

aggregate, or to the private sector. The CAA provision discussed in this notice requires states to submit SIPs. This notice merely provides a finding that California has not met that requirement. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

EPA believes that VCS are inapplicable to today's action because it does not require the public to perform activities conducive to the use of VCS.

I. Submission to Congress and the Comptroller General

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. 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a "major" rule as defined by 5 U.S.C. 804(2).

J. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 17, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Particulate matter, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: February 28, 2002.

Wayne Nastri,

Regional Administrator, Region IX.

[FR Doc. 02-6270 Filed 3-15-02; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001, 1003, 1005 and 1008

RIN 0991-AB09

Medicare and Federal Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections

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

ACTION: Final rule.

SUMMARY: This final rule sets forth several revisions and technical corrections to the OIG regulations pertaining to fraud and abuse in Federal health care programs. This rule contains revisions and clarifications with respect to the definition of the term "item or service," the reinstatement procedures relating to exclusions resulting from a default on health education or scholarship obligations, the factors considered in determining civil money penalty amounts for patient dumping violations, and several other matters. In addition, this rule makes a number of minor technical corrections to the current regulations in order to clarify various issues and inadvertent errors appearing in the OIG's existing regulatory authorities.

EFFECTIVE DATE: These regulations are effective on April 17, 2002.

FOR FURTHER INFORMATION CONTACT: Joel J. Schaer, Office of Counsel to the Inspector General, (202) 619-0089.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Inspector General's (OIG's) exclusion authorities are intended to protect the Federal health care programs and their beneficiaries from untrustworthy health care providers, i.e., individuals and entities whose behavior has demonstrated that they pose a risk to program beneficiaries or to the integrity of these programs.

These authorities encompass both mandatory exclusions (section 1128(a) of the Social Security Act (the Act)) and permissive exclusions (section 1128(b) of the Act). The *mandatory* exclusion authorities require the OIG to exclude from program participation any individual or entity convicted of a "program-related" crime; patient abuse or neglect; or certain felonies related to health care delivery, governmental health care programs or controlled substances. Mandatory exclusions must be imposed for a minimum 5-year period. The *permissive* authorities do not require the imposition of an exclusion, and may either be (1) "derivative" exclusions that are based on actions previously taken by a court or other law enforcement or regulatory agencies, or (2) "non-derivative" exclusions that are based on OIG-initiated determinations of misconduct, e.g., poor quality care or submission of false claims for Medicare or Medicaid payment. With certain exceptions, there are no specified minimum periods of exclusion under these permissive authorities.

In addition, as an administrative remedy to remedy health care fraud and abuse, section 1128A of the Act allows the OIG to seek civil money penalties (CMPs), assessments and exclusions against those engaged in filing false claims (and certain other offenses) against the Department's programs and beneficiaries. Since enactment in 1981, the CMP provisions have been expanded to apply to numerous types of fraud and abuse activities related to Medicare and other Federal health care programs. Providers who may be subject to any of the OIG's administrative sanctions have full due process rights, including administrative hearings and appeals to the Federal courts.

On October 20, 2000, the OIG published a proposed rule in the **Federal Register** (65 FR 63035) that proposed several revisions and technical corrections to the OIG regulations codified in 42 CFR chapter V.

II. Summary of the Proposed Rule, Response to Public Comments and Provisions of the Final Rule

In response to the proposed rule, the OIG received a total of 6 timely-filed public comments from organizations, associations and other interested parties. Set forth below is a brief explanation of the intended revisions set forth in the proposed rule, a summary of the comments received and a response to those concerns, and a description of the final changes and

clarifications being made to 42 CFR chapter V as a result of this final rule.

A. Limitations Period for Exclusions

Proposed change: In response to questions raised as to whether a limitations period is applicable to the imposition of OIG program exclusions, the OIG proposed to clarify § 1001.1 to clarify that there is no time limitation on the imposition of a program exclusion. In *Wesley J. Hammer v. IG*, DAB 1693 (1999), the Departmental Appeals Board ruled that exclusion under section 1128(b)(7) of the Act, where such exclusion is based on an act which is described in section 1128A of the Act, is subject to the 6 year statute of limitations contained in section 1128A.

Comment/Response: The proposed rule stated that there would be no time limitation on the OIG's imposition of a program exclusion since no statute of limitations is specified in the Act with respect to exclusions under section 1128, and program exclusions are remedial in nature. Two commenters questioned this interpretation. The commenters suggested that if a program exclusion is based on the Secretary's determination that there has been a violation of another statute, the program exclusion action should be subject to the same limitations period that would apply to an action taken under the other statute. If not, the commenters believed that an individual or entity could be excluded for activities that occurred years before and that do not bear on their current trustworthiness or integrity. In addition, the commenters expressed concern that after the passage of significant time, evidence becomes difficult or impossible to gather and thus there is a need for a statute of limitations with respect to the imposition of program exclusions.

The comments raise concerns about exclusions under section 1128(b)(7) of the Act, the only exclusion authority that is based upon the Secretary's determination that there was an act committed that is a violation of another statute.¹ Based on the concerns raised by the commenters, the OIG has chosen not to finalize the proposed revision, but to leave the current regulation unchanged.

B. Actual Versus Reasonably Expected Loss

Proposed change: With regard to financial loss and threshold amounts with respect to exclusion actions, we

proposed to revise §§ 1001.102(b)(1) and 1001.201(b)(2)(i) to increase the financial loss considered to be an aggravating factor from \$1,500 to \$5,000 to more properly reflect the current health care economy and establish a more reasonable threshold amount as a basis for lengthening a period of exclusion, and to reflect as an aggravating factor both the actual and intended loss to the programs associated with the conduct of the sanctioned individual or entity. The OIG received two public comments on this proposed revision.

Comment: Commenters objected to allowing "intended loss" to be considered as an aggravating factor, asserting that the concept of intent is subjective and allows for speculation and difficulty in questions of proof and defense. They indicated that while an objective approach is used to determine whether an actual loss has occurred, it is subjective to determine whether an individual or entity intended to cause a loss when no actual loss has occurred. One commenter indicated that an internal OIG decision should not carry the same weight as a decision that was adjudicated by a third party. Because the OIG would be able to consider "intended losses" based on "similar acts not adjudicated," commenters believed the OIG would have significant latitude to give weight to "unsubstantiated allegations, charges supported by inadmissible evidence, statements that have not been subject to cross-examination * * *" that would not be supported by the judicial process.

Response: We have clarified and amended the proposed change to this section to provide that the OIG will consider acts "that caused, or reasonably could have been expected to cause, a financial loss. * * *" The purpose of this provision is to consider the magnitude of the individual or entity's conduct when determining the appropriate length of exclusion. The trustworthiness of an individual or entity relates to the amount of loss their conduct reasonably could have been expected to cause, regardless of whether the conduct was discovered before or after the payment was made. For example, the fact that a Medicare contractor detected a false claim prior to payment, and therefore no loss was incurred by the program, does not reduce the culpability and untrustworthiness of those responsible for the submission of the false claim.

The OIG intends to consider "reasonably expected loss" only in those situations where there is adequate reliable evidence to discern the amounts that would have been paid as a result of

the individual's or entity's false claim or other improper conduct had the conduct not been detected prior to the payment of the claims.

Comment: Regarding the proposed increase of the threshold amount for an aggravating factor to \$5,000 (from \$1,500), one commenter asked whether the \$5,000 amount would also apply to intended loss as well as to actual loss. The commenter also questioned whether the higher threshold amount would mean that prosecution would not be pursued if the loss is less than \$5,000.

Response: We will consider the total reasonably expected loss in assessing whether this \$5,000 threshold has been met for the purpose of determining the length of exclusion. This threshold is only relevant to determine the length of exclusion and has no relationship with a prosecutor's decision or whether to pursue certain cases.

Final rule revision: We are revising the language in §§ 1001.102(b)(1) and 1001.201(b)(2)(i) to indicate that among the factors that may be considered to be aggravating and a basis for lengthening the period of exclusion are acts resulting in the conviction, or similar acts, "that caused, or reasonably could have been expected to cause, a financial loss" to a Government program or to one or more entities of \$5,000 or more.

C. Expansion of the Scope of Exclusion to "all Federal Health Care Programs"

Proposed change: Section 4331(c) of the Balanced Budget Act (BBA) of 1997 extended the scope of all OIG exclusions beyond Medicare and State health care programs to all Federal health care programs. While several revisions to implement this expansion were made to the OIG exclusion regulations in the final rulemaking addressing BBA (July 22, 1999; 64 FR 39420), conforming revisions were not made in §§ 1001.102(c), 1001.951 and 1001.952. We proposed to amend these regulatory sections to accurately reflect this expanded authority. The OIG received no public comments on this proposed change.

Final rule revision: We are revising §§ 1001.102(c), 1001.951 and 1001.952 to accurately reflect the scope of an OIG exclusion beyond the Medicare and State health care programs to all other Federal health care programs.

D. Clarification on Length of Exclusion in § 1001.102(b)(9)

Proposed change: The OIG proposed a minor technical change in § 1001.102 that would have involved inserting the word "even" before the limiting clause "if the adverse action is based on the

¹ Section 1128(b)(7) provides the authority to permissively exclude an individual or entity for fraud, kickbacks or other prohibited activities.

same * * *” in existing paragraph (b)(9) of this section.

Comment: One commenter believed that the effect of this change would be that the exclusion period could be lengthened based on an adverse action, whether or not the action served as the basis of the imposition of the exclusion.

Response: Upon further review, the OIG has decided not to make this change to § 1001.102(b)(9).

E. Discount Safe Harbor

Proposed change: We proposed several clarifying wording changes in the safe harbor discount provision, set forth in § 1001.952(h), to be consistent with similar context language used in the same paragraph, and clarifying the definition of the term “rebate” in paragraph (h)(4) of this section to make clear that a rebate is a price reduction after the time of sale.

Comment/Response: We received several comments regarding these proposed revisions and clarifications to § 1001.952(h) and other technical corrections to our other safe harbor regulations. The OIG is continuing to evaluate these comments and plans to address specific changes to § 1001.952 at a future date through separate rulemaking.

Final rule revision: As indicated above in section II.C., at this time we are only revising those portions of § 1001.952 to correct technical errors appearing in the regulations text to extend the scope of any OIG exclusion beyond the Medicare and State health care programs to all other Federal health care programs.

F. Reinstatement of Individuals as a Result of an Exclusion Based on Default of Health Education Loan or Scholarship Obligations

Proposed change: The current regulation at § 1001.1501 provides that an individual will be excluded until the Public Health Service (PHS) notifies the OIG that the obligations have been resolved to the PHS’s satisfaction. Because the regulatory language is unclear as to exactly when a determination may be made that a default is cured or that the financial obligations have been adequately resolved, the proposed rule provided for exclusion “until such time as PHS notifies the OIG that . . . there is no longer an outstanding debt.” Specifically, we proposed to revise paragraph (b) of this section to clarify that once an individual is excluded, he or she will be reinstated only (1) after the debt is repaid by the individual, or (2) where there is no longer an

outstanding debt as determined by the PHS (e.g., the debt has been written off).

Comment: One commenter believed it was unclear what effect the changing of “right to request reinstatement” in the current rule to “right to apply for reinstatement” in the proposed rule will be. The commenter requested that any revision should minimize the administrative delay in reinstating such individuals once the PHS has concluded that there is no longer an outstanding debt.

Response: This is a minor revision concerning internal communications between PHS and the OIG that will cause no administrative delays in allowing individuals eligible to apply for reinstatement. All individuals who have been excluded under this authority must formally apply for such reinstatement in accordance with the procedures that are set forth in their exclusion letter and the applicable regulations.

Final rule revision: We are clarifying and revising § 1001.1501 to indicate that, with respect to an exclusion resulting from the default of a health education loan or scholarship obligations, an individual will be excluded until such time as PHS notifies the OIG that the default has been cured or that there is no longer an outstanding debt, and upon such notice, the OIG will inform the individual of his or her right to apply for reinstatement.

G. Waivers of Exclusions

Proposed change: We proposed to amend § 1001.1801 to permit any Federal health care program to request the waiver of an exclusion. This amendment was designed to conform the waiver provisions of section 1128 of the Act to statutory amendments that broadened the scope of an OIG program exclusion to all Federal health care programs.

Response: While the OIG received no public comments on this proposed change, we have determined that this revision would be more appropriately addressed through the legislative process. Although Congress expanded the OIG’s exclusion authority in the Health Insurance Portability and Accountability Act (Pub. L. 104–191) to all “Federal health care programs,” it did not make a corresponding change to the statutory waiver for exclusions (sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act), i.e., only States are authorized to request such waivers. We now believe that legislative action, rather than a regulatory change, is necessary to address this issue.

H. Collateral Estoppel and Appeal of Exclusions

Proposed change: Section 1001.2007 has contained a provision that precludes the relitigation of the underlying determination in the administrative appeal of exclusions. We proposed to clarify in this section that a civil judgment rendered by a Federal, State or local court is an additional type of prior determination that may be given collateral estoppel effect in an exclusion action, and may not be relitigated in the exclusion proceeding. The OIG received no public comments on this proposed change.

Final rule revision: We are revising § 1001.2007(d) consistent with the language set forth in the earlier proposed rule.

I. Reversed or Vacated Decisions

Proposed change: With respect to appeals of exclusions, § 1001.3005 does not specify at what point in the appeal process reinstatement will occur where an OIG action is reversed or vacated on appeal. We proposed to amend this section to provide that when an exclusion action is reversed or vacated at any stage of an administrative appeal process, the OIG will reinstate the individual or entity at that time retroactive to the effective date of the underlying exclusion. The OIG received no public comments on this proposed change.

Final rule revision: We are amending § 1001.3005, Reversed or vacated decisions, by revising paragraph (a) and adding a new paragraph (e) to specify at what point in the appeal process retroactive reinstatement will occur.

J. Definition for “Item or Service”

Proposed change: To reflect the varying reimbursement systems and mechanisms in place, we proposed to modify the definition of the term “item or service” in § 1003.101 to clarify that, in addition to itemized claims or cost reports, the term also includes any item or service that is reimbursed through any health care payment mechanism, such as a prospective payment system. The OIG received no public comments on this revised definition.

Final rule revision: The OIG is adopting the change as proposed.

K. Calculation of Penalty Amount for Patient Dumping Violations

Proposed change: The existing language in § 1003.106(a)(4) allows the OIG to take into account a “prior history of offenses” with respect to patient dumping in determining the amount of CMP imposed for a patient dumping violation. We proposed an amendment

to § 1003.106(a)(4)(iii) that would allow the OIG and the administrative law judge (ALJ) to consider other “instances”—and not just “offenses”—regardless of when they occurred, that is, not just “prior to” the matter conduct upon which the CMP action is based.

Comment: Commenters expressed the view that CMP amounts in patient dumping cases should be based only on judgments and other actions which have been adjudicated, such as convictions or administrative sanctions. The commenters believed that allowing the OIG the authority to “bypass” courts and the administrative appeals process would penalize physicians for alleged behavior that has not been ruled upon by a court or an ALJ. One commenter stated that in determining CMP amounts under this provision, the OIG should only be allowed to cite subsequent offenses to the same extent that the OIG now considers prior offenses. Without such limitation, the commenter believed that physicians’ due process rights would be violated since they would not be able to contest the underlying alleged behavior.

Response: In assessing the appropriate CMP amount in a dumping case, we continue to believe that it is appropriate to include matters which occurred after the events that resulted in the OIG’s issuance of a letter to a provider proposing a CMP. Specifically, with respect to the provider’s “prior history,” we have found instances, which may occur several years later between the time of the initial event and the initiation of litigation, where a provider has committed other acts similar in nature to the violation that is the basis for the proposed CMP. The OIG believes that those other similar acts should be considered so that an appropriate CMP can be determined and assessed. By considering not just “prior history” as a factor, an appropriate penalty may be higher, for example, for a party with multiple instances of problematic conduct, as compared to a party who has only one such instance.

With respect to amending the current reference of “offenses” to “instances,” we believe that the current term restricts consideration of incidents that are relevant to the provider’s culpability but have not resulted in convictions, or judicial or administrative decisions. Because these prior similar incidents generally become known during the administrative appeals process, we believe that the term “offenses” is too limiting, and that the revision in the regulations will allow the OIG and the ALJs a broader range of conduct and options to consider in their determinations. The primary concerns

expressed by the commenter do not apply because the ALJ will be able to fully evaluate all evidence in the record in deciding the amount of a CMP and give appropriate weight to such evidence. When the OIG is able to consider subsequent instances of conduct by the provider, the ALJ, Departmental Appeals Board and the courts will still remain free to accept or reject this additional information and evidence in determining an appropriate CMP amount.

Final rule revision: We are amending § 1003.106 by adding a new paragraph (a)(4)(iii) to include as a factor in determining the amount of penalty for patient dumping violations any other instances where the respondent failed to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital’s emergency department, or to effect an appropriate transfer.

L. Time Frames Governing the Discovery Process

Proposed change: To ensure that the hearing process proceeds in an orderly and timely manner, and to allow parties a reasonable period of time to produce requested documents or object to a request, we proposed to expand the specified time frames set forth in § 1005.7(e)(1) from the current 15 days to 30 days. The OIG received no public comments on this proposed change.

Final rule revision: We are revising § 1005.7(e)(1) to expand the specified time frames governing the discovery process to 30 days.

M. Written Testimony of Experts

Proposed change: We proposed to amend § 1005.16 to give the ALJs discretion to admit prior written sworn expert testimony that has been subject to cross-examination. The OIG received no public comments on this proposed revision.

Final rule revision: We are revising paragraph (b) of § 1005.16, Witnesses, to specifically state that the ALJ may, at his or her discretion, admit prior sworn testimony of experts which has been subject to adverse examination, such as a deposition or trial testimony.

N. Admissibility of Evidence in Administrative Proceedings

Proposed change: In order to protect the credibility of witnesses from being inappropriately attacked through the introduction of evidence regarding bad character, we proposed to amend § 1005.17, Evidence, to require adherence to Rule 608 of the Federal Rules of Evidence (FRE) in administrative proceedings.

Response: While the OIG received no public comments on this proposed change, there is a concern that requiring ALJs to apply specific evidentiary rules in an administrative hearing would unnecessarily restrict the evidence the ALJ may consider. The OIG will continue to evaluate the scope of this amendment, and has chosen not to finalize the proposed revision to § 1005.17 at this time.

O. Additional Technical Revisions

Proposed changes: Minor technical errors in §§ 1003.100 and 1008.37 were also proposed for correction in the proposed rule. The OIG received no public comments on this proposed change.

Final rule revisions: We are making technical revisions to § 1003.100(b) to properly reflect the basis and purpose of the OIG’s CMP and assessment authorities that were set forth in two different OIG rulemakings. Specifically, we are amending § 1003.100 by revising paragraphs (b)(1)(iv), (b)(1)(xii) and (b)(1)(xiii), and by adding paragraphs (b)(1)(xiv) and (b)(1)(xv) to accurately reflect the range of existing CMP and assessment authorities delegated to the OIG. In addition, we are correcting a typographical error appearing for a United States Code citation which appears in § 1008.37, as indicated in the proposed rule.

III. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980; Public Law 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any given year).

This is not a major rule as defined at 5 U.S.C. 804 (2), and it is not economically significant since it will not have a significant effect on program expenditures and there are no additional substantive costs to implement the resulting provisions. The revisions in this rule are either technical in nature or are designed to further

clarify OIG statutory requirements. Specifically, these provisions are intended to clarify the scope of the OIG's existing authorities to exclude individuals and entities from Medicare, Medicaid and all other Federal health care programs, and to strengthen current legal authorities pertaining to the imposition of CMPs against individuals and entities engaged in prohibited actions and activities. We believe that any aggregate economic effect of these revised regulatory provisions will be minimal and will impact only those limited few who engage in prohibited behavior in violation of the statute. As such, we believe that the aggregate economic impact of these final regulations is minimal and would have no appreciable effect on the economy or on Federal or State expenditures.

The RFA, and the Small Business Regulatory Enforcement and Fairness Act of 1996 which amended the RFA, requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies. Most hospitals (and most other providers) are considered to be small entities, either by nonprofit status or by having revenues of \$5 million to \$25 million or less in any 1 year. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural providers. This analysis must conform to the provisions of section 604 of the RFA. While these provisions may have some impact on small entities and rural providers, we believe that the aggregate economic impact of this rulemaking will be minimal since it is the nature of the conduct and not the size or type of the entity that will result in a violation of the statute and the regulations. As a result, this rule should not have a significant impact on a substantial number of small entities, or a significant impact on the operations of a substantial number of small rural providers.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local or tribal Governments, in the aggregate, or by the private sector, of \$110 million. We believe that there are no significant costs associated with these revisions that would impose any mandates on State, local or tribal governments, or the

private sector that will result in an expenditure of \$110 million or more (adjusted for inflation) in any given year.

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirements costs on State and local Governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this rule will not significantly effect the rights, roles and responsibilities of States or local Governments. The Office of Management and Budget has reviewed this rule in accordance with Executive Order 12866. In *Paperwork Reduction Act*—The provisions of these 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 1003

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

42 CFR Part 1005

Administrative practice and procedure, Fraud, Penalties.

42 CFR Part 1008

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

Accordingly, 42 CFR chapter V 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 1001.101 is amended by republishing the introductory text and by revising paragraph (c), introductory text, to read as follows:

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

* * * * *

(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 financial misconduct—

* * * * *

3. Section 1001.102 is amended by republishing the introductory text for paragraph (b) and revising paragraph (b)(1), and by republishing the introductory text for paragraph (c) and revising paragraph (c)(1) 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, that caused, or were intended to cause, a financial loss to a Government program or to one or more entities of \$5,000 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);

* * * * *

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

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss (both actual loss and intended loss) to Medicare or any other Federal, State or local governmental health care program due to the acts that resulted in the conviction, and similar acts, is less than \$1,500;

* * * * *

4. Section 1001.201 is amended by republishing the introductory text for paragraphs (b) and (b)(2) and revising paragraph (b)(2)(i), and by republishing the introductory text for paragraph (b)(3) and revising paragraph (b)(3)(i) to read as follows:

§ 1001.201 Conviction relating to program or health care fraud.

* * * * *

(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—

(i) The acts resulting in the conviction, or similar acts that caused,

or reasonably could have been expected to cause, a financial loss of \$5,000 or more to a Government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals. (The total amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made);

* * * * *

(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 (both actual loss and reasonably expected 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 **\$1,5000**;

* * * * *

5. Section 1001.951 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 1001.951 Fraud and kickbacks and other prohibited activities.

* * * * *

(b) * * *
(1) * * *

(ii) The nature and extent of any adverse physical, mental, financial or other impact the conduct had on program beneficiaries or other individuals or the Medicare, Medicaid and all other Federal health care programs;

* * * * *

6. Section 1001.952 is amended as follows:

- a. By republishing the introductory text;
- b. Republishing the introductory text to paragraph (b), revising paragraph (b)(5), removing the undesignated paragraph following paragraph (b)(6), and adding a sentence at the end of paragraph (b)(6);
- c. Republishing the introductory text to paragraph (c), revising paragraph (c)(5), removing the undesignated paragraph following paragraph (c)(6), and adding a sentence at the end of paragraph (c)(6);
- d. Republishing the introductory text to paragraph (d) and revising paragraph (d)(5);
- e. Republishing introductory text to paragraph (e)(1) and revising paragraph (e)(1)(ii);
- f. Republishing introductory text to paragraph (e)(2) and revising paragraph (e)(2)(ii);
- g. Republishing introductory text to paragraph (f) and revising paragraph (f)(2);

h. Revising introductory text to paragraph (h); introductory text to paragraph (h)(1) and introductory text to paragraph (h)(1)(iii); introductory text to paragraph (h)(2); introductory text to paragraph (h)(3) and introductory text to paragraph (h)(3)(iii); and paragraph (h)(5)(iii);

i. Revising paragraph (i);
j. Republishing the introductory text to paragraph (j), adding a sentence at the end of paragraph (j)(2), and removing the undesignated paragraph following paragraph (j)(2);

k. Republishing introductory text to paragraph (n) and revising paragraph (n)(6);

l. Republishing introductory text to paragraph (o) and revising paragraph (o)(5); and

m. Revising introductory text for paragraph (s).

The revisions to § 1001.952 read as follows:

§ 1001.952 Exceptions.

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

* * * * *

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

* * * * *

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

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

* * * * *

(c) *Equipment rental.* As used in section 1128B of the Act, “remuneration” does not include any

payment made by a lessee or equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met—

* * * * *

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

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

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

* * * * *

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

* * * * *

(e) *Sale of practice.* (1) As used in section 1128B of the Act, “remuneration” does not include any payment made to a practitioner by another practitioner where the former practice is selling his or her practice to the latter practitioner, as long as the following two standards are met—

* * * * *

(ii) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in

part under Medicare, Medicaid or other Federal health care programs after 1 year from the date of the first agreement pertaining to the sale.

(2) As used in section 1128B of the Act, "remuneration" does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met—

* * * * *

(ii) The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made under Medicare, Medicaid or other Federal health care programs.

* * * * *

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

* * * * *

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

* * * * *

(h) *Discounts.* As used in section 1128B of the Act, "remuneration" does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section.

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable

standards within one of the three following categories—

* * * * *

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—

* * * * *

(2) The seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within one of the following three categories—

* * * * *

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs. The offeror must comply with all of the applicable standards within the following three categories—

* * * * *

(iii) If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the offeror must comply with the following two standards—

* * * * *

(5) * * *

(iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;

* * * * *

(i) *Employees.* As used in section 1128B of the Act, "remuneration" does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For

purposes of paragraph (i) of this section, the term *employee* has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

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

* * * * *

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

* * * * *

(n) *Practitioner recruitment.* As used in section 1128B of the Act, "remuneration" does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than 1 year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her specialty area, as defined in Departmental regulations, that is served by the entity, as long as all of the following nine standards are met—

* * * * *

(6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

* * * * *

(o) *Obstetrical malpractice insurance subsidies.* As used in section 1128B of the Act, "remuneration" does not include any payment made by a hospital or other entity that is providing malpractice insurance (including a self-funded entity), where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined in section

1861(gg) of the Act) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as all of the following seven standards are met—

* * * * *

(5) The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

* * * * *

(s) *Referral arrangements for specialty services.* As used in section 1128B of the Act, “remuneration” does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part under Medicare, Medicaid or any other Federal health care programs in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the following four standards are met—

* * * * *

7. Section 1001.1501 is amended by revising paragraph (b) to read as follows:

§ 1001.1501 Default of health education loan or scholarship obligations.

* * * * *

(b) *Length of exclusion.* The individual will be excluded until such time as PHS notifies the OIG that the default has been cured or that there is no longer an outstanding debt. Upon such notice, the OIG will inform the individual of his or her right to apply for reinstatement.

8. Section 1001.2007 is amended by revising paragraph (d) to read as follows:

§ 1001.2007 Appeal of exclusions.

* * * * *

(d) When the exclusion is based on the existence of a criminal conviction or a civil judgment imposing liability by Federal, State or local court, a determination by another Government agency, or any other prior determination where the facts were adjudicated and a final decision was made, the basis for the underlying conviction, civil judgment or determination is not reviewable and the individual or entity may not collaterally attack it either on substantive or procedural grounds in this appeal.

* * * * *

9. Section 1001.3005 is amended by revising paragraph (a) and by adding a new paragraph (e) 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—

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

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

(3) An OIG exclusion action that is reversed or vacated at any stage of an individual’s or entity’s administrative appeal process.

* * * * *

(e) If an action which results in the retroactive reinstatement of an individual or entity is subsequently overturned, the OIG may reimpose the exclusion for the initial period of time, less the period of time that was served prior to the reinstatement of the individual or entity.

PART 1003—[AMENDED]

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

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1320a–7e, 1320b–10, 1395u(j), 1395u(k), 1395cc(g), 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 (b)(1)(iv), (b)(1)(xii) and (b)(1)(xiii); and by adding paragraphs (b)(1)(xiv) and (b)(1)(xv) to read as follows:

§ 1003.100 Basis and purpose.

* * * * *

(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;

* * * * *

(xii) Offer inducements that they know or should know are likely to influence Medicare or State health care program beneficiaries to order or receive particular items or services;

(xiii) Are physicians who knowingly misrepresent that a Medicare beneficiary requires home health services;

(xiv) 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; or

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

* * * * *

3. Section 1003.101 is amended by republishing the introductory text and by revising the definition for the term *item or service* to read as follows:

§ 1003.101 Definitions.

For purposes of this part:

* * * * *

Item or service includes—

(a) any item, device, medical supply or service provided to a patient (i) which is listed in an itemized claim for program payment or a request for payment, or (ii) for which payment is included in other Federal or State health care reimbursement methods, such as a prospective payment system; and

(b) in the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

* * * * *

4. Section 1003.106 is amended by republishing the introductory text for paragraphs (a) and (a)(4) and by revising paragraphs (a) and (a)(4)(iii) to read as follows:

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

(a) *Amount of penalty.* * * *

(4) In determining the amount of any penalty in accordance with § 1003.102(c), the OIG takes into account—

(iii) Any other instances where the respondent failed to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital’s emergency department or to effect an appropriate transfer;

* * * * *

PART 1005—[AMENDED]

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 1005.7 is amended by revising paragraph (e)(1) to read as follows:

§ 1005.7 Discovery.

* * * * *

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request will either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part will be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. (The party receiving a request for production may also file a motion for protective order any time prior to the date the production is due.)

* * * * *

3. Section 1005.16 is amended by revising paragraph (b) to read as follows:

§ 1005.16 Witnesses.

* * * * *

(b) At the discretion of the ALJ, testimony (other than expert testimony) may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts which has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to all other parties along with the last known address of such witnesses, in a manner that allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing will be exchanged as provided in § 1005.8.

* * * * *

PART 1008—[AMENDED]

1. The authority citation for part 1008 continues to read as follows:

Authority: 42 U.S.C. 1320a-7d(b).

2. Section 1008.37 is revised to read as follows:

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social Security Act (42 U.S.C. 1320a-3(a)(1)) and part 420 of this chapter.

(Approved by the Office of Management and Budget under control number 0990-0213)

Dated: October 19, 2001.

Janet Rehnquist,
Inspector General.

Approved: November 23, 2001.

Tommy G. Thompson,
Secretary.

[FR Doc. 02-6350 Filed 3-15-02; 8:45 am]

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NATIONAL SCIENCE FOUNDATION

45 CFR Part 689

RIN 3145-AA39

Research Misconduct

AGENCY: National Science Foundation (NSF).

ACTION: Final rule.

SUMMARY: NSF is issuing a final rule that revises its existing misconduct in science and engineering regulations. These revisions implement the Federal Policy on Research Misconduct issued by the Executive Office of the President's Office of Science and Technology on December 6, 2000. They will enable NSF to continue to address allegations of research misconduct.

DATES: This rule is effective April 17, 2002.

FOR FURTHER INFORMATION CONTACT: Anita Eisenstadt, Office of the General Counsel, at 703-292-8060.

SUPPLEMENTARY INFORMATION: The Office of Science and Technology Policy issued a final Federal research misconduct policy on December 6, 2000 in 65 FR 76260-76264 ("the Federal policy"). The Federal policy consists of a definition of research misconduct and basic guidelines to help Federal agencies and Federally funded research institutions respond to allegations of research misconduct. The policy directs Federal agencies that support or conduct research to implement it within one year.

On January 25, 2002, NSF published a proposed rule to revise its existing misconduct regulations (45 CFR part 689) to make them fully consistent with the Federal policy. (67 FR 3666-3669). NSF invited public comment on the proposed rule. NSF received four comments that were supportive of the proposed rule.

Three of these commenters, however, expressed general concern for the protection of confidentiality of inquiries and investigations of alleged research misconduct. They suggested that NSF add language to the regulation that provides that to the extent permitted by

law, NSF will protect research misconduct investigative and adjudicative files as exempt from mandatory disclosure under the Freedom of Information Act and the Privacy Act. The commenters noted that this language is consistent with the Federal policy.

NSF stated in the preamble to the proposed rule that, consistent with the Federal policy, we would continue to protect research misconduct investigative and adjudicative files as exempt from mandatory disclosure under the Freedom of Information Act and the Privacy Act, to the extent permitted by law. (67 FR 3666). In response to these comments, we will include this language in § 689.2 of the final rule.

One of the commenters also expressed concern over the preponderance of evidence standard of proof for a finding of research misconduct. The commenter expressed concern that this standard will increase the risk of a false finding of research misconduct, and recommended a higher standard of proof such as "clear and convincing evidence" or "beyond a reasonable doubt."

The Federal policy adopted the preponderance of evidence standard. In the preamble to the Federal policy, OSTP noted that this is the uniform standard of proof for most civil fraud cases and most Federal administrative proceedings, including debarment. (65 FR 76262). Awardee institutions have the discretion to apply a higher standard of proof in their internal misconduct proceedings. However, if a higher standard is used, and the awardee institution wishes for NSF to defer to its investigation, the awardee institution should also evaluate whether the allegation is proven by a preponderance of evidence.

Determinations

The Office of Management and Budget has reviewed this final rule under Executive Order 12866. The rule is not an economically significant rule or a major rule under the Congressional Review Act. The Congressional Review Act provides that agencies shall submit a report, including a copy of all final rules, to each House of Congress and the Comptroller General of the United States. The Foundation will submit this report, identifying this rule as non-major, prior to the publication of this rule in the **Federal Register**.

The Unfunded Mandate Reform Act of 1995, in sections 202 and 205, requires that agencies prepare several analytic statements before proposing a rule that