(g) *Failure to remit a fee.* (1) EPA will not provide certification, re-certification, accreditation, or re-accreditation for any individual, firm or training program which does not remit fees described in paragraph (c) of this section in accordance with the procedures specified in paragraph (d) of this section.

(2) EPA will not replace identification cards or certificates for any individual, firm or training program which does not remit fees described in paragraph (c) of this section in accordance with the procedures specified in paragraph (e) of this section.

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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:** Final rule.

**SUMMARY:** This final rule addresses revisions to the OIG's administrative sanction authorities to comport with sections 211, 212 and 213 of the Health Insurance Portability and Accountability Act (HIPAA) 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 revisions serve to expand the scope of certain basic fraud authorities, and revise and strengthen the current legal authorities pertaining to exclusions from the Medicare, Medicaid and all other Federal health care programs.

**EFFECTIVE DATE:** October 2, 1998.

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

**SUPPLEMENTARY INFORMATION:**

## I. Background

*The Health Insurance Portability and Accountability Act of 1996*

On September 8, 1997, the Office of Inspector General (OIG) published proposed rulemaking (62 FR 47182) addressing the program exclusion provisions set forth in the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191. Among other things, the HIPAA provisions revised or expanded the authorities pertaining to exclusion from Medicare and the State health care programs. With respect to the OIG's program exclusion authorities, the HIPAA provisions served to (1) broaden the OIG's mandatory exclusion authority; (2) establish minimum periods of exclusion for certain permissive exclusions; and (3) establish a new permissive exclusion authority applicable to individuals with ownership or control interest in sanctioned entities.

(The Balanced Budget Act (BBA) of 1997, Public Law 105–33, also enacted new or expanded exclusion and civil money penalty authorities. Among the provisions in the BBA, section 4331(c) amended sections 1128(a) and (b) of the Act to (1) provide that the scope of an OIG exclusion extends beyond Medicare and the State health care programs to all Federal health care programs (as defined in section 1128B(f) of the Act) [1], and (2) enable the OIG to directly impose exclusions from all Federal health care programs. While regulations implementing the BBA exclusion provisions are being developed under separate rulemaking by the Department, for purposes of clarity, we are conforming language in this final rule to be consistent with the statute and the expanded scope of an OIG exclusion that encompasses all Federal health care programs. As a result, in all references in this preamble and in the regulations, as amended, we are substituting the phrase ''Medicare and the State health care programs'' with the phrase ''Medicare, Medicaid and all other Federal health care programs.'' Additional regulatory changes in 42 CFR part 1001 with regard to this expanded scope of an OIG exclusion will be specifically addressed in the BBA-implementing regulations referenced above.)

Because the new HIPAA statutory provisions afford the Department some policy discretion in their implementation, the OIG developed proposed rulemaking to address both the new statutory provisions of HIPAA and other technical revisions to the OIG's exclusion authorities, that were previously codified in 42 CFR parts 1000, 1001, 1002 and 1005. The proposed rule established a 60-day public comment period during which interested parties were invited to submit written comments to the OIG on these proposed changes.

## II. Summary of the Proposed Rule

*1. The HIPAA Exclusion Provisions*

The proposed rule set forth the Department's three new exclusion authorities to be codified in 42 CFR part 1001 as follows:

• *Mandatory OIG exclusion from Medicare and State health care program participation.* Section 211 of HIPAA expanded the OIG's minimum 5-year mandatory program exclusion authority to cover any felony conviction under Federal, State or local law relating to health care fraud, even if governmental programs are not involved. Felony convictions relating to controlled substances were also made a basis for a mandatory exclusion. Accordingly, we proposed to revise § 1001.101 to address the mandatory provisions set forth in new sections 1128(a)(3) and (4) of the Act. To appropriately restrict the imposition of mandatory program exclusions to only those individuals and entities who might reasonably be expected to have future contact with Medicare, Medicaid and all other Federal health care programs, we proposed to limit applicability of this provision only to those individuals or entities that (1) are or have been health care practitioners, providers or suppliers; (2) hold or have held a direct or indirect ownership or control interest in a health care entity; or (3) are or have been officers, directors, agents or managing employees of such an entity, or are or have ever been employed in any capacity in the direct or indirect provision of health care items or services.

• *Establishment of minimum periods of exclusion for certain permissive exclusions.* The proposed rule addressed the establishment of minimum periods of exclusion in 42 CFR part 1001 ranging from 1 to 3 years for permissive exclusions from the Medicare , Medicaid and all other Federal programs. In accordance with section 212 of HIPAA—

(1) A standard period of exclusion of 3 years would be established for convictions of misdemeanor criminal health care fraud offenses; criminal offenses relating to fraud in non-health Federal or State programs; convictions relating to obstruction of an investigation of health care fraud; and

[1] In accordance with section 1128B(f) of the Act, the term ''Federal health care program'' means (1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under 5 U.S.C. 89; or (2) and State health care program, as defined in section 1128(h) of the Act.

convictions of misdemeanor offenses relating to controlled substances. Aggravating and mitigating circumstances may be taken into account to lengthen or shorten this period, as appropriate.

(2) For permissive exclusions from Medicare, Medicaid and all other Federal programs resulting from the revocation, surrender or suspension of an individual's or entity's health care license relating to professional competence, professional performance or financial integrity, an exclusion would be imposed for a period not less than the period during which the individual's or entity's license was revoked or suspended.

(3) For permissive exclusions derived from the suspension or exclusion from other Federal health care programs, such as CHAMPUS, Veterans and other State health care programs, relating to an individual's or entity's professional competence, professional performance or financial integrity, an exclusion would be imposed for a period not less than the period the individual or entity is excluded or suspended from that Federal or State health care program.

(4) A minimum one-year period of exclusion would be established for individuals or entities who are found to have submitted claims for excessive charges or who furnished unnecessary or substandard items or services; and health maintenance organizations that are found to have failed to provide medically necessary items and services. (An inadvertent error was made in the proposed rule in addressing the scope of the minimum one-year period of exclusion. A technical revision is set forth in section IV. of this preamble.)

• *Permissive exclusion of individuals with ownership or control interest in sanctioned entities.* In accordance with section 213 of HIPAA, a new § 1001.1051 was proposed to implement permissive exclusions applicable to individuals who have a majority ownership interest in, or have significant control over the operations of, an entity that has been convicted of an offense or excluded. Under this section, we proposed that the length of exclusion generally be for the same period as that of the sanctioned entity with which the individual had a relationship.

*2. Additional Technical and Conforming Changes*

In addition to proposing codification in regulations of the HIPAA exclusion provisions, we also set forth for comment a number of proposed technical and conforming changes designed to clarify OIG exclusion authority policy currently codified in 42 CFR parts 1000, 1001, 1002 and 1005. Among the revisions set forth in the proposed rule—

• We proposed revising § 1001.2 to indicate that the term ''incarceration'' would include imprisonment or any type of confinement, with or without supervised release.

• Because the term ''patient'' has been narrowly defined in some instances to restrict its scope to only an individual in a traditional medical care setting, we proposed to revise §§ 1001.2 and 1001.101 to define the term to include any individual receiving health care services, including any item or service provided to meet his or her physical, mental or emotional needs, regardless of whether it is reimbursed under Medicare, Medicaid or any other Federal health care program and regardless of the location in which it is provided.

• In order to distinguish between more and less egregious cases involving patient abuse or neglect, we proposed adding a new aggravating factor to § 1001.102(b) to indicate that the OIG would consider whether the action that resulted in the conviction was premeditated, part of a continuing pattern of behavior, or consisted of non-consensual sexual acts.

• In allowing greater flexibility to consider an additional conviction if the individual or entity is convicted of both Medicare fraud and another offense, such as tax evasion, we proposed to amend various sections of 42 CFR part 1001 to allow the Department to consider any other conviction or civil or administrative sanction prior to, concurrent with or subsequent to the conviction upon which the exclusion was based.

• We proposed to revise §§ 1001.2002 and 1005.15 to indicate that the initial notice letter of exclusion to the affected individual or entity could be amended should any additional information or wrongdoing occur or come to the attention of the OIG subsequent to the letter, and that these additional items or information may be introduced into evidence by either party at the hearing before the administrative law judge.

• To encourage greater cooperation by individuals and entities, and to afford the OIG greater flexibility in identifying and addressing issues related to program fraud and abuse, we proposed adding a new mitigating factor applicable to the authorities in 42 CFR part 1001 that would take into account whether the cooperation of an individual or entity resulted in additional cases being investigated or reports issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses.

• In § 1001.701, we proposed to more clearly explain the imposition of exclusions under section 1128(b)(6) of the Act concerning excessive charges or costs and to whom an individual's or entity's excess charges or costs apply.

• We proposed to clarify the term ''agent'' in § 1001.1001 by reiterating existing OIG policy concerning the legitimacy of transfer of a health care entity from an excluded individual to a spouse, and the circumstances constituting divestment of ownership and control of the entity by the excluded individual.

• To clarify that the obtaining of a program provider number or equivalent would not automatically result in an individual's or entity's reinstatement into the programs, we proposed revising §§ 1001.1901, 1001.3001 and 1001.3002 to clarify existing OIG policy that an excluded individual or entity continues to be excluded until officially reinstated by the OIG, regardless of whether a provider number or equivalent is obtained prior to this OIG action. In § 1001.1901, we also proposed to reiterate current HCFA policy regarding payment of the first claim of a supplier after notice of a provider's exclusion, i.e., HCFA will not pay for items and services furnished by a supplier past the fifth day following the date of the written notice to the supplier of the provider's program exclusion.

• Because the OIG has the obligation to impose an exclusion on individuals or entities when the statutory requirements of section 1128 of the Act are met, regardless of whether the individual or entity is paid by the programs directly, or the items or services are reimbursed by the programs indirectly through claims of a third party who is a direct provider, we proposed to clarify the definition of ''furnished'' in § 1000.10 to indicate that exclusions would apply to any individual or entity that provides or supplies items or services, directly *or indirectly.* In this section, we proposed to make clear that no payment would be made to any direct provider for items and services manufactured, distributed or otherwise provided by an excluded individual or entity.

• With regard to the Medicaid State agency's obligations to notify the OIG of certain actions, we proposed revising § 1002.3 to state that the Medicaid agency would be required to promptly notify the OIG of *any and all* actions—including suspension actions, settlement agreements and situations where the individual or entity voluntarily agrees to withdraw from the

program to avoid a formal sanction action—that it takes to limit any individual's or entity's ability to participate in its program.

## III. Response to Comments and Summary of Revisions

In response to the notice of proposed rulemaking, the OIG received a total of 109 timely-filed public comments from various health care providers and organizations, State and professional medical societies and associations, and other interested parties. Set forth below is an abstract of the various comments and recommendations received, our response to those concerns, and a summary of the specific revisions and further clarifications being made to the regulations at 42 CFR parts 1000, 1001, 1002 and 1005 as a result of the proposed HIPAA exclusion rule and these public comments.

*Section 1000.10, Definition of the term ''furnished''*

*Comment:* We proposed to clarify the current definition of the term ''furnished'' in § 1000.10 to indicate that exclusions will apply to any individual or entity that provides or supplies items or services, directly *or indirectly*.[2] A total of 22 comments responded to this proposed revision. Citing sections 1128a–7a and 1128(b)(7) of the Act and the legislative history of the 1987 amendments to the Act, a number of commenters questioned whether the OIG had the statutory authority to take remedial action and exclude individuals or entities from participation in Medicare and Medicaid if such individuals or entities do not directly ''participate'' in these programs by submitting claims for reimbursement to them. Commenters further stated that the expansion of the exclusion authority to indirect providers was proposed and contemplated in previous OIG rulemakings (55 FR 12205, April 2, 1990; 57 FR 3298, January 29, 1992)—addressing revisions to OIG sanction authorities resulting from Public Law 100–93—and that no new circumstances or substantive reasons exist now that warrant further consideration of this revision.

*Response:* As indicated in the preamble to the proposed rule, the OIG intends to change its position on this issue. In 1992, we elected to publicly state in the preamble to the final exclusion regulations implementing the Medicare and Medicaid Patient and Program Protection Act of 1987 our intention to refrain from exercising our exclusion authority in the case of manufacturers or distributors that could be subject to exclusion but do not submit claims to the programs for the items they supply (57 FR 3298, January 29, 1992). While we were cognizant at that time of our authority to exclude such indirect providers, and said so explicitly in the preamble to that final rule, we were also concerned that it would be difficult to administer exclusions against entities that are not reimbursed directly by the Department. We have now concluded that such exclusions should be undertaken, when warranted by the conduct of such entities, notwithstanding the administrative burdens.

In our earlier discussion of the effect of an exclusion, we cited section 1862(e) of the Act, which denies both payment for items and services provided by an excluded individual or entity *and* payment for services furnished at the medical direction or on the prescription of an excluded physician. This provision reflects the intent of Congress and the Secretary that the Government not pay—directly or indirectly—for the services of untrustworthy individuals and entities with whom the Department has determined it should cease doing business. Historically, with each set of amendments to the original 1977 exclusion statute (section 1128(a) of the Act) mandating ''suspension'' of ''physicians and other practitioners'' from the programs subsequent to any conviction for a program-related crime, Congress has expanded the scope of the exclusion authority to permit, and sometimes to mandate, exclusion of a wider scope of ''untrustworthy'' individuals and entities.

For example, in the 1980 amendments to section 1128(a) of the Act, Congress stated that it was broadening the exclusion authorities to make such authorities ''apply to other categories of health professionals, such as administrators of health care institutions' (House Report 96–1167, p. 5572). The Report by Congress went on to say that ''[i]n the case of those professionals who do not directly furnish medical care or services, *payment would not be made to the provider for the cost of any services furnished to or on behalf of the provider by the convicted professional* * * *'' (underlining added). We believe that the 1980 amendments made it clear that indirect providers that were convicted were to be excluded, and that the effect of such an exclusion would be that items and services furnished by these indirect providers could not be reimbursed. We believe this is consistent with the Department's interpretation of its current authority to exclude any individual or entity that violates the prohibitions of section 1128 of the Act.

Further, in the Balanced Budget Act (BBA) of 1997, Congress again indicated its continued expectation that indirect providers of items and services will be excluded from the programs. In the BBA, Congress enacted a civil money penalty (CMP) to deter providers from doing business with excluded individuals or entities. The new statutory authority—section 1128A(a)(6) of the Act—permits the Secretary to impose a CMP against any person (defined broadly in the statute to include entities) who ''arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a federal health care program * * * for the provision of items or services for which payment may be made under such a program.'' Implicit in the enactment of this CMP authority is Congress' expectation that indirect providers who do not submit claims to the programs are subject to exclusion. Services furnished by such indirect providers, and items manufactured or supplied by them, would be unreimbursable due to the excluded status of the individual or entity. In addition, the direct provider who submits a request for reimbursement for such items or services is subject to a CMP. Thus, from 1980 to the present, Congress has consistently and repeatedly expressed its view that any individual and entity that furnishes items or services that are reimbursable under the programs is subject to exclusion from the programs, regardless of whether that individual or entity directly presents a bill to the program.

Thus, we have concluded that our original regulatory policy, while perhaps sensible from the standpoint of administrative ease of enforcement, is not fully consistent with the legislative intent of section 1128 of the Act. Furthermore, it is not appropriate to continue to exempt untrustworthy manufacturers and distributors of products from exclusion, when many other providers are excluded every year due to similar concerns.

[2] The term ''indirectly'' means the provision of items and services manufactured, distributed or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that provide items and services to providers, practitioners or suppliers who submit claims to these programs for such items and services. The term ''indirectly'' does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.

*Comment:* Many commenters believed that the proposed rule failed to provide sufficient information about how an exclusion would be applied to indirect providers and to which indirect providers it would apply. Commenters indicated that this definition of ''furnished'' would neither be fair nor effective since the use of an exclusion against individuals or entities that do not receive reimbursement from the Medicare or Medicaid programs will have more of a punitive effect on innocent third parties than it would on the actual wrongdoer. Commenters indicated that limiting the number of available or appropriate sources of equipment or supplies would have anti-competitive effects and could result in beneficiaries being denied services or supplies. In addition, the commenters stated that direct providers may be inappropriately denied reimbursement, unfairly burdened with monitoring responsibilities, and inappropriately subject to False Claims Act prosecution. Some commenters believed that since some equipment manufacturers and suppliers rely heavily on their ability to sell their products to providers who receive Medicare and Medicaid program reimbursement, this lack of ability to sell their products to program providers would effectively force them out of business.

*Response:* Since 1980, the Department has been excluding many ''indirect'' providers of items and services that are reimbursed by the programs. Nurses, home health aides and laboratory technicians, for example, cannot submit claims yet have often been excluded from the programs. During their exclusion period, no employer, such as a hospital or nursing home, may be paid by the programs for any services furnished by these individuals. Employees of companies who provide transportation to nursing home residents, accountants who keep the account books for health care institutions, and an employee of a Medicare carrier who stole checks that belonged to physicians as payment for services provided to beneficiaries are all examples of individuals who have been excluded from the programs. In all cases, the costs attributable to their services may not be charged on cost reports or be claimed by an employer in any other way during the period of their exclusion.

As discussed above, the new CMP authority enacted in BBA is the most recent indication that Congress has not carved out an exception for indirect providers simply because they do not participate in the programs directly through submitting claims and receiving direct reimbursement. Through the new BBA CMP authority, Congress, in fact, has provided the OIG with a new tool to enforce exclusions against indirect providers. By making direct providers liable if they submit claims for others who are excluded, the direct provider is likely to be deterred from doing so. Because fewer of these impermissible claims should be submitted, it should become less common for the programs to unwittingly pay indirectly for items and services furnished by excluded parties.

By law, the Department has an ongoing obligation to impose mandatory exclusions when warranted. Notwithstanding the difficulty in monitoring and administering exclusions against so-called ''indirect'' providers, we believe that an exception for indirect providers and suppliers is not appropriate as a matter of policy. Just as nurses, home health aides, administrators and others who do not bill the programs directly for their services have been excluded over the years, we believe that untrustworthy manufacturers and suppliers of drugs, medical devices and durable medical equipment and other reimbursable items must be treated in a similar fashion.

In addition to revising the definition for the term ''furnished'' in § 1000.10, we are addressing some concerns raised by adding definitions to this section for the terms ''directly'' and ''indirectly,'' as used in the definition of ''furnished,'' to specifically clarify the meaning of these terms.

*Comment:* Commenters recommended that clearer, more specific guidance was necessary on how the OIG intended to administer this authority. Specifically, a number of commenters raised concerns about the effect that this revision would have on current inventories held by providers, and the potential confusion that could result when more than one manufacturer is licensed to manufacture a product, e.g., a prescription drug. It was indicated by some commenters that determining the actual manufacturer of certain products could sometimes be extremely difficult or impossible. Clarification was also requested on the impact on providers who receive a physician's prescription, for example, for a specific item or equipment manufactured by an excluded entity.

*Response:* In clarifying the definition of the term ''furnished,'' we are indicating that exclusions of indirect providers *may* be imposed, when appropriate. We would not expect that manufacturers would often be convicted and subject to a mandatory exclusion. However, on those exceptional or infrequent occasions when a manufacturer *is* convicted, we cannot justify treating it more favorably than we would treat others similarly convicted. Moreover, the concern for protecting the programs from those who are untrustworthy applies to all those convicted of health care criminal offenses.

We are fully aware that exclusion of a manufacturer or supplier may have a significant effect on direct providers, practitioners or suppliers who would be paid by the programs for items or services manufactured, distributed or otherwise provided by an excluded entity. We are committed to exercising this sanction authority carefully and prudently, and acting only where the excluded provider's product can be clearly identified. We are committed to assisting affected beneficiaries to avoid hardship as a consequence of any exclusion of a manufacturer or supplier. Moreover, we are committed to ensuring that no inappropriate hardships will be imposed on direct providers who unknowingly bill Federal health care programs for items and services furnished by an excluded indirect provider. The new civil money penalty provision authorized by section 4304(a) of BBA against those who arrange or contract with an excluded individual or entity will only be used where a direct provider ''knows or should know'' of the exclusion.

While it is impossible to predict every possible scenario and to provide much specific guidance in this document, there is, however, some general guidance that we can offer. Under our proposed revisions, we never intended that items within a direct provider's existing inventory be affected by the exclusion of a manufacturer. Specifically, any health care items that a practitioner, provider or supplier has in inventory from the excluded manufacturer prior to the effective date of the exclusion of the manufacturer will not be affected by the exclusion, and claims may be submitted for the furnishing of such items by the practitioner, provider or supplier. This will include all supplies and items maintained in inventory by a practitioner, provider or supplier that are billed to Medicare or other Federal health care programs through a claims form or on a cost report.

In addition, in an attempt to alleviate some concerns raised by commenters, we have decided to amend § 1001.1901(c)(3) by adding a new provision to permit payment for health care items ordered from an excluded manufacturer prior to the effective date of the exclusion and delivered up to 30 days after the effective date of such

exclusion.[3] We believe this will further protect beneficiaries and direct providers from significant financial harm due to the indirect provider's exclusion.

In those unusual cases where a manufacturer is convicted of health care-related fraud, the OIG will carefully examine the products or services being provided or distributed, and on a case-by-case basis provide the necessary guidance to affected direct providers. Our interest is in enforcing the exclusion while guaranteeing, with reasonable assurance, that no substantial harm comes to program beneficiaries and direct providers. When appropriate and permitted by law, the OIG will entertain a request for waiver of an exclusion, such as, for example, if a convicted pharmaceutical company manufactures the only drug deemed effective to treat a particular disease. If a waiver is requested by a State agency and the OIG deems that such waiver is appropriate and should be implemented nationally, we believe that the OIG has the discretion to extend the waiver to all State Medicaid programs, as well as to Medicare.

*Comment:* Several commenters addressed the potential adverse impact of a manufacturer's exclusion on direct providers and suppliers, indicating that providers such as hospitals could suffer extreme administrative and financial costs in complying with this exclusion authority. Commenters stated that since direct providers or suppliers would not be paid for a particular item or supply furnished by an excluded entity, providers or suppliers may have to collect or maintain additional information to demonstrate to the programs that the item for which it is seeking payment was not furnished by an excluded entity.

*Response:* We do not agree that there will be significant new administrative costs to direct providers, such as hospitals, nursing homes and physicians, in ensuring that they do not submit claims for items manufactured or supplied by excluded parties. Exclusions of manufacturers are rare and usually well-publicized in the press and other media. Further, the OIG will quickly inform the public of the exclusion over the internet, as it does with all exclusions. Direct providers must keep themselves apprised of all exclusions, not only to ensure that their claims are reimbursable, but also to ensure that they are not subject to the new CMP for contracting with or employing an individual or entity that is excluded. We do not believe that the revision to the definition of ''furnished'' will place significant new burdens on direct providers above and beyond the responsibility they already have to refrain from doing business with excluded parties.

*Section 1001.2, Definitions*

*Comment:* One commenter believed that amending the term ''exclusion,'' that is, by adding the words ''ordered or prescribed'' to prohibit Medicare payment to providers that furnish services ordered or prescribed by an excluded provider, confuses the issue of fraud and the real need for medical care since a provider, such as a physician, that has been excluded from the Medicare program may still order services that are medically necessary that need to be furnished by another entity.

*Response:* We believe the commenter has misinterpreted the statutory language. The revised definition of the term ''exclusion'' is being set forth to conform and be consistent with statutory language in Public Law 100–93 under which items and services will not be reimbursed under the programs when furnished, ordered or prescribed by an excluded individual or entity. Although an excluded individual or entity may continue to order or prescribe items and services, those items and services are not reimbursable under the programs.

*Comment:* We proposed revising the definition of the term ''patient'' to ensure that it includes any individual who is receiving any health care items or services to meet physical, mental or emotional needs, whether or not the item or service is reimbursed under Medicare, Medicaid or any Federal health care program and irrespective of the location of where the service is provided. While supportive of this approach, one commenter believed that the statute was not necessarily intended to extend to patient neglect and abuse related to items and services ''wholly unconnected'' with Medicare, Medicaid and all other Federal health care programs, and believed that we should look at other statutory authorities elsewhere to sanction abuse of such individuals before expanding the existing definition.

*Response:* Section 1128(a)(2) of the Act does not directly relate to Medicare, Medicaid or any other specific Federal health care program. This statutory provision covers conduct against any patient regardless of that individual's relationship with these programs. The OIG believes that the statute is intended to prohibit neglect and abuse of *all* individuals receiving health care items and services, regardless of the care giver or the location within which the items or services are provided, and is adopting this definition to ensure consistent interpretation of this provision.

**Part 1001, Additional Aggravating Factor in Determining Length of Exclusion; Conviction of More Than One Offense**

*Comment:* We proposed revising one of the aggravating factors in §§ 1001.102 through 1001.951, that would permit consideration of any adverse actions by other Federal, State or local government agencies or boards based on the same conduct as a basis for lengthening an exclusion. The proposed factor was set forth to consider ''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 a 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'' (underlining added). A number of commenters disagreed that the OIG should have the discretion to consider other convictions, whether in the past or contemporaneous, as an aggravating factor. Commenters argued that in the case of an individual or entity that was the subject of various ''adverse actions'' by a locality on a matter, unrelated to a later conviction, such other actions should have no bearing on the appropriate length of an individual's program exclusion, and believed that some limits should be placed on the consideration of adverse actions since different agencies (especially ones with no health care responsibilities) may reach varying conclusions based on very different policy considerations. Commenters stated that since simultaneous convictions may be based on only one course of conduct and represent a prosecutor's decision to charge essentially the same conduct under various offenses, we should not be allowed to increase an exclusion period where an individual is convicted of multiple offenses at the same time he or she is convicted of the offense that forms the basis for the exclusion.

*Response:* While the language set forth in these sections is permissive, it is specifically designed to address the issue of an individual's or entity's trustworthiness. Thus, we are revising the language throughout part 1001 so that the factor will be relevant to the

[3] For the first year from the effective date of this provision only, we are permitting payment for health care items ordered from an excluded manufacturer prior to the effective date of the exclusion and delivered up to a 60 day period after the effective date of the exclusion.

same conduct and circumstances that serves as the basis for the imposition of the OIG exclusion. We believe that the revised language is fairer, while allowing the OIG to attain the intended goal of allowing an increased sanction only if the adverse action was related in some way to the original basis for the exclusion. The intent of the revised language is to 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. Inclusion of this aggravating factor will permit the OIG to increase a length of exclusion when an individual is convicted of Medicare fraud and any other offense, such as drug distribution or income tax evasion. The aggravating factor will take into consideration separate and different types of convictions that occurred concurrently; we do not intend to use the basis of the OIG exclusion more than once as a factor in lengthening an exclusion.

**Part 1001, New Mitigating Factor in Determining Length of Exclusion**

*Comment:* A number of commenters supported the proposed new mitigating factor in §§ 1001.102(c)(3) , 1001.201(b)(3)(iii), 1001.301(b)(3)(ii), 1001.401((c)(3)(i), 1001.501(b)(3)(i) and 1001.601(b)(3)(ii) 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. The commenters believed that this additional factor would positively impact on individuals' cooperation and encourage offenders to assist board investigators and other State authorities. One commenter, however, stated that the value of some information may not be determined until much later, and recommended that credit should also be given to individuals and entities that cooperate and provide information that is not immediately validated by the commencement of a new case or report issuance since preliminary investigations may require a significant amount of time before a case is opened or a report prepared.

*Response:* While we expect this mitigating factor to be taken into consideration only in those situations where the law enforcement agency validated the person's information by opening up a case investigation or by issuing a report, we nevertheless believe that this additional factor will afford the OIG greater flexibility in identifying and addressing issues related to program waste, fraud and abuse.

*Section 1001.701, Excessive Claims or Furnishing of Unnecessary or Substandard Items or Services*

*Comment:* In an effort to more clearly define the scope of an action under section 1128(b)(6) of the Act, we proposed to revise § 1001.701(a)(1) to further clarify to whom an individual's or entity's excess charges or costs apply. Many commenters strongly objected to what they believed was the OIG's setting of Medicare payment policy (for bills submitted on the basis of costs or charges) at the best price charged to any payer. Specifically, the proposed language addressed possible exclusion of providers that have ''submitted, or caused to be submitted, bills or request for Medicare, Medicaid and all other Federal 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.'' Many of the commenters indicated that this proposed revision would create excessive administrative and billing difficulties that would require a comprehensive and consistent review of charges to all customers. Further commenters stated that this proposal would have substantive implications for providers who work with managed care programs, discouraging providers from entering into these discounted rate arrangements or possibly forcing physicians participating in these programs to increase their contract rates in an effort to recover what may constitute a loss on Medicare program claims. In addition, commenters indicated that the proposed revision fails to take into account that most physician payments under Medicare are now determined by a resource-based relative value scale system.

*Response:* Many commenters misunderstood our proposal. The proposed rule intended to subject those who submit bills based on costs or charges to liability for exclusion if they presented bills for amounts ''substantially in excess'' of lowest prices charged any customer. Nevertheless, persuasive arguments have been raised, and we are withdrawing our proposed modification to § 1001.701 at this time. We have become convinced that the prohibitions of section 1128(b)(6)(A) of the Act have very limited applicability with respect to the current Medicare reimbursement system. The recently-enacted Balanced Budget Act of 1997, Public Law 105–33, either directly mandates prospective payment or provides authority for the Secretary to develop additional fee schedules to replace almost all existing cost or charged-based reimbursement methodologies. The purpose of fee schedules is to bring Medicare reimbursement more in line with market rates. As fee schedules are implemented, providers may have less incentive and less opportunity to claim Medicare payment that is substantially in excess of their usual charges. Therefore, we would expect this statutory authority to have declining relevance within the Medicare reimbursement system. Moreover, the statute contains the undefined term ''substantially in excess,'' which makes enforcement action difficult. As such, we now believe that modifying the definition of ''usual charges'' will have very little impact.

*Section 1001.801. Minimum Period of Exclusion*

*Comment:* Based on section 212 of HIPAA, we proposed amending § 1001.801(c) to require a minimum exclusion period of one year for managed care organizations that are found to have failed to provide medically necessary items or services. One commenter believed that the OIG was in error in interpreting section 212 applicability to this provision. The commenter indicated that section 212 of HIPAA establishes minimum periods of exclusion for some activities prohibited under section 1128(b) of the Act, specifically only those activities described in section 1128(b)(6)(B) of the Act. As a result, the commenter stated that under the exclusion authority in § 1001.801 for managed care organizations that fail to provide medically necessary services, there is no legal authority to mandate a one-year minimum exclusion period. The commenter indicated that under the proposed language if a single physician acts inappropriately, and the managed care organization in which he or she is participating finds out about the issue and acts appropriately and promptly to address the problem, in this instance the OIG would be inappropriately forced to impose a one year exclusion.

*Response:* We believe the commenter is correct in this regard and that the concerns set forth are valid. As a result, we are amending paragraph (c)(1) of this section.

*Section 1001.1051, Exclusion of Individuals With Ownership or Control Interest in Sanctioned Entities*

*Comment:* In accordance with a new HIPAA provision, we proposed to add § 1001.1051 to permit the exclusion of

individuals (1) who have a ''direct or indirect'' ownership or control interest in a sanctioned entity if the individual ''knows or should know'' of the action constituting the basis for the conviction or exclusion, and (2) who are officers or managing employees of a sanctioned entity. Commenters indicated that because the exclusion is potentially applicable in the latter category to persons with no knowledge of the sanctioned entity's wrongdoing, the OIG should provide specific criteria on which decisions are based on whether to seek the imposition of a permissive exclusion against such individuals. Some commenters recommended that the OIG follow a ''deliberate ignorance'' standard for excluding officers and managing employees of sanctioned entities. Commenters indicated that in failing to use a standard of ''deliberate ignorance,'' the OIG would be targeting individual physicians who may have no reason to know whether the entity with which they are affiliated was convicted or excluded. As a result, these commenters believed that to exclude an officer or managing employee without having to show some knowledge of the underlying sanction would be excessive and inappropriate. In addition, some commenters were concerned that the proposed rule did not specifically preclude exclusion of an officer or managing employee who joins a previously sanctioned entity after commission of the conduct on which the sanction was based, and when he or she had no relationship with the entity at the time of the commission of the wrongful actions.

*Response:* In accordance with the statute, in the case of an officer or managing employee, the OIG does not have to demonstrate that such individuals acted in deliberate ignorance of the offense constituting the sanctionable action. It appears that Congress believed that any person serving as an officer or managing employee of the entity is presumed to have specific knowledge of the actions constituting the basis for the exclusion. Our language in § 1001.1051(a) is consistent with the statute and does not afford the OIG policy discretion in this regard when considering the relationship between an officer or managing employee and a sanctioned entity during the period the sanctionable actions were committed.

*Comment:* Several commenters objected to the fact that the period of exclusion for individuals under § 1001.1051(c)(1) would be the same as the period of exclusion for the entity, if the entity is excluded. Commenters stated that an individual's reinstatement request under this section should be judged on its own merits rather than linked to a particular entity's status. The commenters believed that arbitrary application of this provision would impact on individuals, especially in situations where the entity may in fact no longer exist.

*Response:* The language in § 1001.1051(c) is being revised to address these concerns in some respects. While the length of exclusion for such individuals will be for the same period of time as that of the sanctioned entity with which he or she has had the prohibited relationship, any individual excluded under this provision may apply for reinstatement in accordance with the procedures set forth in § 1001.3001 of the regulations.

*Section 1001.1901, Scope and Effect of Exclusion*

*Comment:* We proposed revising § 1001.1901(b)(3) to indicate that submitting, or causing to submit, claims for items or services ordered or prescribed by an excluded individual or entity may be sufficient grounds to deny reinstatement to the programs. One commenter believed that this provision would prevent an excluded person not only from program participation, but also from operating in the health care arena at all during the period of exclusion, and as such, was unwarranted and impermissible.

*Response:* We believe that the revised language is not overly broad, serves to more clearly define what an excluded individual or entity can do, and specifically re-enforces existing OIG policy set forth in exclusion notice letters currently sent to individuals and entities. Accordingly, we are retaining the language in paragraph (b)(3) of this section as set forth in the proposed rule.

*Section 1001.2001, Elimination of In-Person Hearings Prior to When Exclusion is Proposed*

*Comment:* We proposed deletion of § 1001.2001(b) which provides for an in-person hearing when an exclusion is proposed under section 1128(b)(6)(B) and (C) of the Act. Paragraph (b) of § 1001.2001 states that with respect to such exclusions the individual or entity ''may submit, in addition to the information described in paragraph (a) of this subsection, a written request to present evidence or argument orally to an OIG official.'' Several commenters opposed the elimination of an opportunity for oral evidence and argument, and believed it was essential that providers be given full due process rights before the effective date of the exclusion and not after the exclusion has gone into effect. Commenters stated that failure to present information directly and in person presents a significant due process problem, and believed that a provider facing exclusion should be permitted the opportunity to present its case in person rather than just on paper. For example, one commenter, representing orthotic and prosthetic interests stated that since most people are not familiar with the fabrication or use of certain items or devices, a visual demonstration often easily clears up a misunderstanding that would continue were it to be based solely upon written information, and would enhance the possibility of resolving issues at an early stage. In addition, some commenters stated that although a provider still retains the ability to challenge the proposed exclusion, an exclusion by the OIG would remain in effect during the formal appeals process until overturned, thus potentially resulting in financial harm to that provider. As an example, one commenter stated that a successful appeal during a formal appeals process would be meaningless for a managed care organization that was excluded, had its contract terminated and had its Medicare and Medicaid members disenrolled or subsequently enrolled into other health plans.

*Response:* As we indicated in the preamble discussion of the proposed rule, the vast majority of cases involving a proposal to exclude are medical in nature, with the OIG relying on a Medicare intermediary or carrier, a peer review organization or other medical reviewer to provide medical review of a case prior to it being referred by the OIG. In addition to relying on this prior medical review, under the revised regulation the provider is still afforded an opportunity to submit any appropriate written material to the OIG for review and consideration. We believe this revised approach will usually be the most appropriate, efficient and timely use of resources for protecting the programs and its beneficiaries. However, we recognize that there may be situations where the OIG may, at its discretion, wish to hear oral argument prior to deciding whether to impose an exclusion. As a result, we will permit individuals and entities to request, in conjunction with their written submission, an opportunity to present oral argument to an OIG official. Regardless of whether oral argument is allowed, individuals and entities will still retain the ability to challenge in the administrative process any OIG proposed exclusion. The administrative process includes, among other things,

the right to call witnesses, the cross-examination of witnesses, and the presentation of evidence to an Administrative Law Judge, as set forth in 42 CFR part 1005.

*Section 1001.2005, Notice to State Licensing Agencies*

*Comment:* We proposed deleting § 1001.2005(b) and revising this section to indicate that while the Department will continue to notify State and local agencies of the circumstances leading to an exclusion, it would not be tied to a specific notification process. Commenters believed that whether or not the Department advocates specific State and local actions may significantly influence the actions generally taken by these agencies, and recommended that any revision to this section include guidelines regarding the OIG's intended position on notification of exclusions to these agencies and the designation of a general time frame within which the agencies may be notified of the exclusions.

*Response:* The statute obligates the Department to notify State and local agencies of any exclusion action taken by the OIG, but is not does not require us to delineate the precise methods as to when and how this notification will occur. We believe it would be an unnecessary paperwork burden to establish specific notification procedures to be used, and thus remained opposed to placing such internal procedures in regulations. We are, however, sensitive to the commenters concerns of keeping State and local agencies promptly and directly informed of any exclusion action taken by the OIG. As a result, in an effort to increase the effectiveness of the process and allow the use of alternative means of notification, we are reinserting paragraph (b) of this section, but will continue to reserve the right to alter this notification process to consider alternative, more efficient methods as appropriate.

*Section 1001.3001, Timing and Method of Request for Reinstatement*

*Comment:* We proposed to revise this section to permit submission of a request for reinstatement only after the full period of exclusion has expired. Commenters believed that this provision, as interpreted, would guarantee that the period of exclusion would exceed the period originally specified since it would also incorporate the amount of time taken by the OIG to process a reinstatement request. One commenter believed that this was especially problematic since the regulation does not impose constraints on the amount of time the OIG may take in processing such requests.

*Response:* We believe that commenters' concerns are valid and are agreeing to take no action in revising the existing regulatory language with regard to the time frames for reinstatement. We are also withdrawing the conforming change proposed in § 1001.3002(a). We are, however, clarifying in § 1001.3001(a) that obtaining a program provider number or equivalent, in and of itself, does not reinstate an individual's or entity's eligibility nor does it connote permission to bill the programs. Thus, merely obtaining a program provider number or equivalent from HCFA, a State agency or other Federal health care agency cannot vitiate an exclusion by the OIG; an exclusion will remain in effect until such time as the OIG formally reinstates the individual or entity.

*Section 1001.3002, Basis for Reinstatement*

*Comment:* A technical revision was proposed in § 1001.3002(a)(1)(ii) to delete the ''unwillingness and inability'' factor as a basis for consideration by the OIG in making a reinstatement determination. One commenter used this opportunity to take exception to the language in this paragraph that the OIG will make a determination that the types of actions that formed the basis for the original exclusion ''will not recur.'' The commenter believed that such a standard is impossible to prove, and provides too much discretion to the OIG in determining whether an individual or entity is to be reinstated in the programs. As a result, the commenter recommended that the term ''will not recur'' be deleted.

*Response:* Use and consideration of this term is specifically required by the statutory language set forth in section 1128(g)(2)(B) of the Act.

*Section 1002.3, Disclosure of Information*

*Comment:* One commenter recommended that we clarify the reporting requirements imposed on State Medicaid agencies in § 1002.3 with respect to actions taken to limit an individual's or entity's participation in a State program. Specifically, the commenter suggested that guidance be provided as to when a State agency is obligated to report ''suspension actions, settlement agreements and situations where an individual or entity voluntarily withdraws from the program in order to avoid a formal sanction.''

*Response:* Under section 1128(b)(5) of the Act, the OIG is authorized to exclude from program participation any individual or entity ''suspended or excluded from participation, or otherwise sanctioned * * *'' under a Federal or State health care program ''for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity'' (42 CFR 1001.601). Since 1992, § 1001.601(a)(2) of our regulations has defined the phrase ''otherwise sanctioned'' to cover ''all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called * * *,'' including where there is a voluntary withdrawal from program participation in order to avoid a formal sanction.[4] With respect to a State agency's obligation to report sanctions to the OIG, § 1002.3 sets forth and clarifies the circumstances under which a ''voluntary withdrawal'' should be reported.

The OIG is obligated under the statute to review providers who no longer qualify to participate in a State's Medicaid program, and relies on State Medicaid agencies to report on a timely and complete basis those cases where a provider has been sanctioned, including where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

Typically, when a State agency receives a complaint or allegation, or is made aware of other circumstances, regarding a physician or other health care provider that causes the State agency to open an investigation or review, the physician or provider is sent a letter and given an opportunity to respond. Under this scenario, withdrawal from the State program *after* notice and opportunity to respond, and *prior* to the completion of a formal proceeding, would subject the physician or provider to possible exclusion under section 1128(b)(5) of the Act.

Informal contacts with the provider, short of written notice, have been viewed as not constituting the start of a formal proceeding. If a provider withdraws from program participation at this early stage of an investigation or review prior to when formal charges or notification has been made, and the provider has not been offered an opportunity to respond, such a withdrawal would not be grounds for an exclusion. Under this situation, the State Medicaid agency is not required to report the matter to the OIG.

[4] Administrative decisions have upheld exclusions under section 1128(b)(5) of the Act based on a physician withdrawing from participation in a State Medicaid program in order to avoid a formal sanction under this language (see Hassan M. Ibrahim, M.D. DAB CR445 (1996)).

We wish to clarify that consistent with the first example, in those situations where a written notice of charges or allegations has been given by the State agency to a provider with an opportunity to respond, and he or she voluntarily withdraws from program participation in order to avoid formal sanction, the State Medicaid agency is obligated under § 1002.3(b)(3) to report the matter to the OIG for review and a determination by the OIG of whether an exclusion under section 1128(b)(5) of the Act is appropriate. We are revising the section heading to § 1002.3 to more accurately reflect the requirements of this section.

## IV. Technical Revisions

We are including in these final regulations a number of technical revisions in parts 1001 and 1005.

- *Section 1001.2, Definitions:* We are clarifying the definition of the term ''patient'' in § 1001.2 to include residents receiving care in a facility described in 42 CFR part 483.
- *Section 1001.1007, Excessive claims or furnishing of unnecessary or substandard items or services:* We are making a technical revision to § 1001.701(d)(1), the regulations implementing section 1128(b)(6) of the Act. We incorrectly stated in the proposed rule that a minimum one-year period of exclusion would apply to violations of section 1128(b)(6)(A) of the Act (claims for excessive charges) and section 1128(b)(2)(B) of the Act (the furnishing of unnecessary or substandard items or services). However, section 1128(c)(3)(F) of the Act, enacted by HIPAA, mandated a minimum one-year period of exclusion only for individuals and entities excluded under section 1128(b)(6)(B) of the Act. As a result, we are clarifying § 1001.701(d)(1) to properly reflect the statutory language.
- *Section 1005.21, Appeals to the DAB:* We are revising the language in § 1005.21(k)(2) and (k)(3) by deleting the current reference to ''the Associate General Counsel, Inspector General Division, HHS,'' and by inserting the term ''Chief Counsel to the IG'' in its place. These changes reflect the recent consolidation of the IG Division of the Office of the General Counsel into the OIG (62 FR 30859, June 6, 1997).

## V. Regulatory Impact Statement

*Executive Order 12866 and Regulatory Flexibility Act*

The Office of Management and Budget (OMB) has reviewed this final 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 substantial 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 final rule, for the most part, implement statutory requirements, and are designed to broaden the scope of the OIG's authority to exclude individuals and entities from the Medicare, Medicaid and all other Federal health care programs. As indicated above, these provisions 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 affected these statutory changes will be minimal in light of the fact that these felony convictions were previously subject to a permissive program exclusion in accordance with section 1128(b)(1) of the Act prior to the enactment of the HIPAA changes.

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 major ownership interest in (or significant control over the operations of) an entity convicted of a program-related offense; (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 also believe the increase in the number of exclusion cases will be small in light of past experience with respect to imposing program exclusions under section 1128(b)(8) of the Act. 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 (in light of past experience with respect to section 1128(b)(8) of the Act), and § 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 final 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 that these final regulations should 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*

1. Reporting Requirements on State Medicaid Agencies in Accordance With § 1002.3

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The valid OMB control number for the information collection requirements with respect to § 1002.3 of these regulations is 0990–0218. Public reporting burden for this collection of information—that is, the burden on the State Medicaid agencies in preparing and submitting the notification to the OIG in accordance § 1002.3—is estimated to average of less than one-half hour per submitted notification, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information.

2. Clarifying Definition of the Term ''Furnished''

With respect to the clarifying definition of the term ''furnished'' being set forth in these regulations, we do not believe there will be any new or significant administrative costs or burden requirements placed on direct providers, such as hospitals, nursing homes and physicians, for ensuring that claims are not submitted for items manufactured or supplied by excluded parties. Specifically, the mandatory exclusion of indirect providers is rare. On those exceptional and infrequent occasions that an indirect provider is convicted and subject to an exclusion, the OIG will quickly make this action known through posting this information on the OIG web site, as is done in the case of all OIG exclusions. Since direct providers are already required to keep themselves apprised of all exclusions (not only to ensure their claims are reimbursable, but also to ensure they are not subject to a CMP for contracting with or employing an individual or entity that has been excluded), we do not believe this clarifying definition places any significant new burdens on direct providers beyond the responsibility already existing to refrain from doing business with excluded parties.

Past OIG experience has indicated that the exclusion of indirect providers, such as in the case of a hospital administrator or a nurse aide in a nursing home setting, have created no significant administrative or cost burden problems to a direct provider. In the cases of a hospital administrator's exclusion or a nurse aide's exclusion, the hospital or nursing home was able to separate out the salaries of these individuals on their cost reports without added or significant burden to them. The vast majority of comments to the proposed rule did not allude to any additional administrative or cost burdens that they faced in this regard.

Further, as we have stated above in this preamble, it is our goal to implement program exclusions in a prudent manner that will minimize any inconveniences or hardship. As a result, we have indicated that, with respect to items in a direct provider's existing inventory which may be affected by the exclusion of a manufacturer, any health care items that a direct provider has in inventory from the excluded manufacturer prior to the effective date of the exclusion of the manufacturer will not be affected by the exclusion, and claims may be submitted for the furnishing of such items by the practitioner , provider or supplier. In addition, as indicated in the regulations, we are permitting payment for health care items that are ordered from an excluded manufacturer prior to the effective date of the exclusion and delivered up to 30 days (or 60 days for the first year from the effective date of this provision) *after* the effective date of such exclusion. We believe this will serve to more effectively protect direct providers from significant financial harm and lessen the impact of any administrative burden on direct providers as a result of an indirect provider's exclusion.

In addition, to provide reasonable assurance that no substantial, harm is encountered by direct providers, we have reiterated in the preamble of this final rule that, when appropriate and permitted under the existing statute, the OIG will entertain requests for waivers of program exclusion in appropriate cases. As a result, we do not anticipate any additional information collection and reporting burden requirements being imposed on direct providers as a result of the exclusion of an indirect provider.

**List of Subjects**

*42 Part 1001*

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

*42 Part 1002*

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

*42 Part 1005*

Administrative practice and procedure, Fraud, Penalties.

Accordingly, 42 Parts 1000, 1001, 1002 and 1005 are amended as set forth below:

## PART 1000—[AMENDED]

A. Part 1000 is amended as follows:

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

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

2. Section 1000.10 is amended by republishing the introductory paragraph; by revising the definition for the term *Furnished*; and by adding, alphabetically, definitions for the terms *Directly* and *Indirectly* to read as follows:

### § 1000.10 General definitions.

In this chapter, unless the context indicates otherwise——

* * * * *

*Directly*, as used in the definition of ''furnished'' in this section, means the provision of items and services by individuals or entities (including items and services provided by them, but manufactured, ordered or prescribed by another individual or entity) who submit claims to Medicare, Medicaid or other Federal health care programs.

* * * * *

*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, Medicaid or other Federal 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.

* * * * *

*Indirectly*, as used in the definition of ''furnished'' in this section, means the provision of items and services manufactured, distributed or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that provide items and services to providers, practitioners or suppliers who submit claims to these programs for such items and services. This term does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.

* * * * *

## PART 1001—[AMENDED]

B. Part 1001 is amended as follows:

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

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

2. Section 1001.2 is 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, Medicaid and all other Federal 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 (including a resident receiving care in a facility as described in part 483 of this chapter), whether or not reimbursed under Medicare, Medicaid and any other Federal 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, recognize 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 will 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—

(1) 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 part 5, appendices B–F;

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

(3) 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 is 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, Medicaid or any Federal 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 and a State health care program) 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 is amended by revising paragraph (b); republishing introductory 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 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, Medicaid and all other Federal 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, 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, Medicaid and all other Federal 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 is amended by revising the section heading; revising paragraph (a); republishing introductory paragraph (b)(2), revising paragraphs (b)(2)(iv) and (v), and adding a new paragraph (b)(2)(vi); and by republishing introductory 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 and 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 of 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, 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, Medicaid and all other Federal 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

* * * * *

6. Section 1001.301 is amended by republishing introductory paragraph (b)(2); revising paragraphs (b)(2)(iv) and (v); by adding a new paragraph (b)(2)(vi); by republishing introductory 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, 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, Medicaid and all other Federal 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 is amended by revising the section heading; revising paragraph (a); by republishing introductory 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, 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, Medicaid and all other Federal 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 is amended by revising paragraph (b)(1); republishing introductory paragraph (b)(2), revising paragraphs (b)(2)(ii) and (iii), and adding a new paragraph (b)(2)(iv); by republishing introductory 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, 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 is 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 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 Medicare, Medicaid and all other Federal health care programs 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, 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's 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 is amended by revising paragraph (d)(1); 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 and services.**

* * * * *

(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 for any exclusion taken in accordance with paragraph (a)(2) of this section.

(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, Medicaid and all other Federal health care programs of $1,500 or more; 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, 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 is 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 for lengthening or shortening the period.

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

* * * * *

(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, 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 is 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 record 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, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

* * * * *

13. Section 1001.951 is 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, 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 is removed.

15. A new section 1001.1051 is 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, Medicaid and all other Federal health care programs.

(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 in accordance with the procedures set forth in § 1001.3001.

16. Section 1001.1101 is amended by republishing the introductory text of (b) and revising paragraph (b)(3) to read as follows:

**§ 1001.1101 Failure 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);

* * * * *

17. Section 1001.1201 is 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

* * * * *

18. Section 1001.1301 is 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).

* * * * *

19. Section 1001.1401 is 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).

20. Section 1001.1601 is 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 physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

* * * * *

21. Section 1001.1701 is 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.* (1) * * *

(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

* * * * *

22. Section 1001.1901 is amended by revising paragraphs (b)(1), (b)(3) and (c)(3); (i) (ii) and (iii) redesignating (c)(4) as (c)(5) and revising paragraph (c)(5)(ii); 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, Medicaid and all other Federal 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 or equivalent, 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.* * * *

(3) * * *

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

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

(iii) Any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion. (For the period October 2, 1998 to October 4, 1999) payment may be made under Medicare or a State health care program for up to 60 days after the effective date of the exclusion for any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of such exclusion and delivered within 60 days of the effect of the exclusion.)

(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 15 days or more after the notice of the provider's exclusion was mailed 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.

23. Section 1001.2001 is 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 and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues. In conjunction with this submission, an individual or entity may request an opportunity to present oral argument to an OIG official.

(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.

24. Section 1001.2002 is 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.

25. Section 1001.2003 is 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—

* * * * *

26. Section 1001.2006 is 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 National Practitioner Data Bank.

* * * * *

27. Section 1001.3001 is amended by revising paragraph (a)(1) 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 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion. Obtaining a program provider number or equivalent does not reinstate eligibility.

* * * * *

28. Section 1001.3002 is amended by revising paragraph (a); republishing introductory paragraph (b), revising paragraphs (b)(3) and (4) and deleting paragraph (b)(5); and by revising introductory paragraph (c) and paragraph (d) to read as follows:

**§ 1001.3002 Basis for reinstatement.**

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

(i) The 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 or equivalent, 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, Medicaid and all other Federal 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) 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.

* * * * *

## PART 1002—[AMENDED]

C. Part 1002 is amended as follows:

1. The authority citation for part 1002 continues 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 is amended by revising the section heading and paragraph (b)(2), and by adding a new paragraph (b)(3) to read as follows:

**§ 1002.3 Disclosure by providers and State Medicaid agencies.**

* * * * *

(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 is 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 is 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 is amended as follows:

1. The authority citation for part 1005 continues 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 is 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—

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3. Section 1005.21 is amended by revising paragraphs (k)(2) and (3) to read as follows:

**§ 1005.21, Appeal to DAB.**

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(k) * * *

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final action of

the DAB will be sent by certified mail, return receipt requested, to the Chief Counsel to the IG. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the Chief Counsel to the IG receives two or more petitions within 10 days after the DAB issues its decision, the Chief Counsel to the IG will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

Dated: March 11, 1998.

**June Gibbs Brown,**

*Inspector General, Department of Health and Human Services.*

Approved: April 13, 1998.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 98–23462 Filed 8–28–98; 4:23pm]

**BILLING CODE 4150–04–P**

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## DEPARTMENT OF TRANSPORTATION

## Research and Special Programs Administration

## 49 CFR Part 195

**[Docket No. PS–117; Amdt. 195–64]**

**RIN 2137–AC87**

## Low-Stress Hazardous Liquid Pipelines Serving Plants and Terminals

**AGENCY:** Research and Special Programs Administration (RSPA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This final rule excludes from RSPA's safety standards for hazardous liquid pipelines low-stress pipelines regulated for safety by the U.S. Coast Guard and low-stress pipelines less than 1 mile long that serve certain plants and transportation terminals without crossing an offshore area or a waterway currently used for commercial navigation. RSPA previously stayed enforcement of the standards against these pipelines to mitigate compliance difficulties that did not appear warranted by the safety risk. The rule change conforms the standards with this enforcement policy and eliminates duplicative and unnecessarily burdensome regulation.

**EFFECTIVE DATE:** October 2, 1998.

**FOR FURTHER INFORMATION CONTACT:** L.M. Furrow at (202)366–4559 or furrowl@rspa.dot.gov.

**SUPPLEMENTARY INFORMATION:**

### Background

In 1994, in response to a new pipeline safety law (49 U.S.C. 60102(k)), RSPA amended the hazardous liquid pipeline safety standards in 49 CFR Part 195 to cover certain low-stress pipelines (59 FR 35465; July 12, 1994). A low-stress pipeline is a pipeline that operates in its entirety at a stress level of 20 percent or less of the specified minimum yield strength of the line pipe (§ 195.3). Except for onshore rural gathering lines and gravity-powered lines, the following categories of low-stress pipelines were brought under the standards: (1) Offshore pipelines; (2) onshore pipelines that transport highly volatile liquids; (3) onshore pipelines located outside rural areas; and (4) onshore pipelines located in waterways currently used for commercial navigation (§ 195.1(b)(3)).

Interfacility transfer lines comprised the largest percentage of low-stress pipelines brought under Part 195. These lines move hazardous liquids for short distances between truck, rail, and vessel transportation terminals, manufacturing plants (including petrochemical plants), and oil refineries, or between these facilities and associated storage or long-distance pipeline transportation.

Information in the rulemaking docket showed that bringing interfacility transfer lines into full compliance with Part 195 would be difficult for many operators. The primary difficulty was that transfer lines are not customarily installed and operated according to Part 195 standards. For example, considering their short length and low operating stress, additional pipe wall thickness is often used to resist expected corrosion instead of cathodic protection as Part 195 requires. Because of this and other disparities, operators were allowed to delay compliance of their existing lines until July 12, 1996 (§ 195.1(c)).

Before the compliance deadline, interfacility transfer line operators and their Washington representatives continued to argue that meeting Part 195 requirements would not bring commensurate safety benefits. The operators were particularly concerned about the strain on resources and potential adverse effects of having to meet the separate federal regulatory regimes of RSPA, the Occupational Safety and Health Administration (OSHA), and the U.S. Coast Guard.

The operators explained that segments of interfacility transfer lines on facility grounds are subject to OSHA's Process Safety Management standards (29 CFR 1910.119). Compliance with these standards affects operation of the off-grounds segments that come under Part 195. Similarly, compliance with Part 195 on off-grounds segments would affect operation of the on-grounds segments. Operators said this overlapping effect would result in analogous administrative costs for records, procedures, and manuals. Worse yet it would create opportunities for mistakes when operating personnel have to meet different requirements with similar objectives. In addition, for transfer lines between vessels and marine transportation-related facilities, the U.S. Coast Guard safety regulations (33 CFR Parts 154 and 156) would compound the overlap problem. Not only would applying Part 195 to these marine terminal transfer lines duplicate agency efforts within DOT, it also would leave the industry uncertain which DOT safety standards apply in particular instances.

At the same time, we began to realize that carrying out adequate compliance inspections on interfacility transfer lines would require a significant increase in resources. We estimated that about 11,000 miles of low-stress pipelines were brought under Part 195, with over a third of the mileage composed of short interfacility transfer lines. Just the job of finding and educating the many operators of these short lines would likely be a major, protracted effort.

In consideration of these industry and government compliance difficulties and the limited public risk involved, we concluded that the potential benefits of complying with Part 195 did not justify the expense for certain short interfacility transfer lines and lines regulated by the Coast Guard. Consequently, we announced a stay of enforcement of Part 195 against these lines (61 FR 24245; May 14, 1996). The stay applied to low-stress pipelines that are regulated by the Coast Guard or that extend less than 1 mile outside plant or terminal grounds without crossing an offshore area or any waterway used for commercial navigation.

Following the stay of enforcement, we published a direct final rule that excluded from Part 195 interfacility transfer lines covered by the stay (62 FR 31364; June 9, 1997). However, because we received a written adverse comment on this action, we withdrew the direct final rule before it took effect (62 FR 52511; October 8, 1997).

Later, based on the direct final rule and comments we had received on it, we again sought to remove the lines from Part 195 by issuing a notice of proposed rulemaking (63 FR 9993; February 27, 1998). Four persons submitted comments on this notice: the Chemical Manufacturers Association, the Independent Liquid Terminals Association, the Independent Fuel Terminal Operators Association, and the American Petroleum Institute. Each of