

control number 2070-0151 had been assigned to these collection activities. In the July 1, 1996 issue of the **Federal Register** (61 FR 33851) (FRL-5379-8), EPA amended the table in 40 CFR part 9 to add this OMB control number to the listing of OMB control numbers for EPA's regulations that appears in § 9.1.

Since there wasn't a formal connection between these subsequent notices and 40 CFR part 745, subpart F, [or 24 CFR part 35, subpart H], the OFR did not make the connection to the information collection requirements contained in these sections. As a result, OFR added the following clause to the Effective Date Note that appears at the end of §§ 745.107, 745.110, 745.113, and 745.115: "This section contains information collection requirements and will not become effective until approval has been given by the Office of Management and Budget."

III. Why Is this Correction Issued as a Final Rule?

EPA is publishing this action as a final rule without prior notice and opportunity to comment because the Agency believes that providing notice and an opportunity to comment is unnecessary and would be contrary to the public interest. As explained above, this action will simply allow OFR to correct the CFR to properly reflect OMB's approval of the information collection requirements contained in 40 CFR part 745, subpart F. EPA therefore finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to make this amendment without prior notice and comment.

IV. Do Any of the Regulatory Assessment Requirements Apply to this Action?

No. This final rule does not impose any new requirements. It only implements a correction to the Code of Federal Regulations (CFR). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require prior consultation with State, local, and tribal

government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). In addition, since this action is not subject to notice-and-comment requirements under the Administrative Procedure Act (APA) or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

V. Will EPA Submit this Final Rule to Congress and the Comptroller General?

Yes. The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). EPA has made such a good cause finding for this final rule, therefore, the removal of the Effective Date Notes can be made to the CFR by OFR after July 22, 1999. Pursuant to 5 U.S.C. 808(2), this determination is supported by the brief statement in Unit IV. of this preamble. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 745

Environmental protection, Hazardous substances, Lead, Lead-based Paint, Reporting and recordkeeping requirements.

Dated: June 29, 1999.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001, 1002 and 1003

RIN 0991-AA95

Health Care Programs: Fraud and Abuse; Revised OIG Sanction Authorities Resulting From Public Law 105-33

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

ACTION: Final rule.

SUMMARY: This rulemaking revises the OIG's exclusion and civil money penalty authorities set forth in 42 CFR parts 1001, 1002 and 1003, as a result of the Balanced Budget Act of 1997, Public Law 105-33. These revisions are intended to protect Medicare and other Federal health care programs by enhancing the OIG's administrative sanction authority through new or revised exclusion and civil money penalty provisions.

EFFECTIVE DATE: This rule is effective on July 22, 1999.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. The Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, was enacted on August 21, 1996, and set forth a number of significant amendments to the OIG's exclusion and civil money penalty (CMP) authorities. Among the various provisions related to the program exclusion authority, HIPAA: (1) Expanded the OIG's minimum 5-year mandatory exclusion authority to cover any felony conviction under Federal, State or local law relating to health care fraud, even if governmental programs were not involved; (2) established minimum periods of exclusion from 1 to 3 years for certain permissive exclusions; and (3) established a new permissive exclusion authority applicable to individuals who have a

majority ownership in, or have significant control over the operations of an entity that has been convicted of a program-related offense. Proposed regulations addressing these revised or expanded OIG exclusion authorities were published in the **Federal Register** on September 8, 1997 (62 FR 47182) and final regulations were issued on September 2, 1998 (63 FR 46676).

In addition, HIPAA revised and strengthened the OIG's existing CMP authorities, and extended the application of the CMP provisions beyond those programs funded by the Department to include all Federal health care programs. Separate OIG proposed rulemaking addressing the revised or expanded CMP provisions resulting from HIPAA were published in the **Federal Register** on March 25, 1998 (63 FR 14393).

B. The Balanced Budget Act of 1997

In conjunction with many of the HIPAA fraud and abuse authorities, the Balanced Budget Act (BBA) of 1997, enacted on August 5, 1997, contained a number of provisions designed to further protect the integrity of Medicare, Medicaid and all other Federal health care programs for current and future beneficiaries, and combat fraudulent and abusive program activities. Specifically, the fraud and abuse provisions of BBA serve to strengthen the OIG's exclusion and CMP authorities with respect to Federal health care programs.

While the new exclusion and CMP authorities under BBA were effective for violations occurring on or after August 5, 1997, since the statutory provisions allowed the Department some policy discretion in their implementation, the OIG developed and issued a proposed rulemaking on September 2, 1998, that solicited public comments on proposed exclusion and CMP regulatory revisions resulting from BBA (63 FR 46736).

II. Summary of the Proposed Rule

In accordance with the Department's expanded and revised exclusion and CMP authorities resulting from BBA, the proposed regulations were designed to codify in 42 CFR parts 1001, 1002 and 1003 as follows:

A. Revised Exclusion Authorities Resulting From BBA

1. *OIG authority to direct exclusions from State health care programs, and to extend application of OIG exclusions to all Federal health care programs*—Prior to BBA, the OIG was authorized under section 1128 of the Act to impose exclusions from participation in Medicare under its own authority, but

could not impose other health care program exclusions directly. Instead, the OIG directed State health care programs (such as Medicaid) to impose parallel exclusions, but had *no* authority with respect to the exclusion from State health care programs, as listed in section 1128(i) of the Act. Section 4331(c) of BBA specifically amended sections 1128(a) and (b) of the Act to extend the scope of an OIG exclusion beyond the Medicare and State health care programs to all Federal health care programs (as defined in section 1128B(f) of the Act), and to enable the OIG to impose exclusions from all Federal health care programs *directly*. We proposed amending various sections of 42 CFR part 1001 to reflect this expanded authority.

The proposed regulations also addressed the effect of this expanded exclusion authority on the employment of excluded individuals, and program reimbursement for items and services they may provide to other Federal health care programs. Prior to BBA, with limited exceptions, no payment could be made under Medicare and the State health care programs for any health care item or service furnished, ordered or prescribed by an excluded individual. However, an individual excluded from Medicare and the State health care programs could still be employed or receive payment from other Federal health care programs, such as Tricare or the Department of Veterans Affairs. With the expanded scope of the exclusion authority, the proposed rule stated that Federal health care agencies may neither reimburse for items and services which excluded individuals provide, order or prescribe, nor pay the salaries or expenses of such persons using Federal funds. As indicated in the proposed rule, in accordance with the BBA provision, with limited exceptions, an exclusion would effectively preclude the employment of an excluded individual in any capacity by a Federal or State agency, or other entity, where payment is made by any Federal health care program.

2. *Permanent exclusions for individuals convicted of 3 or more health care-related crimes, and 10 year exclusions for individuals convicted of 2 health care-related crimes*—Most excluded health care providers become eligible for reinstatement in the Federal and State health care programs after a specified exclusion period. Section 4301 of BBA established a mandatory exclusion period of not less than 10 years for individuals who have been twice convicted of mandatory exclusion offenses under section 1128(a) of the Act. In addition, a permanent program

exclusion must be imposed against those individuals who have been convicted on 3 or more occasions of such mandatory exclusion offenses. Accordingly, we proposed to amend § 1001.102 to reflect these new mandatory exclusion periods.

3. *Exclusion of entities controlled by family or household members of sanctioned individuals*—The OIG is authorized to exclude entities owned or controlled by an individual who has been convicted of a health care related offense, or who has been sanctioned by the OIG. However, some excluded individuals have been able to circumvent the impact of an exclusion and retain silent control of operating health care entities by engaging in paper transfers of their ownership and control interests to family or household members. To address the problem of excluded individuals retaining "silent" control of participating entities, section 4303 of BBA allowed for the exclusion of entities owned or controlled by the family or household members of excluded individuals when the transfer of ownership or control interest in the entity was made in anticipation of, or following, a conviction, CMP or exclusion. We proposed to amend § 1001.1001(a) to reflect this new authority.

B. Revised CMP Authorities Resulting From BBA

1. *CMPs against institutional health care providers that employ or enter into contracts for medical services with excluded individuals*—In some instances, individuals who have been excluded from Medicare or the State health care programs have been able to obtain (or retain) employment, staff privileges or other affiliations with various health care entities that then bill the programs for their services. CMP authority has existed for health maintenance organizations that submit claims for items or services furnished by excluded employees or other excluded individuals with whom they contract, but no parallel sanction authority existed with respect to a group medical practice, hospital, nursing home, home health agency, hospice or other provider that failed to check the credentials of individuals whose services they utilize and bill to Medicare or State health care programs. In accordance with new authority set forth in section 4304(a) of BBA, we proposed amending §§ 1003.102(a) and 1003.103(a) to allow the OIG to impose a CMP of up to \$10,000 against any entity that submits, or causes to be submitted, claims for items or services rendered by employees or other individuals with whom they

contract, and whom they know, or should know, have been excluded from participation in the Federal health care programs.

2. *CMP for failure to report information to the Healthcare Integrity and Protection Data Bank*—Section 221 of HIPAA established a national health care fraud and abuse data collection program, the Healthcare Integrity and Protection Data Bank (HIPDB), for the reporting of final adverse actions (such as convictions, exclusions and licensing restrictions) against health care providers, suppliers and practitioners.¹ While this authority mandated that private health plans, as well as certain State and Federal entities, report adverse actions to the HIPDB, no penalty provision was included to address failure by a health care plan to comply with the reporting requirements. In accordance with section 4331(d) of BBA, § 1003.102(b) of the proposed regulations set forth a new CMP of not more than \$25,000 against any health plan that fails to report a final adverse action to HIPDB as required by the statute and regulations.

3. *CMPs for health care providers who violate the anti-kickback statute*—Prior to BBA, criminal penalties or program exclusions were the only remedies available against those who offered or received remuneration in return for the referral of business paid for by Federal health care programs, in violation of the anti-kickback statute. Since both remedies are potentially quite severe, section 4304 of BBA set forth an alternative remedy, *i.e.*, a new CMP for violations of the anti-kickback statute. In accordance with this new statutory provision, we proposed to amend §§ 1003.102(b), 1003.103(h) and 1003.104 to implement a CMP of not more than \$50,000 for each kickback violation, and an assessment of up to 3 times the total amount of remuneration offered, paid, solicited or received without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose.

C. Additional Technical and Other Revisions to 42 CFR Parts 1001 and 1003

1. *Technical revisions*—A number of proposed technical revisions consistent with the policy provisions resulting from BBA and the proposed regulatory amendments were also indicated in the notice of proposed rulemaking.

¹ Proposed regulations setting forth the policies and procedures for implementing the new HIPDB were published in the *Federal Register* on October 29, 1998 (63 FR 58341).

Specifically, we proposed to amend the authority citation cites for parts 1001 and 1003, §§ 1001.302 (Basis for reinstatement), 1003.100 (Basis and purpose), and 1003.114 (Collateral estoppel) to reflect the revisions being proposed in accordance with the revised BBA exclusion and CMP authorities. In addition, we proposed a revision to § 1003.109(a)(3), to delete the phrase “the amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable).” This language appears in paragraph (a)(4) of this section, and appears inadvertently in paragraph (a)(3).

2. *Proposed revision to OIG reinstatement considerations*—We also proposed to add two new elements to § 1001.3002(b), pertaining to the OIG’s review of an individual’s or entity’s request for reinstatement in the Federal health care programs after the individual’s or entity’s exclusion period. The first new proposed element was designed to address the OIG’s expectation that excluded parties adequately and promptly inform all their clients or patients of the exclusion so that the clients or patients will have a clear understanding that items and services provided, directed or ordered by that individual or entity will not be paid for under any Federal health care program. Under § 1001.1901(b) of the proposed regulations, Medicare reimbursement is authorized to a beneficiary for the first claim submitted for an item or service provided by the excluded party, at which time the beneficiary is notified that future claims will be denied due to the provider’s excluded status. (We did not believe that notification only *after* the submission of a claim provides adequate protection for program beneficiaries.) By stating in the proposed regulations that the OIG, in making its reinstatement decisions, would consider whether a provider has adequately and promptly informed clients or patients of an exclusion, we hoped to offer an incentive for providers to give the earliest possible notification to beneficiaries of their exclusion.

A second proposed reinstatement element was designed to codify existing OIG policy which, in making reinstatement decisions, considers whether the individual or entity has, during the period of exclusion, submitted claims or caused claims to be submitted, or payments to be made by any Federal health care program for items or services the excluded party furnished, ordered or prescribed, including health care administrative services during the period of exclusion. By setting forth this regulatory

clarification, we hoped to make clear that the submission of claims for payment to any Federal health care program during a provider’s period of exclusion will jeopardize the provider’s reinstatement into the programs.

III. Responses to Comments and Summary of Revisions

In response to the notice of proposed rulemaking, the OIG received a total of five timely-filed public comments from various health care associations and other interested parties. Set forth below is a synopsis of the various comments and recommendations received, our response to those concerns, and a summary of the specific revisions and clarifications being made to the regulations.

Section 1001.102 Factors in Length of Exclusion

Comment: Two commenters raised concern over the language in proposed § 1001.102(b)(6), one of the possible aggravating factors which would provide a basis for lengthening the period of exclusion. The provision would consider whether the “individual or entity has at any time been overpaid a total of \$1,500 or more by Medicare, Medicaid or any Federal health care program as a result of improper billings.” The commenters indicated that this language was too general and gives no clear indication of what constitutes “improper billings.” The commenters stated that any overpayments of \$1,500 or more, whether part of the same circumstance that led to the exclusion in the first place, or ones that are billing error mistakes or simple negligence, could be deemed an aggravating circumstance. The commenters indicated that aggravating factors should serve as valid predictors of future violations of Medicare and other Federal program statutes and regulations and, therefore, urged that the OIG delete the \$1,500 threshold.

Response: It is not our intention to consider overpayment of \$1,500 or more based on inadvertent billing errors as an aggravating circumstance. We agree with the commenters that the \$1,500 threshold for overpayments needs to be related to improper conduct, such as the submission of false, fraudulent or otherwise improper claims for payment. This criterion with respect to determining aggravating circumstances has been included in the OIG’s regulations since 1992 and has not been identified as a problem by either providers or the OIG. Therefore, this provision, which was not proposed for

any revision in our proposed rule, will not be revised at this time.

Section 1001.3002(b)(5) Basis for Reinstatement

Comment: Two commenters raised concern over the proposed language in § 1001.3002(b)(5) that would add a new factor in determining whether an individual or entity can be reinstated to participate in Federally-funded health care programs. Specifically, we indicated that the OIG would consider “whether the individual or entity, during the period of exclusion, has adequately and promptly informed its clients or patients that any items or services provided will not be reimbursable under any Federal health care program.” One commenter requested that the OIG clarify both the terms “adequate” and “prompt” so that an excluded individual can be aware of whether they have met the criteria for reinstatement. The commenter also asked for additional clarification what is meant by a physician’s or entity’s “clients and patients.”

A second commenter recommended that the language in this paragraph be deleted entirely, stating that an excluded party’s unwillingness to notify those affected should not have a bearing on his or her fitness to be readmitted to the health care programs.

Response: We have considered the comments regarding this proposed factor for reviewing reinstatement requests, and agree that this factor may impose an additional burden on excluded individuals and entities with respect to notification of patients and clients and that this notification obligation is not mandated by law. In addition, we are persuaded by the fact that beneficiaries are adequately protected, since the current procedures provide for payment of the first claim submitted by or on behalf of a beneficiary for services furnished, ordered or prescribed by an excluded provider or practitioner, and simultaneous notification regarding the exclusion. Moreover, we believe that it would be very difficult to monitor such notifications by excluded individuals and entities in order to assess their trustworthiness for purposes of future participation in Federal health care programs. Based on these reasons, we are deleting this proposed factor from those to be evaluated in assessing a reinstatement request.

Section 1003.102(a) CMP for Relationships With Excluded Individuals

Comment: A commenter was concerned that the OIG misinterpreted

the statute (42 U.S.C. 1320a–7a(a)(6)) and congressional intent with regard to the basis for CMPs arising from relationships with excluded individuals. They indicated that the proposed regulations imply the existence of an affirmative duty on providers to monitor, on an ongoing basis, the eligibility of employees and others with whom they enter into contracts to participate in the Federal health care programs. The commenter believed that the conditional phrase “or should have known” in proposed § 1003.102(a)(2) would effectively impose a duty upon contracting providers to monitor the list of excluded individuals and entities on a regular basis or risk imposition of a CMP. The commenter raised questions regarding (1) how often should they check on employees and contracting parties, e.g., when employees are hired and when contracting parties enter into a contract, or rechecked at regular intervals), and (2) which persons should be checked, e.g., ongoing contracts, subcontractors or employees of a corporation with whom they are contracting. The commenter believed the appropriate burden should be on the OIG or the excluded individual or entity to notify contracting providers with whom they have employment or other contractual relationships of their exclusion from the Federal health care programs.

Response: Providers and contracting parties have a duty to check the sanction report on the OIG web site prior to entering into employment or contractual arrangements with new hires or run the risk of CMP liability if they fail to do so. All exclusion information is maintained on the OIG web site (www.dhhs.gov/progorg/oig) and updated on a regular basis. While it is not possible for the OIG to be aware of every employment arrangement being entered into by providers and excluded individuals or entities, the OIG does notify and inform employers of excluded individuals and entities when such pending employment arrangements are specifically known to the OIG. In addition, hospitals are under an affirmative obligation to query the National Practitioner Data Bank (NPDB) when they grant privileges, and subsequently at 2-year intervals, to determine whether any actions have been taken against physicians that they employ. Information on exclusions is contained in the NPDB.

Comment: Another commenter contended that use of the OIG’s Sanction Report posted on the Internet is confusing and inadequate. The commenter stated that the current information contained on the OIG web

site is not easily accessible, requiring providers to create their own “cumulative list” and to manually input data which could leave providers open to fraud and abuse claims because of simple mistakes or errors. In light of the new CMP authority under BBA for providers contracting with or employing an individual or entity that is excluded from the Federal health care programs, the commenter requested that the OIG reevaluate the current Sanction Report to create a “cumulative list” of excluded individuals and entities that providers can easily access and use.

Response: We believe that the current OIG web site containing the Cumulative Sanction Report is accessible, with large numbers of users of this web site having no problems in obtaining the information needed. However, we have also been aware that some users want to be able to do an on-line search for a single individual or entity, and agree that the sanction report on the web site needs to be modified to be more user-friendly in order to permit parties to look for one name at a time. Early in 1999, the OIG web site was modified so that parties can search by either name or location in order to ascertain an individual’s or entity’s exclusion status, as well as being able to download the entire file.

It should also be pointed out that the OIG’s web site is not the sole source of information regarding sanctioned individuals and entities. The NPDB, which hospitals are required to query, contains information on our sanctioned providers. In addition, the exclusion information is also available on the GSA list of “Parties Excluded from Federal Procurement and Nonprocurement Programs” and is on-line searchable.² Furthermore, the new HIPDB will contain the OIG exclusion information. With the various avenues of information on excluded individuals and entities available, we believe parties will be able to readily obtain the necessary information on current Federal health care program exclusions.

Comment: The preamble discussion of the proposed rule stated the OIG’s concern that “individuals who have been excluded from Medicare or State health care program participation have, nonetheless, been able to obtain (or retain) employment, staff privileges or other affiliation with various health care entities * * *.” A commenter emphasized that it is both possible and common for a physician to have medical staff privileges at a hospital without having either an employment or a contractual relationship with the

² See <http://anet.gov/epl/s/>.

hospital, particularly in States that prohibit the corporate practice of medicine. The commenter further stated that a physician's medical staff privileges at a hospital and his or her provision of items and services covered by Medicare mean that the hospital and the physician are "arranging" for the provision of such services.

Response: We agree with the commenter's point regarding the reference to staff privileges. A medical staff relationship, in the absence of any employment or contractual relationship or arrangement, in and of itself, remains outside the scope of these regulations. However, when claims are generated by physicians having privileges in the hospital for services they furnish, order or prescribe, the hospital must be held accountable if the items or services are provided by excluded physicians. Clearly, an excluded physician cannot have any Federal or State health care program payments made for items and services that they furnish, order or prescribe; not to hold a hospital or other organization accountable for allowing such a person to generate bills to the programs would be inappropriate.

Section 1003.102(b) CMP for Failure To Report Information to the HIPDB

Comment: One commenter believed that the OIG should not proceed with regulations relating to the new CMP for failure to report information to the HIPDB until the implementing regulations for the new data bank have been finalized.

Response: The OIG published proposed regulations in the **Federal Register** on October 30, 1998 (63 FR 58341) addressing policies and procedures for implementing the new HIPDB. Those proposed regulations are designed to address, among other things, how and when specific information is to be reported to the data bank; the requirements for the disclosure and confidentiality of information received by the HIPDB; applicable fees when requesting data bank information; and the process for disputing the accuracy of HIPDB information. The HIPDB is not expected to be operational until final regulations are in place some time later this year. The OIG will take no CMP action for failure to report information to the HIPDB until the issuance of final implementing regulations regarding reporting to the HIPDB.

Section 1003.103 Amount of Penalty

Comment: One commenter indicated that the proposed regulatory language in § 1003.103(h)(1), that indicates that the OIG may impose "a penalty of \$50,000"

against persons who commit an act in violation of the anti-kickback statute, is not consistent with the statutory language set forth in BBA. The statutory language (42 U.S.C. 1320a-7a(a)) indicates that a person may be subject to a civil money penalty of not more than * * * \$50,000 for each such act." The commenter recommended that the rule be modified to comport with the statutory language.

Response: We agree that the proposed language was inconsistent, and are amending paragraph (h)(1) of this section to indicate that the OIG may not impose "a penalty of *not more than* \$50,000" (emphasis added).

Section 1003.106 Factors in Calculating CMPs

Comment: One commenter cited an ambiguity in the preamble and proposed regulations text at § 1003.106(a)(1)(vii) with regard to determinations on the amount of a penalty. The commenter states that the preamble discussion indicates one of the criteria for determining the appropriate amount of penalty would be "whether the contracting provider knew or should have known of the exclusion." Also, the commenter indicates that the proposed language in § 1003.106(a)(1)(vii) describes this factor as "whether the contracting provider knew of the exclusion when employing or otherwise contracting with an excluded individual or entity." The commenter recommended adding the word "actually" before the word "knew" in this paragraph.

The commenter also believed a number of additional factors relating to the overall culpability of a contracting party should be considered. They included (i) the volume or value of items or services provided by an excluded individual or entity with which the contracting provider has an employment or contractual relationship; (ii) whether the contracting provider has in place an effective compliance program; and (iii) the length of time between when the provider knew or should have known of the exclusion, and when the provider terminated the employment or other contractual relationship with the excluded individual or entity.

Response: In making any determinations regarding the amount of penalty, the OIG intends to draw clear distinctions between cases where there was actual versus constructive knowledge. As a result, we are amending the language in § 1003.106(a)(1)(vii) to indicate that in determining the amount of any penalty in accordance with this provision, we

will take into account whether "the contracting provider *actually* knew of the exclusion when employing or otherwise contracting with an excluded individual or entity * * *" (emphasis added).

Comment: Two commenters raised objection to the existing factor, being redesignated as paragraph (a)(1)(ix) in this section, which allows the OIG to assess penalties in accordance with "[S]uch other matters as justice may require." The commenters believe that this language is unacceptably vague wide-ranging.

Response: The language in § 1003.106(a)(1)(ix), among other places in part 1003, is not new, and is intended to encompass other mitigating and aggravating factors that may arise on a case-by-case basis. It was included in the CMP statutory authority when initially enacted in 1981. This phrase allows for the consideration of individual factors, both aggravating and mitigating, that may be meaningful to one distinct case. For example, the additional factors cited by a commenter and referenced above, relating to the overall culpability of a contracting party, may be considered under this factor.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the September 2, 1998 proposed rule. A brief description of the provisions of this final rule follow.

- In § 1001.2, we are adding a definition for the term "Federal health care program," and are making conforming changes to include the term "and other Federal health care programs" in §§ 1001.1(a), 1001.201(b)(3)(iii)(A), 1001.301(b)(2)(ii), 1001.401(c)(2)(ii), 1001.1301(b)(2)(iii), 1001.1401.(b)(1) and (b)(4), 1001.1501(a)(3), 1001.1901(b)(1), 1001.3003, 1001.303 and 1002.2(a). Similar proposed revisions to §§ 1001.301(b)(3)(ii)(A) and 1001.401(c)(3)(i)(A) have already been addressed in the OIG final regulations published on September 2, 1998 (63 FR 46676) addressing revised OIG exclusion authorities resulting from Public Law 104-191.

- In the proposed rule, we set forth in § 1001.2, Definitions, a revised definition for the term "exclusion." A revised definition of the term was promulgated in the OIG final regulations published on September 2, 1998 (63 FR 46676) addressing revised OIG exclusion authorities resulting from Public Law 104-191. We are retaining that definition of the term "exclusion," set forth in the September 2, 1998 final

rule, in these final regulations as well. We are also adding a definition in § 1001.2 for the term "Federal health care program."

- The proposed rule indicated our intention to amend § 1001.102(b) by revising paragraphs (b)(5) and (b)(6), and by adding a new paragraph (b)(7). However, in the proposed rule, we inadvertently deleted existing paragraph (b)(5). In addition, final OIG regulations published on September 2, 1998 (63 FR 46676) added a new paragraph (b)(8). As a result, in these final regulations we are revising current paragraphs (b)(6) and (b)(7) (and not (b)(5) and (b)(6) as the proposed rule indicated); redesignating the recently-added paragraph (b)(8) as new paragraph (b)(9); and adding a new paragraph (b)(8) (designated as new (b)(7) in the proposed rule). We are also adding a new § 1001.102(d) to reflect the new mandatory lengths of exclusion.

- We are amending § 1001.1001(a) to reflect the statutory authority that allows for the exclusion of entities controlled by family or household members of sanctioned individuals. In § 1001.1001(a)(2), we are also adding definitions for the terms "immediate family member" and "member of household," consistent with the statute.

- To reflect the revised scope of exclusions under title XI of the Act, that allows the Secretary, through the OIG, to direct the imposition of exclusions from all Federal health care programs and to directly impose exclusions from all Federal health care programs, we are revising § 1001.1901(a), (b)(1), introductory paragraph (c)(3) and (c)(5)(i). While the proposed rule indicated our intention of revising paragraph (c)(4)(i) (and not (c)(5)(i)) of this section, the OIG final regulations published on September 2, 1998 (63 FR 46676) amended paragraph (b)(1), and redesignated paragraph (c)(4) as (c)(5) and added a new paragraph (c)(4) in its place. The changes being made in § 1001.1901 in this rule reflect the revisions and redesignation made in the September 2, 1998 final rule.

- With respect to considerations in the OIG's review of an individual's or entity's request for reinstatement in the Federal health care programs after the individual's or entity's exclusion period, we are not including the language proposed for a new § 1001.3002(b)(5) as indicated in the proposed rule. However, we are adopting the language proposed for new paragraph (b)(6) of this section, and are now designating this as new paragraph (b)(5). Technical revisions to § 1001.3002(b)(3) and (b)(4) are also being made.

- Sections 1003.102(a)(2) and 1003.103(a) are being revised to reflect the new CMP authority against entities that submit, or cause to be submitted, claims for health care services rendered by employees or other individuals under contract whom they know, or should know, have been excluded from participation in the Federal health care programs. We are also revising § 1003.106(a)(1) to set forth five criteria to be considered in determining the penalty amount.

- We are amending § 1003.102(b)(5) to address CMPs imposed against any health plan that fails to report information on an adverse action required to be reported to the new HIPDB. Section 1003.103(g) is being added to set forth the penalty amount for such violations.

- A new § 1003.102(b)(11)—to codify the CMP authority for health care providers who violate the anti-kickback statute, and a new § 1003.103(h), as revised in accordance with the discussion above, to address the maximum penalty amount—are being added. Section 1003.104 is also being revised to address assessments of not more than three times the amount of remuneration offered, paid, solicited or received with regard to this violation.

- Technical amendments are also being made in §§ 1001.302, 1003.100 and 1003.114 to reflect the regulatory changes set forth in the OIG's revised exclusion and CMP authorities revisions in accordance with BBA.

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 entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

The provisions set forth in this final rulemaking implement new or revised OIG statutory requirements set forth in Public Law 105–33. These provisions are designed both to broaden the scope of the OIG's authority to exclude individuals and entities from Medicare, Medicaid and all other Federal health care programs, and strengthen current legal authorities pertaining to the imposition of CMPs against individuals and entities engaged in prohibited actions and activities. These regulations implement the new statutory requirements by (1) expanding the application of the OIG's exclusions to all Federal health care programs; (2) implementing permanent exclusions for individuals convicted of three or more offenses for which an exclusion can be imposed under section 1128(a) of the Act, and 10 year exclusions for individuals convicted of two or more such offenses; (3) allowing for the exclusion of entities controlled by family or household members of sanctioned individuals; and (4) establishing new CMPs in three specific areas.

With regard to the OIG's new exclusion authorities, the process for excluding individuals and entities who are convicted in accordance with these new provisions remains essentially the same, even though the types of convictions requiring mandatory exclusions have been broadened. While there may be a resulting increase in the number of mandatory and permissive exclusions imposed as a result of the expanded scope of the OIG's exclusion authority, we do not believe these increases will be significant. The clarification of exclusion authority in § 1001.1001 regarding a sanctioned individual's transfer of ownership or control interest to a family or household member, for example, should not result in a significant increase in exclusion actions in accordance with section 1128(b)(8) of the Act since the provision is likely to act as an effective deterrent against the occurrence of such transfer arrangements. In addition, we do not foresee significant increases resulting from the implementation of section 4301 of BBA and § 1001.102, regarding the permanent exclusion of individuals convicted of three or more health care related crimes. The authority for promulgating this exclusion is clear cut, and should limit the total number of repeat exclusions effectuated by the OIG against such fraudulent providers.

The final regulations addressing the new OIG CMPs also remain consistent with the congressional intent of BBA and with the OIG's existing CMP authority which allows for imposition of

civil money penalties against individuals and entities who commit fraud. These CMPs are targeted to a limited group of individuals and entities; that is, those institutional health care providers that employ or enter into medical service contracts with excluded individuals, health care plans that fail to report information to the HIPDB, and health care providers who violate the anti-kickback statute.

As indicated, these final regulations are narrow in scope and effect, comport with congressional and statutory intent, and strengthen the Department's legal authorities against those who defraud or otherwise act improperly against the Federal and State health care programs. Since the vast majority of individuals, organizations and entities involved in delivering health care do not engage in the prohibited activities and practices described in this rulemaking, we believe that the aggregate economic impact of these regulations will not be economically significant. Since there is minimal economic effect on the industry as a whole, there would be little likelihood of effect on Federal or State expenditures to implement these regulations.

With regard to the effect of these regulations on a substantial number of small entities, the provisions are targeted specifically to those individuals and entities who would defraud or abuse the health care programs, rather than to the health care industry as a whole. While some of the perpetrators of fraud effected by this rule may be small entities, it is the nature of the violation and not the size of the entity that will induce action on the part of the OIG.

In summary, we have concluded, and the Secretary certifies, that since this final rule will not have a significant economic impact on Federal, State or local economies and expenditures, nor have a significant economic impact on a substantial number of small entities, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The provisions of these final regulations impose no new reporting or recordkeeping requirements necessitating clearance by OMB.

List of Subjects

42 CFR Part 1001

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

42 CFR Part 1002

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

42 CFR Part 1003

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

Accordingly, 42 Parts 1001, 1002 and 1003 is amended as set forth below:

PART 1001—[AMENDED]

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

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(h), 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 1001.1 is amended by revising paragraph (a) to read as follows:

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in Medicare, Medicaid and all other Federal health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

3. Section 1001.2 is amended by adding a definition for the term Federal health care program to read as follows:

§ 1001.2 Definitions.

Federal health care program means any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program as defined in this section.

4. Section 1001.102 is amended by revising paragraphs (b)(6) and (b)(7); redesignating existing paragraph (b)(8) as (b)(9); and by adding new paragraphs (b)(8) and (9) to read as follows:

§ 1001.102 Length of exclusion.

(b) (6) The convicted individual or entity has a prior criminal, civil or administrative sanction record;

(7) The individual or entity has at any time been overpaid a total of \$1,500 or more by Medicare, Medicaid or any other Federal health care programs as a result of intentional improper billings;

(8) The individual or entity has previously been convicted of a criminal offense involving the same or similar circumstances; or

(9) * * *

(d) In the case of an exclusion under this subpart, based on a conviction occurring on or after August 5, 1997, an exclusion will be—

(1) For not less than 10 years if the individual has been convicted on one other occasion of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act (The aggravating and mitigating factors in paragraphs (b) and (c) of this section can be used to impose a period of time in excess of the 10-year mandatory exclusion); or

(2) Permanent if the individual has been convicted on two or more other occasions of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act.

5. Section 1001.201 is amended by revising the heading and paragraph (b)(3)(iii)(A) to read as follows:

§ 1001.201 Conviction relating to program or health care fraud.

(b) Length of exclusion. * * *

(3) * * *

(iii) * * *

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

6. Section 1001.301 is amended by revising paragraphs (b)(2)(ii) to read as follows:

§ 1001.301 Conviction relating to obstruction of an investigation.

(b) * * *

(2) * * *

(ii) The interference or obstruction had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or on the Medicare, Medicaid or other Federal health care programs;

7. Section 1001.401 is amended by revising the heading and paragraph (c)(2)(ii) to read as follows:

§ 1001.401 Conviction relating to controlled substances.

(c) * * *

(2) * * *
 (ii) The acts that resulted in the conviction or similar acts had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or the Medicare, Medicaid or other Federal health care programs;

8. Section 1001.1001 is amended by revising paragraph (a)(1)(ii); and by amending paragraph (a)(2) by adding definitions for the terms *Immediate family member* and *Member of household* to read as follows:

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

(a) * * *
 (1) * * *
 (ii) Such a person—
 (A)(1) Has a direct or indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

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

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

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

(5) Is an agent of the entity; or

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

(B) Was formerly described in paragraph (a)(1)(ii)(A) of this section, but is no longer so described because of a transfer of ownership or control interest to an immediate family member or a member of the person's household as defined in paragraph (a)(2) of this section, in anticipation of or following a conviction, assessment of a CMP, or imposition of an exclusion.

(2) * * *

Immediate family member means, a person's husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild. * * *

Member of household means, with respect to a person, any individual with

whom they are sharing a common abode as part of a single family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.

* * * * *

9. Section 1001.1301 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 1001.1301 Failure to grant immediate access.

* * * * *

(b) * * *

(2) * * *

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

* * * * *

10. Section 1001.1401 is amended by revising paragraphs (b)(1) and (b)(4) to read as follows:

§ 1001.1401 Violations of PPS corrective action.

* * * * *

(b) * * *

(1) The impact of the hospital's failure to comply on Medicare, Medicaid or any of the other Federal health care programs, program beneficiaries or other individuals;

* * * * *

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

* * * * *

11. Section 1001.1501 is amended by revising paragraph (a)(3) to read as follows:

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) * * *

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

* * * * *

12. Section 1001.1901 is amended by revising paragraphs (a), (b)(1), (c)(3) introductory text and (c)(5)(i) to read as follows:

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in § 1001.2.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is

reinstated into the Medicare, Medicaid and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, Medicaid or any of the 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 person 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.

* * * * *

(c) * * *

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

* * * * *

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

* * * * *

13. Section 1001.3002 is amended by republishing introductory paragraph (b) introductory text, revising paragraphs (b)(3) and (b)(4); adding new paragraph (b)(6); and by revising paragraph (c)(1) to read as follows:

§ 1001.3002 Basis for reinstatement.

* * * * *

(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 obligations;

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

* * * * *

(6) Whether the individual or entity has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by any Federal health care program, for items or services the excluded party furnished, ordered or prescribed, including health care administrative services.

(c) * * *

(1) Has properly reduced his or her ownership or control interest in the entity below 5 percent;

* * * * *

14. Section 1001.3003 is revised to read as follows:

§ 1001.3003 Approval of request for reinstatement.

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

(1) Give written notice to the excluded individual or entity specifying the date of reinstatement;

(2) Notify HCFA of the date of the individual's or entity's reinstatement;

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

(4) To the extent applicable, give notice to others that were originally notified of the exclusion.

(b) A determination by the OIG to reinstate an individual or entity has no effect if a Federal health care program has imposed a longer period of exclusion under its own authorities.

15. Section 1001.3005 is amended by revising paragraphs (a) introductory text, (b) and (d) to read as follows:

§ 1001.3005 Reversed or vacated decisions.

(a) An individual or entity will be reinstated into Medicare, Medicaid and other Federal health care programs retroactive to the effective date of the exclusion when such exclusion is based on—

* * * * *

(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, HCFA and other Federal health care programs will make payment for services covered under

such program that were furnished or performed during the period of exclusion.

* * * * *

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

PART 1002—[AMENDED]

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 1002.2 is amended by revising paragraph (a) to read as follows:

§ 1002.2 General authority.

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

* * * * *

PART 1003—[AMENDED]

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

Authority: 42 U.S.C. 1302, 1320-7, 1320a-7a, 1320a-7e, 1320b-10, 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2).

2. Section 1003.100 is amended by revising paragraphs (a) and (b)(1)(iv), (viii), (x) and (xi) and adding paragraph (b)(1)(xii) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1128E, 1140, 1876(i)(6), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Public Law 99-660 (42 U.S.C. 1320a-7, 1320a-7a, 1320a-7e, 1320a-7(c), 1320b(10), 1395mm, 1395ss(d), 1396(m), 11131(c) and 11137(b)(2)).

(b) * * *

(1) * * *

(iv)(A) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99-660, and regulations specified in 45 CFR part 60, or

(B) Are health plans and fail to report information concerning sanctions or

other adverse actions imposed on providers as required to be reported to the Healthcare Integrity and Protection Data Bank (HIPDB) in accordance with section 1128E of the Act;

* * * * *

(viii) Have submitted, or caused to be submitted, certain prohibited claims, including claims for services rendered by excluded individuals employed by or otherwise under contract with such person, under one or more Federal health care programs;

* * * * *

(x) Have collected amounts that they know or should know were billed in violation of § 411.353 of this title and have not refunded the amounts collected on a timely basis;

(xi) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity which, if made directly, would violate the provisions of § 411.353 of this title; or

(xii) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act.

* * * * *

3. Section 1003.102 is amended by revising paragraphs (a)(2) and (b)(5); and by adding a new paragraph (b)(11) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

(a) * * *

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent, including a claim for any item or service furnished by an excluded individual employed by or otherwise under contract with that person;

* * * * *

(b) * * *

(5) Fails to report information concerning—

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

(ii) An adverse action required to be reported to the Healthcare Integrity and Protection Data Bank as established by section 221 of Public Law 104-191 and set forth in section 1128E of the Act.

* * * * *

(11) Has violated section 1128B of the Act by unlawfully offering, paying, soliciting or receiving remuneration in return for the referral of business paid for by Medicare, Medicaid or other Federal health care programs.

* * * * *

4. Section 1003.103 is amended by revising paragraph (a); and by adding new paragraphs (g) and (h) to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) and (d) through (h) of this section, the OIG may impose a penalty of not more than \$10,000 for each item or service that is subject to a determination under § 1003.102.

* * * * *

(g) The OIG may impose a penalty of not more than \$25,000 against a health plan for failing to report information on an adverse action required to be reported to the Healthcare Integrity and Protection Data Bank in accordance with section 1128E of the Act and § 1003.102(b)(5)(ii).

(h) For each violation of § 1003.102(b)(11), the OIG may impose—

(1) A penalty of not more than \$50,000, and

(2) An assessment of up to three times the total amount of remuneration offered, paid, solicited or received, as specified in § 1003.104(b).

5. Section 1003.104 is revised to read as follows:

§ 1003.104 Amount of assessment.

(a) The OIG may impose an assessment, where authorized, in accordance with § 1003.102 (except for § 1003.102(b)(11)), of not more than three times the amount claimed for each item or service which was a basis for the penalty. The assessment is in lieu of damages sustained by the Department or a State because of that claim.

(b) In accordance with § 1003.102(b)(11), the OIG may impose an assessment of not more than three times the total amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose.

6. Section 1003.105 is amended by revising the section heading, paragraph (a)(1) introductory text and paragraph (b)(1) to read as follows:

§ 1003.105 Exclusion from participation in Medicare, Medicaid and other Federal health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, in lieu of or in

addition to any penalty or assessment, the OIG may exclude from participation in Medicare, Medicaid and other Federal health care programs the following persons for a period of time determined under § 1003.107—

* * * * *

(b)(1)(i) With respect to determinations under § 1003.102(b)(2) or (b)(3), a physician may not be excluded if the OIG determines that he or she is the sole community physician or the sole source of essential specialized services in a community.

(ii) With respect to determinations under § 1003.102(b)(5)(ii), no exclusion shall be imposed.

* * * * *

7. Section 1003.106 is amended by redesignating paragraph (a)(1)(vii) as paragraph (a)(1)(ix); by adding new paragraphs (a)(1)(vii) and (a)(1)(viii); and by revising paragraphs (a)(1)(ii), (a)(1)(iii), (a)(1)(vi), (a)(2)(i), (a)(2)(ii) and (a)(2)(iii) to read as follows:

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

(a) * * *

(1) * * *

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

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

* * * * *

(vi) The amount of financial interest involved with respect to § 1003.102(b)(10);

(vii) Whether the contracting provider actually knew of the exclusion when employing or otherwise contracting with an excluded individual or entity in accordance with § 1003.102(a)(2);

(viii) The harm to patients or any Federal or State health care program which resulted or could have resulted from the provision of care by a person or entity with which the contracting provider is expressly prohibited from contracting under section 1128A(a)(6) of the Act; and

(ix) * * *

(2) * * *

(i) The nature and circumstances of the failure to properly report information, or the improper disclosure of information, as required;

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

(iii) The materiality, or significance of omission, of the information to be

reported, or the materiality of the improper disclosure of, or use of, or access to information, as appropriate;

* * * * *

8. Section 1003.109 is amended by revising paragraph (a) introductory text and paragraph (a)(3) to read as follows:

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in Medicare, Medicaid and any other Federal health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent, written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

* * * * *

(3) The reason why such claims, requests for payments or incidents subject the respondent to a penalty, assessment and exclusion;

* * * * *

9. Section 1003.114 is amended by revising paragraph (a) to read as follows:

§ 1003.114 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability under § 1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

* * * * *

Dated: February 4, 1999.

June Gibbs Brown,
Inspector General.

Approved: April 8, 1999.

Donna E. Shalala,
Secretary.

[FR Doc. 99-18515 Filed 7-21-99; 8:45 am]

BILLING CODE 4150-04-P

DEPARTMENT OF DEFENSE

48 CFR Part 201

[DFARS Case 98-D024]

Defense Federal Acquisition Regulation Supplement; Electronic Publication of DFARS

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Director of Defense Procurement has issued a final rule amending the Defense Federal