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Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

Dated: October 13, 2000.

J. Charles Fox,

Assistant Administrator for Water.

[FR Doc. 00–27034 Filed 10–19–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001, 1003, 1005 and 1008

RIN 0991–AB09

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth several revisions and technical corrections to the OIG regulations. This rule proposes revisions or clarifications to the definition of the term ''item or service'', to the reinstatement procedures relating to exclusions resulting from a default on health education or scholarship obligations, and to the limitations period applicable to exclusions. In addition, this rule would make a number of minor technical corrections to the current regulations, and serves to clarify various issues and inadvertent errors appearing in the OIG's existing regulatory authorities in order to achieve greater clarity and consistency.

DATES: To assure consideration, public comments must be mailed and delivered to the address provided below by no later than 5 p.m. November 20, 2000.

ADDRESSES: Please mail or deliver your written comments to the following address: Department of Health and Human Services, Office of Inspector General, Room 5246, Attention: OIG–62–P, Washington, D.C. 20201.

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

SUPPLEMENTARY INFORMATION: Consistent with existing regulatory authority, the OIG is proposing the following revisions to 42 CFR chapter V, many of which are technical in nature:

• *Limitations Period for Exclusions; § 1001.1 (Scope of Exclusions).*

The purpose of an OIG program exclusion is to protect Medicare, Medicaid and all other Federal health care programs from fraud and abuse, and to protect beneficiaries of those programs from untrustworthy providers. Questions have been raised as to whether a limitations period is applicable to the imposition of OIG program exclusions. The OIG frequently determines that conduct which occurred several years in the past does not warrant an exclusion (other than an exclusion that is mandated by statute). However, there is no statute of limitations specified for exclusions in the Social Security Act (the Act).[1] Moreover, program exclusions are remedial in nature,[2] and it is the OIG's position that if we determine that an exclusion is necessary to protect the programs and beneficiaries from untrustworthy individuals and entities, we are authorized to impose such an exclusion without being subject to a limitations period. To eliminate any confusion on this point, we are clarifying § 1001.1 to indicate that there is no time limitation on the imposition of a program exclusion.

Thus, for example, when a program exclusion imposed under section 1128(b)(7) of the Act is based on violations of another statute, such as the civil money penalty (CMP) statute (section 1128A of the Act), which has a 6 year statute of limitations, the program exclusion is not similarly time limited.

• *Amendment to § 1001.101(c) (Basis for Liability)*

In introductory paragraph (c) of § 1001.101, we propose to add the word ''financial'' before the word ''misconduct.'' This revision would be consistent with the statutory language set forth in section 1128(a)(3) of the Act which specifically uses the word ''financial'' to describe the felony under which the OIG will exclude an individual or entity. The revision to this paragraph is intended to mirror the statutory language.

• *Revisions to §§ 1001.102 and 1001.201 With Respect to Financial Loss and the Threshold Amount*

Currently, §§ 1001.102 and 1001.201 set forth an aggravating factor for lengthening the period of exclusion when an individual's conviction, or similar acts, resulted in financial loss of $1,500 or more. First, we are proposing 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. We believe that this revision would more properly reflect the current economics of health care fraud in the programs and would establish a more reasonable threshold amount as an aggravating factor to be considered as a basis for lengthening a period of exclusion.

In addition, we are proposing to clarify §§ 1001.102(b)(1) and 1001.201(b)(2)(i) to reflect as an aggravating factor both the actual and intended loss to the programs associated with this conduct. We believe that any loss—not just the actual, out-of-pocket loss—that is designed to cause harm to the programs should be taken into consideration. For example, in a situation where an individual intends to commit damage to the programs by filing false cost reports, but whose plans are detected and prevented from reaching fruition by an intermediary who intercepts the damage before it can occur, we believe the intended loss, and not just any actual loss, should also be taken in consideration as a valid measure of the individual's culpability. Accordingly, we would also clarify §§ 1001.102(b)(1) and 1001.201(b)(2)(i)

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[1] See section 1128 of the Act; 42 U.S.C. 1320a–7.

[2] See *Manocchio* v. *Kusserow* (961 F.2d 1539 (11th Cir. 1992)), which held that exclusions are remedial.

to specifically indicate that any intended loss to the programs would be considered as an aggravating factor in assessing an individual's behavior and trustworthiness. Parallel changes to §§ 1001.102(c)(1) and 1001.201(b)(3)(i) would also be made.

In addition,

• *Clarification of Paragraph (b)(9) in § 1001.102 (Length of Exclusion)*

Section 1001.102 addresses the length of an exclusion, and paragraph (b) of that section sets forth various factors that may be considered to be aggravating and a basis for lengthening the period of exclusion. We propose to revise paragraph (b)(9) by adding the word ''even'' to indicate that one factor we would consider is ''[w]hether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by a Federal, State or local government agency or board, *even* if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion'' (underlining added). The inclusion of the word ''even'' was inadvertently omitted in the revisions to § 1001.102(b) that were set forth in the OIG final rulemaking issued on September 2, 1998 (63 FR 46676), addressing revised OIG exclusion authorities resulting from Public Law 104–191, and a subsequent revision set forth in final rulemaking issued on July 22, 1999 (64 FR 39420), addressing revised OIG sanction authorities resulting from Public Law 105–33.

• *Revisions to §§ 1001.102(c)(1), 1001.951 and 1001.952 To Encompass Acts Occurring With Respect to ''All Other Federal Health Care Programs''*

Section 231 of Public Law 104–191, the Health Insurance Portability and Accountability Act (HIPAA) of 1996, amended the CMP and criminal provisions in section 1128A and 1128B of the Act (42 U.S.C. 1320a–7a and 1320a–7b) to encompass acts occurring with respect to a ''Federal health care program,'' as defined in section 1128B(f) of the Act. Section 4331(c) of Public Law 105–33, the Balanced Budget Act (BBA) of 1997, further amended section 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 other Federal health care programs and to enable the OIG directly to impose exclusions from all other Federal health care programs. In the final regulations addressing OIG exclusion authorities resulting from HIPAA (63 FR 46676) and in the final rulemaking addressing revised OIG sanction authorities resulting from the BBA (64 FR 39420), while we made several revisions to part 1001 to include the term ''Federal health care program,'' conforming revisions were not made in §§ 1001.102(c)(1), 1001.951 and 1001.952. We propose to amend these sections to accurately reflect this expanded authority.

• *Additional Technical Revisions to § 1001.952*

On November 19, 1999, we published a final rule setting forth clarifications to the initial OIG safe harbor provisions in 1991 and establishing additional safe harbor provisions under the anti-kickback statute (64 FR 63518). In that final rule, certain minor technical errors appeared in the regulations text when published, which we are proposing to clarify or correct at this time. Specifically, in paragraph (h)(1)(ii), we are proposing to substitute the phrase ''Department or a State health care program,'' with the phrase ''Department or health agency,'' to be consistent with similar context language used in this same paragraph. (The italics appearing in introductory paragraph (h)(1) in the November 19, 1999 final rule would also be removed.) In addition, in paragraph (h)(2) (ii)(A), the current introductory phrase reads: ''[W]here a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, * * *'' We are proposing to clarify this discussion by amending this introductory statement to read as ''[W]here the value of the discount is known at the time of sale, * * *'' This would be consistent with the current introductory language appearing in paragraph (h)(2)(ii)(B) of § 1001.952. We are also clarifying the definition of the term ''rebate'' in § 1001.952(h)(4) to make clear that a rebate is a price reduction after the time of sale. We are further proposing to clarify the language in paragraph (h)(5)(ii) by including an example as to what is meant by the phrase ''same methodology'' as used in this discussion. The example is consistent with the November 19, 1999 final rule preamble discussion. The additional language would indicate that the ''same methodology'' would reflect, as an example, the same DRG, prospective payment or per diem payment, but would not include fee schedules. For clarification purposes, we are also proposing to include a comma after the word ''reflected'' in this same paragraph to make clear that the phrase ''where appropriate and as appropriate'' modifies both the terms ''disclosed'' and ''reflected.''

In addition, we are also proposing to clarify, gramatically, the introductory language for paragraph (r) to more clearly state the conditions under which ''remuneration'' does not include a payment that is a return on an investment interest for ambulatory surgical centers. Also, in paragraph (r)(2)(ii), we are proposing to substitute the word ''physician's'' for the word ''surgeon's,'' which was inadvertently set forth in the November 19, 1999 final regulations. As corrected, the paragraph would read as: ''(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures (as defined in this paragraph).''

With regard to § 1001.952, we are only requesting comments on the changes set forth specifically in this proposed rule. We expect to address other substantive revisions to aspects of the November 19, 1999 new safe harbors, as appropriate, through a separate clarifying proposed rule.

• *Revision to § 1001.1501 (Default of Health Education Loan or Scholarship Obligations)*

Under section 1128(b)(14) of the Act, and § 1001.1501 of the implementing regulations, the OIG may exclude any individual that the Public Health Service (PHS) determines is in default on repayment of scholarship obligations or loans made in connection with health profession education. The current regulations provide that an individual may be excluded until such time as PHS notifies the OIG that the default has been cured or the obligations have been resolved to the PHS's satisfaction. This regulatory language has resulted in some uncertainty as to exactly when a determination may be made that a default is cured or that the obligations have been adequately resolved.

We propose to revise § 1001.1501(b) to make it clear that once an individual is excluded, he or she will be eligible for reinstatement only (1) after the debt is repaid by the individual or (2) when there is no longer an outstanding debt as determined by the PHS (*e.g.,* the debt has been written off). We specifically propose to revise paragraph (b) to indicate that an individual will be excluded until such time as PHS notifies the OIG that the individual's debt has been paid or resolved. Upon receipt of notice from PHS, the OIG will, in turn, inform the individual of his or her right to apply for reinstatement. In addition, we are amending this

paragraph to specifically state that an individual who has had his or her debt written off by PHS will be eligible to apply to the OIG for reinstatement any time following PHS's notification to the individual that there is no longer an outstanding debt.

• *Clarification to § 1001.1801 (Waivers of Exclusions)*

We are proposing to expand the designated programs which may request a waiver of an exclusion to conform with statutory amendments which broadened the scope of an OIG program exclusion. Prior to the BBA, an exclusion was applicable only to participation in Medicare and all State health care programs (as defined in section 1128(h) of the Act). In section 4331 of the BBA, Congress amended sections 1128(a) and (b) of the Act to provide that an exclusion will be from all ''Federal health care programs,'' as defined in section 1128B(f) of the Act. Notwithstanding this authority, current law only permits waivers to be requested by State health care programs.

Although Congress expanded the scope of exclusion under section 1128 of the Act to participation in all other Federal health care programs, it did not explicitly broaden the authority to request a waiver of an exclusion under either section 1128(c)(3)(B) or 1128(d)(3)(B) of the Act to include requests of waivers by Federal health care programs other than Medicare or State health care programs. However, we believe that the clear congressional intent was to broaden both the scope and applicability of the entire exclusion authority to ''all other Federal health care programs.'' Thus, we believe that it would be consistent for the implementing regulations to provide for a parallel approach with respect to requests for waiver of an exclusion. We are, therefore, proposing to amend § 1001.1801 to specify that a ''Federal health care program'' may request a waiver, thus replacing the current provision which only authorizes such waiver requests from a ''State health care program.''

• *Collateral Estoppel Effect in § 1001.2007 (Appeal of Exclusions)*

Many of the OIG exclusion authorities are predicated on prior determinations made by courts or other administrative agencies. Section 1001.2007 of the OIG regulations currently contains a provision that precludes, in the administrative appeal of such exclusions, the relitigation of the underlying determination. We are proposing to further clarify paragraph (d) of this section to specifically state that a civil judgment rendered by a Federal, State or local court is an additional type of prior determination that may serve as the basis for an exclusion (and may not be relitigated in the exclusion proceeding). This clarification is predicated on the general principles of collateral estoppel.

• *Revision to § 1001.3005 (Reversed or Vacated Decisions)*

Section 1001.3005 provides that an individual or entity will be reinstated into the Medicare program retroactive to the effective date of the exclusion when such exclusion is based on either (1) a conviction that is reversed or vacated on appeal, or (2) an action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal. However, current regulations do not specify at what point in the appeal process retroactive reinstatement will occur. We are proposing to modify § 1001.3005 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. However, the regulation would make clear that the exclusion would be reimposed if the administrative decision reversing or vacating the exclusion is overturned upon further appeal.

• *Revisions to § 1003.100 (Basis and Purpose)*

Section 1003.100 sets for the basis and purpose for the OIG's CMP and assessment authorities. In final rulemaking published on July 22, 1999 (64 FR 39428), § 1003.100 was amended by, among other things, revising (b)(1)(iv), (viii), (x) and (xi) and by adding a new paragraph (b)(1)(xii). These revisions to § 1003.100 were not properly reflected in the OIG final rulemaking on April 26, 2000 (65 FR 24415) that also made additional revisions to this section. Accordingly, we are amending § 1003.100 to accurately reflect paragraph (b)(1)(iv). In addition, paragraphs designated in the July 22, 1999 final rule as (b)(1)(viii) and (b)(1)(xii) would now being set forth as paragraphs (b)(1)(xiv) and (b)(1)(xv), respectively, in the section.

• *Revision to the Definition of the Term ''Item and Service'' in § 1003.101 (Definitions)*

The current definition of the term ''item or service'' set forth in § 1003.101 follows the statutory language by defining the term to *include* items or services paid either in accordance with (1) an itemized claim or (2) an entry or omission on a cost report. Some health care providers have mistakenly believed that this definition *only* covered goods and services paid on the bases of those two methodologies, and did not cover goods or services paid in accordance with one of the various prospective payment methodologies. To reflect the varying reimbursement systems and mechanisms in practice, we are proposing to modify the current definition of the term ''item and service'' in this section to clarify that, in addition to itemized claims or cost reports, the term ''item and service'' includes any item or service that is reimbursed through any health care payment mechanism, such as prospective payment systems.

• *Clarifying Factor in § 1003.106(a)(4) for Determining the Amount of Penalty for Patient Dumping Violations*

Section 1003.106(a)(4) sets forth six factors to be taken into account in determining a CMP amount for violations in accordance with § 1003.102(c), the patient anti-dumping provisions. One of the criteria for considering the amount of CMP to impose in a patient dumping case is ''the prior history of offenses'' under the Patient Anti-Dumping Act. The current language allows the OIG only to consider ''prior'' offenses, and does not allow the consideration of similar conduct after the incident in question. For example, if the OIG is pursuing a case against a physician responsible for an inappropriate transfer, and it is learned that the physician was later terminated for causing another inappropriate transfer, we cannot currently consider this in determining the CMP amount, even though we believe that this conduct is relevant in making a determination. In order to permit the OIG to consider this subsequent act in determining the amount of penalty to be assessed, we are proposing to revise paragraph (a)(4)(iii) of this section to allow the OIG to consider as a factor other related or similar allegations subsequent to the incident under review.

• *Revised Time Frames in § 1005.7(e) (Discovery)*

Section 1005.7(e) sets forth procedures and time frames governing the discovery process. The time frames set forth in paragraph (e)(1) are intended to ensure that the hearing process proceeds in an orderly and timely manner, and to induce parties to produce documents within a reasonable period of time. While the 15-day period set forth in the current regulations may be adequate in many cases, it has been

suggested that the time frames given to parties to comply fully with requests for documents and for raising objections may be too short a period of time. Because we believe it is practical to provide greater flexibility and establish more reasonable and appropriate time frames consistent with the Federal Rules of Civil Procedure, we are recommending amending § 1005.7(e)(1) to expand the specified time frames to 30 days. (Section 1005.7(e)(3) already permits the administrative law judge (ALJ) the discretion to further expand or modify these time frames, on a case-by-case basis, for parties to comply and object with discovery.)

- *Revision to § 1005.16 (Witnesses)*

The OIG is proposing to amend § 1005.16(b) to give the ALJ discretion to admit written expert testimony that is reliable. Under the current regulations, the ALJ is not permitted to accept reliable written testimony, such as depositions, trial testimony and administrative proceedings, from experts. We are proposing to revise paragraph (b) by further stating that ''[T]he ALJ may admit prior sworn testimony of experts which has been subject to adverse examination, such as a deposition or trial testimony.'' We believe this revision would allow the ALJ the discretion to admit written testimony of experts if he or she finds it is relevant and reliable.

- *Revision to § 1005.17 (Evidence)*

Section 1005.17 addresses the admissibility of evidence in administrative proceedings. While the ALJs are not strictly bound by the Federal Rules of Evidence (FRE), paragraph (b) of this section permits the ALJs to apply the FRE where appropriate, *e.g.*, to exclude unreliable evidence. However, we believe that there is a need to protect the credibility of witnesses from being attacked by the introduction of evidence of character and conduct not conforming to the limitations of Rule 608 of the FRE. Without such limitations, the introduction of such character and conduct evidence is purely at the discretion of the ALJ who may choose to hear testimony that would be excluded under Rule 608. Because of the unpredictability of this situation, witnesses may be reluctant to testify for fear that their credibility will be attacked by the introduction of highly personal information that may be embarrassing or upsetting, but not highly probative of the witnesses' character for truthfulness or untruthfulness. Therefore, we are proposing to amend § 1005.17 by adding a new paragraph to require adherence to Rule 608 of the FRE in administrative proceedings under this section. We believe that by requiring adherence to Rule 608, the use of character and conduct evidence will be appropriately limited and more predictable for all parties. We do not intend to foreclose other forms of impeachment, such as evidence of criminal conviction or prior inconsistent statements.

- *Revision to U.S.C. Citation in § 1008.37*

In the OIG final rule published in the **Federal Register** on July 16, 1998 (63 FR 38311) addressing the issuance of advisory opinions by the OIG, an inadvertent error was made in citing the United States Code referenced in § 1008.37, disclosure of ownership and related information. The citation error in § 1008.37, which refers to 42 U.S.C. 1302a–3(a)(1), would be corrected to read as 42 U.S.C. 1320a–3(a)(1).

Regulatory Impact Statement

The Office of Management and Budget (OMB) has reviewed this proposed rule in accordance with the provisions of Executive Order 12866, and has determined that it does not meet the criteria for an economically significant regulatory action. Specifically, 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, section 202 of the Unfunded Mandates Reform Act, Public Law 104–4, requires that agencies prepare an assessment of anticipated costs and benefits on any rulemaking that may result in an expenditure by State, local or tribal government, or by the private sector of $100 million or more in any given year. Further, under the Small Business Enforcement Act (SBEA) of 1996, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule, and under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the economic effect of a rule on small business entities and analyze regulatory options that could lessen the impact of the rule. Executive Order 13132, Federalism, further requires agencies to determine if a rule will have a significant affect on States, on their relationship with the Federal Government, and on the distribution of power and responsibility among the various levels of Government.

Executive Order 12866

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity and available information. Regulations must meet certain standards, such as avoiding unnecessary burden. We believe that this proposed rule would have no significant economic impact. The proposed revisions set forth in this rulemaking are either technical in nature or are designed to further clarify OIG statutory requirements.

Specifically, these provisions are designed 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 would be minimal and would 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 proposed regulations is minimal and would have no appreciable effect on the economy or on Federal or State expenditures.

Unfunded Mandates Reform Act of 1995. Additionally, in accordance with the Unfunded Mandates Reform Act of 1995, we believe that there are no significant costs associated with these proposed revisions that would impose any mandates on State, local or tribal governments, or the private sector that will result in an expenditure of $100 million or more in any given year. As indicated, these proposed revisions are narrow in scope and effect, comport with congressional and statutory intent, and clarify the Department's legal authorities against those who defraud or otherwise act improperly against the Federal and State health care programs. Accordingly, we believe that a full analysis under the Act is not necessary.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA) of 1980, and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, we are required to determine if this rule will have a significant economic effect on a substantial number of small entities

and, if so, to identify regulatory options that could lessen the impact. While these clarifying provisions may have an impact on small entities, we believe that the aggregate economic impact of this rulemaking would be minimal, since it is the nature of the violation and not the size of the entity that will result in a violation of the statute. Since the vast majority of individuals and entities potentially affected by these regulations do not engage in prohibited arrangements, schemes or practices in violation of the law, we believe that these proposed regulations would not have a significant economic impact on a number of small business entities.

Executive Order 13132, Federalism

We have also reviewed this rule under the threshold criteria of Executive Order 13132, Federalism, and we have determined that this rulemaking would not have significantly affect the rights, roles and responsibilities of States. In summary, we have concluded, and the Secretary certifies, that since this rule would have no significant economic impact on Federal, State or local economies, 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 proposed regulations impose no new reporting or recordkeeping requirements necessitating clearance by OMB.

Response to Public Comments

Comments will be available for public inspection beginning on November 3, 2000 in Room 5518 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 4:30 p.m., (202) 619–0089. Because of the large number of comments we normally receive on regulations, we cannot acknowledge or respond to them individually. However, we will consider all timely and appropriate comments when developing the final rule.

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 would be amended as set forth below:

PART 1001—[AMENDED]

1. The authority citation for part 1001 would continue 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 would be amended by redesignating existing paragraph (b) to read as paragraph (c) and by adding a new paragraph (b) to read as follows:

§ 1001.1 Scope and purpose.

* * * * *

(b) A program exclusion is deemed to be remedial in nature and designed to protect Medicare, Medicaid and other Federal health care programs and their beneficiaries from fraudulent individuals and entities. Accordingly, an exclusion is neither time-barred nor subject to any limitations period, even when the exclusion is based on violations of another statute which may have a specified limitations period.

(c) * * *

3. Section 1001.101 would be amended by republishing the introductory text and by revising introductory paragraph (c) 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—

* * * * *

4. Section 1001.102 would be amended by republishing the introductory text for paragraph (b) and revising paragraphs (b)(1) and (b)(9), 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, resulted in financial loss (both actual loss and intended 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);

* * * * *

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

(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;

* * * * *

5. Section 1001.201 would be amended by republishing the introductory text for paragraph (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) * * *

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

(i) The acts resulting in the conviction, or similar acts, resulted in financial loss (both actual loss and intended 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 intended loss) to a Government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than $1,500;

* * * * *

6. Section 1001.951 would be 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;

* * * * *

7. Section 1001.952 would be 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)(5), 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)(5), 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) revising paragraph (e)(2)(ii);

g. Republishing introductory paragraph (f) and revising paragraph (f)(2) ;

h. Revising introductory paragraph (h); introductory paragraph (h)(1), introductory paragraph (h)(1)(ii) and introductory paragraph (h)(1)(iii); introductory paragraph (h)(2) and paragraph (h)(2)(ii)(A); introductory paragraph (h)(3) and introductory paragraph (h)(3)(iii); paragraph (h)(4); and paragraphs (h)(5)(ii) and (h)(5)(iii);

i. Revising paragraph (i);

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

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

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

m. Revising introductory paragraph (r) and paragraph (r)(2)(ii); and

n. Revising the introductory text for paragraph (s).

The revisions to § 1001.952 would 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 program.

(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 of 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 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 attributable 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 program.

(d) *Personal services and management contracts.* As used in section 1128B of the Act , ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent , as long as all of the following 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 practitioner is selling his or her practice to the latter practitioner, as long as both of 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 one

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 the 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—

* * * * *

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

* * * * *

(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 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—

* * * * *

(ii) * * *

(A) Where the value of the discount is known at the time of sale, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or

* * * * *

(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 individual 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—

* * * * *

(4) For purposes of this paragraph, a *rebate* is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is given *after* the time of sale.

(5) * * *

(ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology (*e.g.,* under the same DRG, prospective payment, or per diem, but not including fee schedules) and the reduced charge is fully disclosed to the Federal health care program and accurately reflected, where appropriate, and as appropriate, to the reimbursement methodology;

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

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

* * * * *

(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 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 to another 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.

* * * * *

(r) *Ambulatory surgical center.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is in return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, the operating and recovery room space of which is dedicated exclusively to the ASC; patients referred to the investment entity by an investor are fully informed of the investor's investment interest; and all of the applicable standards are met within one of the following four categories—

* * * * *

(2) * * *

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures (as defined in this paragraph).

* * * * *

(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—

* * * * *

8. Section 1001.1501 would be 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. 9. Section 1001.1801 would be amended by revising paragraphs (a), (b), (e) and (f), and by deleting paragraph (g) to read as follows:

§ 1001.1801 Waivers of exclusions.

(a) The OIG has authority to grant or deny a request from a Federal health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The waiver request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a Federal health care program for a waiver of the exclusion will only be considered if the individual is the sole community physician or if the individual or entity is the sole source of essential specialized items or services.

* * * * *

(e) In the event a waiver is granted, the OIG may determine the scope of the waiver to apply to particular items, services, locations or programs.

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

10. Section 1001.2007 would be 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.

* * * * *

11. Section 1001.3005 would be 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 would continue 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 would be 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 would be 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—

(1) 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

(2) 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 would be amended by republishing the introductory text for paragraph (a)(4) and by revising paragraph (a)(4)(iii) to read as follows:

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

(a) * * *

(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 would continue to read as follows:

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

2. Section 1005.7 would by 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 would be 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 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.

* * * * *

4. Section 1005.17 would be amended by redesignating existing paragraphs (g) through (j) respectively as new paragraphs (h) through (k); and by adding a new paragraph (g) to read as follows:

§ 1005.17 Evidence.

* * * * *

(g) Evidence related to the character and conduct of witnesses may be introduced only as permitted under Rule 608 of the Federal Rules of Evidence.

* * * * *

PART 1008—[AMENDED]

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

Authority: 42 U.S.C. 1320a–7d(b).

2. Section 1008.37 would be 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: May 31, 2000.

Michael F. Mangano,

Principal Deputy Inspector General.

Approved: June 29, 2000.

Donna E. Shalala,

Secretary.

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