§ 101–46.203 What special authorizations have been made for use of the exchange/sale authority?

(a) You may exchange, without monetary appraisal or detailed listing or reporting, books and periodicals in your libraries not needed for permanent use for other books and periodicals.

(b) In acquiring items for historical preservation or display at Federal museums, you may exchange historic items in the museum property account without regard to the FSC group or the requirement in § 101–46.202(b)(3), provided the exchange transaction is documented and certified by the head of your agency to be in the best interests of the Government and all other provisions of this part are met. The documentation must contain a determination that the item exchanged and the item acquired are historic items.

Subpart 101–46.3—Exchange and Sale Procedures

§ 101–46.300 What are the exchange procedures?

(a) Most exchange transactions should occur when a vendor delivers a replacement item and removes the item being replaced. This is the most efficient and cost effective exchange procedure because the item being replaced may remain in use up to the time the replacement item is delivered, when it is immediately removed by the vendor, and storage, handling, and administrative costs are minimized.

(b) You may internally reassign eligible items no longer needed by one organizational unit to another unit for exchange with the supplier of a replacement item. Physical movement of the reassigned item is not required unless specified by the contract.

§ 101–46.301 What are the sales procedures?

(a) The methods of sale, terms and conditions of sale, and forms prescribed in § 101–45.304 of this subchapter shall be used in the sale of property being replaced, except for the provisions of § 101–45.304–2(a) of this subchapter regarding negotiated sales. Section 3709, Revised Statutes (41 U.S.C. 5), is applicable to such sales and specifies the following conditions under which property being replaced can be sold by negotiation:

(1) The reasonable value involved in the contract does not exceed $500, or

(2) Otherwise authorized by law.

(b) Property eligible for exchange/sale may be sold by negotiation at fixed prices in accordance with the provisions of § 101–45.304–2(b) of this subchapter.

§ 101–46.302 What are the accounting requirements for the proceeds of the sale?

Except as otherwise authorized by law, proceeds from sales of personal property disposed of under this part must be accounted for in accordance with the General Accounting Office Policy and Procedures Manual for Guidance of Federal Agencies, Title 7, Fiscal Procedures, Section 5.5D.

Dated: September 2, 1997.

G. Martin Wagner,

Associate Administrator for Governmentwide Policy.

[FR Doc. 97–23669 Filed 9–5–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1000, 1001, 1002 and 1005

RIN 0991–AA87

Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting From Public Law 104–191

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This rulemaking addresses proposed revisions to the OIG's sanction authorities in conjunction with sections 211, 212 and 213 of the Health Insurance Portability and Accountability Act of 1996, along with other technical and conforming changes to the OIG exclusion authorities set forth in 42 CFR parts 1000, 1001, 1002 and 1005. These proposed revisions are specifically designed to expand the protection of certain basic fraud authorities, and revise and strengthen the current legal authorities pertaining to exclusions from the Medicare and State health care programs.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on November 7, 1997.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–20–P, Room 5246, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–20–P.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619–0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION: Comments will be available for public inspection September 22, 1997 in Room 5550 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C., on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m., (202) 619–0089.

I. Background

A. Overview of OIG Exclusion Authorities

All exclusions imposed by the Office of Inspector General (OIG) are based on the authorities set forth in sections 1128, 1156 and 1892 of the Social Security Act (Act). In imposing these exclusions, the Secretary's primary objective and obligation is to protect the health and safety of patients receiving care under the Medicare and State health care programs, and to safeguard the integrity of these programs. The authorities contained in these sections of the Act were designed to protect the programs and their beneficiaries from unfit health care providers, individuals and businesses whose behavior has demonstrated that they pose a risk to program beneficiaries or to the integrity of the Medicare and State health care programs.

In 1987, the OIG's civil administrative sanction authorities were significantly revised and expanded by the Medicare and Medicaid Patient and Program Protection Act (MMPPPA), Public Law 100–93. Congress enacted MMPPPA ''to improve the ability of the [Department] to protect the Medicare and Medicaid programs for fraud and abuse, and to protect the beneficiaries of these programs from incompetent practioners and from inappropriate and inadequate care.'' MMPPPA authorized both mandatory and discretionary program exclusions intended to protect the integrity of the Medicare and State health care programs, as well as beneficiaries.

Manadatory exclusions. Section 1128(a) of the Act specifically sets forth the exclusion authorities with *mandated* enforcement provisions. This section of the Act requires the OIG to exclude from program participation any individuals or entities convicted of a *program-related* crime or patient abuse or neglect. These mandatory exclusions must be imposed for a minimum 5-year period.

Permissive exclusions. In addition, section 1128(b) sets forth a variety of sanction authorities all of which are *permissive* authorities that do not

necessarily mandate an action by the Department. Prior to recent statutory changes discussed below, a conviction relating to the delivery of a health care item or service that was not program-related, whether a felony or a misdemeanor, served as grounds for a permissive exclusion only. A number of these authorities are ''derivative'' exclusions, based on actions previously taken by a court, or other law enforcement or regulatory agencies. For example, these exclusions have been based on convictions for fraud, theft, financial misconduct and controlled substance violations, as well as license suspensions and revocations, and sanctions by other health agencies. Other permissive exclusions are ''non-derivative'' exclusions, that is, they are based on OIG-initiated determinations of misconduct that relate to such matters as quality of care and access of information. There were no specified minimum periods of exclusion under these permissive exclusion authorities, with the exception of the exclusion for failure to grant ''immediate access'' under section 1128(b)(12) of the Act.

These authorities have provided for the imposition of an exclusion from the Medicare (title 18), Medicaid (title 19), Maternal and Child Health Service Block Grant (title 5) and Block Grants to States for Social Services (title 20) programs, and are codified in 42 CFR parts 1001 and 1002 of the OIG regulations.

B. The Health Insurance Portability and Accountability Act of 1996

In the first significant amendments to the OIG's exclusion authorities since MMPPA, the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191, contains many important improvements to the laws that are intended as major steps towards the elimination of health care fraud and abuse. Among other things, HIPAA revises and strengthens the OIG's current sanction authorities pertaining to exclusions from Medicare and the State health care programs. Specifically, HIPAA broadens the OIG's mandatory exclusion; and establishes a new permissive exclusion applicable to individuals with ownership or control interest in sanctioned entities.

The revisions to the OIG's sanction authorities regarding our mandatory exclusion authority and the permissive exclusion authorities related to fraud under section 1128(b)(1) of the Act are effective upon enactment; the amendments regarding the minimum exclusion period and the permissive exclusion of individuals with ownership or control interest are effective on January 1, 1997. The provisions do allow, however, the Department some policy discretion in their implementation. As a result, we are developing this proposed rulemaking to address these new statutory provisions, along with other technical revisions to the OIG's exclusion authorities codified in 42 CFR parts 1000, 1001, 1002 and 1005.

II. Provisions of the Proposed Rule

A. Mandatory OIG Exclusion From Participation in the Medicare and State Health Care Programs

Section 211 of HIPAA has expanded the minimum 5-year mandatory exclusion authority of the OIG to cover *any felony conviction* under Federal, State or local law relating to health care fraud, even if governmental programs were not involved. Felony convictions relating to controlled substances are also the basis for a mandatory exclusion. The expanded mandatory exclusion provisions serve to recognize the seriousness of such felony convictions and ensure that beneficiaries of the Medicare and State health care programs are well protected from dealing with such individuals and entities. Section 211 still provides the Secretary with discretionary authority to exclude those individuals and entities from Medicare and State health care programs who have been convicted of a misdemeanor criminal health care fraud offense or who have been convicted of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct in programs (other than health care programs) funded by any Federal, State or local agency.

In accordance with section 211 of HIPAA, we would revise § 1001.101 of our regulations by adding new paragraphs (c) and (d) to address the mandatory provisions set forth in sections 1128a(3) and 1128a(4) of the Act. In terms of the scope of this provision, in order to appropriately restrict the imposition of these mandatory exclusions to only individuals and entities who might reasonably be expected to have future contact with Medicare, the State health care programs or other health care programs or systems, we are also proposing in §§ 1001.101(d) and 1001.401(a) to limit the applicability of this provision to any individual or entity that: (1) Is or has ever been a health care practitioner, provider or supplier; (2) holds or has held a direct or indirect ownership or control interest, as defined in section 1124(a)(3) of the Act, in an entity that is a health care provider or supplier; or (3) is or has ever been an officer, director, agent or managing employee, as defined in section 1126(b) of the Act, of such an entity, or is or has ever been employed in any capacity in the health care industry. A conforming change to our regulations at § 1001.102(b)(1), consistent with the sections 1128(a)(3) 1128(a)(4) of the statute, would also be made to reference any fraudulent acts—including theft, breach of fiduciary responsibility or other financial misconduct—committee in other governmental programs as a basis for an exclusion by the OIG from Medicare and the State health care programs.

The section heading for § 1001.201 would be revised to read as ''Conviction relating to fraud'' to indicate that this authority is not just relating to program and health care fraud. The section heading for § 1001.401 would be revised to read as ''Misdemeanor conviction relating to controlled substances.''

B. Establishment of Minimum Periods of Exclusion for Certain Permissive Exclusions

The absence of a statutorily required minimum exclusion period for permissive exclusions has resulted in an exceptional amount of administrative litigation over the issue of the length of exclusion in these cases. Since the reasonableness of the length of exclusions imposed is the single most litigated issue, this has required significant agency resources in each instance to defend the exclusion period imposed by the OIG. Section 212 has established minimum periods of exclusion from 1 to 3 years for permissive exclusions from the Medicare and State health care programs.

For (1) convictions of *misdemeanor* criminal health care fraud offenses, (2) criminal offenses relating to fraud in non-health care Federal or State programs, (3) convictions relating to obstruction of an investigation of health care fraud and (4) convictions of misdemeanor offenses relating to controlled substances, section 212 of HIPAA has established a minimum period of exclusion of 3 years, unless the Secretary determines that a longer or shorter period is appropriate due to aggravating or mitigating circumstances.

For permissive exclusions from Medicare and the State health care programs as a result of revocation, surrender or suspension of an individual's or entity's health care license, section 212 establishes a minimum exclusion period that would be not less than the period during which the individual's or entity's license was

revoked or suspended. Likewise, for permissive exclusions due to a suspension or exclusion from other Federal health care programs (such as CHAMPUS or the Veterans' Administration) or other State health care programs for reasons bearing on an individual's or entity's professional competence, professional performance or financial integrity, section 212 of HIPAA also establishes a minimum period of exclusion of not less than the period the individual or entity is excluded or suspended from that Federal or State health care program. As indicated above, this statutory provision is effective for any exclusion imposed or proposed by the OIG on or after January 1, 1997.

In addition, section 212 establishes a minimum of a 1-year period of exclusion for (1) individuals or entities who are found to have submitted (or caused to be submitted) claims for excessive charges, or who furnished (or caused to be furnished) unnecessary items or services; or (2) health maintenance organizations (as defined by section 1903(m) of the Act), or entity under a waiver established by section 1915(b)(1) of the Act, that are found to have failed to provide medically necessary items and services. The establishment of these minimum exclusion periods will aid to conserve governmental resources by reducing the amount of litigation and will foster more consistency.

Consistent with these statutory amendments, we would revise §§ 1001.701(d)(1) and 1001.801(c)(1) to add that with regard to the length of exclusion under these authorities, in no case may the period be shorter than one year. Furthermore, we would also revise § § 1001.501 and 1001.601 to state that the length of exclusion under this authority will never be for a period of time less than the period during which the individual or entity is excluded from that Federal or State health care program.

C. Permissive Exclusions of Individuals With Ownership or Control Interest in Sanctioned Entities

Prior to HIPAA, section 1128(b)(8) of the Act permitted the Secretary to exclude an entity when a convicted individual had an ownership, control or agency relationship with such entity. However, if an entity, rather than an individual, was convicted of Medicare or State health care program fraud, the OIG did not have the authority to exclude the individuals(s) who owned or controlled the entity and who may, in fact, have been responsible for the fraud. This created an obvious loophole whereby an individual who was indicted for fraud along with a business entity owned or controlled by that individual could avoid program exclusion by agreeing to have the business entity plead guilty and pay the fines. Having avoided conviction, the individual was then free to form a new corporation and continue to participate in the health care programs.

Section 213 of HIPAA has now expanded the statute by adding a new permissive exclusion authority (section 1128(b)(15) of the Act) applicable to individuals who have an ownership interest in, or have significant control over the operations of, an entity that has been convicted of a program-related offense. Specifically, under this provision, an individual who has a direct or indirect ownership or control interest in a sanctioned entity and who knows, or should know, of the action constituting the basis for the conviction or exclusion, may also be excluded from participation in Medicare and the State health care programs if the entity has been convicted of an offense under sections 1128(a) or 1128 (b)(1) through (b)(3) of the Act, or otherwise excluded from program participation. Under this authority, the culpable individual is also subject to program exclusion even if not initially convicted or excluded.

Accordingly, we would add a new § 1001.1051, Exclusion of individuals with ownership or control interest in sanctioned entities, to reflect the new statutory authority. Consistent with the statute, under this regulatory authority the OIG would need to demonstrate that, in the case of an investor, the individual acted in deliberate ignorance of the offense constituting the sanctionable action. In the case of an officer or managing employee of the business entity, the OIG will not need to demonstrate such knowledge. Under proposed § 1001.1051, when the entity has been excluded, the length of the individual's exclusion would be for the same period as that of the sanctioned entity with which the individual has had the prohibited relationship. Consistent with statutory intent, we are defining the term ''sanctioned entity'' under this section to mean an entity that has been convicted of any offense under §§ 1001.101 through 1001.104 of these regulations, or that has been terminated or excluded from participation in Medicare or a State health care program. Thus, under this authority, when an entity is no longer reimbursed under Medicare or the State health care programs as a result of a termination or exclusion by the Department, the owners of the entity will be subject to an exclusion as well.

In a conforming change, we also propose to revise § 1001.3002 by adding a new paragraph to clarify that if the specified criteria of this section are met, an individual excluded in accordance with the new proposed § 1001.1051 would be reinstated only upon an OIG determination that the excluded entity upon which the individual's exclusion was based has been reinstated in accordance with §§ 1001.3002(a) or 1001.3005.

D. Technical and Conforming Regulatory Revisions

In addition to the changes to the OIG regulations at 42 CFR parts 1001 and 1002 to comply with the revised sanction provisions set forth in HIPAA, we are proposing a number of technical and conforming regulatory changes in accordance with the HIPAA. Specifically, under the new statute, the OIG has been delegated authority for 3 new authorities referenced in Public Law 104–191—sections 1128 (a)(3) and (a)(4) and 1128 (b)(15) of the Act. As a result, technical and conforming changes to the OIG regulations are necessary. In addition, several minor conforming changes are also being proposed to correct omissions from previous regulatory issuances, and to clarify and expand the applicability of the existing regulations. A limited number of policy decisions are being proposed that relate to the clarification of (1) The definition of the term ''furnished;'' (2) the OIG's exclusion authority under section 1128(a)(2) of the Act concerning patient neglect and abuse convictions; (3) time limits on payments to suppliers for services by excluded providers; (4) when a reinstatement request will be received in accordance with an OIG exclusion taken under section 1128(b)(5) of the Act; and (5) terms ''incarceration'' and ''patient.''

Section 1000.10, General definitions: We would clarify the current definition of the term ''furnished'' to indicate that exclusions will apply to any individual or entity that provides or supplies items or services, directly *or indirectly.* When an individual or entity is excluded from Medicare and the State health care programs, the effect of the exclusion is that the programs may not pay for items and services furnished by that excluded individual or entity. The OIG has the authority—and sometimes the obligation when a mandatory exclusion is appropriate—to impose an exclusion on individuals or entities when the statutory requirements of section 1128 of the Act are met, regardless of whether (1) The individual or entity is paid by the programs directly or (2) the items or

services provided by the individual or entity are reimbursed by the programs indirectly through the submission of claims by a third party who is a direct provider, supplier or practitioner. In the past, we have elected not to exercise this authority in the case of manufacturers or distributors that do not submit claims for the items they provide because of concern that it would be difficult to administer exclusions against such entities are not reimbursed directly by the Department. At this time, the OIG is proposing to change this approach by exercising the authority given to us and clarifying the existing definition for ''furnished.''

Notwithstanding the difficulty in monitoring and administering exclusion against so-called ''indirect'' providers—such as manufacturers and distributors of drugs, medical devices and other items of durable medical equipment reimbursable under Medicare and the State health care programs—the OIG has determined that an exception for indirect providers and suppliers is not appropriate as a matter of policy. As a result, in clarifying the definition for the term ''furnished,'' we would make clear that exclusions of indirect providers will be imposed when appropriate, and that the effect of such exclusions will be that no payment may be made to any direct provider, practitioner or supplier for items or services manufactured, distributed or otherwise provided by any excluded individual or entity.

Section 1001.2, Definitions: Throughout part 1001, the current regulations list various aggravating factors to be considered as a basis for lengthening a period of exclusion. One aggravating factor in all instances when the exclusion is based on a conviction is whether the sentence imposed by the court included incarceration. Because many white collar criminals are not actually placed in jails, there has been some uncertainty over what incarceration entails. Consistent with Federal sentencing guidelines, we are proposing to add a definition in § 1002 for the term ''incarceration'' to include imprisonment or *any type of confinement with or without supervised release.* This would include, but would not be limited to, a correctional facility or other community confinement (such as a work release center), as well as house arrest and home detention.

We are proposing a new definition for the term ''patient'' to include any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or emotional needs, whether or not the item or service is reimbursed under Medicare or a State health care program and regardless of the location in which it is provided. We are concerned that the term ''patient'' has been narrowly defined in some instances to restrict its meaning to only an individual in a traditional medical care setting or within a traditional physician/patient relationship. We believe that the statute intended to prohibit neglect and abuse of *all* individuals receiving health care items and services regardless of the caretaker or the location within which the items or services are provided.

We are also proposing two changes to the existing definition of the term ''exclusion.'' To conform to the statutory language set forth in MMPPPA, Public Law 100–93, we are adding the words ''ordered or prescribed'' to indicate that items and services will not be reimbursed under Medicare and the State health care programs when furnished, *ordered or prescribed* by a specified individual or entity (underlining added). Under this definition, we are also codifying current OIG policy to indicate that even after an exclusion has expired, the individual or entity will not be eligible for program reimbursement until they are formally reinstated by the OIG.

A revision to the term ''sole source of essential specialized services in the community'' is also being proposed to indicate that it is a health *professional* shortage area (formally known as a health man power shortage area); and that this designation is now made by the Health Resources Services Administration, and not the Public Health Service. A proposed change under the term ''professionally recognized standards of health care'' would remove the specific references to the ''Food and Drug Administration,'' the ''Health Care Financing Administration'' (HCFA) and the ''Public Health Service,'' and substitute ''the Department'' as the entity in general who may declare a particular treatment modality as not being safe and effective.

Section 1001.101, Basis for liability: We are proposing to revise paragraph (b) to clarify the scope of the term ''neglect or patient abuse'' to indicate that it covers both the individual's custodial as well as medical treatment. In recent years, we have been seeing more cases arise from abuse and neglect in residential settings where the abused or neglected individual is not referred to as a ''patient.'' Further, the individual may not be receiving strictly medical care treatment, but rather may be provided with custodial care, such as ensuring that medicines are taken and meals are prepared. In implementing the OIG's exclusion authorities, administrative law judges (ALJs) have varied in their interpretation of the statute and have not developed a consistent standard for defining a patient and patient abuse. In order to provide consistent protection for all individuals similarly situated, notwithstanding the variations of State law, we are proposing to revise the regulations to indicate that the delivery of a health care service includes the provision of any items or services to an individual designed to meet their physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare or a State health care program.

Section 1001.102, Length of exclusion: We are proposing to add a new factor that may be considered aggravating and therefore a basis for lengthening the exclusion period. In order to help distinguish between more egregious and less egregious cases involving patient abuse, we propose to include a new § 1001.102(b)(4) to provide that in the case of any conviction involving patient abuse or neglect, we will consider whether the action that resulted in the conviction (1) was premeditated, (2) was part of a continuing pattern of behavior, or (3) consisted of non-consensual sexual acts.

In addition, we are proposing an additional aggravating factor for consideration in § 1001.102 and elsewhere throughout part 1001 (see §§ 1001.201(b)(2)(vi), 1001.301(b)(2)(vi), 1001.401(c)(2)(v), 1001.501(b)(2)(iv), 1001.601(b)(2)(iii), 1001.701(d)(2)(v), 1001.801(c)(2)(v), 1001.901(b)(4), and 1001.951(b)(1)(iv). The proposed factor specifically relates to any other adverse action taken by any other Federal, State or local government agency or board based on the same set of circumstances that is serving as the basis for imposition of the exclusion. This additional factor is consistent with ALJ decisions regarding aggravating factors and the length of exclusion.

Further, § 1001.102(b) and the other sections referenced above, as currently written, do not allow the OIG to increase the length of exclusion if an individual or entity was convicted of other offenses at the same time as he or she was convicted of the offense that served as the basis for the exclusion. For example, this aggravating factor permits the OIG to increase the length of exclusion when the individual convicted of Medicare fraud has a *prior* drug conviction or income tax evasion conviction. However, if the individual is *simultaneously* convicted of Medicare fraud and any other offense, such as drug distribution or income tax evasion, there is currently no aggravating factor

that permits the OIG to consider the additional conviction or convictions. We believe it is not sensible to factor in conduct or wrongdoing that occurred in the past to demonstrate that an individual or entity lacks trustworthiness, but not to give as much weight to more recent conduct. To address this problem and allow greater flexibility to the OIG, we are proposed to amend § 1001.102(b) to indicate that in determining the length of exclusion, the OIG will consider whether the individual or entity (1) was convicted of other offenses besides those which formed the basis for the exclusion, or (2) has a documented history of criminal, civil or administrative wrongdoing. This would permit the OIG to consider any conviction prior to, concurrent with or subsequent to the conviction upon which the exclusion is based. (Parallel changes would be made, as applicable, throughout part 1001 in §§ 1001.201(b)(2), 1001.301(b)(2), 1001.401(c)(2), 1001.501(b)(2), 1001.601(b)(2), 1001.701(d)(2), 1001.801(c)(2), 1001.901(b), 1001.951(b)(1), 1001.1101(b), 1001.1201.(b), 1001.1301(b)(2), 1001.1401(b), 1001.1601(b)(1) and 1001,1701(c)(1).)

In addition to these aggravating factors, we are also proposing to include in § 1001.102(c)(3) (as well as in §§ 1001.201(b)(3)(iii), 1001.301.(b)(3)(ii), 101.401(c)(3)(i), 1001.501(b)(3)(i) and 1001.601(b)(3)(ii)) a new mitigating factor that would take into account whether the cooperation of an individual or entity resulted in additional cases being investigated, or reports being issued, by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses. This new mitigating factor would only be taken into consideration in those situations where the law enforcement agency validated the person's information by opening up a case or by writing a report where, for example, a system vulnerability to HCFA or other program agency is identified and a solution recommended. We believe that the inclusion of this additional mitigating factor would (1) encourage greater cooperation by individuals and entities, and (2) afford the OIG greater flexibility in identifying and addressing issues related to program waste, fraud and abuse.

Section 1001.501, License revocation or suspension: Consistent with and to conform to the new statutory authority, we would delete paragraph (c) of § 1001.501, currently setting forth exceptions related to the length of exclusion for license revocation or suspension.

Section 1001.601, Exclusion or suspension under a Federal or State health care program: Prior to HIPAA, § 1001.601 set forth both mitigating and aggravating factors that are to be considered in determining the length of exclusion under this authority. To conform with the statute, we would revise paragraph (b)(3) of this section to indicate that with the establishment of a base exclusion period under this authority, mitigating factors may only be considered if aggravating factors exist that would justify a longer exclusion beyond the base period.

We are also proposing to clarify OIG policy and correct an inadvertent inconsistency that exists in the language set forth in § 1001.601(b)(4). The current paragraph states that ''[t]he OIG will normally not consider a request for reinstatement * * * until the period of exclusion imposed by the OIG expires.'' This language has created a problem for these OIG exclusions which are based entirely on State-imposed exclusions, and which must continue until the State exclusion ends. Since the law requires the Medicaid program to exclude for *the same* period as Medicare, this has resulted in a loop that makes it technically impossible for either the OIG of the State to end the exclusion except by an arrangement to do so simultaneously. Specifically, in many instances, a State is prepared to reinstate an individual or entity but is unable to do so because of the existing Medicare exclusion that the OIG has imposed in as a result of the original State Action. To solve this problem, we are proposing to revise paragraph (b)(4) of this section to state that if an individual or entity is eligible to apply for reinstatement, and the sole reason that the State has denied reinstatement is that the existing exclusion under Medicare imposed by the OIG is still in effect, the OIG will consider a request for reinstatement.

Section 1001.701, Excessive claims or furnishing of unnecessary or substandard items or services: In an effort to more clearly define the scope of an action under section 1128(b)(6) of the act, we are proposing to revise paragraph (a)(1) of this section to further clarify to whom an individual's or entity's excess charges or costs apply. The revised language would indicate that the OIG may exclude an individual or entity that has submitted, or caused to be submitted, bills or requests for Medicare or State health care program payments that contain charges or costs that are substantially in excess of their usual charges or costs for items or services furnished *to any of their customers, clients or patients.* We specifically welcome comments on this OIG policy clarification.

Section 1001.953, OIG report on compliance with investment interest safe harbor: We would delete this section since the time frame being reflected in this section is no longer operative. The current language stipulates that an OIG report to the Secretary be prepared within 180 days of the effective date addressing the investment interest safe harbor provisions. Those provisions were published as part of a final rulemaking (56 FR 35952, July 29, 1991) became effective upon the date of its publication. The report was not prepared for several reasons. The overriding reason for not issuing this report within the stipulated time frame was that it was not practical to effectively study this subject area until health care businesses had the opportunity to alter their practices to take advantage of this safe harbor. By the time a study might appropriately have been undertaken, this subject was superseded to a large degree by the enactment of section 1877 of the Act.

Section 1001.1001; Exclusion of entities owned or controlled by a sanctioned person: Questions have been raised regarding the legitimacy of the transfer of health care entities from excluded individuals to their spouses, and the circumstances under which such a transfer should constitute divestment of ownership and control of the entity by the excluded individual, and should thus preclude exclusion of the entity under § 1001.1001. In an effort to reiterate and emphasize existing OIG policy on this matter, we are proposing to revise the definition set forth in § 1001.1001(a)(2) for the term ''agent.'' This policy was clearly enunciated in the preamble of the final regulations implementing amendments to the OIG's exclusion authorities resulting from Public Law 100–93 (57 FR 3309, January 29, 1992), and we are now proposing to codify it in regulations.

Section 1001.1901, Scope and effect of exclusion: Some individuals and entities have mistakenly believed that merely obtaining a program provider number would automatically result in their reinstatement back into the programs. This has never been the case; an individual or entity must formally be reinstated by the OIG in order to again participate in the Medicare and State health care programs. We would revise paragraph (b)(1) of this section, regarding the effect of an exclusion on excluded individuals and entities, to specifically clarify existing OIG policy that an excluded individual or entity

continues to be excluded until officially reinstated by the OIG, regardless of whether he, she or it has obtained a program number—either as an individual or as a member of a group—prior to their being reinstated for program participation. (A similar clarification would be made in §§ 1001.3001(a)(1) and 1001.3002(a) to indicate that the obtaining of a program provider number does not in and of itself reinstate eligibility for an entity or an individual, either as a single person or as a member of a group.) The word ''person'' appearing in the first sentence of paragraph (b)(1) would be revised to read as ''individual or entity.''

In addition, we would revise paragraph (b)(3) of this section to clearly indicate that submitting claims, or causing claims to be submitted or payment to be made by the programs for items or services that were furnished, ordered or prescribed by the excluded individual or entity—including any administrative and management services or salaries—may serve as the basis for denying the individual's or entity's reinstatement back into the programs. The addition of this language would serve to more clearly define what an excluded individual or entity can do, and would codify and re-enforce existing OIG policy that is currently contained in the exclusion notice letters sent to individuals and entities.

We are also proposing to add a new § 1001.1901(c)(4) that serves to codify the current HCFA policy with regard to payment to suppliers for claims after notice of an excluded provider's exclusion. Specifically, we would reiterate that HCFA will not pay for any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 5 days or more after the date that notice of the provider's exclusion was mailed by the contractor to the supplier.

Section 1001.2001, Notice of intent to exclude: We propose to delete existing paragraph (b) of § 1001.2001. The language currently states that if the OIG proposes to exclude an individual or entity in accordance with § 1001.701 or 1001.801, the individual or entity may submit a written request to present evidence or argument orally to the OIG. In eliminating the in-person hearing on these cases, the individual or entity would still have the opportunity to submit additional material for review to the OIG. The vast majority of cases for proposed exclusion are medical in nature, and while the OIG contracts for the review of medical records and related material, we do not retain an in-house medical review officer that would be readily accessible to hear and review such submitted material. We believe this existing provision does not represent an effective use of time and current OIG resources, and are therefore proposing to delete this language. This change would not diminish due process since the individual or entity retains the ability to challenge the OIG's proposed exclusion.

Section 1001.2002, Notice of exclusion: We are proposing to amend this section by adding a new paragraph (e) indicating, consistent with existing OIG policy, that the notice letter to the affected individual or entity could be amended should any additional information come to our attention or wrongdoing occur subsequent to the issuance of the initial notice letter. We are also proposing to make a similar clarifying change in § 1005.15 by revising paragraph (f) to explicitly state that, with certain exceptions, additional items or information—including any aggravating and mitigating circumstances that arose or became known subsequent to the issue of the notice letter—may be introduced by either party.

Section 1001.2003, Notice of proposal to exclude: A discrepancy currently existing between the language in § 1001.2003(a)—indicating that an exclusion is effective 60 days after the date of notice, unless an individual or entity files a written request for a hearing—and the language set forth in § 1005.2(c)—that a request for a hearing is to be filed 60 days after the notice letter is received by the respondent, which is presumed to be 5 days after the date of the notice unless there is a reasonable showing to the contrary. To be consistent in our language and intent, we would revised § 1001.2003(a) to reference the language and procedure set forth in § 1005.(c). i.e., that a request for a hearing be made 60 days after service of the notice letter.

Section 1001.2005, Notice to State licensing agencies: We propose deleting paragraph (b) of this section. While the regulations would still indicate that the Department will notify the appropriate State or local agencies or authorities responsible for licensing or certification of the circumstances leading to an individual's or entity's exclusion, we do not want to be locked into a specific notification process if alternative methods can be considered for notifying provider licensing and certification boards.

Section 1001.2006, Notice to others regarding exclusion: Section 221 of HIPAA established a new national health care fraud and abuse data collection program for the reporting of final adverse actions against health care providers, suppliers and practitioners. As a result, we would revise § 1001.2006(a) to indicate that, in addition to the general public and program beneficiaries, the Department will not also provide notice of the exclusion and its effective date to the new Adverse Action Data Bank.

Section 1001.3001, Timing and method of request for reinstatement: Because there has been some misunderstanding as to when an exclusion period ends, in addition to clarifying that the act of obtaining a provider number does not reinstate program eligibility (see discussion of § 1001.1901 above), we would also revise paragraphs (1) (a) and (b) to indicate that an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001, 1001.1051 and 1001.1101) may submit a request for reinstatement to the OIG only *after the minimum period of exclusion* specified in the notice of exclusion has expired. A conforming change would also be made in § 1001.3002(a)(1).

Section 1001.3002, Basis for reinstatement: Section 214(b) of HIPAA has amended the statute by indicating that in making a determination on whether to sanction a practitioner or other person—based on a recommendation from a Peer Review Organization (PRO)—for failing to comply with statutory obligations relating to quality and medical necessity of health care services, the Department will no longer to be required to prove that the practitioner or other person was either unwilling or unable to comply with such obligations. While this statutory change is being addressed through separate rulemaking addressing the PRO sanctions process and changes to part 1004 of our regulations, we would make a conforming change to paragraph (b) of § 1001.3002 to delete the ''unwillingness and inability'' factor as a basis for consideration by the OIG in making a reinstatement determination.

Section 1002.3, Disclosure by providers; information on persons convicted of crimes: Under part 1002, which addresses State-initiated exclusions from the Medicaid program, we would revise § 1002.3(b) to codify in regulations as new paragraph (b)(3) concerning Medicaid State agency requirements for notification to the OIG. Specifically, the new paragraph would clearly state that the Medicaid agency is required to promptly notify the OIG of *any and all* actions it takes to limit the individual's or entity's ability to participate in its program. Th is would include, but would not be limited to: (1)

Suspension actions, (2) settlement agreements and (3) situations where the individual or entity may have voluntarily agreed to withdraw from the program in order to avoid a formal sanction action.

III. Regulatory Impact Statement

Executive Order 12866 and Regulatory Flexibility Act

The Office of Management and Budget (OMB) has reviewed this proposed rule in accordance with the provisions of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and has determined that it does not meet the criteria for a significant regulatory action. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety distributive and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a number of small businesses the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule.

The provisions set forth in this proposed rulemaking, for the most part, implement statutory requirements, and are designed to lengthen and broaden the scope of the OIG's authority to include individuals and entities from the Medicare and the State health care programs. As indicated above, these provisions would implement the new statutory requirements regarding the period of exclusion for some individuals and entities by: (1) Broadening the minimum 5-year mandatory exclusion authority to cover felony convictions under Federal, State or local law relating to health care fraud, and (2) establishing minimum periods of exclusion for certain permissive exclusions. We believe that the number of individuals and entities effected by this lengthening of exclusions would be minimal.

Further, while the provisions in this rule serve to clarify the OIG's sanction authorities by (1) Establishing a new permissive exclusion applicable to individuals having majoring ownership interest in (or significant control over the operations of) an entity convicted of a program-related offenses; (2) clarifying what would constitute patient abuse or neglect for purposes of exclusion; and (3) setting forth a definition for ''furnished'' that would apply to individuals and entities that provide or supply items or services directly or indirectly, we likewise believe the increase in the number of exclusion cases will be small. Specifically, while the statutory requirement to impose exclusions in cases of certain types of convictions has been broadened in sections 1128 (a)(3) and (a)(4) of the Act, the process for excluding individuals and entities who are convicted in accordance with the new requirements remains essentially the same. Cases to be processed under the new mandatory provisions set forth in sections 1128 (a)(3) and (a)(4) for the minimum mandatory 5-year exclusion were previously processed under the permissive authority provisions in sections 1128 (b)(1) and (b)(3) of the Act, with a benchmark of 3 years. As a result, while there may be minor increases in the number of mandatory exclusions imposed, we see no significant increase or decrease in the number of these cases. Similarly, the clarification of what constitutes patient neglect or abuse should not result in a significant increase in the number of cases under section 1128(a)(2) of the Act, but merely support prior findings of abuse and neglect while delivering health care services.

In addition, we do not anticipate a significant workload resulting from the implementation of section 1128(b)(15) of the Act, and proposed § 1001.1051 of these regulations, as the requirements for effectuating this authority are rather stringent at the present time, and will limit the number of exclusions to be implemented under this authority.

Since the vast majority of individuals, organizations and entities addressed by these regulations do not engage in such prohibited activities and practices, we believe that any aggregate economic effect of these revised exclusion regulations will be minimal, affecting only those limited few who engage in prohibited behavior in violation of the statute. As such, this proposed rule should have no significant economic impact. Similarly, while some sanctions may have an impact on small entities, it is the nature of the violation and not the size of the entity that will result in an action by the OIG. We believe that the aggregate economic impact of this rulemaking should be minimal, affecting only those limited few who have chosen to engage in prohibited arrangements, schemes or practices in violation of statutory intent. Therefore, we have concluded, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a number of small business entities, and that a regulatory flexibility analysis is not required for this rulemaking.

Paperwork Reduction Act

Section 1002.3 of this rulemaking contains information collection requirements that require approval by OMB. We are required to solicit public comments under section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. Specifically, we are inviting comments on (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the collection of information; (3) ways to enhance the quality, utility and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on practitioners and other persons, including through the use of automated collection techniques or other forms of information technology.

Title: Information on persons convicted of crimes.

Summary of the collection of information: In order to effectuate the requirements of section 1128(b)(5) of the Social Security Act, authorizing the OIG to exclude individuals and entities that are sanctioned by a Federal or State agency (including State Medicaid agencies), a State Medicaid agency must promptly notify the OIG of any action it takes to limit an individual's or entity's participation in Medicaid. To implement this statutory authority, we are clarifying in § 1002.3 of the regulations the scope of conduct constituting a basis for State Medicaid notice of denials of participation or imposition of a sanction. Specifically, under section 1902(a) (39) and (41) of the Social Security Act, State agencies are required to notify the Secretary when a provider has been denied participation status in Medicaid, or has been terminated, suspended or ''otherwise sanctioned'' under the Medicaid program. We are clarifying what actions fall within the ambit of these provisions. The reporting obligation set forth in § 1002.3 is consistent with the requirements of the statute.

Respondents: The ''respondents'' for the collection of information described in § 1002.3 are the individual State Medicaid agencies.

Estimated number of respondents: The OIG annually receives approximately 500 notifications from State Medicaid agencies regarding actions taken against an individual or entity. While we are specifically clarifying that these actions are to

include any suspension actions, settlement agreements and situations where an individual or entity voluntarily withdraws from the program to avoid a formal sanction, we believe that the number of actions reported by the State agencies to the Secretary will remain low.

Estimated number of responses per respondent: 1.

Estimated total annual burden on respondents: We believe that the burden on the State Medicaid agencies in preparing the notification to the OIG will be minimal. We estimate that the average burden for each submitted notification to the OIG will be less than one-half hour. The total burden for this information collection activity is estimated not to exceed 250 hours annually.

Comments on these information collection activities should be sent to both:

Cynthia Agens Bauer, OS Reports Clearance Officer, ASMB Budget Office, Room 503–H, Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, FAX: (202) 690–6352

Allison Herron Eydt, OIG Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 715 17th Street, N.W., Washington, D.C. 20053, FAX: (202) 395–6974

Comments on these paperwork reduction requirements should be submitted to the above individuals within 60 days following the **Federal Register** publication of this proposed rule.

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.

42 CFR Part 1005

Administrative practice and procedure, Fraud, Penalties.

Accordingly, 42 CFR Parts 1000, 1001, 1002 and 1005 would be amended as set forth below:

A. Part 1000 would be amended as follows:

PART 1000—[AMENDED]

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

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

2. Section 1000.10 would be amended by republishing the introductory paragraph and by revising the definition for the term *Furnished* to read as follows:

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

* * * * *

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare or State health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.

* * * * *

B. Part 1001 would be amended as follows:

PART 1001—[AMENDED]

1. The authority citation for part 1001 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1359u(k), 1395y(d), 1395y(e), 1395cc(b)(2) (D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

(2) Section 1001.2 would be amended by revising the definitions for the terms *Exclusion, Professionally recognized standards of health care,* and *Sole source of essential specialized services in the community;* and by adding definitions for the terms *Incarceration* and *Patient* to read as follows:

§ 1001.2 Definitions.

* * * * *

Exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under Medicare or the State health care programs until the individual or entity is reinstated by the OIG.

* * * * *

Incarceration means imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest and home detention.

* * * * *

Patient means any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare or a State health care program and regardless of the location in which such item or service is provided.

* * * * *

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, recognized as applying to those peers practicing or providing care within a State. When the Department 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 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 Health Resources Services Administration as a health professional 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 of specialized services in a reasonably defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

* * * * *

3. Section 1001.101 would be revised to read as follows:

§ 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;

(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 delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare or a State health care program);

(c) Has been convicted, under Federal or State law, of a felony that occurred

after August 21, 1996 relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other misconduct—

(1) In connection with the delivery of a 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 health care program (other than Medicare or the State health care programs) operated by, or financed in whole or in part, by any Federal, State or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds, or has held, a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in an entity that is a health care provider or supplier, or is, or has ever been, an officer, director, agent or managing employee (as defined in section 1126(b) of the Act) of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

4. Section 1001.102 would be amended by revising paragraph (b); republishing the introductory text of paragraph (c); and revising paragraph (c)(3) to read as follows:

§ 1001.102 Length of exclusion.

* * * * *

(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 a government program or to one or more entities of $1,500 or more. (The entire amount of financial loss to such programs or entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);

(2) The acts that resulted from 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) In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern or behavior, or consisted of non-consensual sexual acts;

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

(6) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(7) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare or State health care programs, or other third-party payers, as a result of improper billings; or

(8) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for imposition of the exclusion.

(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 the basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

* * * * *

(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,

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

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

5. Section 1001.201 would be amended by revising the section heading; revising paragraph (a); republishing the introductory text of paragraph (b)(2), revising paragraphs (b)(2) (iv) and (v), and adding a new paragraph (b)(2)(vi); and by republishing the introductory text of paragraph (b)(3) and revising paragraphs (b)(3)(i) and (b)(3)(iii) to read as follows:

§ 1001.201 Conviction relating to fraud.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of—

(1) A misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) 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

(ii) With respect to any act or omission in a health care program, other than Medicare or a State health care program, operated by, or financed in whole or in part by, any Federal, State or local government agency; or

(2) Fraud, theft, embezzlement, breach or fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program, other than a health care program, operated by or financed in whole or in part by any Federal, State or local government agency.

(b) *Length of exclusion.* * * *

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

* * * * *

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

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(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 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;

* * * * *

(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,

(B) Additional cases being investigated or reports being used by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

* * * * *

6. Section 1001.301 would be amended by republishing the

introductory text of paragraph (b)(2); revising paragraphs (b)(2) (iv) and (v); by adding a new paragraph (b)(2)(vi); by republishing the introductory text of paragraph (b)(3); and by revising paragraph (b)(3)(ii) to read as follows:

§ 1001.301 Conviction relating to obstruction of an investigation.

* * * * *

(b) *Length of exclusion.* * * *

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

* * * * *

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

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

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

* * * * *

(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,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

* * * * *

7. Section 1001.401 would be amended by revising the section heading; revising paragraph (a); by republishing the introductory text of paragraph (c)(2); by revising paragraphs (c)(2) (iii) and (iv); by adding a new paragraph (c)(2)(v); by republishing introductory paragraph (c)(3); and by revising paragraph (c)(3)(i) to read as follows:

§ 1001.401 Misdemeanor 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 misdemeanor relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds or has held a direct or indirect ownership or control interest, as defined in section 1124(a)(3) of the Act, in an entity that is a health care provider or supplier, or is or has been an officer, director, agent or managing employee, as defined in section 1126(b) of the Act, of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

* * * * *

(c) *Length of exclusion.* * * *

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

* * * * *

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

(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(v) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any other Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(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,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

* * * * *

8. Section 1001.501 would be amended by revising paragraph (b)(1); republishing the introductory text of paragraph (b)(2), revising paragraphs (b)(2) (ii) and (iii), and adding a new paragraph (b)(2)(iv); by republishing the introductory text of paragraph (b)(3) and revising paragraph (b)(3)(i); and by deleting paragraph (c) to read as follows:

§ 1001.501 License revocation or suspension.

* * * * *

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not 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 for exclusion—

* * * * *

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

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

(iv) The individual or entity has been the subject of any other adverse action by any other Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(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—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

* * * * *

9. Section 1001.601 would be amended by revising paragraph (b) to read as follows:

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

* * * * *

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which the individual or entity license is excluded or suspended from a Federal or State health care program.

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

(i) The acts that resulted in the exclusion, suspension or other sanction under the Federal or State healthy 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) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(iii) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only if any of the aggravating factors set forth 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 or entity's cooperation with Federal or State officials resulted in—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

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

(4) If the individual or entity is eligible to apply for reinstatement in accordance with § 1001.3001 of this part, and the sole reason for the State denying reinstatement is the existing Medicare exclusion imposed by the OIG as a result of the original State action, the OIG will consider a request for reinstatement.

10. Section 1001.701 would be amended by republishing introductory paragraph (a) and revising paragraph (a)(1); revising paragraph (d)(1); and by republishing introductory paragraph (d)(2), revising paragraphs (d)(2) (iii) and (iv), and adding paragraph (d)(2)(v) to read as follows:

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items or 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 to any of their customers, clients or patients; or

* * * * *

(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 set forth in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period. In no case may the period be shorter than 1 year.

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

* * * * *

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

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

(iv) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

* * * * *

11. Section 1001.801 would be amended by revising paragraph (c)(1); and by republishing introductory paragraph (c)(2), revising paragraphs (c)(2) (iii) and (iv), and adding a new paragraph (c)(2)(v) to read as follows:

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

* * * * *

(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 set forth in paragraphs (c)(2) and (c)(3) of this section form a basis of lengthening or shortening the period. In no case may the period be shorter than 1 year.

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

* * * * *

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

(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(v) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

* * * * *

12. Section 1001.901 would be amended by republishing introductory paragraph (b), revising paragraph (b)(3), redesignating existing paragraph (b)(4) as (b)(5), and adding a new paragraph (b)(4) to read as follows:

§ 1001.901 False or improper claims.

* * * * *

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

* * * * *

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior is to be considered neutral);

(4) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

(5) Other matters as justice may require.

13. Section 1001.951 would be amended by republishing introductory paragraph (b)(1), revising paragraph (b)(1)(iii), redesignating existing paragraph (b)(1)(iv) as (b)(1)(v), and adding a new paragraph (b)(1)(iv) to read as follows:

§ 1001.951 Fraud and kickbacks and other prohibited activities.

* * * * *

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

* * * * *

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(iv) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, even if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

* * * * *

§ 1001.953 [Removed]

14. Section 1001.953 would be removed.

15. Section 1001.1001 would be amended by republishing the heading for paragraph (a) and introductory paragraph (a)(2); and by revising the

definition for the term *agent* set forth in paragraph (a)(2) to read as follows:

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

(a) *Circumstances for exclusion.*
* * *

(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. The excluded individual may be considered an agent even if he or she has transferred ownership or control interest to his or her spouse or children. For example, if the excluded individual transfers control of an entity to his or her spouse, but still acts on behalf of the entity or exercises some control over the entity, the excluded individual would be an agent since he or she would have the implied authority to act on behalf of that entity.

* * * * *

16. A new § 1001.1051 would be added to read as follows:

§ 1001.1051 Exclusion of individuals with ownership or control interest in sanctioned entities.

(a) *Circumstance for exclusion.* The OIG may exclude any individual who—

(1) Has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of this section; or

(2) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such an entity.

(b) For purposes of paragraph (a) of this section, the term *sanctioned entity* means an entity that—

(1) Has been convicted of any offense described in §§ 1001.101 through 1001.401 of this part; or

(2) Has been terminated or excluded from participation in Medicare or a State health care program.

(c) *Length of exclusion.* (1) If the entity has been excluded, the length of the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has the prohibited relationship.

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

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

17. Section 1001.1101 would be amended by revising paragraph (b)(3) to read as follows:

§ 1001.1101 Failed to disclose certain information.

* * * * *

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

* * * * *

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

* * * * *

18. Section 1001.1201 would be amended by revising paragraph (b)(4) to read as follows:

§ 1001.1201 Failure to provide payment information.

* * * * *

(b) * * *

(4) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

* * * * *

19. Section 1001.1301 would be amended by revising paragraph (b)(2)(iv) to read as follows:

§ 1001.1301 Failure to grant immediate access.

* * * * *

(b) * * *

(2) * * *

* * * * *

(iv) Whether the entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).

* * * * *

20. Section 1001.1401 would be amended by revising paragraph (b)(5) to read as follows:

§ 1001.1401 Violations of PPS corrective action.

* * * * *

(b) *Length of exclusion.* * * *

* * * * *

(5) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).

21. Section 1001.1601 would be amended by revising paragraph (b)(1)(iv) to read as follows:

§ 1001.1601 Violations of the limitations on physician charges.

* * * * *

(b) *Length of exclusion.* (1) * * *

(iv) Whether the physicians has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

* * * * *

22. Section 1001.1701 would be amended by revising paragraph (c)(1)(v) to read as follows:

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

* * * * *

(c) *Length of exclusion.* * * *

(v) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

23. Section 1001.1901 would be amended by revising paragraphs (b)(1) and (b)(3); revising existing paragraph (c)(4) and redesignating is as (c)(5); and by adding a new paragraph (c)(4) to read as follows:

§ 1001.1901 Scope and effect of exclusion.

* * * * *

(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 individual or entity furnishing such item or service knew, or had reason to know, of the exclusion. This section applies regardless of whether an individual or entity has obtained a program provider number, either as an individual or as a member of a group, prior to being reinstated.

* * * * *

(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 and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) *Exceptions to paragraph (b)(1) of this section.*

* * * * *

(4) HCFA will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 5 days or more after that notice of the provider's exclusion was mailed by the contractor to the supplier.

(5) * * *

(ii) Notwithstanding paragraph (c)(5)(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.

24. Section 1001.2001 would be revised to read as follows:

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (b) 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 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) Exception. If the OIG proposes to exclude an individual or entity under the provisions of §§ 1001.1301, 1001.1401 or 1001.1501 of this part, paragraph (a) of this section will not apply.

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

25. Section 1001.2002 would be amended by adding a new paragraph (e) to read as follows:

§ 1001.2002 Notice of exclusion.

* * * * *

(e) No later than 15 days prior to the final exhibit exchanges required under § 1005.8 of this chapter, the OIG may amend its notice letter if information comes to light that justifies the imposition of a different period of exclusion other than the one proposed in the original notice letter.

26. Section 1001.2003 would be amended by revising introductory paragraph (a) to read as follows:

§ 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 receipt of the notice (as defined in § 1005.2 of this chapter) 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—

* * * * *

27. Section 1001.2005 would be revised to read as follows:

§ 1001.2005 Notice to state licensing agencies.

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.

28. Section 1001.2006 would be amended by republishing introductory paragraph (a); revising paragraphs (a)(1) and (a)(7); redesignating existing paragraph (a)(8) as (a)(9); and by adding a new paragraph (a)(8) to read as follows:

§ 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 is known to be serving as an employee, administrator, operator, or in which the individual 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);

* * * * *

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

(8) The Adverse Action Data Bank; and

* * * * *

29. Section 1001.3001 would be amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraphs (a)(2) and (a)(3) of this section or in § 1001.501(b)(4) of this part, an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001, 1001.1051 and 1001.1501) may submit a written request for reinstatement to the OIG only after the minimum period of exclusion specified in the notice of exclusion has expired. Obtaining a program provider number does not reinstate eligibility.

(2) An entity excluded under § 1001.1001 of this part may apply for reinstatement prior to the minimum period of exclusion 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.

* * * * *

30. Section 1001.3002 would be amended by revising paragraph (a); republishing introductory paragraph (b), revising paragraphs (b) (3) and (4) and removing paragraph (b)(5); revising introductory paragraph (c); revising existing paragraph (d) and redesignating paragraphs (d), (e), and (f) as paragraphs (e), (f) and (g) respectively; and by adding a new paragraph (d) to read as follows:

§ 1001.3002 Basis for reinstatement.

(a)(1) The OIG will authorize reinstatement if it determines that—

(i) The minimum period of exclusion has expired;

(ii) 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

(iii) There is no additional basis under sections 1128 (a) or (b) or 1128A of the Act for continuation of the exclusion.

(2) Submitting claims or causing claims to be submitted or payments to be made by the programs for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement. This section applies regardless of whether an individual or entity has obtained a program provider number, either as an individual or as a member of a group, prior to being reinstated.

(b) In making the reinstatement determination, the OIG will consider—

* * * * *

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

(4) Whether HCFA has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations.

(c) If the OIG determines that the criteria in paragraphs (a)(1) (ii) and (iii) 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—

* * * * *

(d) If the OIG determines that the criteria in paragraphs (a)(1) (ii) and (iii) of this section have been met, an individual excluded in accordance with § 1001.1051 will be reinstated upon a determination with paragraph (a) of this section of § 1001.3005.

(e) Reinstatement will not be effective until the OIG grants the request and provides notice under § 1001.3003(a) of this part. Reinstatement will be effective as provided in the notice.

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

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

C. Part 1002 would be amended as follows:

PART 1002—[AMENDED]

1. The authority citation for part 1002 would continue to read as follows:

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).

2. Section 1002.3 would be amended by revising paragraph (b)(2) and by adding a new paragraph (b)(3) to read as follows:

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

* * * * *

(b) *Notification to Inspector General.*

* * *

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

(3) The agency must also promptly notify the Inspector General of any action it takes to limit the ability of an individual or entity to participate in its program, regardless of what such an action is called. This includes, but is not limited to, suspension actions, settlement agreements and situations where an individual or entity voluntarily withdraws from the program to avoid a formal sanction.

* * * * *

3. Section 1002.203 would be amended by revising paragraph (a) to read as follows:

§ 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 or 1001.1051 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 or 1001.1051 of this chapter.

* * * * *

4. Section 1002.211 would be amended by revising paragraph (a) to read as follows:

§ 1002.211 Effect of exclusion.

(a) *Denial of payment.* Except as provided for in § 1001.1901 (c)(3), (c)(4) and (c)(5)(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.

PART 1005—[AMENDED]

D. Part 1005 would be amended as follows:

1. The authority citation for part 1005 would continue to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

2. Section 1005.15 would be amended by revising introductory paragraph (f)(1) to read as follows:

§ 1005.15 The hearing and burden of proof.

* * * * *

(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 and information, including aggravating or mitigating circumstances that arose or became known subsequent to the issuance of the notice letter, may be introduced by either party during its case-in-chief unless such information or items are—

* * * * *

Dated: March 13, 1997.

June Gibbs Brown,

Inspector General, Department of Health and Human Services.

Approved: June 18, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–23379 Filed 9–5–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Negotiated Rulemaking Committee on the Shared Risk Exception; Meetings

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

ACTION: Meeting of Negotiated Rulemaking Committee.

SUMMARY: In accordance with the Federal Advisory Committee Act, this document announces the dates and location for the fourth and fifth set of meetings by the Negotiated Rulemaking Committee on the Shared Risk Exception. The purpose of this committee is to negotiate the development of an interim final rule addressing the shared risk exception to the Federal health care programs' anti-kickback provisions, as statutorily-mandated by section 216 of the Health Insurance Portability and Accountability Act of 1996.

DATES: The fourth series of meetings will be held from 9:00 a.m. to 5:00 p.m. on October 8 and 9, 1997, and from 9:00 a.m. to 2:00 p.m. on October 10, 1997. The fifth series of meetings will be held from 9:00 a.m. to 5:00 p.m. on November 19, 20 and 21, 1997.

ADDRESSES: The October meeting will be held in the OIG Conference Room, Room 5542, Cohen Building, 330 Independence Avenue, S.W.,