, and therefore, must be subject to searches at any time. For example, it may be necessary to conduct a survey in the middle of the night to determine if nighttime staffing is truly adequate.

The places of such inspections are also specified. Inspections may only be made of entities that represent themselves to be specific types of institutions—such as a hospital, home health agency or laboratory—and the types of institutions subject to inspection are clearly delineated in the regulations. Finally, the scope of such searches are also defined, that is, the inspectors may examine the premises and documents that are necessary to allow a survey agency to determine whether that facility meets statutory standards that are specified in the regulations.

With regard to searches by the OIG or MFCUs, by regulation the scope of the searches are narrowly tailored in that they are limited to searches for documents. Everyone who participates in the government health care programs is, or should be, aware by the nature of the detailed statutory and regulatory schemes governing such programs, and the fact that they are entering into a business arrangement with the government, that the government can and must review records relating to their participation in the health care programs. In some cases, this will involve review of records for patients not covered by government programs, but those who participate are aware of the need for government review of the provider's quality of care. Further, the regulatory scheme imposes proper limitations. The regulations provide that the request must be made during reasonable business hours. The searches are limited in place, since they only involve review of records rather than inspections of premises, and they are limited in scope as only involving searches which are necessary for the OIG or MFCUs to fulfill their statutory and regulatory functions.

Requiring access in cases where the OIG or a MFCU has reason to suggest there is a statutory or regulatory violation is a proper implementation of the statute. As the legislative history states, Congress intended that requests for immediate access by the OIG MFCUs "only apply to situations where there is information to suggest that the individual or entity has violated statutory or regulatory requirements under titles V, XI, XVIII, XIX or XX." (House Report 100-85, *supra* at 10.) Moreover, searches where there are "reasonable grounds" to believe a violation of law has occurred have been upheld where they meet reasonable legislative or administrative standards, as is the case here (see *Griffin* v. *Wisconsin*, 483 U.S. 868 (1986)).

*Comment:* A number of commenters believed that the regulations should state that individuals or entities will not be excluded under § 1001.1301 due to clerical errors in failing to provide information.

*Response:* Whether exclusion is appropriate will depend on the circumstances surrounding the failure to provide information, and there may be differing views on whether a failure to provide information was truly inadvertent. We decline to include the limitation suggested by the comments in the regulations, but, as a practical matter, the OIG does not intend to use this authority in cases where the failure to provide information was inadvertent. Moreover, a provider can avoid this problem by simply giving the information that was erroneously not provided to the requesting agency at the time the request for immediate access is made.

*Comment:* Commenters pointed out that any request for immediate access should be based on information that suggests a serious violation of sections 1128A or 1128B of the Act.

*Response:* Section 1128(b)(12) of the Act does not limit this authority to use only in cases of suspected violations of sections 1128A or 1128B.

*Comment:* One commenter questioned the Secretary's authority to authorize searches by MFCUs.

*Response:* The commenter is mistaken. Section 1128(b)(12)(D) of the Act specifically authorizes immediate access to MFCUs. However, by regulation we are requiring that written requests for documents made by MFCUs be signed by the IG or his or her designee.

*Comment:* Commenters felt that MFCUs should be given immediate access in the same way State survey agencies are.

*Response:* State survey agencies are not only reviewing documents, but need access to a facility to determine current conditions. Although there is always a risk that documents will be destroyed or altered, the regulations provide that in cases where the MFCU has reason to believe that such destruction or alteration will occur, the MFCU can have on the spot access. Otherwise, we believe it is reasonable to allow providers some period of time to compile and review records. Of course, if it is later determined that a provider altered or destroyed records, the provider may be subject to sanctions, for example, for obstruction of an investigation.

*Comment:* Commenters stated that while the regulations require access to determine if laboratories meet the requirements of sections 1861(s) (12) and (13) of the Act, these sections do not relate to laboratories.

*Response:* We have corrected these statutory references in the final regulations.

*Comment:* According to several commenters, when requesting immediate access, the OIG should provide the individual or entity with a written statement of the subject's rights, and obligations, and this statement should include the definitions of "reasonable request" and "immediate access."

*Response:* We agree, and have incorporated this in the final regulations. This statement, which will be in the form of a letter requesting immediate access, will set forth the nature of the request such as the documents sought, the authority for it, and will also serve as the notice of intent to exclude and opportunity to response (in lieu of any such notice and opportunity under § 1001.2001), explaining the potential exclusion sanction and the length of the potential exclusion.

*Comment:* A number of commenters indicated that the regulations should set forth the OIG's statutory functions that can be the basis for a request for immediate access.

*Response:* The OIG's authority is derived from 5 U.S.C. App. 3. We do not believe it is necessary to include this in the regulations, but the authority for the request for immediate access will be included in the letter requesting access.

*Comment:* Commenters pointed out that a party should be allowed to know what information the OIG or a MFCU has that leads the OIG or the MFCU to believe the party has violated a statutory and regulatory requirement at the time access is requested, rather than having this information told only to an ALJ at an exclusion hearing.

*Response:* In advising a party of the documents requested, the statutory authority for the request, and the name of the official authorizing the request, a party has enough protections by which to verify the legitimacy of the request. A party has no right to know the nature of the underlying investigation. It is not appropriate for the OIG or a MFCU to reveal sources of information or the nature of the investigation, since a party is obligated to comply regardless of the nature of the investigation, and since providing such knowledge could impede the investigation.

*Comment:* In requests for immediate access by survey agencies under §§ 1001.1301(a)(1) (i) and (ii), some commenters believed that it is unclear whether access to documents or to the physical premises is permitted. Where access to the physical plant is sought, commenters felt that the regulations should provide for access that will not unduly interfere with patient privacy and treatment.

*Response:* Survey agencies have the right to review both the physical plant and documents. Congress intended for this provisions to grant survey agencies the ability to determine the extent of compliance with relevant requirements; both the physical plant and documents are important sources of information. Survey agencies need the flexibility to be able to conduct surprise surveys, but it is expected that any interference with patient privacy or treatment would be only that which is necessary to enable the survey agencies to fulfill their statutory functions.

*Comment:* Several commenters stated that the regulations provide that a party will not be considered to have failed to provide immediate access if, in response to a request by the OIG or a MFCU, a party can provide a compelling reason why documents cannot be produced. According to the comments received, this exception should also be included in the regulations applicable to requests for access by survey agencies under §§ 1001.1301(a)(1) (i) and (ii).

*Response:* We agree and have modified the final regulations accordingly.

*Comment:* One commenter indicated that the regulations should require that the request be made to a person with authority.

*Response:* We intend to make the request to someone in control. With respect to requests for documents, the request will be addressed to the custodian of records. With respect to requests for access by survey agencies, the request will be made to the owner, administrator or other person functioning in that capacity, or his or her delegatee.

*Comment:* Numerous commenters criticized the definition of "failure to grant immediate access" in the context of requests by the OIG or MFCUs. Many commenters argued that a 24 hour period is too short and would not give the subject enough time to verify that the request is genuine or to determine whether it had custody of the requested documents. Commenters suggested that the time for compliance should be tolled while the subject is verifying the legitimacy of the request. Further, some commenters felt that providing 24 hours was too long a period of time and that the information should be required on the spot in all situations.

*Response:* We believe that 24 hours is enough time for subjects to verify the legitimacy of the request. We believe that problems with identifying the appropriate person to be called will be alleviated because this information will be included in the statement of rights that will be provided to the subject. The subject can compile the documents while verifying the legitimacy of the request at the same time. Moreover, the regulations do not require that any copies be made, but only that the records be made available. Finally, subjects will not be excluded if they can provide a compelling reason why the request cannot be satisfied.

*Comment:* Commenters believed that it is not clear how the OIG can determine that there are exigent circumstances, i.e., risk of destruction, that justify on the spot access in the absence of probable cause. Commenters argued that exigency must be determined from an objective perspective. Exigent circumstances could always be deemed to occur in a case involving fraud.

*Response:* We do not intend to use this authority in every case, but we must have an ability to obtain documents immediately if there is a legitimate concern that the documents will be altered. We believe this will be resolved by looking at the circumstances surrounding a case. For example, if a subject has been extremely recalcitrant in providing information, or if the OIG had previously been provided with information from this subject that included altered documents, that would be reason to believe that this act may occur again. We have revised the regulations to clarify that exigent circumstances apply where the OIG or the MFCU reasonably believes that the documents will be altered or destroyed.

*Comment:* Some commenters argued that the regulations exceeded statutory

authority in providing for an exclusion longer than the length of time access was denied up to 90 days. One commenter suggested that the exclusion should last at least one year from the date access was denied.

*Response:* Section 1128(c)(3)(C) of the Act expressly limits the length of the exclusion for an individual, but does not impose any limitation on the length of the exclusion for an entity. The regulations, in setting an upper limit for individuals but not for entities, properly implement the statute. Moreover, we believe that the circumstances surrounding the failure to provide information can so vary that it would be inappropriate to set forth a minimum length of exclusion period.

*Comment:* Some commenters felt that the proposed regulations did not sufficiently protect individual privacy rights or the confidentiality of medical records. Some commenters felt that only the records of program beneficiaries should be made available to the government. One commenter believed that the final rule should affirmatively state that patients do not waive their privacy rights by participating in a government health care program.

*Response:* We disagree with these comments. All health care providers, as a condition of their participation in the Medicare and Medicaid programs, are obligated to furnish to the government any records or other confidential information necessary to determine appropriate reimbursement (see, for example, sections 1815(a) and 1833(e) of the Act). Thus, under Federal law, the government's interests in ensuring the integrity of its health care programs supercedes patients' privacy rights under certain conditions. As part of the mandate to investigate fraud and abuse in the Medicare and State health care programs (5 U.S.C. App. 3, 6(a)(2)), the Inspector General may need to review health care providers' medical records in order to determine whether there has been a violation of one or more authorities implemented under these regulations. In deciding whether to seek access to confidential information during the course of an investigation, the IG attempts, on a case by case basis, to strike a fair balance between the privacy rights of patients and the Federal interest in obtaining and safeguarding evidence. Whenever confidential information is material to an investigation, the IG's policy is to assess whether the Federal interest in the information outweighs the privacy concerns of individuals involved. For example, if there is evidence that a psychiatrist sought Medicaid reimbursement for individual therapy sessions when he or she actually provided group therapy (which is reimbursed at a lesser rate), obtaining access to the psychiatrist's appointment book may be essential to determine whether the psychiatrist committed fraud.

The IG's approach fully accords with established legal precedent in this area. When the government seeks confidential records in order to enforce a statutory scheme enacted to protect the public health or safety, the public interest prevails over individual claims of privacy (see *United States* v. *Westinghouse Electric Corporation*, 638 F. 2d 570 (3d Cir. 1970)). In particular, there is a compelling public interest in investigating fraud committed against government health care programs, and privacy protections afforded under State law must succumb to that interest (see *St. Lukes Regional Medical Center, Inc.* v. *United States*, 717 F. Supp. 665, 666 (N.D. Iowa 1989)). We believe that these regulations allow for lawful and appropriate disclosure of confidential information that is material to Medicare and Medicaid fraud investigations. They are not intended to protect unnecessary invasions of privacy.

• *Section 1001.1401*

This provision permits the exclusion of hospitals that fail to comply substantially with corrective action plans required by HCFA in accordance with section 1886(f)(2)(B) of the Act, which are imposed to correct practices that circumvent the prospective payment system.

*Comment:* One commenter questioned that part of the preamble to the proposed regulations that stated that issues relating to the underlying inappropriate admissions or practice patterns may not be contested in an exclusion hearing. The commenter was concerned that there be an appeals mechanism for the underlying issues.

*Response:* The OIG has the authority to exclude a hospital that has failed to comply substantially with a corrective action plan under section 1886(f)(2) of the Act. Section 1886(f)(2) provides that the provisions of sections 1128(c)–(g) apply to determinations made under section 1886(f)(2). Sections 1128(c)-(g) set forth procedures relating to implementation of exclusions, including rights to appeal. A provider will, therefore, have the rights to appeal provided for in sections 1128(c)-(g) to appeal the merits of the determination that it has failed to comply substantially with a corrective action plan.

• *Section 1001.1501*

This provision permits the exclusion of individuals who default on health education loans or scholarship obligations.

*Comment:* Commenters stated that there is little relationship between failure to pay one's scholarship obligations and the right to participate in Medicare. Moreover, these commenters indicated that this section seems extremely unfair to an entity, which could be excluded under § 1001.1001 based on the actions of a single individual who failed to pay student loans.

*Response:* A physician reaps financial benefits from participating in Medicare and Medicaid. There is plainly a connection between requiring a physician who is benefitting from government programs to meet his or her financial obligations to the government, by repayment of loans. These regulations are a proper interpretation of statutory authority (section 1128(b)(14) of the Act). An entity will always have an opportunity to terminate its relationship with a sanctioned individual before an exclusion will be imposed.

*Comment:* Section 1128(b)(14)(B) of the Act requires that the Secretary take into account access of beneficiaries to physician services in determining whether to impose an exclusion, and this should be included in the regulations.

*Response:* We agree, and have changed the final rule accordingly. We have also included in the regulations the other limitation set forth in section 1128(b)(14)(A), which mandates that the Secretary may not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

*Comment:* Some commenters stated that although the regulation provides that the OIG must determine that the PHS has taken all reasonable administrative steps to obtain payment of the loans or other obligations before imposing an exclusion, it fails to state what steps are reasonable.

*Response:* The Secretary is expected to use alternative administrative tools whenever feasible. Whether it is feasible or reasonable to use alternative administrative means will depend on the circumstances surrounding a particular case.

We are, however, clarifying § 1003.1501(a)(2) to indicate that whenever PHS has complied with the

Medicare offset provisions of section 1892 of the Act, the OIG will find that "all reasonable steps" have been taken and that no other administrative steps are necessary. The basis for this policy is that, in enacting an almost identical exclusion authority in section 1892(a)(3)(B) shortly after it enacted the exclusion authority in section 1128(b)(14), Congress effectively defined the term "all reasonable steps" as used in section 1128(b)(14). Since section 1892 makes clear that no more is required of the Secretary prior to excluding a defaulter than to offer an offset agreement, we believe that it would be illogical to interpret section 1128(b)(14) as requiring more, especially in light of the fact that section 1892 is (1) the more recently enacted statute and (2) an even stricter statute in that it makes exclusions mandatory and not permissive.

• *Section 1001.1601*

This provision permits the exclusion of physicians who violate the limitations on physician charges under Medicare. For services furnished during the period January 1, 1987 to December 31, 1990, the issue is whether the physician billed in excess of the maximum allowable charge determined in accordance with section 1842(j)(1)(c) of the Act. Since January 1, 1991, the issue is whether the physician billed in excess of the limiting charge determined in accordance with section 1848(g)(2) of the Act. Based on comments and our review of this section, we have deleted the limitation that was erroneously included in the proposed regulations which stated that an exclusion under this authority is limited to the Medicare program. As stated in the preamble to the proposed regulations, Public Law 100-360 extended this exclusion to all programs.

*Comment:* According to several comments received, beneficiary access to alternative services should be considered in determining whether to impose an exclusion, rather than only being a factor in determining the length of the exclusion.

*Response:* We agree and have modified the final rule accordingly. This authority implements section 1842(j) of the Act, and paragraph (j)(3)(B) of that section of the law mandates that the Secretary take into account access of beneficiaries to physicians' services in determining whether to impose an exclusion. We have also included in the final regulations the requirement, set forth in section 1842(j)(3)(A) of the Act, that the Secretary may not exclude a physician if that physician is a sole community physician or the sole source of essential specialized services in a community.

*Comment:* Section 1842(j)(1)(B) of the Act provides that an exclusion may only be imposed in cases where a physician knowingly and willfully bills on a repeated basis in excess of the maximum allowable charge. One commenter felt that the regulations should include the qualification that the exclusion may only be imposed if the act occurred repeatedly.

*Response:* We agree and have modified this provision accordingly.

*Comment:* Some commenters indicated that the regulations should set forth a minimum monetary level justifying the imposition of an exclusion.

*Response:* The decision of whether to exclude someone is not based solely on monetary consequences to the program. The requirement that the excessive billing be made on a repeated basis before an exclusion will be imposed counters any concern that an exclusion will be imposed for a single or de minimis violation.

*Comment:* Commenters pointed out that the final regulations would clearly define the term "knowingly and willfully" as used in § 1001.1601 of the regulations.

*Response:* We intend for these terms to be interpreted according to their accepted legal meaning in Federal law.

*Comment:* Some commenters questioned why section 1842(j)(1)(B)(ii) of the Act contains a sunset provision on this authority, but that the regulations does not.

*Response:* We have modified these regulations to clarify that an exclusion under section 1842(j)(1)(B) of the Act only applies to services furnished between the period January 1, 1987 and December 31, 1990.

*Comment:* A number of commenters felt that physicians excluded under this authority should have a hearing prior to imposition of the exclusion, since safety of beneficiaries is not a concern.

*Response:* Because a CMP may also be imposed for conduct sanctionable under § 1001.1601, and because prior hearings are available for all CMP authorities, we are providing for a hearing prior to an exclusion under this section. This issue is discussed more fully in section IV.F.1. of this preamble.

• *Section 1001.170*

This provision permits the exclusion of physicians who bill for services of assistants at surgery during cataract operations.

*Comment:* Commenters specifically pointed out that, although not cited in the proposed rule, section 1842(k) of the Act requires the Secretary to take into account access of beneficiaries to physicians' services in determining whether to impose an exclusion.

*Response:* We agree and have modified the final regulations accordingly. We have also included in the regulations the statutory mandate that the OIG may not exclude a physician who is the sole community physician or the sole source of essential specialized services in the community (section 1842(j)(3) of the Act).

*Comment:* One commenter argued that a physician should have a hearing before an ALJ prior to imposition of the exclusion.

*Response:* We agree and have modified the final regulations accordingly.

*Comment:* One commenter stated that exclusion for providing an assistant at cataract surgery is too severe a penalty, and stated that the PRO prior approval program is adequate.

*Response:* Congress determined that exclusion is an appropriate remedy for this conduct. The OIG will exercise its discretion to impose exclusions only in those cases where it is the appropriate remedy.

*D. Part 1001, Subparts B and C—Aggravating and Mitigating Circumstances*

*Comment:* Commenters stated that an ALJ should be free to consider any factors whatsoever in determining whether the length of an exclusion should be reduced, and that the mitigating factors included in the regulations should be examples rather than an exhaustive list.

*Response:* The legislative history directs the Secretary to consider any mitigating circumstances in setting the period of exclusion. The Secretary has the authority to determine what circumstances are mitigating. Moreover, these factors only relate to the length of the exclusion. The OIG considers many factors in deciding whether to impose an exclusion in the first place.

*Comment:* Some commenters felt that the regulations should give specific guidance as to how aggravating and mitigating factors will be weighted.

*Response:* We do not intend for the aggravating and mitigating factors to have specific values; rather, these factors must be evaluated based on the circumstances of a particular case. For example, in one case many aggravating factors may exist, but the subject's cooperation with the OIG may be so significant that it is appropriate to give that one mitigating factor more weight than all of the aggravating. Similarly, many mitigating factors may exist in a

case, but the acts could have had such a significant physical impact on program beneficiaries that the existence of that one aggravating factor must be given more weight than all of the mitigating. The weight accorded to each mitigating and aggravating factor cannot be established according to a rigid formula, but must be determined in the context of the particular case at issue.

*Comment:* Several commenters expressed concern that certain provisions, such as § 1001.102, provide that it will be an aggravating factor if the acts underlying the exclusion had an impact on programs or individuals, while other sections, such as § 1001.201, provide that only if the acts had a significant adverse impact will the impact be considered aggravating. Commenters believed that this factor should be consistently stated in the regulations. In addition, commenters indicated that the mitigating factor in § 1001.701, stating that it will be mitigating if the violations had no adverse impact on individuals or the programs, should be changed to make it mitigating if the violations had no significant adverse impact.

*Response:* An aggravating factor is one that does not automatically exist in every case, but when it does exist, justifies a longer period of exclusion. Every case resulting in an exclusion will involve circumstances that had an impact on the program or beneficiaries. To be an aggravating factor, we agree that the impact must be more than minimal, that is, it must have been significant, and we have modified the regulations accordingly. With regard to the mitigating factor set forth in § 1001.701, we have deleted that factor since, on review, we do not think this mitigating factor would ever apply; we believe that there will be no case where there is absolutely no adverse impact on individuals or the programs. We believe that the issue of the extent of the harm caused by a violation under § 1001.701 is addressed by the fact that it will be considered mitigating if there were few violations and they occurred over a short period of time.

*Comment:* Sections 1001.102, 1001,201, and 1001.301 provide that it will be considered mitigating if someone had a mental, emotional or physical condition, before or during commission of the offense, that reduced the individual's culpability. A commenter questioned whether it would be mitigating if such a condition developed after commission of the offense.

*Response:* This factor was intended to take into account the factors that might reduce the offender's culpability in committing the offense, and development of a condition after the commission of the offense would not be relevant. We have also clarified that such a condition will only be considered if the court reached the conclusion that such a factor existed which reduced the offender's culpability; the mere appearance of such an allegation in the pre-sentencing report would not be enough. Moreover, this factor will not be considered as mitigating if there is an ongoing problem that has not been resolved, such that the program and their beneficiaries continue to be at risk.

*Comment:* Sections 1001.102, 1001.201, 1001.301, and 1001.401 state that an individual's or entity's cooperation is a mitigating factor if the cooperation resulted in others being convicted or excluded from Medicare or a State health care program. Commenters contended that cooperation itself should be considered mitigating, regardless of whether another individual or entity was sanctioned.

*Response:* As a practical matter, we generally consider cooperation in determining whether to impose a permissive exclusion at all. We believe, however, that only significant cooperation should be considered mitigating, and the imposition of a sanction as a result of cooperation establishes that the cooperation was significant. We believe the significance of cooperation is more properly evaluated by those in a position to utilize the information, rather than by an ALJ. We have, however, modified the regulations to provide that cooperation shall be a mitigating factor if it led to imposition of a CMP, in addition to whether it led to a conviction or exclusion.

*Comment:* Commenters stated that some aggravating factors, such as that the acts resulted in loss of $1,500 or more, were committed over a period of 1 or more years, and had a significant impact on the programs or individuals, will likely exist in every case, and thus serve no purpose but to allow the OIG to routinely increase the length of the exclusion. Similarly, commenters indicated that certain mitigating factors, such as an individual or entity being convicted of three or fewer misdemeanors, and the loss to the government or other individuals or entities being less than $1,500 (§§ 1001.102 and 1001.201), will never exist. These individuals felt that the existence of 3 or fewer misdemeanors should be mitigating by itself.

*Response:* We disagree with these comments. Our experience has shown that none of the aggravating factors included in these final regulations are present in every case. Moreover, we believe the amount of the loss relates to the degree of risk to the programs, and we believe $1,500 is a reasonable benchmark for distinguishing between significant and less significant risk.

*Comment:* Proposed §§ 1001.102 and 1001.201 provided that it will be considered aggravating if the total loss exceeds $1,500, and stated that the total amount of financial loss would be considered, including any amounts resulting from similar acts not adjudicated. Commenters stated that this factor should not be used since the excluded party has not been given an opportunity to contest these acts.

*Response:* Acts that have not been adjudicated are not considered in determining whether an exclusion must or should be imposed. Other acts are considered only in determining the length of the exclusion. We are aware of numerous cases where there is evidence that an individual or entity committed many similar acts but, as a condition for entering into a plea agreement, only pled guilty to one charge. It is part of the OIG's responsibility to review all factors surrounding a case to determine the reasonable length of an exclusion. The approach we have taken is not unlike sentencing in the criminal context, where a judge may consider many different acts of the defendant in setting the appropriate sentence, not just the ones that form the basis for the conviction. We have also modified this factor so that, although $1,500 will be the benchmark of significant loss to the government, no specific monetary figure is included for impact to program beneficiaries or other individuals, since, to those persons, a loss much less than $1,500 may be significant. We have also deleted "financial" from § 1001.201(b)(2)(iii) since the financial impact is dealt with in paragraph (b)(2)(i) of that section.

*Comment:* Some commenters questioned whether the mitigating factor relating to the loss to the programs being less than $1,500 could apply if someone pleads guilty to one offense which is less than $1,500, where there is evidence that the individual committed offenses that total greater than $1,500.

*Response:* We are not concerned about the applicability of this factor to plea bargains, because the factor states that it requires the consideration of not only the acts that resulted in the conviction, but also similar acts.

*Comment:* Proposed §§ 1001.201 through 1001.801 provided that it will be a mitigating factor if alternative sources of the type of health care items or services furnished by the excluded individual or entity are not available. A

number of commenters believe that the regulations should be modified to state that it will be mitigating if alternative sources are not reasonably available.

*Response:* We believe this is implicit in the regulations. The purpose of this mitigating factor is to protect program beneficiaries, and if services are not reasonably available to them then, as a practical matter, they are not available. Of course, in evaluating the factor, we will look to whether there are service providers who accept Medicare and Medicaid patients, rather than merely whether services are available generally.

*Comment:* Several commenters pointed out that the unavailability of alternative sources of the type of health care items or services furnished by the entity will never be a mitigating factor for HMOs sanctioned under § 1001.801 if non-plan providers are considered alternative.

*Response:* An exclusion is remedial and is designed to protect the program and its beneficiaries. It is not in the interests of the beneficiaries to include in the program an HMO that substantially fails to provide necessary services. Thus, if another entity can provide these services, the medical needs of the beneficiaries are met and there is no need to keep the HMO in the program. There may be circumstances, however, where unique services will only be provided by physicians who are part of the HMO, and this factor will, in those situations, apply.

*Comment:* Commenters stated that the regulations should be consistent in identifying the parties on whom the impact of the action will be evaluated for purposes of determining the existence of aggravating and mitigating factors. For example, proposed § 1001.102 provided that it would be aggravating if there was an adverse impact on individuals, and § 1001.201 provided that it would be aggravating if there was a significant adverse impact on individuals or the program. One commenter stated that these regulations should be consistent, and that considering effect on anyone besides program beneficiaries is overly broad.

*Response:* We have modified the regulations to provide that under all of these provisions we will evaluate the impact on the programs, program beneficiaries and other individuals. It is reasonable to consider the impact conduct had on any and all persons in determining whether program beneficiaries are at risk.

*Comment:* According to the concerns of some commenters, a prior sanction record should serve as an aggravating factor only if there was a pattern of wrongdoing with respect to Medicare or a State health care program.

*Response:* We believe that a prior sanction record is an aggravating factor because it shows an unwillingness to comply with the law.

*Comment:* A number of commenters indicated that the absence of a prior record of convictions or other sanctions should be a mitigating factor.

*Response:* We disagree. We do not believe anyone deserves special credit (in the form of a reduced period of exclusion) for doing what is expected, that is, obeying the law.

*Comment:* Proposed §§ 1001.501 and 1001.601 provided that it would be aggravating if the period of license loss or exclusion from participation set by the derivative agency does not take into account the impact that the sanctioned party's conduct had or could have had on Federal or State health care programs. One commenter believed that this factor is too speculative.

*Response:* It is the OIG's responsibility to assess all circumstances that relate to the risk of future participation in the health care programs.

*Comment:* Proposed §§ 1001.501 and 1001.601 provided that mitigating factors would only be considered if aggravating factors justify lengthening the exclusion beyond the time imposed by the derivative agencies. Some commenters felt that the regulations should allow for consideration of mitigating circumstances even in the absence of aggravating circumstances.

*Response:* These exclusions rely on the determination of another agency that has had the opportunity to fully evaluate a situation. In most cases, we will accept the derivative agency's length of exclusion as controlling for Medicare purposes, and we do not believe it is appropriate to focus on issues that have already been considered in that other forum. In cases where we exercise our independent discretion to extend the length of the exclusion, it is then appropriate to allow new information to be considered both in favor of lengthening and reducing the period of exclusion.

*Comment:* According to some commenters' concerns, an individual's financial condition is relevant and should be considered mitigating in determining the length of the exclusion imposed under §§ 1001.901 or 1001.951.

*Response:* CMPs and exclusions serve different functions. In setting a CMP, the purpose is to make an individual or entity pay for bad conduct both to compensate the government and deter future similar conduct. In cases where the OIG imposes a CMP only, the OIG has determined that the program is not at risk by allowing the sanctioned party to continue to participate, and it is not in the interest of the program and their beneficiaries to make the penalties so extreme that they are either uncollectible or act to prevent the sanctioned party from being able to afford to continue participating in the programs. If it is determined that someone should be excluded from the programs because continued participation puts the program at risk, the fact that the exclusion may affect his or her financial condition is not our concern; our concern is in protecting the programs.

*E. Part 1001, Subpart D—Waivers and Effect of Exclusion*

1. Waiver of Exclusions

*Comment:* One commenter stated that in addition to waiving State health care program exclusions on behalf of individuals or entities excluded from participation in Medicare, the OIG should permit State licensure authorities to waive imposition of sanctions.

*Response:* Nothing in these regulations requires States to take particular licensing or disciplinary action against excluded providers. When the OIG excludes an individual or entity from participation in Medicare, it is obligated by statute to notify State licensing agencies of the exclusion, and to request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy (section 1128(e) of the Act). These regulations implement that statutory provision, but do not require State licensing agencies to take any specific action against excluded providers (§ 1001.2005). Thus, State licensing agencies may refrain from sanctioning individuals or entities excluded from Medicare so long as the law and policy within a particular State authorizes the waiver of licensure or disciplinary sanctions.

*Comment:* A few commenters requested that we broaden the circumstances under § 1001.1801(b) by which a request to waive a permissive exclusion may be granted to State health care programs. The proposed regulation limited waiver requests in the case of permissive exclusions to the same conditions that waiver requests are statutorily authorized in the case of mandatory exclusions; that is, where the excluded party is the sole community physician or the sole source of essential specialized services in a community. One commenter stated that these conditions for considering waiver

requests would not ensure community access to long term care services, such as nursing home placement, because the existence of other sources of long term care may not reflect the actual availability of beds. Another commenter felt that the criteria for assessing waiver requests should be expanded to include consideration of whether an exclusion would compromise beneficiary access to needed services. A third commenter suggested that the OIG should agree to consider a waiver request whenever a State health care program can demonstrate that waiver would be in the public interest.

*Response:* We have considered the above comments, and we agree that the conditions for OIG consideration of State health program waiver requests under proposed § 1001.1801 may not protect beneficiary or other program needs in some instances. For example, when a cardiologist is excluded from the State health care programs, while there may be several other physicians in the community that provide cardiology services, it may be that none of these physicians participate in Medicaid. In this type of situation, imposing a Medicaid exclusion would deprive Medicaid beneficiaries of needed services, although the excluded party was not a sole community physician or sole source of essential specialized services.

In order to provide the OIG with greater flexibility to protect program interests when the imposition of an exclusion would threaten such interests, we are amending this provision in two ways. First, as discussed earlier in this preamble, we are modifying the definition of "sole community physician" by removing the language restricting this definition to providers practicing in health manpower shortage areas under 42 CFR part 5. Second, we are adding a new paragraph (c) to § 1001.1801, to allow the OIG, at its discretion, to waive imposition of a permissive exclusion when such waiver would be in the public interest.

*Comment:* One commenter stated that the language in § 1001.1801(d) should be changed to clarify that waiver would apply only with respect to those programs for which waiver is specifically requested. For example, if a State agency requests waiver from the Medicaid program, waiver should be granted for that program alone, and not for the Maternal and Child Health Care program (title V) or the Block Grants program to States (title XX).

*Response:* We agree with this comment, and have modified the proposed § 1001.1801(d), codified now as paragraph (e) in these final regulations, to clarify that if a waiver request is made with respect to certain State health care programs, it will only apply to those State programs. However, under § 1001.1801(g) of this final rule, if in the course of considering a waiver request with respect to one or more State health care programs, the OIG determines that imposition of a Medicare exclusion will deprive Medicare beneficiaries of access to needed services, the OIG may waive the Medicare exclusion in conjunction with granting the State program waiver request.

2. Scope and Effect of Exclusion

In the proposed rule, we requested comments on a number of possible approaches to implementing Executive Orders 12549 and 12689, which provide that debarments, suspensions, and other exclusion actions taken by any Federal agency will have government-wide effect. The language that was proposed would have expanded the scope of these exclusions to all Federal nonprocurement health programs.

*Comment:* There were only two commenters on the issue of the government-wide effect of the regulations. One agreed with the expanded scope and the other expressed the opinion that there was no legal authority for giving government-wide effect to these sanction authorities which relate only to Medicare and State health programs. Neither commenter specifically discussed the alternate approaches set forth in the preamble to the proposed rule, one of which was to provide, by regulation, that the exclusions will apply to all Federal nonprocurement programs.

*Response:* We have decided to adopt this latter approach. With respect to our legal authority for this provision, we have concluded, in consultation with the Department of Justice, that Executive Order 12549 requires us to give government-wide effect to all exclusions imposed under these regulations. However, since the scope of this Executive Order is limited to Federal nonprocurement programs and activities, it does not authorize us to extend the government-wide effect of our exclusions to procurement programs and activities.

We have also concluded that to limit the scope of the government-wide effect to nonprocurement health programs is not authorized by the Executive Order, nor does it comport with the intent of the order. Such an interpretation would have anomalous results. For example, under such a limited interpretation, an individual who was convicted of Medicare fraud, and thus excluded from participation in Medicare and State health care programs, would still be eligible to run a Head Start Program or receive a grant from the Department of Housing and Urban Development to build low-income housing, notwithstanding his or her history of defrauding the government. This is exactly the sort of result that the Executive Order was designed to prevent.

We recognize that in some situations the government-wide effect of a Medicare exclusion may pose an undue hardship and may be unnecessary to project the integrity of government programs. For example, if an exclusion from Medicare is based on a license revocation by a State licensure board, and the sole basis for the revocation is the incompetence of the physician or other health care professional, it might be unfair to bar that individual from participating in Federal programs unrelated to the practice of medicine. Any unfairness in a specific case may be remedied, however, since paragraph 2(c) of the Executive Order authorizes an agency head to grant an exception permitting an excluded party to participate in a particular transaction.

*Comment:* Some commenters felt that the proposed regulations unfairly penalized institutional providers who employ excluded individuals or entities. For example, one commoner objected to the provisions of proposed § 1001.1001, authorizing the exclusion of entities owned or controlled in whole or in part by individuals sanctioned under section 1128 or 1128A of the Act. Another commenter felt that proposed regulation § 1001.1901(b), prohibiting Medicare and State health care program reimbursement for items or services furnished by, at the medical direction of, or on the prescription of an excluded physician, unfairly penalized institutional providers who employ excluded physicians in accordance with contracts that cannot be terminated upon notice of the exclusion. The commenter stated that the risk of legal action by excluded providers or by their patients if ordered items or services were not furnished would make the providers feel constrained to provide such items or services. The commenter also believed that § 1001.1901(b) discriminated against institutional providers by denying payment to these facilities for items or services ordered by excluded providers, but not denying payment to provider-based physicians who perform services in conjunction with or related to those performed by excluded physicians, e.g., an

anesthesiologist working with an excluded surgeon.

*Response:* Both proposed §§ 1001.1001 and 1001.1901(b) were based on statutory mandate (sections 1128(b)(8) and 1862(e)(1)(B) of the Act). To the extent that these provisions impose sanctions against, or deny reimbursement to, institutional providers that employ excluded individuals, the Department has simply implemented what Congress required. Moreover, with respect to the comments that § 1001.1901(b) unfairly penalizes institutional providers, we believe that providers can structure their contracts with physician employees so as to protect themselves from having to continue an employment relationship once they become aware that a physician has been excluded. Because, under § 1001.1901, any person furnishing items or services ordered or prescribed by an excluded physician must know or have reasons to know of the physician's exclusion, the provision justly avoids penalizing facilities that employ excluded physicians unknowingly. Under § 1001.2006(a)(1), the Department would give notice of a physician's exclusion to any provider known to be employing the physician.

With respect to the comment that failure to provide services ordered by excluded physicians might entail legal risk, we point out that § 1001.1901 does not prohibit providers from continuing to provide services for legal or any other reasons. The provision, which tracks the statutory language of section 1863(e)(1)(B) of the Act, denies payment for services furnished at the medical direction or on the prescription of an excluded physician. The provision reflects the intent of Congress and the Secretary that the government not pay—directly or indirectly—for the services of untrustworthy individuals or entities with whom the Department has determined it should cease doing business.

Finally, with respect to the comment that § 1001.1901(b) discriminates against institutional providers in contrast to other hospital based physicians, we disagree. Other hospital based physicians who perform services ordered by an excluded physician (such as a radiologist who does X-rays at the request of an excluded cardiologist) will be reimbursed for their own services, not those of the excluded physician. By contrast, institutional providers that bill for items or services furnished by or at the medical direction or on the prescription of an excluded physician, seek reimbursement for items or services used or performed by, or at the direction of, the excluded physician.

Furthermore, institutional providers control and influence the excluded physician's ability to continue serving program beneficiaries in ways that other individual physicians simply cannot. Individual physicians influence the referral of services in particular cases; however, institutional providers are in a position to determine whether an excluded physician can continue treating beneficiaries at all. Therefore, because their control over the ability of excluded physicians to treat beneficiaries is far greater, we believe it is reasonable to deny payment to institutional providers who seek reimbursement for items or services furnished by excluded providers.

*Comment:* A few commenters were concerned that both the proposed regulatory provisions governing the effect of exclusions and exceptions to the nonpayment of claims for services of excluded parties were unclear. For example, one commenter pointed out that the proposed rule should have expressly stated that an excluded individual or entity does not automatically become eligible to participate in Medicare or State health care programs once the exclusion period ends. Other commenters were confused about the exception specified under proposed § 1001.1901(d)(1)—now being codified as § 1001.1901(c)(1) in these final regulations—for payment of the first claims of part B enrollees who are without notice of an exclusion. These commenters were concerned that excluded practitioners could, under this provision, avoid the impact of an exclusion by continuing to furnish services to program beneficiaries, and having those beneficiaries then submit claims to Medicare for reimbursement.

*Response:* We agree that these regulations should clarify that excluded individuals or entities must be reinstated into Medicare or the State health care programs in order to begin participating in these programs after a period of exclusion has lapsed. Therefore, we are amending § 1001.1901(b) to clarify that the effect of an exclusion lasts unless and until an individual is reinstated in accordance with the procedures set forth under part 1001, subpart F.

With respect to the payment of enrollees' first claims for services furnished by excluded providers, it should be noted that under section 1848(g)(4) of the Act, physicians and suppliers are required to complete and submit all claims forms for services provided to beneficiaries on or after September 1, 1990.

We are adding a new paragraph (b)(3) to § 1001.1901 to clarify that an excluded individual or entity who submits or causes the submission of claims for items or services furnished during the exclusion period is liable under the CMP law and criminal law. The Secretary's intent in paying the first claim of beneficiaries under § 1001.1901(c)(1) is not to legitimize excluded parties causing their patients to submit claims during the exclusion period (see *The Inspector General* v. *Berney R. Keszler, M.D., P.A.*, Docket No. C-167 (Departmental Appeals Board/Civil Remedies Division) (November 1, 1990), at 28)). Rather, the intent is that beneficiaries not be forced to pay for services provided by someone whom the beneficiaries did not know was excluded. Hence, we will pay the first claim, and then notify the beneficiaries of the excluded status of the individual or entity and that further claims for items or services furnished by such individual or entity will not be paid.

*F. Part 1001, Subpart E—Notice and Appeals*

1. Statutory Authority and Constitutional Issues

*Comment:* Several commenters expressed concern that the proposed rule did not afford constitutionally adequate due process to individuals and entities who are excluded from participation in Medicare and the State health care programs. These commenters stated that, because the inability to participate in government health care programs can be professionally and financially devastating, it would violate due process to exclude an individual or entity from program participation without a prior opportunity to contest the exclusion. Some commenters felt that parties excluded for *any* reason authorized under MMPPPA should be permitted to request a hearing prior to imposition of the exclusion. Other commenters believed that the OIG should provide for such a hearing prior to imposing any of the non-derivative exclusions, or any exclusions necessary to safeguard the health or safety of program beneficiaries.

*Response:* In accordance with section 1128(f)(2) of the Act, we provided for a prior hearing in the case of exclusions imposed under section 1128(b)(7) for violations of the CMP law (§ 1001.901) and for kickbacks and other illegal activities under section 1128B of the Act (§ 1001.951), unless the health and safety

of individuals receiving services warranted otherwise. We have also provided for a prior hearing in the case of exclusions imposed for violations of Medicare physician charge limitations under § 1001.1601, and exclusions imposed for fraudulent billing for services of an assistant during cataract surgery under § 1001.1701. We have done this because the conduct involved in these two exclusion authorities subjects an individual or entity to a CMP in addition to, or in lieu of, the exclusion authority authorized here, and the CMP may only be imposed after an ALJ hearing. We believe that fundamental fairness, as well as economy of resources, make a single unified proceeding the appropriate mechanism for imposing sanctions under §§ 1001.1601 and 1001.1701.

However, we do not believe that prior hearings would be appropriate for any other exclusion authorities implemented in these regulations, and have therefore provided for post-exclusion hearings for all exclusion authorities except §§ 1001.901, 1001.951, 1001.1601 and 1001.1701. As we stated in the preamble to the proposed regulations, case law makes clear that due process does not require a hearing prior to the imposition of an exclusion from Medicare or State health care programs (see *Mathews* v. *Eldridge*, 424 U.S. 319 (1976); *Ram* v. *Heckler*, 792 F.2d 444 (4th Cir. 1986)). When an agency exercises discretionary authority, due process is satisfied so long as the affected party is given "notice and an opportunity to respond * * * (t)he opportunity to present reasons, either in person or in writing, why proposed action should not be taken" (see *Cleveland Bd. of Education* v. *Loudermill*, 470 U.S. 532, 105 S.Ct. 1487, 1495 (1985)). This final rule reflects this constitutional principle. Under § 1001.2001, we have provided for notice and an opportunity to respond, in writing, as well as in person for certain exclusion authorities, in cases in which the OIG's exercise of authority to exclude individuals or entities is not mandated by law. Thus, § 1001.2001(a) provides for issuance of a "notice of intent to exclude" granting 30 days to provide "documentary evidence and written argument in response" prior to imposition of (1) a permissive exclusion (except those imposed under §§ 1001.1301 through 1001.1501 for reasons stated below) and (2) a mandatory exclusion imposed for more than the minimum 5 year period required by law. With respect to exclusions imposed under §§ 1001.701 and 1001.801 for submitting excessive claims or for furnishing unnecessary items or services, as these cases typically involve complicated issues, we have maintained proposed § 1001.2001(b), allowing for the opportunity to present oral as well as written evidence.

With respect to the exclusion authorities implemented in §§ 1001.1301 through 1001.1501, we have determined that the procedures provided in § 1001.2001(a) for notice and opportunity to respond should not apply. Sections 1001.1401 and 1001.1501 each involve exclusions based on conduct determined to violate statutes regulated by other divisions of the Department. Under § 1001.1401, the OIG may exclude any hospital that HCFA determines has substantially failed to comply with a corrective action required by HCFA under section 1886(f)(2)(B) of the Act. Under § 1001.1501, the OIG may exclude individuals whom PHS determines are in default on health education scholarship or loan obligations. The exclusion remains in effect until PHS notifies the OIG that the default was cured. Because the OIG would impose sanctions under §§ 1001.1401 and 1001.1501 only after HCFA or PHS determined such action to be appropriate, providing excluded parties an opportunity to respond to the OIG would not be meaningful. Thus, we have not included §§ 1001.1401 and 1001.1501 within the ambit of exclusion authorities covered under § 1001.2001(a).

We also do not provide for issuance of a notice of intent to exclude and the opportunity to respond under § 1001.2001(a), in the case of exclusions imposed under § 1001.1301. These exclusions allow the OIG to exclude any individual or entity that fails to grant immediate access upon reasonable request under (1) §§ 1001.1301(a)(1) (i) and (ii) to survey agencies or other entities attempting to inspect health care facilities in accordance with Medicare and Medicaid statutory requirements, and (2) §§ 1001.1301(a)(1) (iii) and (iv), to Federal or State investigators seeking to review the individual's or entity's records to determine whether fraud has been committed under a Federal or State health care program. Under proposed §§ 1001.1301(a)(1) (iii) and (iv), we granted individuals and entities from whom immediate access to documents is requested the opportunity to "provide a compelling reason" why such records cannot be produced. In the final rule, we also apply this provision in the case of facilities from whom immediate access is requested in order to conduct surveys or reviews under §§ 1001.1301(a)(1) (i) and (ii). Thus, these facilities will also have opportunity to explain to OIG officials why immediate access should be denied, and therefore do not need additional opportunity to respond under § 1001.2001 (see § 1001.1301(a)(2)).

Proposed § 1001.2001(a) did not apply to mandatory exclusions imposed for a period exceeding 5 years. However, the OIG's authority under section 1128(a) of the Act to exclude a party for more than 5 years is discretionary, much like the OIG's permissive exclusion authorities under section 1128(b) of the Act. For that reason, we have modified § 1001.2001(a) to extend its application to mandatory exclusions imposed for periods exceeding 5 years. Consistent with our longstanding practice, for mandatory exclusions imposed for not more than five years, § 1001.2002(a) provides for issuance of a written notice 20 days prior to the effective date of the exclusion.

2. Notice of Intent to Exclude

*Comment:* We received a number of comments regarding the provision governing notice of intent to exclude under § 1001.2001. Some commenters felt that the notice of intent to exclude under § 1001.2001(a) should be by certified mail, and that the notice should be deemed received on the return receipt date, rather than a presumed date of 5 days after the date on the notice. One commenter requested that we set forth standards in these regulations for how the OIG would evaluate documentary evidence and written argument in response to a notice of intent to exclude, and when a hearing would be granted.

*Response:* When the OIG receives information in response to a notice of intent to exclude, it evaluates the information supplied in order to determine whether, in light of exigent or mitigating circumstances surrounding the conduct authorizing the exclusion, justice requires permitting the individual or entity to remain a participating Medicare provider. We have modified the language in § 1001.2001 to clarify that, in making these determinations, we will consider any evidence concerning whether the exclusion is warranted and any related issues, such as argument pertaining to the proper length of exclusion. The OIG's determinations in each case depend on the unique information supplied, and we cannot reduce that process to a uniform set of standards.

With respect to the OIG's policy on granting requests for a hearing under § 1001.2001(b), whenever a hearing request is made in conjunction with the submission of documentary evidence and written argument, the request is always granted.

With respect to the comments that we send these notices by certified mail, the OIG currently sends by certified mail all notices relating to the imposition of exclusions, including notices of intent to exclude under § 1001.2001, notices of exclusion under § 1001.2002, and notices of proposals to exclude under § 1001.2003. However, it is not administratively feasible for the OIG to await the return of certified mail receipt forms before proceeding to impose exclusions. We believe that a presumption that notices are received within 5 days after the date on the notice is both reasonable and legally sound. The courts customarily use presumptions of this nature so that parties may consider particular documents sent in the course of litigation to have been received by a date certain. In fact, the Federal Rules of Civil Procedure (FRCP) provide parties with only 3 extra days of time, not 5, when notice is by mail (see FRCP, section 6(e)). For these reasons, we are retaining in the final rule the presumption that notice is received within 5 days of the date on the notice.

3. Notice of Exclusion

*Comment:* One commenter objected to the fact that, under these regulations, individuals or entities excluded for 5 years under a mandatory exclusion authority are notified of the exclusion only 20 days prior to its effect, and do not have the opportunity to present evidence in their defense prior to the imposition of the exclusion. This commenter suggested that even in situations when the OIG believed it was statutorily obligated to impose an exclusion under section 1128(a) of the Act, there could be a mistake of identity or some other reason why imposing an exclusion would be improper.

*Response:* Under this rule, no exclusion takes effect immediately upon notice to the provider. Under § 1001.2002, mandatorily excluded individuals or entities are always notified by the OIG 20 days prior to the effective date of the sanction. This period of 20 days provides ample time for rectifying any mistakes of identity or similar errors before the exclusion takes effect. Furthermore, if the OIG were to implement an exclusion in error, the excluded party would be reinstated retroactively.

4. Notice of Proposal to Exclude

*Comment:* A few commenters expressed concern about the OIG's responsibility under § 1001.2003(c) to determine whether a threat to the health and safety of Medicare or State health care program beneficiaries warranted imposition of an exclusion prior to the completion an ALJ hearing. One commenter felt that the ALJ, not the OIG, should make this determination. Another commenter felt that the requirement under § 1001.2003(a)(5) that petitioners notify the OIG of any reasons why the health and safety of individuals do not warrant a pre-hearing exclusion unfairly shifted the burden of proof on this issue to the health care provider.

*Response:* We disagree that § 1001.2003(a)(5) shifts the burden of proof. It merely requires providers to supply relevant information and any defenses to assist the OIG in determining whether an exclusion should be imposed prior to a full ALJ hearing. We also disagree with the comment that an ALJ, rather than the OIG, should make this determination. The Department has a responsibility to protect the integrity of its programs and to ensure that program dollars are not being paid to health care providers who pose a danger to the health or safety of program beneficiaries. In order to carry out that responsibility, the Department must be able to sever its relationships with such providers immediately. Under §§ 1001.2001 and 1001.2003, the OIG would already have solicited and received relevant medical and other information regarding a provider it determined posed a danger to the programs. Therefore, the OIG, rather than an ALJ, is in the best position to evaluate all material evidence in a prompt manner.

5. Notice to Third Parties Regarding Exclusion

*Comment:* We received a number of comments on the regulatory provisions governing notice to third parties of exclusions. Several commenters stated that, in light of the probable damaging effect of an exclusion on the professional reputation of health care providers, the OIG should not notify third parties of exclusions under §§ 1001.2004 through 1001.2006 until all avenues of appellate review were exhausted. One commenter felt that OIG should be required under § 1001.2006 to notify the National Practitioner Data Bank of exclusions imposed under these authorities, so that this information would be available to all government and private agencies networked to this health care sanctions data collection organization.

*Response:* The OIG has an agreement with the National Practitioner Data Bank to provide it with notices of all exclusions. With respect to the comment that we should forego notification of exclusions to third parties until exclusions imposed by ALJs are upheld on appeal, we believe this would contravene legislative intent. Under section1128(e)(1) of the Act, prompt notification of these parties is required. It should be noted that under § 1001.3003(a)(3), prompt notification of reinstatement will be made to those agencies and organizations originally informed about the exclusion. We have modified the language in this provision to clarify that notification will be to the extent applicable; that is, it will be made to all entities originally notified about the exclusion that are still in business or, with respect to government contractors, still operating as a contractor for a government health care program.

6. Appeal of Exclusions

*Comment:* A few commenters felt that the "preponderance of the evidence" standard set forth in § 1001.2007(c) was improper given the potential harm exclusions cause providers' professional careers. One commenter was especially concerned about the use of this standard in cases involving exclusions imposed under § 1001.951 for conduct violating the criminal anti-kickback statute. One commenter stated that the standard was inconsistent with legislative intent.

*Response:* The preponderance of the evidence standard is the traditional standard of proof in administrative hearings, and, as such, ought to be applied in these administrative proceedings (see *Delikosta* v. *Califano*, 478 F. Supp. 640, 643 n. 4 (S.D.N.Y. 1979)).

Moreover, as we pointed out in the proposed regulations, the legislative history of MMPPPA reflects Congress' intent that the preponderance of the evidence standard be applied in kickback exclusion appeals (see H.R. Rep. No. 85, Part 1 at 10 (1987); H.R. Rep. Part 2, No. 85 at 9 (1987); S. Rep. No. 109, at 10 (1987)).

*Comment:* Several commenters felt that § 1001.2007(a) improperly limited the issues upon which parties could appeal an exclusion before an ALJ. Section 1001.2007 limits the issues on appeal to whether (1) the statutory basis for imposing the exclusion exists and (2) the length of the sanction is unreasonable. One commenter felt that if OIG failed to meet its notice requirements under part 1001, subpart E, this should be a basis for appeal of the exclusion. Another party felt that providers convicted of program related convictions in States affording fewer due process protections than those granted under Federal law should be

able to attack the underlying conviction at their hearing to contest the exclusion.

*Response:* We have deliberately limited the issues that may be appealed under § 1001.2007, in keeping with the authority under section 1128 of the Act delegated to the OIG. Under section 1128(a), Congress mandated that the Secretary exclude individuals and entities convicted by States of program related crimes, or of crimes involving patient abuse. The OIG, to whom this authority has been delegated, is statutorily obligated to implement exclusions whenever such convictions have occurred. The due process afforded by States in convicting their citizens is not a factor we are authorized to consider.

In section 1128(b) of the Act, Congress authorized the Secretary to impose exclusions at its discretion under the various circumstances described in that section. As the Secretary's delegatee under section 1128, the OIG has been vested with that discretionary authority. Because the decision whether to exclude an individual or entity under section 1128(b) is the OIG's alone, the ALJ does not have authority to review the exercise of discretion by the OIG to exclude someone under section 1128(b), or to determine the scope or effect of the exclusion. In addition, the OIG's decision to exclude may not be appealed under § 1001.2007.

The OIG's broad discretion is also reflected in the language of § 1001.2007(a)(2), restricting the ALJ's authority to review the length of an exclusion imposed by the OIG. Under that section, the ALJ's authority is limited to reviewing whether the length is unreasonable. So long as the amount of time chosen by the OIG is within a reasonable range, based on demonstrated criteria, the ALJ has no authority to change it under this rule. We believe that the deference § 1001.2007(a)(2) grants to the OIG is appropriate, given the OIG's vast experience in implementing exclusions under these authorities.

With respect to the comment that failure to provide adequate notice should be a basis for appeal of an exclusion, we disagree. At most, it could be the basis for recalculating the effective date of the exclusion. Moreover, under these regulations, all excluded individuals and entities are notified at least 20 days before the effect of an exclusion. To date, no individuals or entities have ever been excluded without proper notice. In the unlikely event that an individual or entity was excluded without proper notice, the OIG, if informed of the error, will take the steps necessary to ensure protection of the excluded party's opportunity to be heard, and appeal rights.

*G. Part 1001, Subpart F—Reinstatement Into the Programs*

*Comment:* Various commenters believed that the reinstatement procedures set forth in the proposed regulations are unconstitutional. Some of these commenters felt that the provision authorizing the OIG to deny reinstatement without the possibility of review is a denial of due process in violation of the Fifth Amendment. Others felt that the provisions authorizing the OIG to consider evidence of conduct occurring before the date of the exclusion violates an individual's First Amendment right to privacy.

*Response:* The provisions of the proposed regulations setting forth the reinstatement procedures merely implement the authority given to the Department by Congress. Section 1128(g) of the Act specifically provides that termination of an exclusion is not automatic, and grants the Secretary the authority to promulgate regulations setting forth the procedures for applying to the Department for reinstatement.

Further, the legislative history to MMPPPA makes it clear that the Secretary has the discretion to grant or deny a request for reinstatement, and provides that the decision is not subject to administrative or judicial review:

> The Committee bill maintains current law by providing that the decision of whether or not to grant an applicant's request for reinstatement is vested by law in the Secretary's discretion and thus is not subject to judicial review. (House Report 100-85, *supra* at 13.)

Concerning the OIG's consideration of an excluded individual's conduct prior to the date of the notice of exclusion, section 1128(g) of the Act states that:

> the Secretary may terminate the exclusion if the Secretary determines, on the basis of the conduct of the applicant which occurred after the date of the notice of exclusion or *which was unknown to the Secretary at the time of the exclusion* * * * (emphasis added)

Thus, consistent with the statute and its legislative history, the OIG is authorized to consider conduct of the individual or entity occurring prior to the date of the notice of exclusion, provided the OIG was not aware of such conduct at the time of the exclusion, as provided in § 1001.3002 of the proposed regulations.

Under section 1128(g), the decision whether to reinstate individuals excluded from the Medicare and State health care programs is vested by law in the Secretary's discretion and is not subject to judicial review. Prior to the passage of MMPPPA, reinstatement decisions were not subject to administrative or judicial review. When it enacted MMPPPA, Congress indicated that it did not expect the Department to change current legal procedures for reinstatement (see H.R. Rep. No. 85, Part 1, at 13, H.R. Rep. No. 85, Part 2, at 13). Thus, we believe that Congress, in section 1128(g) of the Act, did not intend to provide for administrative or judicial review for reinstatement decisions. Under section 1128(g), the Department is authorized to determine whether a previously excluded individual or entity can now be trusted to do business with the Government honestly and fairly. Because of its vast experience administering sanctions against health care providers, the OIG is in a better position than the ALJs to make these determinations. We have added paragraph (f) to § 1001.3002 to clarify that ALJs are not authorized to reinstate excluded individuals or entities under these regulations.

*Comment:* One commenter expressed concern about the provision in § 1001.3004(b) that subsequent requests for reinstatement following an initial denial will not be considered for one year. This commenter felt that there may be instances when a year is not sufficient time for the OIG to determine whether the criteria governing reinstatement under § 1001.3002(a) have been met.

*Response:* We agree that a year may be insufficient for purposes of assessing whether the conduct for which the provider was excluded is likely to recur, or whether the provider meets the other criteria set forth under § 1001.3002(b). For example, a physician excluded under section 1128(b)(4) of the Act for reasons bearing upon his or her professional competence may have moved to a different jurisdiction to begin practicing again just prior to his or her initial request for reinstatement. In that case, if the OIG were required to consider a new request within a year following the denial of the initial request, that might be insufficient for purposes of determining whether the provider had remained incompetent or was deserving of reinstatement. For that reason, we are modifying § 1001.3004(b) to state that after a denial of reinstatement, a subsequent request will not be considered for at least one year.

*H. Part 1002—State-Initiated Exclusions From Medicaid*

*Comment:* One commenter was concerned that the regulations violate the Social Security Act and the Fifth

amendment right to due process, because they invite States to add punishments beyond those authorized by Federal law.

*Response:* This comment appears to refer to § 1002.2(b), which simply states that nothing in the regulations limit a State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law. State agencies may prosecute and sanction providers on their own initiative when State law authorizes them to do so. Nothing in section 1128(d) of the Act or its legislative history indicates that the Federal statutory provisions governing the length of exclusions were intended to supplant State law provisions governing exclusions from State health care programs. In fact, section 1128(d)(3)(B)(ii) provides that "a State health care program may provide for a period of exclusion which is longer than the period of exclusion under title XVIII (Medicare)."

*Comment:* Several commenters expressed their opposition to §§ 1002.210, 1002.212, and 1002.213 through 1002.215 of the proposed regulations. These provisions set forth procedural safeguards to be followed by the States when excluding an individual. The commenters believed that a Federal agency should not promulgate regulations that require a State to carry out administrative tasks that are not specifically set out in the underlying statute.

*Response:* In accordance with section 1902(p)(1) of the Act, State Medicaid agencies have the authority to initiate exclusions of individuals or entities who could be excluded from Medicare by the Federal government under sections 1128, 1128A or 1866(b)(2) of the Act. The Department is authorized to require State agencies to develop mechanisms for implementing and terminating exclusions imposed under these authorities. Under section 1902(a)(39) of the Act, which sets forth the requirements for State Medicaid plans, the State programs are obligated to "provide that the State agency shall exclude any specified individual or entity from participation * * * when required to do so pursuant to section 1128 or section 1128A." In addition, section 1902(a)(4) of the Act states that plans must provide "such methods of administration * * * as are found by the Secretary to be necessary for the proper and efficient operation of the plan." These provisions clarify, by statute, that we may require States to adopt certain administrative procedures when they impose exclusions at the direction of the Secretary under the Secretary's exclusion or CMP authorities.

Furthermore, when an individual or entity has been excluded, suspended, or otherwise sanctioned by a State Medicaid agency, the OIG is authorized to exclude that individual or entity from Medicare and all State health care programs in accordance with section 1128(b)(5) of the Act, that is, to "piggyback" onto the State-initiated exclusion an additional nationwide exclusion from Medicare and *all* State health care programs. Thus, the OIG's exclusion is based upon a State agency's determination that a provider is unfit to participate in their State Medicaid program. In making that determination, the agency must afford the provider certain minimum due process safeguards before effectuating the exclusion, such as notifying the provider of the proposed exclusion and the basis therefore, and giving the provider a chance to respond to the allegations against them either in person or in writing. We received comments from one State agency stating that many or most States already have due process safeguards built into their exclusion process. However, as discussed above, because the administrative procedures followed in State-initiated exclusions may impact upon the OIG's authority to initiate exclusions under section 1128(b)(5), we believe it is important to insure that *all* States have minimum due process safeguards in effect when initiating exclusions from State Medicaid programs. We believe the administrative procedures set forth in the regulations provide such safeguards. In fact, they are based on the OIG's own procedures for initiating exclusions. Finally, in addition to the reasons set forth above, we believe the fact that Medicaid is a joint State and Federally-funded program supports the OIG's authority to set forth in regulations administrative procedures to be followed in State-initiated exclusions. Accordingly, we are not adopting the comments on this issue.

*Comment:* In accordance with § 1002.230(a) of the proposed regulations, the State Medicaid agency is required to 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 of the Medicaid program." One MFCU pointed out that they routinely notify the OIG when they obtain State convictions. The comment from the MFCU stated that in order to avoid having both the MFCU and the State agency report to the OIG on the same convictions, proposed § 1002.230 should be revised to add the following language at the end of the last sentence in paragraph (a): "* * * except when the State MFCU has so notified the OIG."

*Response:* We have adopted the MFCU's comment, and have revised § 1002.230(a) accordingly.

*Comment:* One commenter stated that the different definitions of the term "exclusion" in §§ 1002.203(b) and 1002.211 is confusing because it implies that an exclusion under subpart B—Mandatory Exclusions—is different than an exclusion under subpart C—Permissive Exclusions. This commenter suggested putting a general definition of "exclusion" in § 1001.2, Definitions.

*Response:* The definition of the term "exclusion" set forth in § 1002.203(b) pertains to subpart B of the regulations, which implements section 7 of Public Law 100-93 governing mandatory exclusions by State agencies. Section 7 of Public Law 100-93 provides that in order for a State to receive payments for medical assistance under section 1903(a) of the Act, with respect to payments the State makes to a HMO or to an entity furnishing services under a waiver approved under section 1915(b)(1), the State must exclude from participation such an entity if it could be excluded under section 1128(b)(8) of the Act, or if it had a substantial contractual relationship with an individual or entity that could be excluded under section 1128(b)(8). For the narrow purpose of implementing an exclusion under section 7 of Public Law 100-93, § 1002.203 points out that an exclusion includes the refusal to enter into or renew a participation agreement, or the termination of such an agreement, with the excluded entity. In part 1002, subpart B is entirely separate from subpart C, which pertains to permissive exclusions. Section 1002.211 defines the term "exclusion" for purposes of subpart C. In contrast to § 1002.203(b) of subpart B, in which the definition of "exclusion" focuses on a contract agreement between a State and an HMO or an entity furnishing services under a waiver by way of contract, § 1002.211 is broader in that it applies to all individual and entities, and focuses on the withhold of payments rather than the status of an agreement. Since the two different definitions are unique to the subparts in which they are set forth, we have chosen not to adopt the commenter's recommendation to consolidate them under one definitional section.

*Comment:* One commenter suggested changing § 1002.2(b) to read: "Nothing

contained in this part should be construed to limit a State's own authority to exclude an individual or entity from Medicaid for cause for any period authorized by State law."

*Response:* We are not adopting this comment. Section 1002.2(b) as it is written simply provides that nothing contained in part 1002 implementing the Federal statute limits the State's authority under State law to exclude an individual or entity. It is up to the various courts and legislative bodies to interpret how the individual States may apply the authority given to them under State law, not the OIG. Further, it would be inappropriate for the OIG to define on behalf of State agencies the terms of their agreements with health care providers.

*Comment:* One commenter expressed concern that the term "agent" as used in § 1002.3(c) is very broad and may allow Medicaid agencies to unfairly exclude certain providers.

*Response:* The final regulations include a definition of the term "agent" modeled after the definition set forth in the HCFA regulations (42 CFR 455.100), implementing sections 1124(a)(3) and 1126 of the Act and which ties into the OIG's exclusionary authority under section 1128(b)(8) of the Act. Section 1002.3(c) parallels section 1128(b)(8) of the Act, giving State agencies the same authority as the Federal government to exclude an entity controlled by a sanctioned individual. The final regulations define "agent" as anyone who has the express or implied authority to obligate or act on behalf of an entity. As discussed above, we intend for this definition to mainly cover agency relationships where the agent has, or is able to have, a significant role in the entity.

*I. Part 1003—Civil Money Penalties and Exclusions*

1. General Comments

*Comment:* Several commenters expressed concern about the application of § 1003.114, which relates to the applicability of the doctrine of collateral estoppel to CMP proceedings. One commenter believed that there cannot be a "final determination" for purposes of collateral estoppel until a party has exhausted all of his or her available appeal rights. Another commenter felt that the collateral estoppel doctrine should only apply when the prior proceeding was a judicial or administrative proceeding with sufficient safeguards to protect against bias or error. A third commenter stated that the regulations should require that the issue decided in the prior proceeding must be identical to the one at issue in order for collateral estoppel to apply.

*Response:* Section 1003.114 sets forth the basic doctrine of collateral estoppel. In order to safeguard the due process rights of respondents in CMP proceedings, we intend to apply § 1003.114 in full accordance with recognized legal standards. However, we do not feel this is the appropriate forum to address discrete legal issues relating to the application of the collateral estoppel doctrine. Rather, we believe that the legal issues raised by the commenters may be best addressed on a case-by-case basis as they arise, so that the ALJs can objectively dispose of them in accordance with the governing law and the facts of each case. Thus, we have chosen not to revise § 1003.114 as the commenters had requested.

*Comment:* One commenter felt that § 1003.109(a)(5) should be expanded to include the right to request an extension of time to respond to the OIG's notice of proposed determination beyond the 60 days set forth in that provision.

*Response:* In § 1005.2 of this final rule, we have provided a 60-day period in which a petitioner or respondent in any exclusion or CMP proceeding may request a hearing. This is a change from the rules that previously applied to CMP cases. Under § 1003.109 of the prior regulations, respondents were entitled to only 30 days in which to request a hearing, but also in which they could request an extension of that 30-day period for "good cause." In practice, the OIG never granted an extension of more than 30 additional days. Thus, the maximum period in which to respond never exceeded 60 days.

We have decided to simplify the process for all concerned by entitling all respondents to 60 days in which to request a hearing. We are thereby doubling the usual period of time previously available to respondents, while eliminating the labor involved in generating "good cause" requests and responding to them. Section 1003.109(a)(5) of this rule now merely requires the notice of proposed determination for CMP cases to include the 60-day timeframe set forth in § 1005.2. Therefore, no change in this section is appropriate.

*Comment:* We received comments to the effect that the OIG should not be limited to considering the mitigating factors set forth in §§ 1003.106 (b)(1) and (b)(2), but rather, the OIG and the ALJ should be able to consider any factors that may be mitigating.

*Response:* In accordance with § 1003.106(a)(5), in determining the amount of any CMP or assessment, the Department must take into account "such other matters as justice may require." This catch-all phrase already allows the OIG and the ALJ to consider any other mitigating factors that may exist.

*Comment:* Some commenters expressed confusion regarding the effect of the Supreme Court's decision in *United States* v. *Halper* on the scope of damages that the Inspector General may recover in CMP cases.

*Response:* The courts have recognized that civil penalty statutes entitle the government to recover full compensation for its damages, and that ordinarily, application of a statutory "fixed penalty plus double damages" provision does no more than make the government whole (*United States* v. *Halper*, 109 S.Ct. 1892, 1900, 1902 (1989); *Rex Trailer Co.* v. *United States*, 350 U.S. 148, 152–154, 76 S.Ct. 219, 222 (1956)). This is due, in part, to the fact that the government's losses involve more than merely the amount disbursed on account of false or improper Medicare or Medicaid claims (*Mayers* v. *United States Department of Health and Human Services*, 806 F. 2d 995, 999 (11th Cir. 1986)). In CMP cases, the government's damages typically include, in addition to actual improper payments made, (1) costs of detection, investigation and prosecution of fraud, (2) diversion of scarce resources from the direct provision of health services, and (3) loss of public confidence in the integrity of Medicare or State health care programs, and in the government's ability to properly manage them (*The Inspector General* v. *Harold Chapman and Autumn Manor, Inc.*, No. C–5 (1985), *aff'd, Chapman* v. *Department of Health and Human Services*, 821 F. 2d 523, 528 (10th Cir. 1987); *Mayers, supra* at 999).

We have modified the guidelines under §§ 1003.106 (c) and (d) for determining appropriate monetary sanctions in order to codify existing case law governing the process of determining penalties and assessments under the CMP law. We have clarified that the United States or any State government is entitled to full compensation for any damages and costs arising from CMP violations. We have specifically identified the costs of investigation, prosecution and administrative review as amounts to be taken into account in determining appropriate monetary sanctions. Finally, we have converted the guidelines under § 1003.106 to binding rules, except to the extent that their application in a particular case could result in an amount that exceeds constitutional limitations. This final modification reflects the intent of the original

regulations that the latitude inherent in the non-binding guidelines is meant only to "provide for the exceptional case" (48 FR 38827, August 26, 1983).

Under this approach, the ALJ must compute the amount of the penalty and assessment in accordance with the guidelines set forth in § 1003.106, and then make a determination as to whether that amount exceeds constitutional limits. Should the ALJ determine that the prescribed amount is excessive and violative of the constitution, the ALJ would be required to explain the reasons for that conclusion. The ALJ would then be authorized to reduce the amount, but only to the point where the amount was no longer constitutionally impermissible. Both the determination that the amount computed under the regulations was constitutionally infirm and the amount of the required reduction would be subject to administrative and judicial review.

*Comment:* With regard to § 1003.102 of the proposed regulations, one commenter wished to know under what circumstances a person "should have known" that a claim was false or fraudulent, or not provided as claimed.

*Response:* Congress has indicated that the "should know" standard of knowledge under section 1128A of the Act places upon Medicare and Medicaid providers the duty to ascertain the truth and accuracy of claims submitted by them:

> Providers who bill the Medicare, Medicaid and MCH programs have an affirmative duty to ensure that the claims for payment which they submit, or which are submitted on their behalf by billing clerks or other employees, are true and accurate representations of the items or services actually provided. (H. Rep. No. 100-391, 100 Cong., 2d Sess., pp. 533-535 (1987))

Thus, under the "should know" standard of liability, the duty to ascertain the truth and accuracy of a claim exists at all times. Further, the "should have known" standard has been interpreted as subsuming reckless disregard for the consequences of a person's acts, as well as negligence in preparing and submitting or in directing the preparing and submitting of claims (see *Mayers* v. *U.S. Department of Health and Human Services*, 806 F.2d 995 (11th cir. 1986), *cert. denied*, 484 U.S. 822 (1987); *The Inspector General* v. *Edward J. Petrus, Jr., M.D., and the Eye Center of Austin*, Docket No. C-147 (Oct. 10, 1990), pg. 42)).

Further guidance as to the meaning of "should have known" can be found in the *Restatement of Torts (2d)* at section 12 (1965):

> The words "should know" are used throughout the Restatement * * * to denote the fact that a person of reasonable prudence and intelligence or of the superior intelligence of the actor would ascertain the fact in question in the performance of this duty to another, or would govern his conduct upon the assumption that such fact exists. (See *In the Case of the Inspector General* v. *Corazon C. Hobbs, M.D.*, Decision of ALJ Charles E. Stratton, Docket No. C-55 (December 5, 1989), pg. 27, citing the restatement.)

Whether a health care provider or practitioner "should have known" that an item or service has not been provided as claimed or that a claim is false or fraudulent is fact intensive, and will therefore be determined on a case-by-case basis.

2. Other Crimes, Wrongs, or Acts as an Aggravating Circumstance

As mentioned in the preamble to the proposed regulations, we solicited comments on whether it would be appropriate to include a provision in the regulations stating that proof of "other crimes, wrongs, or acts" is an aggravating circumstance in OIG sanction cases.

*Comment:* We received one comment objecting to the inclusion of such a provision. The commenter believed that the mere existence of a prior wrongful act should not serve as an aggravating factor if that act were unrelated to the Medicare or Medicaid program.

*Response:* We have decided to add into the final regulations a new § 1003.106(b)(4), "Other Wrongful Conduct." This provision makes it an aggravating factor if the OIG proves that a respondent engaged in wrongful conduct, other than the conduct at issue, relating to government programs or in connection with the delivery of a health care item or service. Although the OIG anticipates that the wrongful conduct raised for purposes of this provision will be Medicare and Medicaid-related, there may be wrongful conduct that is unrelated to Medicare and Medicaid that is considered to be aggravating, such as where a respondent has proved himself or herself to be untrustworthy in dealing with other government programs. The OIG may present evidence of "other wrongful conduct" as an aggravating factor even if such conduct was not specifically mentioned in the notice of proposed determination initiating the CMP proceeding.

In accordance with § 1003.106(b)(4), "other wrongful conduct" includes but is not limited to, evidence that the conduct for which the OIG is seeking civil sanctions is part of a larger pattern or scheme of the same or similar wrongful conduct. For example, the OIG has evidence to show that an individual submitted 200 false claims. The OIG only initiates an CMP action based on 100 of those claims because the statute of limitations has run on the 100 claims remaining. In accordance with § 1003.106(b)(4), the OIG may present evidence of the remaining claims as an aggravating factor.

Finally, it is important to note that the absence of "other wrongful conduct" is not a mitigating factor.

3. Effect of Regulations on Other CMP Provisions

*Comment:* Several commenters expressed concern that § 1003.102 does not incorporate the provisions of section 1128A(b) of the Act, which prohibits incentives to physicians in order to reduce or limit services to Medicare or Medicaid patients. The commenters believed that the regulations fail to provide substantive guidance or place procedural restrictions on the Department's implementation of section 1128A(b) of the Act, effective on April 1, 1991.

*Response:* With respect to the procedural guidelines for the implementation of section 1128A(b) of the Act, the OIG currently intends for the administrative procedures set forth at part 1003 of these regulations to govern proceedings initiated for alleged violations of section 1128A(b). In fact, the OIG currently intends for the administrative procedures set forth at part 1003 to govern all proceedings initiated under the CMP authorities contained in the Social Security Act, even those not specifically mentioned in the regulations, e.g., section 1867 of the Act. We acknowledge that the various CMP authorities set forth in the Act and the sanctions that accompany them may vary from those specifically described in the regulations in such a way that certain procedures set forth at part 1003 do not make sense when they are applied to them. Where that is the case, the regulations will be used as a framework for the proceedings, and will govern to the extent they are applicable.

Whenever the OIG initiates a CMP proceeding, it will notify each respondent that the procedural regulations set forth at part 1003 will govern. It is well-established that if a party is notified of the standards and procedures that will be applied in a particular case, an agency can bring an action against that party even in the absence of regulations (see *Patchogue Nursing Center* v. *Bowen*, 797 F.2d 1137, 1143 (2d Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987); *Central Arkansas Auction Sale, Inc.* v. *Bergland*, 570 F.2d 724, 727 (8th Cir. 1977), *cert. denied*, 436 U.S. 957

(1978)). With respect to the implementation of the substantive provisions of section 1128A(b) of the Act, the Department is currently working on separate regulations. However, it is not necessary for such regulations to be in place before the OIG may exercise its authority under that provision once it takes effect on April 1, 1991. An agency may exercise its statutory functions even in the absence of specific implementing regulations (see *Securities and Exchange Commission* v. *Chenery Corp.*, 332 U.S. 194 (1947); *Abbott-Northwestern Hospital, Inc.* v. *Schweiker*, 698 F.2d 336 (8th Cir. 1983)). Thus, once the OIG gives such notice regarding section 1128A(b) of the Act, there is legal support for using the administrative procedures set forth at part 1003 to implement CMP authorities not specifically mentioned in the regulations.

*J. Part 1005—Appeals of Exclusions and CMPs*

General Comments

*Comment:* We received a number of comments concerning the authority of ALJs. One commenter suggested that we amend § 1005.2 to permit ALJs to dismiss requests for hearing that fail to meet the requirements of paragraph (d). This commenter pointed out that if no factual or legal basis for a hearing was identified by the requesting party, the ALJ should dismiss the request for hearing. Another commenter objected to the provision under § 1005.4(c) that the ALJ may not enjoin an act of the Secretary. Finally, one commenter suggested that ALJs should be able to render directed verdicts in these cases.

*Response:* With respect to the comment that ALJs should be able to dismiss requests for hearing if there is no factual or legal dispute, we agree, and have revised § 1005.2(e) accordingly. It should also be noted that under § 1005.4(b)(12) an ALJ may dismiss a case, in whole or in part, by summary judgment, where there is no disputed issue of material fact. With respect to the objection to § 1005.4(c), we note that the ALJ's own authority in these proceedings is derived from the Secretary by delegation (sections 1128A(f) and 205(b) of the Act). Since the ALJ's authority to hear cases comes from the Secretary, the ALJ cannot overrule acts of the Secretary which may have an impact on these cases. The full scope of the ALJ's limited authorities in these proceedings is contained in § 1005.2.

We have also clarified under §§ 1005.4(c) (5) and (7) that ALJs may not review the OIG's exercise of discretion to impose a penalty, assessment or exclusion under these authorities. It should also be noted that in a case where the ALJ upholds the OIG's exclusion determination, the ALJ is not authorized under these regulations to modify the date of commencement of the exclusion identified in the OIG's notice of exclusion.

We have also provided in § 1005.4(c)(6) that in any case where an ALJ finds that an individual or entity has committed an act described in section 1128(b) of the Act, the ALJ is not authorized to reduce to zero the exclusion period proposed by the Inspector General. In other words, when the ALJ finds a violation, he or she must remedy it with some period of exclusion. We believe that this requirement is consistent with congressional intent in enacting section 1128 which explicitly provides for exclusion as the appropriate remedy for the commission of any of the acts specified in the statute. Thus, in every case where the Inspector General has exercised his or her discretion to impose an exclusion, and where the ALJ concurs that violation did occur, some period of exclusion is necessary to remedy the violation.

Although circumstances such as the absence of proof of harm to beneficiaries or the programs may mitigate the length of exclusion, they do not eliminate the need for some remedial period of exclusion. Inherent in the structure and far-reaching effect of section 1128 is the notion that any violation compromises the integrity of the programs and thereby places the programs and its beneficiaries at risk.

We do not agree with the comment that ALJs should be authorized to impose directed verdicts in these cases. If a directed verdict is rendered prior to the presentation of both parties' cases, the record will be incomplete in the event that the initial decision were subsequently reversed on appeal. We have encountered this situation in the past, and the only remedy in such a case is a new trial. Thus, it can be less efficient in the long run, and can delay and frustrate justice, to authorize directed verdicts in these proceedings.

*Comment:* One commenter suggested that these regulations should require a pre-hearing conference before the ALJ to attempt settlement of the case.

*Response:* We agree that ALJs should encourage parties to settle their cases prior to hearing. We are therefore adding a provision to § 1005.6 to clarify that ALJs should investigate the possibility of settlement during pre-hearing conferences.

*Comment:* Several commenters were concerned that the type of discovery provided for under § 1005.7 was too limited. One conmenter suggested that the Administrative Procedure Act (APA) mandates broader discovery rights in exclusion appeals under these authorities. Some commenters felt that the prohibition against discovery other than documentary requests was unfair, particularly in light of the OIG's testimonial subpoena authority under part 1006. One commenter felt it was inappropriate to place the burden of showing that discovery should be allowed on the party *seeking* discovery, rather than having the other party show cause why discovery should not be conducted.

Some commenters felt that this provision left unanswered important questions regarding discovery procedure. One commenter wanted to know if data stored in computers could be discoverable. Another commenter was concerned over whether the OIG, in response to a discovery request, was required to seek or obtain material in the possession of other branches or divisions of the agency.

*Response:* Generally, discovery is not required to be made available in administrative proceedings. Under the APA, agencies are free to decide the extent of discovery to which parties to administrative proceedings will be entitled (see *Pacific Gas & Electric Co.* v. *FERC*, 746 F. 2d 1383, 1387 (9th Cir. 1984); *National Labor Relations Board* v. *Valley Mold Co.*, 530 F. 2d 693, 695 (6th Cir. 1976); *Frilette* v. *Kimverlin*, 508 F. 2d 205, 208 (3d Cir. 1974); *Silverman* v. *Commodity Futures Trading Commission*, 549 F. 2d 28 (7th Cir. 1977)).

With respect to exclusion and CMP proceedings, we have determined that discovery should be limited to documentary exchanges in order to avoid the time-consuming discovery fights that commonly beset civil litigation. Since discovery is to be as limited as possible, we believe it is appropriate to place the burden of showing why it is needed on the party seeking discovery under § 1005.7(c)(3). Further, we have clarified in § 1005.7(a) that discovery requests may only be made from one party to "another party." Therefore, the OIG may only be requested to produce documents in the possession of the OIG, as a party to the proceeding under § 1005.2(b), and not documents potentially in the possession of other branches or divisions of the Department, such as HCFA.

We have also inserted a provision that protects against the disclosure of interview reports or statements obtained

by any party of persons who will not be called as witnesses, and analyses and summaries prepared in conjunction with the investigation or litigation of the case (§ 1005.7(d)). This protection extends to respondents as well as the government, and thus is broader than the provision included in the proposed rule that would have protected only "internal government documents."

While limited discovery is necessary to ensure timely and efficient disposition of these proceedings, it does not operate unfairly against petitioners and respondents. In exclusion and CMP cases, it is usually the petitioner and respondent, rather than the OIG, who possess the vast bulk of discoverable evidence. With respect to the comment that the OIG is favored because it can subpoena witnesses under part 1006, it should be clarified that the investigative subpoena provisions under part 1006 apply only to CMP investigations. That is, the subpoena is not available to the OIG once litigation has begun. The authority enables the OIG to obtain evidence from otherwise uncooperative witnesses during the course of investigations. It is not a litigation discovery provision.

In response to the comment concerning the discoverability of computer data we have added a provision to § 1005.7(c) dealing with information stored in computers. Although that section prohibits "the creation of a document," we have added language indicating that where requested data is stored in a computer, a party has the right to request that the information be provided in a form that can be used by the requesting party, i.e., a "hard copy" or print out of the data, or a computerized version of the data, such as a computer disk. It is anticipated that the parties will cooperate with one another by providing information in a format that is useful to the other party.

2. Exchange of Witness Lists, Statements and Exhibits

*Comment:* A few commenters felt that we should clarify the procedures under § 1005.8(b) with respect to evidence that was not exchanged at least 15 days prior to the hearing as required by § 1005.8(a).

*Response:* The 15-day rule set forth in § 1005.8(a) requires opposing parties to disclose the documents that will be presented at the hearing and, in addition, information concerning witnesses who will testify. One purpose of the rule is to provide parties the opportunity to subpoena any individuals for whom the opposing party has submitted statements in lieu of live testimony. Thus, the right to cross-examination of witnesses under § 1005.16(d) extends only to individuals subpoenaed to testify, and does not include declarants or interviewees. However, the chief purpose of the provision is to grant both parties adequate time to prepare to contest the other side's case. This purpose is defeated if one party fails to comply with the exchange provisions of § 1005.8(a). Therefore, if a party objects to the admission of evidence not disclosed in compliance with § 1005.8(a), the ALJ normally should not admit the evidence.

However, in extraordinary situations, a party may be unable to disclose evidence at least 15 days prior to the hearing. For example, a relevant document may have been created only 5 days before the hearing. Under such circumstances, the ALJ may admit evidence not exchanged in accordance with § 1005.8(a), unless its admission would substantially prejudice the objecting party. If admission of evidence not disclosed in compliance with § 1005.8(a) would cause substantial prejudice, the ALJ may do one of two things. The ALJ may exclude the evidence and go forward with the hearing, or the ALJ may, at his or her discretion, recess the hearing to allow the objecting party the opportunity to prepare and respond to the evidence.

Thus, under § 1005.8(b), the ALJ should only consider the issue of prejudice once a determination has been made that there were extraordinary grounds for the failure to comply with § 1005.8(a). If no such grounds exist, the evidence should always be excluded and the hearing should go forward.

With respect to § 1005.8(c), we believe that, prior to the hearing, ALJs should resolve objections to the authenticity of documents exchanged in accordance with § 1005.8(a). In presenting their cases, parties should be able to rely on the authenticity of documents provided to opposing counsel, unless a specific objection has been made before hand. We have modified § 1005.8(c) accordingly.

3. Witnesses

*Comment:* One commenter objected to the admission of statements in lieu of live testimony unless both sides consented to admission of the statement. This commenter felt it was unfair for petitioners and respondents to bear the burden of subpoenaing witnesses to contradict any such statements submitted by the OIG.

*Response:* We disagree. Written statements in lieu of live testimony have always been admissible in CMP proceedings, and have served a valuable purpose in cases where live witnesses were unavailable. For example, the statement of a now deceased Medicare beneficiary describing his or her knowledge of a physician's conduct could be relevant and material in a CMP case against that physician. Since both parties have the right to submit statements in lieu of testimony, each party bears the burden of subpoenaing witnesses whose statements are proposed as exhibits by the opposing party. The courts have held such statements admissible in administrative proceedings, despite their heresay character and absent any cross-examination of the witness who gave the statement (see *Richardson* v. *Perales*, 402 U.S. 389, 91 S.Ct. 1420 (1971)).

4. Burden of Proof

*Comment:* One commenter stated that the burden of proof for exclusions based on kickbacks should be the same as for CMP cases.

*Response:* We agree, and have revised § 1001.15 to provide that the burden of going forward and the burden of persuasion are the same for exclusions initiated under § l001.951 as for CMP cases initiated under part 1003.

*Comment:* Many commenters asserted that the APA requires that the burden of persuasion always rests with the government in exclusion cases.

*Response:* These commenters are mistaken as a matter of law. As we discussed in some detail in the preamble to the proposed rule, the APA requires the government—in this case, the OIG—to have the burden of going forward with evidence sufficient to make a *prima facie* case to support an exclusion; it does not require the OIG to bear the burden of persuasion in such cases.

*Comment:* Many commenters asserted that it is fundamentally unfair for the government not to bear the burden of persuasion in exclusion cases.

*Response:* As discussed above, with respect to kickback and CMP exclusions we have placed the burden of persuasion on the government because Congress intended "special due process protections" to accompany such exclusions (see Senate Report 100-109, *supra*, at 12-13). We have also decided to place the burden of proof on the government for PRO exclusions under part 1004 of this regulation.

With respect to all of the OIG's other exclusion authorities, however, we have decided not to specify by regulation which party bears the burden of going forward or which party bears the burden of persuasion. Instead, we have opted to continue to rely on the ALJs to allocate

the burden of proof as they deem appropriate.

*Comment:* Several commenters argued that it would be unfair to allow a party to raise new facts during its case-in-chief when the opposing party had no adequate notice and opportunity to respond.

*Response:* To ensure that no party is unfairly prejudiced by items or information raised at the hearing which were not set forth in the original notice letter, we have revised § 1005.15(f) to clarify that admission of such new evidence at a hearing is subject to the restrictions set forth in §§ 1005.8 and 1005.17.

5. Evidence

*Comment:* One commenter felt that the ALJ should not be given discretion in § 1005.17(b) to decide whether to apply any rules of evidence. The commenter felt that inconsistent application of the evidentiary rules would frustrate the ability of parties to prepare for hearing, and could result in arbitrary determinations by ALJs.

*Response:* The discretion we have provided in § 1005.17(b) is not unbridled. We expect the ALJs to continue their current practice of admitting evidence that may be barred by the rules of evidence, such as hearsay, if a determination is made that the evidence is reliable. However, if an ALJ believes that proffered evidence inadmissible under the rules of evidence is wholly unreliable, the ALJ should exclude the evidence.

*Comment:* In the proposed regulations, we solicited comments as to whether we should recognize and include Rule 404(b) of the Federal Rules of Evidence in the hearing procedures under part 1005. Rule 404(b) allows for the introduction of evidence of other crimes, wrongs or acts under certain circumstances, such as to prove knowledge, lack of mistake, or existence of a scheme. We also solicited comments on whether the rules should clarify that proof of "other crimes, wrongs or acts" is an aggravating circumstance in OIG sanction cases. Two-thirds of the comments we received supported the inclusion of Rule 404(b) in these regulations. On the other hand, one commenter said that such a rule would be unfair to petitioners and respondents because of the difficulty of challenging the accuracy of prior wrongful acts given the limited discovery available under this part.

*Response:* We agree with the majority of commenters that evidence of prior bad acts, including prior false claims, admitted for the purposes listed in Federal Rule of Evidence 404(b) is relevant and material and should be admitted. Such evidence should be considered proof of aggravating circumstances affecting the amount of damages awarded in CMP cases. Because the evidence provides proof of aggravating circumstances, and does not demonstrate facts relevant to the actual counts at issue, the evidence should be admitted even if the acts occurred prior to the statute of limitations period applicable to the claims at issue. Because evidence of aggravating circumstances bears only upon the amount of damages that should be imposed, and not a party's liability, evidence of prior bad acts should be admissible even if the prior bad acts were not mentioned in the IG's letter of notice to the petitioner or respondent. We have added a new paragraph (g) to § 1005.17 in accordance with these views.

We do not agree that discovery of the relevant facts concerning prior wrongful acts will be hampered by the limited discovery available under this part. Petitioners and respondents can seek any and all documents the OIG would use as exhibits to prove prior acts, such as plea agreements or judgments of conviction. Furthermore, at least 15 days prior to the hearing the petitioner or respondent is entitled to a list of any and all witnesses who might testify about the party's prior bad acts (§ 1005.8).

6. Initial Decision

*Comment:* A few commenters pointed out that, although parties are afforded 30 days within which to appeal the initial decision of an ALJ under § 1005.21(a), under proposed § 1005.20(d), the initial decision is not binding until 60 days after it is issued. This situation creates a gap of 30 days within which the ALJ decision will not be binding even if neither party decides to appeal it.

*Response:* We agree that the ALJ decisions should take effect immediately upon termination of the period within which the parties may appeal, when neither party appeals the decision. Therefore, we are modifying § 1002.20(d) to make initial decisions binding 30 days after they are issued by an ALJ, unless the decisions are timely appealed.

7. Appeal to the Secretary and Stay of Initial Decision

*Comment:* One commenter was concerned that the standards for internal agency review of ALJ decisions set forth in § 1005.21(h), and the authority of the Secretary to decline review of ALJ decisions under § 1005.21(g), violate due process.

*Response:* Under the APA, the Department is not required to provide for internal agency review of ALJ decisions imposing or upholding CMP or exclusion sanctions (5 U.S.C. 557). Moreover, a Federal agency may either adopt or reject the decision of an ALJ, and if it is fully satisfied with the ALJ's findings, it need not render a separate opinion (see *Starrett* v. *Special Counsel*, 792 F. 2d 1246, 1252 (4th Cir. 1986); *Braswell Motor Freight Lines, Inc.* v. *United States*, 275 F. Supp. 98, 103 (D.C. Tex. 1967) *aff'd* 389 U.S. 569, 88 S.Ct. 692 (1968); *Younger Bros., Inc.* v. *United States*, 238 F. Supp. 859, 860-61 (D.C. Tex. 1965)). Despite the fact that there is no legal requirement for internal agency review of ALJ decisions, we have chosen to provide such review in order to improve the administration and consistency of Department decisions imposing or implementing sanctions under the authorities set forth in Public Law 100-93. We have limited internal agency review to whether the decision is supported by substantial evidence, in the parallel manner that Congress, under sections 1128(f) and 205(g) of the Act, limited judicial review of agency decisions. We believe that this review process will eliminate erroneous sanctions decisions by the Department while, at the same time, granting appropriate deference to the credibility and other factual determinations of the ALJ.

*Comment:* A few commenters felt that the final rule should contain a provision stating when decisions by the DAB become final and binding on the parties.

*Response:* We agree that some clarification as to when agency action becomes final is needed, particularly in light of the provisions governing requests for stay of CMP decisions under § 1005.22. Accordingly, we are making several modifications to the proposed rules. First, we are revising § 1005.21(j) to clarify that a ruling by the DAB, including a decision to decline review of an ALJ's decision, becomes final and binding on the parties 60 days after the date on which the DAB serves the parties with a copy of the Secretary's decision.

This 60-day rule regarding finality reflects the Secretary's fundamental position that imposition of sanctions in CMP cases not be affected by the pendency of any appeals (see preamble to 1983 CMP regulations at 48 FR 38836, August 26, 1983). The procedure set forth in proposed § 1005.22 for filing with the ALJ a request for stay of a final CMP decision would appear to conflict with the Secretary's position that final

agency action in CMP cases is binding on the parties.

Accordingly, we have restricted the provision for stay pending judicial review in CMP cases. Under § 1005.22(b), following the DAB's decision, a respondent may seek a stay of any penalty or assessment imposed, but there is no authority providing for the stay of an exclusion. Furthermore, a stay of a penalty or assessment pending judicial review will only be granted if the respondent posts a bond or provides other adequate security.

*Comment:* One commenter objected to the fact that the provision for stay in § 1005.22 applies only to CMP cases and not to exclusion cases.

*Response:* The language and history of sections 1128(c) and 1128(f) of the Act indicate that Congress intended exclusions to take effect upon reasonable notice to the affected individual, and prior to the exhaustion of administrative and judicial remedies. In fact, section 1128(f) of the Act states that any individual or entity "that is excluded," that is, against whom the exclusion has already been made effective, is entitled to a hearing. Even in the exception carved out by Congress for exclusions under section 1128(b)(7), for which the statute affords extra due process protections, Congress still provided that such exclusions would become effective after an ALJ hearing (see Senate Report 100-109, *supra*, at 12-13). Clearly, Congress intended that exclusions would be imposed and effective pending appeals beyond the ALJ hearing.

*K. Part 1006—Investigational Inquiries*

*Comment:* One commenter was concerned about the provision in § 1006.4(g)(3)(iv), allowing the OIG to propose revisions to the transcript of a witness' testimonial interview. The commenter suggested that the testimony of an independent witness should not be susceptible to government revisions.

*Response:* By this provision, we meant to indicate that the OIG could propose corrections to the record transcribing the interview with the witness, if the record was incorrect. We did not mean to suggest that the OIG could propose substantive changes to the witness' testimony. We are revising the language of § 1006.4(g)(3)(iv) to clarify our intent.

*Comment:* One commenter felt that the targets of CMP investigations should be permitted to review the transcripts of investigative interviews of witnesses obtained under part 1006.

*Response:* We disagree. Targets of investigations have no legal right to review witness interview transcripts during the investigative phase of a case. These interviews are taken for investigative purposes prior to any litigation, often in order to determine whether there is *prima facie* evidence to pursue a CMP action. If the OIG subsequently determines that litigation is warranted, the transcript would become available in discovery. Furthermore, under § 1005.8, if the OIG planned to introduce the transcript into evidence at the hearing, it would provide a copy to the respondent at least 15 days prior to the hearing.

**V. Technical Revisions**

*A. Subpoenas Directed at OIG Officials*

Respondents or petitioners have occasionally sought the presence at a hearing of senior OIG officials. Requiring such individuals to appear and testify is extremely burdensome and detrimental to the proper functioning of the OIG. These officials could not perform their professional duties if they were forced to appear whenever any individual charged with a violation of an exclusion or CMP authority requested it. For that reason, under § 1005.9(c) of these regulations, we have provided that the OIG may comply with a subpoena to an OIG official by designating any OIG representative to appear and testify.

There is ample support in case law for this public policy. For example, courts have refused to allow parties to depose or subpoena the testimony of high level agency officials regarding administrative decisions committed to their discretion (see *Cornejo* v. *Landon*, 524 F. Supp. 118, 122 (E.D. Ill. 1981); *Simplex Time Recorder Co.* v. *Secretary of Labor*, 766 F.2d 575, 586 (D.C. Cir. 1985); *U.S.* v. *Morgan*, 313 U.S. 409, 421-22 (1940)). Agency officials cannot be compelled to provide information orally in an administrative proceeding unless the information "is not available from depositions of * * * other persons * * * or * * * through interrogatories or other discovery methods" (see *Cornejo* v. *Landon*, 524 F. Supp. at 122). The purpose of that rule is "to relieve agency decision-makers from the burdensomeness of discovery, allowing them to spend their valuable time on the performance of official functions and to protect them from inquiries into the mental processes of agency decisionmaking." *Id.*

*B. Substitution of the Term "Exclusion" for "Suspension"*

The term "suspension" has been changed to the term "exclusion" in part 1003 in the interests of uniformity and in order to clear up any confusion caused by the fact that both Congress and the Department have used the terms interchangeably. "Suspension" was the term Congress used in section 1128(a) of the Act prior to the passage of MMPPPA when it referred to the Secretary's authority or obligation to bar a provider from participation in government health care programs. In 1987, MMPPPA changed the term in the law to "exclusion." It is clear from the legislative history that changing the language did not change the meaning or effect of the Secretary's authority. In fact, in House and Senate Reports preceding the passage of MMPPPA, Congress used the term "exclusion" to refer to the Department's sanctioning authority although section 1128A did not contain the term at that time (see H.R. Rep. No. 85, 100th Cong. 1st Sess. 5 (1987)). Moreover, the Department's regulations make it clear that the effect of a suspension and the effect of an exclusion are identical (compare § 1001.115, Effect of Exclusion, and § 1001.126, Effect of Suspension). Under both regulations, payment will not be made to health care providers (including practitioners) for items or services furnished on or after the effective date of the sanction. Further, the same exceptions to the payment prohibition apply in both cases. (Compare §§ 1001.115 (b) and (c), and §§ 1001.126 (d) and (e).)

*C. Definition of "Claim" Under Part 1003*

We are revising § 1003.102(b) to reflect a 1987 technical statutory amendment to the definition of "claim" in the CMP law (section 1128A(i)(2) of the Act). Prior to 1987, the definition of "claim" in the CMP law was limited to applications for payment submitted by a provider of services to Medicare or a State health care program. Effective December 22, 1987, section 4118(e)(10)(B) of Pub.L. 100-203, as added by Public Law 100-360, section 411(k)(10)(D), substituted a new definition of "claim" that does not require submission by a health care provider to a health care program. Section 1128A(i)(2) of the Act now defines "claim" as simply "an application for payments for items and services under titles V, XVIII, XIX or XX of this Act."

Under this former definition of "claim," an assessment "of not more than twice the amount claimed," as provided for in section 1128A(a), could not be imposed for CMP violations that did not involve the submission of a claim by a health care provider to a health care program. Therefore, the current CMP regulations did not authorize imposition of an assessment for CMP violations that might not

involve a provider submitting a claim to a health care program (i.e., the violation of an assignment agreement under section 1842(b)(3)(B)(ii) of the Act). However, the definition of "claim" under section 1128A(i)(2) permits imposition of an assessment for CMP violations whenever an application for payment is made, even if it is not submitted by a provider to a health care program. Accordingly, we have modified § 1003.102(b) to clarify that an assessment may be imposed, as authorized, for CMP violations that are not based on the submission of a claim by a provider of services to a health care program.

*D. Inclusion of the Omnibus Budget Reconciliation Act of 1990 Provisions Relating to PROS*

We are also incorporating into part 1004 of these regulations conforming changes consistent with the new statutory authority set forth in section 4205 of Public Law 101-508, the Omnibus Budget Reconciliation Act of 1990. The amendment requires PROs, if appropriate, to offer a corrective action plan to practitioners prior to making a finding under section 1156 of the Act; and requires the Secretary to consider in determining whether a practitioner is willing and able to comply with his or her obligations, whether the practitioner entered into and successfully completed a corrective action plan prior to the PRO's submission of its recommendation and report to the Secretary.

Please note that these revisions to part 1004 are meant only to conform these regulations to new statutory changes resulting from OBRA 1990, and are not meant to be a comprehensive rewrite of this part. A more complete and comprehensive rewrite of the part 1004 regulations is currently under development within the OIG. We hope to issue those revised regulations through a separate notice of proposed rulemaking sometime in the near future.

**VI. Regulatory Impact Analysis**

Executive Order 12291 requires us to prepare and publish a final regulatory impact analysis for any regulation that meets one of the Executive Order criteria for a "major rule," that is, that which 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 areas; 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. 601-612), unless the Secretary certifies that a final regulation would not have a significant economic impact on a substantial number of small entities.

We have determined that these final regulations are not classified as a "major rule" under Executive Order 12291 as these regulations are not likely to meet the criteria for having a significant economic impact. As indicated throughout this preamble, the final provisions in this rulemaking are intended to provide new authorities to the OIG to exclude an individual or entity from Medicare and State health care programs, and to levy CMPs and assessments, if they are engaged in a prohibited activity or practice proscribed by statute. These provisions serve to clarify departmental policy with respect to the imposition of exclusions, CMPs and assessments upon individuals 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 final rule should have no direct effect on the economy or on Federal or State expenditures.

For these reasons, we have determined that no regulatory impact analysis is required. 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 final rule would not have a significant economic impact on a number of small business entities, we have not prepared a regulatory flexibility analysis.

**List of Subjects**

*42 CFR Part 1001*

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

*42 CFR Part 1002*

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

*42 CFR Part 1003*

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

*42 CFR Part 1004*

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

*42 CFR Part 1005*

Administrative practice and procedure, Fraud, Penalties.

*42 CFR Part 1006*

Administrative practice and procedure, Fraud, Investigations, Penalties.

*42 CFR Part 1007*

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

**TITLE 42—PUBLIC HEALTH**

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

42 CFR Chapter V is amended as set forth below:

## PART 1000—INTRODUCTION; GENERAL DEFINITIONS

A. Part 1000 is amended as follows:

1. The authority citation for part 1000 is revised to read as follows:

**Authority:** 42 U.S.C. 1320 and 1395hh.

2. In subpart B, the introductory text of § 1000.10 is republished and § 1000.10 is amended by adding new definitions for the terms *beneficiary* and *furnished* 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.

* * * * *

*Furnished* refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual, or ordered or prescribed by a physician, (either as an employee or in his or her

own capacity), a provider, or other supplier of services.

**§ 1000.20 [Amended]**

3. Section 1000.20 is amended by removing the existing definition for the term *beneficiary*.

B. Part 1001 is 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 of exclusion.

### Subpart C—Permissive Exclusions

1001.201 Conviction relating 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 False or improper claims.
1001.951 Fraud and kickbacks and other prohibited activities.
1001.952 Exceptions.
1001.953 OIG report on compliance with investment interest safe harbor.
1001.1001 Exclusion of entities owned or controlled by a sanctioned person.
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 Scope and effect of exclusion.

### Subpart E—Notice and Appeals

1001.2001 Notice of intent to exclude.
1001.2002 Notice of exclusion.
1001.2003 Notice of proposal 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:** 42 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, and section 14 of Public Law 100–93 (101 Stat. 697).

### 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 into the programs.

**§ 1001.2 Definitions.**

*Controlled substance* means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or

(b) That is deemed a controlled substance 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 otherwise removed;

(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.

*Exclusion* means that items and services furnished by a specified individual or entity will not be reimbursed under Medicare or the State health care programs.

*HHS* means Department of Health and Human Services.

*OIG* means Office of Inspector General of the Department of Health and Human Services.

*PRO* means Utilization and Quality Control Peer Review Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982 (42 U.S.C. 1320c–3).

*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 entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. Where the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA) or the Public Health Service (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. This definition shall not be construed to mean that all other treatments meet professionally recognized standards.

*Sole community physician* means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

*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–F;

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

(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 Services 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 (Block Grants to States for Social Services).

*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 will 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 program beneficiary.

### § 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 will 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 $1,500 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 a significant adverse physical, mental or financial impact on one or more program beneficiaries or other 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 $1,500 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 5 years. Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of 3 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 $1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined 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—

(i) Others being convicted or excluded from Medicare or any of the State health care programs, or

(ii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

## Subpart C—Permissive Exclusions

### § 1001.201 Conviction relating 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, including the performance of management or administrative services relating to the delivery of such items or services, 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 3 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 entities, or had a significant financial impact on program beneficiaries or other individuals. (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 year or more;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

(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 court determined 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—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; 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 or 1001.201.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 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 a significant adverse mental, physical or financial impact on program beneficiaries or other individuals 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 of the criminal proceedings, including sentencing documents, demonstrates that the court determined 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—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; 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 offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law.

(b) For purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 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 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 a significant adverse physical, mental or financial impact on program beneficiaries or other individuals 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—

(A) Others being convicted or excluded from Medicare or any of the State health care programs, or

(B) The imposition of a civil money penalty against others; 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 (including the right to apply for or renew 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) Except as provided in paragraph (c) of this section, 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 program beneficiaries or other individuals;

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

(iii) The acts (or similar acts) had or could have had a significant adverse impact on the financial integrity of the programs.

(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 licensing 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 consider 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, surrendered or otherwise lost.

(c) *Exceptions.* (1) *Length of exclusion.* If, prior to the notice of exclusion by the OIG, the licensing authority of a State (other than the one in which the individual's or entity's license had been revoked, suspended, surrendered or otherwise lost), being fully apprised of all of the circumstances surrounding the prior action by the licensing board of the first State, grants the individual or entity a license or takes no significant adverse action as to a currently held license, an exclusion imposed in accordance with this section may be for a period of time less than that prescribed by paragraph (b)(1) of this section.

(2) *Consideration of early reinstatement.* If an individual or entity that has been excluded in accordance with this section fully and accurately discloses the circumstances surrounding this action to a licensing authority of a different State, and that State grants the individual or entity a new license or takes no significant adverse action as to a currently held license, the OIG will consider a request for early reinstatement.

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

(a) *Circumstance for exclusion.* (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term "or otherwise sanctioned" in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth 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 aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under the Federal or State health care program had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is greater than 3 years; or

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

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

(i) The period of exclusion, suspension or other sanction imposed under the Federal or State health care program is less than 3 years;

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

(4) The OIG will normally not consider a request for reinstatement in accordance with § 1001.3001 until the period of exclusion imposed by the OIG has expired.

**§ 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 such individual's or entity's 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) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The PRO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

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

(1) Submitting, or causing to be submitted, 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, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, 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 order of the physician or other authorized individual.

(d) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (d)(2) and (d)(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 program beneficiaries or other individuals;

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

(iv) The violation resulted in financial loss to Medicare or 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) 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 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 (HMO), 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) HMO 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 a plan, waiver or contract described in paragraph (a)(1) of this section to be provided to individuals covered by such plan, waiver or contract; and

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

(b) The OIG's determination under paragraph (a)(2) of this section—that the medically necessary items and services required under law or contract were not provided—will be made on the basis of information, including sanction reports, from the following sources:

(1) The PRO or other quality assurance organization under contract with a State Medicaid plan for the area served by the HMO or competitive medical plan;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies;

(5) HCFA's HMO compliance office; or

(6) Any other sources deemed appropriate by the OIG.

(c) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 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 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.

(iii) The entity took corrective action upon learning of impermissible activities by an employee or contractor.

**§ 1001.901 False or improper claims.**

(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(b) 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 the 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 program beneficiaries or other individuals 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 will 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—

(A) Sanctioning of other individuals or entities, or

(B) Imposition of a civil money penalty against others; or

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

**§ 1001.952 Exceptions.**

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) *Investment Interests.* As used in section 1128B of the Act, "remuneration" does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following two categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than $50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of items and services, all of the following five applicable standards must be met—

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 781 (b) or (g).

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms equally available to the public through trading on a registered national securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or on the National Association of Securities Dealers Automated Quotation System.

(iii) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(iv) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met—

(i) No more than 40 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.

(ii) The terms on which an investment interest is offered to a passive investor,

if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(vi) No more than 40 percent of the gross revenue of the entity in the previous fiscal year or previous 12 month period may come from referrals, items or services furnished, or business otherwise generated from investors.

(vii) The entity must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

For purposes of paragraph (a) of this section, the following terms apply. *Active investor* means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. *Investment interest* means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units of a partnership, bonds, debentures, notes, or other debt instruments. *Investor* means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. *Passive investor* means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security

(b) *Space Rental.* As used in section 1128B of the Act, "remuneration" does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following five standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease specifies the premises covered by the lease.

(3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (b) of this section, the term *fair market value* means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(c) *Equipment rental.* As used in section 1128B of the Act, "remuneration" does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following five standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (c) of this section, the term *fair market value* means the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

(d) *Personal services and management contracts.* As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following six standards are met—

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise

generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

(6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) *Sale of practice.* As used in section 1128B of the Act, "remuneration" does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(1) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.

(2) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

(f) *Referral services.* As used in section 1128B of the Act, "remuneration" does not include any payment or exchange of anything of value between an individual or entity ("participant") and another entity serving as a referral service ("referral service"), as long as all of the following four standards are met—

(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by the participants for the referral service for which payment may be made in whole or in part under Medicare or a State health care program.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service—

(i) The manner in which it selects the group of participants in the referral service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) *Warranties.* As used in section 1128B of the Act, "remuneration" does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (g)(2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) and (g)(4) of this section—

(1) The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

(2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.

(3) The manufacturer or supplier must comply with either of the following two standards—

(i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (a)(1) and (a)(2) of this section.

(ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

For purposes of paragraph (g) of this section, the term *warranty* means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.

(h) *Discounts.* As used in section 1128B of the Act, "remuneration" does not include a discount, as defined in paragraph (h)(3) of this section, on a good or service received by a buyer, which submits a claim or request for payment for the good or service for which payment may be made in whole or in part under Medicare or a State health care program, from a seller as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section and the seller complies with the applicable standards of paragraph (h)(2) of this section:

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within each category—

(i) If the buyer is an entity which reports its costs on a cost report required by the Department or a State agency, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section.

(ii) If the buyer is an entity which is a health maintenance organization or competitive medical plan acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(iii) If the buyer is not an entity described in paragraphs (h)(1)(i) or (h)(1)(ii) of this section, it must comply with all of the following three standards—

(A) The discount must be made at the time of the original sale of the good or service;

(B) Where an item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service; and

(C) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii)(A) of this section.

(2) With respect to either of the following two categories of buyers, the seller must comply with all of the applicable standards within each category—

(i) If the buyer is an entity described in paragraph (h)(1)(ii) of this section, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is any other individual or entity, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to the Department or a State agency under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice or statement submitted to the buyer, and inform the buyer of its obligations to report such discount; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice or statement submitted to the buyer, inform the buyer of its obligations under paragraph (h)(1) of this section and, when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied.

(3) For purposes of this paragraph, the term *discount* means a reduction in the amount a seller charges a buyer (who buys either directly or through a wholesaler or a group purchasing organization) for a good or service based on an arms length transaction. The term *discount* may include a rebate check, credit or coupon directly redeemable from the seller only to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished. The term *discount* does not include—

(i) Cash payment;

(ii) Furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service;

(iii) A reduction in price applicable to one payor but not to Medicare or a State health care program;

(iv) A reduction in price offered to a beneficiary (such as a routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary);

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration in cash or in kind not explicitly described in this paragraph.

(i) *Employees.* As used in section 1128B of the Act, "remuneration" does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program. For purposes of paragraph (i) of this section, the term *employee* has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

(j) *Group purchasing organizations.* As used in section 1128B of the Act, "remuneration" does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met—

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following—

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

For purposes of paragraph (j) of this section, the term *group purchasing organization* (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare or a State health care program, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, "remuneration" does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards—

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the coinsurance or deductible amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed.

(iii) The hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payor.

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any

Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

**§ 1001.953 OIG report on compliance with investment interest safe harbor.**

Within 180 days of the effective date of this subpart, the OIG will report to the Secretary on the compliance with §§ 1001.952(a)(2)(i) and 1001.952(a)(2)(vi).

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

(a) *Circumstance for exclusion.* (1) The OIG may exclude an entity if:

(i) A person with a relationship with such entity—

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

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

(C) Has been excluded from participation in Medicare or any of the State health care programs, and

(ii) Such a person—

(A) Has a direct or indirect ownership 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 part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof.

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

*Agent* means any person who has express or implied authority to obligate or act on behalf of an entity.

*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* means 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 section 1124, 1124A or 1126 of the Act, and 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 undisclosed 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) (15) and (16) of the Act, and section 353(f) of the Public Health Service 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;

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

(H) A portable x-ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or.

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) 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 intermediate care facilities for the mentally retarded), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 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 this section, the term—

*Failure to grant immediate access* means the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

*Reasonable request* means a written 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.

The request will include a statement of the authority for the request, the rights of the entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the penalties for failure to comply, including when the exclusion will take effect.

(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 reasonably believes 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;

(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 written request for documents, signed by the IG or a delegatee, and made by a properly identified agent of the OIG or a State Medicaid fraud control unit during reasonable business hours, where there is information to suggest that the individual or entity has violated statutory or regulatory requirements under titles V, XI, XVIII, XIX or XX of the Act. The request will include a statement of the authority for the request, the rights of the individual or entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(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 exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on 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).

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, 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.

(c) The exclusion will be effective as of the date immediate access was not granted.

**§ 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 plan 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, program beneficiaries or other individuals;

(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) Except as provided in paragraph (a)(4) of this section, the OIG may exclude any individual that the Public Health Service (PHS) determines 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.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine that PHS has taken all reasonable administrative steps to secure repayment of the loans or obligations. If PHS has offered a Medicare offset arrangement as required by section 1892 of the Act, the OIG will find that all reasonable steps have been taken.

(3) The OIG will take into account access of beneficiaries to physicians' services for which payment may be made under Medicare or State health care programs in determining whether to impose an exclusion.

(4) The OIG will not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

(b) *Length of exclusion.* The individual will be excluded until such

time as PHS 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(i) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed on a repeated basis for such services actual charges in excess of—

(A) The maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) The limiting charges determined in accordance with section 1848(g)(2) of the Act for the period beginning January 1, 1991; and

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

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(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 (or his or her representative) 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;

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Peer Review Organization (PRO) or Medicare carrier; and

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

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) 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 the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(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). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), 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) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) 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.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

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

(g) 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. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

**§ 1001.1901 Scope and effect of exclusion.**

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, State health care programs, and all other Federal non-procurement 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) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare program in accordance with subpart F of this part, 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 or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.

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

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act.

(c) *Exceptions to paragraph (b)(1) of this section.* (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 or other authorized individual 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 or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) 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—

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

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

(4) (i) 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 or other authorized individual 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.

(ii) Notwithstanding paragraph (c)(4)(i) 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 intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion, and the potential effect of an 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 concerning whether the exclusion is warranted and any related issues.

(b) If the OIG proposes to exclude an individual or entity in accordance with §§ 1001.701 or 1001.801, the individual or entity may submit, in addition to the information described in paragraph (a) of this section, a written request to present evidence or argument orally to an OIG official.

(c) Exception. If the OIG proposes to exclude an individual or entity under the provisions of §§ 1001.1301, 1001.1401 or 1101.1501, paragraph (a) of this section will not apply.

(d) 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) Except as provided in § 1001.2003, if the OIG determines that exclusion is warranted, 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 consider a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

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

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with § 1001.1301.

### § 1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§ 1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in § 1001.2002(c). 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. The exclusion will be effective 60 days after the date of the notice unless, within that period, the individual or entity files 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 or 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 administrative law judge (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.

(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 unless an ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, 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(s) or local agencies or authorities 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(c)), 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) Utilization and Quality Control 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, private insurance companies 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) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under § 1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, 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)(1) Except as provided in § 1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

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

(ii) The length of exclusion is unreasonable.

(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing should contain the information set forth in § 1005.2(d) of this chapter.

(b) 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 at a hearing 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 (c) and 1001.601(b)(4), an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) 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) The OIG will authorize reinstatement if it determines that—

(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;

(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; and

(5) For purposes of individuals or entities excluded under part 1004 of this chapter only, the individual's or entity's willingness and ability to provide health care that meets professionally recognized standards.

(c) If the OIG determines that the criteria in paragraphs (a)(2) and (a)(3) of this section have been met, 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.

(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

**§ 1001.3003 Approval of request for reinstatement.**

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

(1) Notify HCFA of the date of the individual's or entity's reinstatement in the Medicare program;

(2) Give written notice to the excluded individual or entity specifying the date when Medicare participation may resume;

(3) Notify State agencies that administer the State health care programs that the individual or entity has been reinstated into the Medicare program; and

(4) To the extent applicable, 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,

(2) A written request to present written evidence and oral argument to an OIG official, or

(3) Both documentary evidence and a written request.

(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 considered until at least one year after the date of denial, or approving the request 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) If an individual or entity is reinstated in accordance with paragraph (a) of this section, HCFA will make payment for 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 is revised to read as follows:

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

### Subpart A—General Provisions

Sec.



### Subpart B—Mandatory Exclusion



### Subpart C—Permissive Exclusions



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



**Authority:** 42 U.S.C. 1302, 1320a-3, 1320a-5, 1320a-7, 1396(a)(4)(A), 1396(p)(1), 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 limit a 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 Federal financial participation (FFP), must provide that it will exclude from participation any 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 1001 or 1003 of this chapter. 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 (c)(3) and (c)(4)(i) 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 State medical licensing board (where applicable), the public, beneficiaries, and others as provided in §§ 1001.2005 and 1001.2006 of this chapter.

**§ 1002.213 Appeals 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 care programs, have been paid, or satisfactory arrangements have been made, that 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, except where the State Medicaid Fraud Control Unit (MFCU) has so notified the OIG.

(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—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

D. Part 1003 is amended as follows:

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

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 11131(c) and 11137(b)(2).

2. The heading for part 1003 is revised to read as set forth above.

3. Section 1003.100 is revised to read as follows:

### § 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128, 1128A, 1140, 1842(j) and 1842(k) of the Social Security Act, and sections 421(c) and 427(b)(2) of Public Law 99–660 (42 U.S.C. 1320a–7, 1320a–7a, 1320b–10, 1395u(j) and 1395u(k), 11131(c) and 11137(b)(2)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, 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;

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

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

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

(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 is amended by removing the definitions *Agent* and *Suspension;* by revising the definitions *Claims, Program* and *Request for payment;* and by adding the definitions *Exclusion, 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.

* * * * *

*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 is revised 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 physician's 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, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) 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—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(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;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(iv) An agreement in accordance with section 1866(a)(1)(G) 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.

(2) Is a non-participating physician under section 1842(j) of the Act and has knowingly and willfully billed individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges for the calendar quarter beginning April 1, 1984;

(3) Is a physician who has knowingly and willfully—

(i) Billed for services as an assistant at surgery during a routine cataract operation, or

(ii) Included in his or her bill the services of an assistant at surgery during a routine cataract operation, and has not received prior approval from the appropriate Peer Review Organization or Medicare carrier for such services based on the existence of a complicating medical condition; or

(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.

(5) Fails to report information concerning a payment made under an insurance policy, self-insurance or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist or other health care practitioner in accordance with section 421 of Pub. L. 99-660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60.

(6) Improperly discloses, uses or permits access to information reported in accordance with part B of title IV of Pub. L. 99-660, in violation of section 427 of Pub. L. 99-660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with part B of title IV in response to a subpoena or a discovery request is considered to be an improper disclosure in violation of section 427 of Pub. L. 99-660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered to be an improper disclosure in violation of section 427 of Pub. L. 99-660.)

(7) Has made use of certain words, letters, symbols or emblems in such a manner that they knew, or should have known, would convey the false impression that an advertisement or other item was authorized, approved or endorsed by the Department, the Social Security Administration (SSA) or HCFA, or that such person or organization has some connection with, or authorization from, the Department, SSA or HCFA. Civil money penalties may be imposed for misuse of—

(i) The words "Social Security," "Social Security Account," "Social Security Administration," "Social Security System," "Medicare," and "Health Care Financing Administration," or any other combination or variation of such words;

(ii) The letters "SSA" or "HCFA," or any other combination or variation of such letters; or

(iii) A symbol or emblem of the Social Security Administration (including the design of, or a reasonable facsimile of the design of, the Social Security card, the check used for payment of benefits under title II, or envelopes or other stationery used by SSA) or of the Health Care Financing Administration, or any combination or variation of such symbols or emblems.

(c) (1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(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) In any case in which it is determined that more than one person was responsible for failing to report information that is required to be reported on a medical malpractice payment, or for improperly disclosing, using or permitting access to information, as described in paragraphs (b)(5) and (b)(6) of this section, each such person may be held liable for the penalty prescribed by this part.

(4) 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 1003.103 is revised to read as follows:

**§ 1003.103 Amount of penalty.**

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

(b) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.102(b)(4).

(c) The OIG may impose a penalty of not more than $10,000 for each payment for which there was a failure to report required information in accordance with § 1003.102(b)(5), or for each improper disclosure, use or access to information that is subject to a determination under § 1003.102(b)(6).

(d) (1) The OIG may impose a penalty of not more than $5,000 for each violation resulting from the misuse of Departmental or program words, letters, symbols or emblems relating to printed media, and a penalty of not more than $25,000 in the case of such misuse relating to a broadcast or telecast, that is subject to a determination under § 1003.102(b)(7) of this part. With respect to multiple violations consisting of substantially identical communications or productions, total penalties may not exceed $100,000 per year.

(2) For purposes of this paragraph, a violation is defined as—

(i) In the case of a direct mailing solicitation, each group mailing of an identical, non-personalized, generic letter or solicitation sent at the same time on the same day. Each unique or personalized letter or solicitation, such as with the individual's name and address appearing in the body of the advertisement or on the mailing envelope or covering, will be treated as a separate and single violation;

(ii) In the case of a printed advertisement, each advertisement or solicitation in each publication or issue of a publication in which it appears. Multiple or separate advertisements will be treated as separate violations; and

(iii) In the case of a broadcast or telecast, the airing of a single commercial or solicitation. Each airing will be a separate violation.

7. Section 1003.105 is 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 OIG subsequently obtains information that the basis for a waiver no longer exists, or the State agency 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) 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 licensing authority, 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 is revised to read as follows:

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

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

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

(ii) The degree of culpability of the person submitting the claim or request for payment, or giving the information;

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

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

(v) Such other matters as justice may require.

(2) In determining the amount of any penalty in accordance with §§ 1003.102 (b)(5) and (b)(6), the Department will take into account—

(i) The nature and circumstances resulting in the failure to report medical malpractice payments or the improper disclosure of information;

(ii) The degree of culpability of the person in failing to provide timely and complete malpractice payment data or in improperly disclosing, using or permitting access to information;

(iii) The materiality, or significance of omission, of the information to be reported with regard to medical malpractice judgments or settlements, or the materiality of the improper disclosure of, or use of, or access to information;

(iv) Any prior history of the person with respect to violations of these provisions; and

(v) Such other matters as justice may require.

(3) In determining the amount of any penalty in accordance with § 1003.102(b)(7), the OIG will take into account—

(i) The nature and objective of the solicitation or other communication, and the degree to which the communication has the capacity to deceive members of the public;

(ii) The frequency and scope of the violation, and whether a specific segment of the population was targeted;

(iii) The degree to which any misrepresentation or deception may have been mitigated by a clear, prominent and conspicuously-placed disclaimer of association with the Government;

(iv) The prior history of the organization in its willingness or refusal to comply with informal requests to correct violations;

(v) The history of prior offenses of the individual or entity in their misuse of Departmental and program words, letters, symbols and emblems; and

(vi) Such other matters as justice may require.

(b) Determining the amount of the penalty or assessment. In taking into account the factors listed in paragraph (a)(1) 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.

(4) *Other wrongful conduct.* It should be considered an aggravating circumstance if there is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings will not apply to proof of other wrongful conduct as an aggravating circumstance.

(5) *Financial condition.* It should be considered a mitigating circumstance if imposition of the penalty or assessment without reduction will jeopardize the ability of the respondent to continue as a health care provider. In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

(6) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature should be taken into account if, in the interests

of justice, they require either a reduction of the penalty or assessment or an increase in order to assure the achievement of the purposes of this part.

(c) In 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(a) and (b)(1) through (b)(4)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximium permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close or at the maximum permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages and costs (as defined in paragraph (d) of this section) sustained by the United States, or any State, as a result of claims or incidents subject to a determination under §§ 1003.102(a) and (b)(1) through (b)(4).

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

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

(3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by § 1003.126, or to compromise any penalty and assessment as provided by § 1003.128.

9. Section 1003.107 is 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 factors set forth in § 1003.106. 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) 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 is revised 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—

(i) a specific statement of respondent's right to a hearing, and

(ii) a statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, 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 § 1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.

**§ 1003.110 [Amended]**

11. Section 1003.110 is amended by removing the word "suspension" and adding in its place the word "exclusion" the three times it appears; and by revising the citation in the first sentence to read as "§ 1003.109(a)".

**§§ 1003.111 through 1003.113 [Removed]**

12. Sections 1003.111 Through 1003.113 are removed.

13. Section 1003.114 is 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 Through 1003.125 [Removed]**

14. Sections 1003.115 through 1003.125 are removed.

15. Section 1003.127 is 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) of the Act because of extraordinary circumstances.

16. Section 1003.128 is 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 PHS, 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 is 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 are removed.

19. Section 1003.132 is 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 1003.133 is 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 sections 1003.134 and 1003.135 are added to read as follows:

**§ 1003.134 Effect of exclusion.**

The effect of an exclusion will be as set forth in § 1001.1901 of this chapter.

**§ 1003.135 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.

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

E. Part 1004 is amended to read as follows:

1. The authority citation for part 1004 is revised to read as follows:

**Authority:** 42 U.S.C. 1302 and 1320c–5.

2. Section 1004.30 is amended by revising paragraph (b) and the introductory text to paragraph (c) to read as follows:

**§ 1004.30 Basic responsibilities.**

* * * * *

(b) When the PRO identifies situations where the obligations specified in § 1004.10 are violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§ 1004.40 and 1004.50.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section (and corrective action, if appropriate), if the PRO determines that the practitioner or other person has—

* * * * *

3. Section 1004.40 is revised to read as follows:

**§ 1004.40 Action on identification of a violation.**

(a) When a PRO identifies a violation, it must determine the source and the nature of the violation.

(b) If the PRO determines that the violation is gross and flagrant, it must proceed in accordance with § 1004.50.

(c) If the PRO determines that the violation is a substantial violation in a substantial number of cases, it must send the practitioner or other person a written initial notice of the identification of a violation containing all of the following information:

(1) The obligation involved.

(2) The situation, circumstances or activity that resulted in a violation.

(3) The authority and responsibility of the PRO to report violations of obligations.

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate.

(5) The sanction that the PRO could recommend to the OIG.

(6) An invitation to submit additional information to or discuss the problem with representatives of the PRO within 20 days of receipt of the notice. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(7) A summary of the information used by the PRO in arriving at its determination of a violation of an obligation and a synopsis of its conclusions.

4. Section 1004.50 is amended by revising paragraphs (b) and (c)(1) to read as follows:

**§ 1004.50 Action on determination of a violation.**

* * * * *

(b) *Contents.* The notice must contain the following information:

(1) The determination of a violation.

(2) The obligation violated.

(3) The basis for the determination.

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate.

(5) The sanction the PRO will recommend to the OIG.

(6) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice, additional information or a written request for a meeting with the PRO to review and discuss the determination, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(7) A copy of the material used by the PRO in arriving at its determination.

(c) *Further review by PRO.* (1) On the basis of additional information received, the PRO shall affirm or modify its determination. If the PRO affirms its determination, it may suggest a method for correcting the situation and a time period for corrective action. If the issue is resolved to the PRO's satisfaction, the PRO shall close the case.

* * * * *

5. Section 1004.60 is amended by adding a new paragraph (c) to read as follows:

**§ 1004.60 Final PRO determination of a violation.**

* * * * *

(c) Provide notice to the State medical board when it submits a report and

recommendation to the OIG with respect to a physician or other authorized individual whom the board is responsible for licensing.

6. Section 1004.90 is amended by revising paragraph (d)(7) to read as follows:

**§ 1004.90 Acknowledgement and review of report.**

* * * * *

(d) *Decision of sanction.* * * *

* * * * *

(7) Whether the practitioner or other person is unable or unwilling to comply substantially with the obligations, including whether, prior to the PRO's recommendation, he or she entered into a corrective action plan and, if so, whether he or she successfully completed such corrective action plan.

* * * * *

**§ 1004.100 [Amended]**

7. Section 1004.100 is amended by removing paragraph (g).

8. Section 1004.110 is revised to read as follows:

**§ 1004.110 Effect of an exclusion on Medicare payments and services.**

The effect of an exclusion will be as set forth in § 1001.1901 of this chapter.

9. Section 1004.120 is revised to read as follows:

**§ 1004.120 Reinstatement after exclusion.**

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 1001.3005 of this chapter.

10. Section 1004.130 is 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 of time for submitting additional information will not be extended.

(ii) Any material received by the HHS after the 30-day period allowed will not be considered by the ALJ or the Departmental Appeals Board (DAB).

(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 is added to read as follows:

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

Sec.



**Authority:** 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

**§ 1005.1 Definitions.**

*Civil money penalty cases* refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose civil money penalties under Medicare or the State health care programs.

*DAB* refers to the Departmental Appeals Board or its delegatee.

*Exclusion cases* refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose exclusions under Medicare or the State health care programs.

**§ 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 ALJ.

(b) In exclusion cases, the parties to the proceeding will consist of the petitioner and the IG. In civil money penalty cases, the parties to the 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, provided in accordance with §§ 1001.2002, 1001.2003 or 1003.109, 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;

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

(4) The petitioner's or respondent's hearing request fails to raise any issue which may properly be addressed in 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, parties, and witnesses;

(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 invalid Federal statutes or regulations or Secretarial delegations of authority;

(2) Enter an order in the nature of a directed verdict;

(3) Compel settlement negotiations;

(4) Enjoin any act of the Secretary;

(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act, or determine the scope or effect of the exclusion,

(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero, in any case where the ALJ finds that an individual or entity committed an act described in section 1128(b) of the Act, or

(7) Review the exercise of discretion by the OIG to impose a CMP, assessment or exclusion under part 1003 of this chapter.

**§ 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;

(10) Such other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings; and

(11) Potential settlement of the case.

(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, except that requested data stored in an electronic data storage system will be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section will not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e) (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, the ALJ will order the parties to 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) (1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ will determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of such evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure to timely exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief:

(i) The testimony of any witness whose name does not appear on the witness list, and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of such evidence would cause substantial prejudice to the objecting party. If the ALJ finds that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless another party objects within a reasonable period of time prior to the hearing, 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 Subpoenas 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) When a subpoena is served by a respondent or petitioner on a particular individual or particular office of the OIG, the OIG may comply by designating any of its representatives to appear and testify.

(d) 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 witnesses to be found.

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

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

(g) 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.

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

(i) 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 subpoenaed 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.

(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 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 timely 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 civil money penalty cases under part 1003, in Peer Review Organization exclusion cases under part 1004, and in exclusion cases under §§ 1001.701, 1001.901 and 1001.951. In civil money penalty cases under part 1003, in Peer Review Organization exclusion cases under part 1004, and in exclusion cases under §§ 1001.701, 1001.901 and 1001.951 of this chapter—

(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.

(c) Burden of proof in all other exclusion cases. In all exclusion cases except those governed by paragraph (b) of this section, the ALJ will allocate the burden of proof as the ALJ deems appropriate

(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) (1) A hearing under this part is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Subject to the 15-day requirement under § 1005.8, additional items or information may be introduced by either party during its case-in-chief unless such information or items are—

(i) Privileged,

(ii) Disqualified from consideration due to untimeliness in accordance with § 1004.130(a)(2)(ii); or

(iii) Deemed otherwise inadmissible under § 1005.17.

(2) After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged in accordance with § 1005.8.

**§ 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 statements 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 of witnesses 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 must exclude irrelevant or 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 must be excluded if it is privileged under Federal law.

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

(g) Evidence of crimes, wrongs or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. Such evidence is admissible regardless of whether the crimes, wrongs or acts occurred during the statute of limitations period applicable to the acts which constitute the basis for liability in the case, and regardless of whether they were referenced in the IG's notice sent in accordance with §§ 1001.2002, 1001.2003 or 1003.109.

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

(i) 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.

(j) The ALJ may not consider evidence regarding the issue of willingness and ability to enter into and successfully complete a corrective action plan when such evidence pertains to matters occurring after the submittal of the case to the Secretary. The determination regarding the appropriateness of any corrective action plan is not reviewable.

**§ 1005.18 The record.**

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.

(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 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 reverse 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 issue the initial decision to 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 DAB 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) Except as provided in paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(e) If an extension of time within which to appeal the initial decision is granted under § 1005.21(a), except as provided in § 1005.22(a), the initial decision will become final and binding on the day following the end of the extension period.

**§ 1005.21 Appeal to DAB.**

(a) Any party may appeal the initial decision of the ALJ to the DAB by filing a notice of appeal with the DAB within 30 days of the date of service of the initial decision. The DAB may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the DAB 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 DAB, the ALJ will forward the record of the proceeding to the DAB.

(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, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

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

(e) The DAB will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the DAB that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence.

(g) The DAB 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) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the DAB will issue to each party to the appeal a copy of the DAB's decision and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review.

(j) Except with respect to any penalty, assessment or exclusion remanded by the ALJ, the DAB's decision, including a decision to decline review of the initial decision, becomes final and binding 60 days after the date on which the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k) (1) Any petition for judicial review must be filed within 60 days after the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final action of the DAB will be sent by certified mail, return receipt requested, to the Associate General Counsel, Inspector General Division, HHS. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the Associate General Counsel receives two or more petitions within 10 days after the DAB issues its decision, the Associate General Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

**§ 1005.22 Stay of initial decision.**

(a) In a CMP case under section 1128A of the Act, the filing of a respondent's request for review by the DAB will automatically stay the effective date of the ALJ's decision.

(b) (1) After the DAB renders a decision in a CMP case, pending judicial review, the respondent may file a request for stay of the effective date of any penalty or assessment with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of such a request will automatically act to stay the effective date of the penalty or assessment until such time as the ALJ rules upon the request.

(2) The ALJ may not grant a respondent's request for stay of any penalty or assessment unless the respondent posts a bond or provides other adequate security.

(3) The ALJ will rule upon a respondent's request for stay within 10 days of receipt.

**§ 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 DAB inconsistent with substantial justice. The ALJ and the DAB 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 is added to read as follows:

## PART 1006—INVESTIGATIONAL INQUIRIES

Sec.



**Authority:** 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. 6(a)(4), App. 3.

**§ 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 signed 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 of 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 corrections the record of 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 is added to read as follows:

## PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

Sec.



**Authority:** 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 is for a period of at least 1 year and involves supervision by the unit.

*Provider* means an individual or entity that 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(q) of the Social Security Act, as amended by the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95-142). 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 of this part.

**§ 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;

(b) If there is no State agency with Statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures that 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 will 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 will not receive funds paid under this part either from or through the Medicaid agency.

(d) The unit will 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 will 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) (1) The unit will 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.

(2) If the initial review indicates substantial potential for criminal prosecution, the unit will investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.

(3) If the initial review does not indicate a substantial potential for criminal prosecution, the unit will refer the complaint 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 will 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 will 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 will 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 will cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.

(f) The unit will safeguard the privacy rights of all individuals and will provide safeguards to prevent the misuse of information under the unit's control.

**§ 1007.13 Staffing requirements.**

(a) The unit will 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; and

(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 will 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 part, 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 part. If the applicant seeks certification under § 1007.7(b), the statement must also specify either that—

(i) There is no State agency with the authority to exercise Statewide prosecuting authority for the violations with which the unit is concerned, or

(ii) 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 part;

(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 part 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 part, 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 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 will 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; and

(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 part; 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 part.

(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 part. 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 will 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.* (1) FFP is available under this part for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement will be limited to costs attributable to the specific responsibilities and functions set forth in this part 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.

(2) (i) Establishment costs are limited to clearly identifiable costs of personnel that—

(A) Devote full time to the establishment of the unit which does achieve certification; and

(B) Continue as full-time employees after the unit is certified.

(ii) 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 part 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 part:

Part 16, subpart C—Department Grant Appeals Process—Special Provisions Applicable To Reconsideration of Disallowances [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: June 6, 1991.

**Richard P. Kusserow,**

*Inspector General, Department of Health and Human Services.*

Approved: October 7, 1991.

**Louis W. Sullivan,**

*Secretary.*

[FR Doc. 92-1939 Filed 1-23-92; 11:42 am]

BILLING CODE 4150-04-M

## DEPARTMENT OF DEFENSE

### 48 CFR Parts 232 and 252

### Department of Defense Federal Acquisition Regulation Supplement; Fraud Payment Reductions

**AGENCY:** Department of Defense (DOD).

**ACTION:** Interim rule with request for comments.

**SUMMARY:** The Director of Defense Procurement has issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to establish policy and procedures for reducing or suspending payments to a contractor when the agency head determines that the contractor's request for advance, partial, or progress payment is based on fraud.

**DATES:** *Effective Date:* January 15, 1992.

*Comment Date:* Comments on the interim rule should be submitted in writing at the address shown below on or before February 28, 1992, to be considered in the formulation of the final rule. Please cite DAR Case 90-318 in all correspondence.

**ADDRESSES:** Interested parties should submit written comments to: Defense Acquisition Regulations Council, ATTN: Mr. Eric Mens, OUSD(A)DP, The Pentagon, Washington, DC 20301-3000. Telefax Number (703) 697-9845.

**FOR FURTHER INFORMATION CONTACT:** Mr. Eric Mens, (703) 697-7266.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

These revisions implement section 836 of the FY 1991 DoD Authorization Act (Public Law 101-510), as amended, which added a subsection (e) to 10 U.S.C. 2307. The statute permits agencies to reduce or suspend payments to a contractor when the agency head determines that the contractor's request for advance, partial, or progress payment is based on fraud.

This DFARS interim rule provides a clause prescription at 232.111-70, establishes agency procedures at a new section 232.173, and establishes a new clause at 252.232-7006, Reduction or Suspension of Contract Payments Upon Finding of Fraud.

**B. Determination To Issue an Interim Rule**

A determination has been made under the authority of the Secretary of Defense to issue this regulation as an interim rule. Urgent and compelling reasons exist to promulgate this rule before affording the public an opportunity to comment because section 836 of the FY 1991 DoD Authorization Act applies to all contracts awarded on or after May 6, 1991. Therefore, it is essential that guidance be issued as expeditiously as possible.

**C. Regulatory Flexibility Act**

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, applies but the interim rule is not expected to have a significant economic impact on a substantial number of small entities because the rule is not expected to impact 20 percent or more of those small businesses who contract with the Department of Defense. Based on an analysis of data for fiscal year 1990, 4,335 out of a total of 16,669 small businesses (or 20 percent of the total number of small businesses) were awarded contracts with advance or progress payment provisions. A small percentage of these (certainly less than 100 percent) can be expected to submit fraudulent payment requests. The rule will have a significant economic impact on only those small businesses who submit requests for advance, partial, or progress payments which may be based on fraud. Moreover, for those affected entities, the economic impact of the DFARS rule flows directly from 10 U.S.C. 2307(e)(5) which states that the contractor must be afforded an opportunity to "submit matters to the head of the agency" in response to the proposed reduction or suspension of payment (see DFARS 232.173-4(e)). An initial regulatory flexibility analysis has therefore not been performed. Comments from small entities concerning the affected DFARS subpart will be considered in accordance with section 610 of the Act. Such comments must be submitted separately and cite 5 U.S.C. 610 (DAR Case 91-610D) in correspondence.

**D. Paperwork Reduction Act**

The Paperwork Reduction Act (Pub. L. 96-511) does not apply because the interim rule falls within the exception provided under 5 CFR 1320.3(c), i.e., matters pertaining to the conduct of a federal criminal investigation or prosecution, or during the disposition of a particular criminal matter.

**List of Subjects in 48 CFR Parts 232 and 252**

Government procurement.

**Claudia L. Naugle,**

*Executive Editor, Defense Acquisition Regulations Council.*

Therefore, 48 CFR parts 232 and 252 are amended as follows:

1. The authority citation for 48 CFR parts 232 and 252 continues to read as follows:

**Authority:** 5 U.S.C. 301, 10 U.S.C. 2202, and Defense FAR Supplement 201.301.

## PART 232—CONTRACT FINANCING

2. Sections 232.111 and 232.111-70 are added to read as follows:

**232.111 Contract clauses.**

**232.111-70 Additional clause.**

Use the clause at 252.232-7006, Reduction or Suspension of Contract Payments Upon Finding of Fraud, in all solicitations and contracts.

3. Sections 232.173 through 232.173-5 are added to read as follows: