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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1000, 1001, 1002, and 1006

RIN 0936-AA05

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities

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

ACTION: Proposed rule.

SUMMARY: This proposed rule amends the regulations relating to exclusion authorities under the authority of the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS or the Department). The proposed rule would incorporate statutory changes, propose early reinstatement procedures, and clarify existing regulatory provisions.

DATES: To ensure consideration, comments must be delivered to the address provided below by no later than 5 p.m.

Eastern Standard Time on [INSERT 60 DAYS FROM FEDERAL REGISTER PUBLICATION DATE].

ADDRESSES: In commenting, please reference file code OIG-403-P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. Electronically. You may submit electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>. (Attachments should be in Microsoft Word, if possible.)

2. By regular, express, or overnight mail. You may mail your printed or written submissions to the following address:

Patrice Drew
Office of Inspector General
Department of Health and Human Services
Attention: OIG-403-P2
Cohen Building
330 Independence Avenue, SW, Room 5541C
Washington, DC 20201

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By hand or courier. You may deliver, by hand or courier, before the close of the comment period, your printed or written comments to:

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330 Independence Avenue, SW, Room 5541C
Washington, DC 20201

Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-1368.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on <http://www.regulations.gov> for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201, Monday through Friday from 9:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

FOR FURTHER INFORMATION CONTACT: Susan Gillin, (202) 619-0335, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of the Regulatory Action

A. Need For Regulatory Action: The Affordable Care Act of 2010 (Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (2010), hereafter ACA) significantly expanded OIG's authority to protect Federal health care programs from fraud and abuse. OIG proposes to update its regulations to codify the changes made by ACA in the regulations. At the same time, OIG proposes updates pursuant to the Medicare Prescription Drug, Improvement,

and Modernization Act of 2003 (MMA) and other statutory authorities, as well as technical changes to clarify and update the regulations.

B. Legal Authority: The legal authority, laid out later in the preamble, for this regulatory action is found in the Social Security Act (the Act), as amended by ACA. The legal authority for the proposed changes is listed by the parts of Title 42 of the Code of Federal Regulations that we propose to modify:

1000: 42 U.S.C. 1302 and 1395hh.

1001: 42 U.S.C. 1302; 1320a-7; 1320a-7b; 1395u(j); 1395u(k); 1395w-104(e)(6); 1395y(d); 1395y(e); 1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv); 1842(k)(1), and sec. 2455, Pub.L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

1002: 42 U.S.C. 1302, 1320a-3, 1320a-5, 1320a-7, 1396(a)(4)(A), 1396a(p), 1396a(a)(39), 1396a(a)(41), and 1396b(i)(2).

1006: 42 U.S.C. 405(d), 405(e), 1302, 1320a-7, and 1320a-7a.

II. Summary of Major Provisions

A. Exclusion Authorities: We propose changes to the exclusion regulations at 42 CFR part 1001 to codify authorities under the MMA and ACA and make technical

changes to existing regulations. Specifically, section 949 of MMA and section 6402(k) of ACA amended section 1128(c)(3)(B) of the Act to expand OIG's waiver authorities. Also, ACA provided that exclusion may be imposed for:

- conviction of an offense in connection with obstruction of an audit;
- failure to supply payment information (ACA expanded this provision to apply to individuals who "order, refer for furnishing, or certify the need for" items or services for which payment may be made under Medicare or any State health care program); and
- making, or causing to be made, any false statement, omission, or misrepresentation of a material fact in applications to participate as a provider of services or supplier under a Federal health care program.

ACA also established a new authority at section 1128(f)(4) of the Act for OIG to issue testimonial subpoenas in investigations of exclusion cases under section 1128 of the Act.

In addition to the changes under the ACA, and pursuant to section 1128(g)(1) of the Act, we propose a modification

to the reinstatement rules for individuals excluded as a result of losing their licenses to allow them to rejoin the programs earlier when appropriate.

III. Costs and Benefits

There are no significant costs associated with the proposed regulatory revisions that would impose any mandates on State, local, or tribal governments or the private sector.

Social Security Act Citation	United States Code Citation
205	42 U.S.C. 405
1102	42 U.S.C. 1302
1124	42 U.S.C. 1320a-3
1126	42 U.S.C. 1320a-5
1128	42 U.S.C. 1320a-7
1128A	42 U.S.C. 1320a-7a
1128B	42 U.S.C. 1320a-7b
1128C	42 U.S.C. 1320a-7c
1128E	42 U.S.C. 1320a-7e
1128J	42 U.S.C. 1320a-7k
1140	42 U.S.C. 1320b-10
1814	42 U.S.C. 1395f
1833	42 U.S.C. 1395l
1835	42 U.S.C. 1395n
1842	42 U.S.C. 1395u
1851	42 U.S.C. 1395w-21
1852	42 U.S.C. 1395w-22
1857	42 U.S.C. 1395w-27
1860D-12	42 U.S.C. 1395w-112
1860D-14A	42 U.S.C. 1395w-114A
1861	42 U.S.C. 1395x
1862	42 U.S.C. 1395y
1866	42 U.S.C. 1395cc
1867	42 U.S.C. 1395dd
1876	42 U.S.C. 1395mm
1877	42 U.S.C. 1395nn
1882	42 U.S.C. 1395ss

1886	42 U.S.C. 1395ww
1892	42 U.S.C. 1395ccc
1902	42 U.S.C. 1396a
1903	42 U.S.C. 1396b
1915	42 U.S.C. 1396n
1927	42 U.S.C. 1396r-8
1929	42 U.S.C. 1396t

I. Background

A. Exclusion Authority

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 who pose a risk to program beneficiaries or to the integrity of these programs. These authorities encompass both mandatory exclusions (section 1128(a) of the Act) and permissive exclusions (section 1128(b) of the Act). The mandatory exclusion authorities require OIG to exclude from Federal health care program participation any individual or entity convicted of a "program-related" crime; a crime related to patient abuse or neglect; or certain felonies related to health care delivery, governmental health care programs, or controlled substances. Mandatory exclusions are for a period of at least 5 years. 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 agency or (2) "affirmative" exclusions that are based on OIG-initiated determinations of misconduct, e.g., poor quality of care, kickbacks, or submission of false claims to a Federal health care program. While there is no 5-year minimum term for permissive exclusions, some permissive authorities have varying minimum or benchmark exclusion terms.

Over the years, several statutory and regulatory provisions have amended or further clarified OIG's exclusion authorities. Specifically, in 1996, provisions within the Health Insurance Portability and Accountability Act of 1996 (HIPAA) revised or expanded OIG's authorities to (1) mandate a 5-year minimum exclusion period for felony convictions relating to health care fraud, even if governmental programs were not involved, and for certain felony convictions relating to controlled substances; (2) establish minimum or benchmark periods of exclusion from 1 to 3 years for certain permissive exclusions; and (3) establish a new permissive exclusion authority applicable to individuals who have an ownership interest in, or have control over, the operations of an entity that has been convicted of a program-related offense. The Balanced Budget Act (BBA) of 1997 further amended OIG's exclusion

authorities by (1) extending the scope of an OIG exclusion beyond Medicare and State health care programs to all Federal health care programs; (2) establishing permanent exclusions for persons convicted of three or more health care-related crimes and 10-year exclusions for persons convicted of two health care-related crimes; and (3) allowing for the exclusion of entities owned or controlled by a family or household member of an excluded individual when a transfer of ownership was made in anticipation of, or following, a conviction. On March 18, 2002, OIG also published several revisions and technical corrections to 42 CFR part 1001 with respect to, among other things, (1) the reinstatement procedures relating to exclusions resulting from a default on health education or scholarship obligations made or secured by the Secretary and (2) expansion of the scope of exclusion to all Federal health care programs.

1. Changes Made by MMA

MMA amended OIG's authority to waive mandatory exclusions in several ways. First, section 949 of MMA amended section 1128(c)(3)(B) of the Act by expanding the waiver provision of the Act to allow waiver requests for individuals excluded under either of the two mandatory exclusion authorities that were added in HIPAA, sections

1128(a)(3) and (a)(4) of the Act. Second, prior to MMA, a waiver request could be made only by the administrator of a State agency for a waiver of the State health care program. Section 949 of MMA expanded the mandatory exclusion waiver provision by permitting the administrator of any Federal health care program to request a waiver for the respective Federal health care program. Third, MMA added a provision requiring the requesting Federal health care program administrator to determine whether the exclusion would impose a hardship on Medicare beneficiaries, in addition to the existing requirement that the requesting administrator determine whether the individual or entity for whom the waiver was requested be the sole community physician or sole source of essential specialized services in a community.

2. Changes Made by ACA

Section 6402(k) of ACA further amended the Act's waiver provisions to permit the administrator of a Federal health care program to request a waiver if the administrator determines that exclusion would impose a hardship on any beneficiary or beneficiaries eligible to receive items or services under a Federal health care program, which broadened the waiver request beyond only Medicare beneficiaries as provided in MMA.

In addition, section 6408(c) of ACA amended section 1128(b)(2) of the Act by expanding the application of the permissive exclusion authority to include individuals convicted of an offense in connection with the obstruction of an audit. Section 6406(c) of ACA broadened the scope of the permissive exclusion authority found in section 1128(b)(11) of the Act to apply to individuals who not only furnish but also "order, refer for furnishing, or certify the need for" items or services for which payment may be made under Medicare or any State health care program and fail to provide payment information. Section 6402(d) of ACA established a new permissive exclusion authority under section 1128(b)(16) of the Act applicable to any individual or entity that knowingly makes, or causes to be made, any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program. Finally, section 6402(e) of ACA established a new authority at section 1128(f)(4) of the Act for OIG to issue testimonial subpoenas in investigations of exclusion cases under section 1128 of the Act.

We propose changes to the OIG regulations at 42 CFR parts 1001 and 1006 to reflect the revised provisions set forth in MMA and ACA.

3. Proposed Policy Changes and Clarifying Changes

We propose a number of changes to the regulations to correct omissions from previous regulatory issuances, to update certain dollar figures related to aggravating factors, and to clarify existing regulatory provisions. We also propose several policy changes. These include proposals to: (1) create early reinstatement procedures for exclusions pursuant to the loss of a health care license; (2) expand the "pay the first claim rule" in § 1001.1901(c) so that it would apply to Medicare Parts C and D; and (3) clarify that no statute of limitations period applies to exclusions imposed under section 1128(b)(7) of the Act.

Part 1002 provides direction to State Medicaid agencies when they exercise their program integrity responsibilities by independently initiating exclusion actions. The regulatory provisions place certain requirements on State agencies when they undertake such exclusions—requirements that are substantially consistent with OIG procedures and are designed to ensure adequate due process. The proposed revisions to part 1002 consist of minimal reorganization, several new headings to clarify the

applicability of certain provisions, language to clarify existing Federal requirements, and a listing of the statutory underpinnings of the provisions in part 1002.

II. Provisions of the Proposed Rule

A. Exclusion Authorities

We propose changes to the OIG regulations at 42 CFR parts 1000, 1001, 1002, and 1006.

1. Changes to Part 1000

1000.10 Definitions of "Directly," "Furnished," and "Indirectly"

We propose a number of technical revisions to the definitions of "directly" and "indirectly" as used in the definition of "furnished." First, we propose adding the word "supply" to the definitions of "directly" and "indirectly" because the definition of "furnished" includes both the provision and supply of items and services.

Next, we propose to remove the phrase "submit claims to" and replace it with "request or receive payment from" immediately preceding "Federal health care programs" in the definitions of "directly" and "indirectly." We would replace the phrase for clarity's sake, and the revised wording would be consistent with the False Claims Act's broad definition of "claim" (31 U.S.C. 3729(b)). This

proposed change would appropriately encompass all current and future payment methodologies.

We further propose removing the redundant sentence within the definition of "indirectly" stating that the word "indirectly" does not include the direct submission of claims by another individual or entity because that clarification is already present within the definition of "directly."

In addition, OIG has always interpreted the definition of "indirectly" at 42 CFR 1000.10, regarding furnishing items or services, to cover any employee or contractor of a provider that receives payment from any Federal health care program related to such items or services. Therefore, we propose adding the word "provided" (with conforming technical edits) within the first part of the definition of "indirectly" to read as follows: "Indirectly, as used in the definition of 'furnished' in this section, means the provision or supply of items and services manufactured, distributed, supplied, or otherwise provided by individuals or entities."

We propose to move the definitions of "ALJ," "Exclusion," "State," and "State health care program" from parts 1001 and 1003 to part 1000. The proposed definitions of "ALJ" and "State" are currently found in part 1003. The

proposed definitions of "Exclusion" and "State health care program" are currently found in part 1001. The proposed definition of "State health care program" includes minor revisions to the definition currently found in part 1001 to include Title XXI, the Children's Health Insurance Program. The BBA added Title XXI to the statutory definition of "State health care program" under section 1128(h) of the Act. We also propose minor revisions to the current part 1000 definitions of "QIO" and "Secretary" because we are removing those definitions from parts 1001 and 1003, respectively.

Lastly, we propose making a technical revision to the definition of "furnished." The current definition includes part of the definition of "indirectly." This is both redundant and somewhat confusing. Therefore, we propose to streamline the definition of "furnished" by removing this language.

1000.20 and 1000.30 Definitions Pertaining to Medicare and Medicaid

We propose removing the definitions currently found at §§ 1000.20 and 1000.30 from part 1000. These definitions are not, and have never been, applicable to the OIG regulations in 42 CFR chapter V. These programmatic definitions, which apply to Medicare and Medicaid (Titles

XVIII and XIX of the Act), were originally included in chapter V for ease of reference, not because they defined terms in chapter V. They are no longer useful, even as a reference source, because exclusions imposed under chapter V are from all Federal health care programs, not only from Medicare and State health care programs as was the case until 1996. Definitions specific to Medicare are at 42 CFR 400.202, and definitions specific to Medicaid are at 42 CFR 400.203. We are retaining the definitions at § 1000.10 that continue to apply to the regulations in chapter V, which were created pursuant to OIG's authorities under Title XI of the Act.

2. Changes to Part 1001

1001.2 Definition of "Ownership or Control Interest"

We propose moving the definition of "ownership or control interest" and its related definitions, including the definition of "managing employee," to the definitions section at § 1001.2. Currently, the definitions are at § 1001.1001, the regulation section related to exclusion of entities owned or controlled by a sanctioned person.

In addition, because we have proposed that the definition of "ownership or control interest" and its related definitions apply to all of part 1001, we would remove references to the statutory definition of these

terms. Therefore, with respect to "ownership or control interest," we propose removing the phrase "as defined in section 1124(a)(3) of the Act" from §§ 1001.101(d) and 1001.401(a). With respect to "managing employee," we also propose removing the phrase "as defined in section 1126(b) of the Act" from §§ 1001.101(d), 1001.401(a), and 1001.1051(a).

We also propose to remove the definitions of "Exclusion," "OIG," "QIO," and "State health care program." As discussed above, we propose to move the definitions of "Exclusion" and "State health care program" from part 1001 to part 1000. We propose to remove the definitions of "OIG" and "QIO" from part 1001 because those definitions are included in part 1000.

1001.101 and 1001.401 Application of Certain Exclusions to Health Care Providers

At §§ 1001.101(d) and 1001.401(a)(1), respectively, we currently restrict the imposition of mandatory exclusions under section 1128(a)(4) of the Act and permissive exclusions under section 1128(b)(3) of the Act by limiting the applicability of these provisions to those individuals or entities that: (1) are, or have ever been, health care practitioners, providers, or suppliers; (2) hold or held ownership or control interests, or are or have been

officers, directors, or managing employees, in health care entities; or (3) are or have ever been employed in any capacity in the health care industry. To continue to protect the programs and their beneficiaries, but not expend OIG's limited resources to unnecessarily exclude people who do not participate in Federal health care programs, we propose to further narrow the application of sections 1128(a)(4) and 1128(b)(3) of the Act ~~to reference the time of the offense~~. Under our proposal, those individuals subject to exclusion would be either (1) current health care practitioners, providers, suppliers, those who furnish items or services, owners, managing employees, or those who are employed in any capacity in the health care industry; or (2) individuals who were health care practitioners, providers, suppliers, those who furnished items or services, owners, managing employees, or those who were employed in any capacity in the health care industry at the time of the offense.

1001.102(b)(1), 201(b)(2), and 701(d)(2)(iv) Financial Loss Aggravating Factors

With respect to the length of an exclusion, §§ 1001.102(b)(1) and 1001.201(b)(2)(i) list, as an aggravating factor, whether the acts resulting in the conviction, or similar acts, caused or were intended to

cause, a financial loss of \$5,000 or more. The regulations related to certain affirmative exclusions at § 1001.701(d)(2)(iv) reference a financial loss of \$1,500 or more. These provisions were last updated in 2002 and 1998, respectively. To update the regulations, we propose increasing the aggravating factor to \$15,000. We believe this updated amount is an appropriate threshold that is consistent with rationale behind the original amount and provides a realistic marker for determining whether someone is untrustworthy. In addition, we propose a grammatical correction by removing the word "that" from the first sentence. Finally, we propose substituting the term "entire" for "total" to be consistent throughout the regulations. Thus, the provision would state: "The acts resulting in the conviction or similar acts, caused, or were intended to cause, a financial loss to a Government program or to one or more entities of \$15,000 or more. (The entire 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)."

1001.102(b)(7) Aggravating Factor Related to Overpayments

We propose removing the aggravating factor relating to an individual or entity being overpaid by Medicare,

Medicaid, or other Federal health care programs as a result of improper billings at § 1001.102(b)(7) because it is duplicative of § 1001.102(b)(1), which provides for an increase in the exclusion period for causing a financial loss to a Government program. In general, being overpaid by Federal health care programs for improper billings is substantially the same as causing a loss to a Government program. Therefore, we propose removing this aggravating factor. This change will require a renumbering of the remaining aggravating factors.

1001.102(b)(9), 1001.201(b)(2)(vi), 1001.301(b)(2)(vi), and 1001.401(c)(2)(v) Other Offenses and Adverse Actions

The aggravating factor set forth for various exclusion authorities at §§ 1001.102(b)(9), 1001.201(b)(2)(vi), 1001.301(b)(2)(vi), and 1001.401(c)(2)(v), which considers other offenses besides those that form the basis for the exclusions, involves two separate concepts: convictions for offenses other than the one resulting in exclusion and adverse actions by governmental entities other than the one resulting in exclusion. Therefore, we propose separating this factor into two separate aggravating factors, renumbering them accordingly, and putting them both in the present perfect tense to more accurately reflect the purpose of the aggravating factor. Accordingly, new §§

1001.102(b)(8), 1001.201(b)(2)(vi), 1001.301(b)(2)(vi), and 1001.401(c)(2)(v) would read: "Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion," and new §§ 1001.102(b)(9), 1001.201(b)(2)(vii), 1001.301(b)(2)(vii), and 1001.401(c)(2)(vi) would read: "Whether the individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion."

1001.102(c)(1) Mitigating Factor Relating to Misdemeanor Offenses and Loss to Government Programs

We propose updating this mitigating factor, which considers whether an individual or entity was convicted of three or fewer misdemeanor offenses and caused losses to Medicare or any other governmental health program of less than \$1,500. First, we propose to clarify that this factor applies only to section 1128(a)(1) of the Act. This factor does not apply to section 1128(a)(2) of the Act because section 1128(a)(2) pertains to patient abuse and neglect, and financial loss is irrelevant. In addition, this mitigating factor does not apply to sections 1128(a)(3) and (4) because each of these exclusions requires a felony

conviction. Finally, we propose to increase the loss amount to \$5,000. We believe this updated amount is an appropriate threshold that is consistent with rationale behind the original amount.

1001.102(d) Effect of Additional Previous Convictions on Term of Exclusion

We propose correcting an inconsistency between the regulatory and statutory language with respect to section 1128(c)(3)(G) of the Act relating to increased minimum exclusion periods for repeat offenders. The statute requires a minimum 10-year period of exclusion for individuals who have been convicted on one previous occasion of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act (whether or not an exclusion was ever imposed) and permanent exclusion for individuals convicted on two or more previous occasions. However, the current regulation at § 1001.102(d) provides for a minimum 10-year period of exclusion for individuals who have been convicted on one other occasion of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act and permanent exclusion for individuals convicted on two or more other occasions. We propose replacing the word "other" with "previous" to be consistent with the statute

and to clarify that if an individual has been previously convicted of an offense that would have mandated exclusion, regardless of whether the individual had been excluded previously, section 1128(c)(3)(G) of the Act requires OIG to exclude for a minimum 10-year period or permanently if the individual has been convicted on two or more previous occasions.

1001.201, 1001.301, 1001.401, 1001.501, 1001.601, 1001.701, 1001.801, 1001.951, 1001.1101, 1001.1201, 1001.1601, and 1001.1701 Mitigating Factor Relating to Alternative Sources

We propose removing the mitigating factor for determining the length of exclusion under various permissive exclusion authorities that considers whether alternative sources of the type of health care items or services furnished by the individual are not available. On the basis of our experience, we believe that this factor could be considered by OIG in determining whether a permissive exclusion should be imposed and whether a waiver is appropriate, but does not relate to the length of exclusion. Therefore, we propose removing this factor.

1001.201(b)(3)(i) Mitigating Factor Relating to Other Offenses and Loss to Government Programs

As in § 1001.102(c)(1), we propose updating the mitigating factor relating to permissive exclusions by

increasing the threshold financial loss amount OIG will consider as a mitigating factor under § 1001.201(b)(3)(i) to \$5,000.

1001.301 Expanded Application of a Specific Permissive Exclusion Authority

Prior to ACA, section 1128(b)(2) of the Act permitted the Secretary to exclude any individual or entity that had been convicted of an offense in connection with the obstruction of an investigation into any criminal offense described under any of the mandatory exclusion authorities or under the permissive exclusion authority related to health care fraud or fraud in a governmental program. However, if an individual or entity was convicted of an offense in connection with the obstruction of an audit, the Secretary did not have a basis to exclude the individual or entity under section 1128(b)(2) of the Act. Section 6408(c) of ACA expanded the authority by allowing the Secretary to exclude an individual or entity that has been convicted of an offense in connection with the obstruction of an investigation or audit related to any criminal offense under the mandatory provisions of the exclusion statute; under the permissive provision related to health care fraud or fraud in a governmental program; or in cases when the investigation or audit related to the use of

Federal health care program funds received, directly or indirectly. This new provision under ACA applies to acts committed on or after January 1, 2010.

Accordingly, we propose to revise § 1001.301 to reflect the changes in ACA by adding "or audit" to the title. In addition, we propose to add a new paragraph reflecting the changes made by section 6408 of ACA.

In addition, we propose adding the financial loss aggravating factor under the permissive exclusion authority related to obstruction of investigations and audits as permitted under section 1128(c)(3)(D) of the Act. The financial loss factor is considered by OIG under most of the mandatory exclusion authorities and other permissive exclusion authorities. Adding this aggravating factor would allow OIG to increase the period of exclusion if the acts, or similar acts, that resulted in the obstruction conviction caused a financial loss of \$15,000 or more.

1001.401 Correction of a Cross-Reference for Aggravating and Mitigating Factors

We propose correcting a cross-reference within the regulatory language at § 1001.401(c). Specifically, § 1001.401(c) mistakenly states: "the aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section," when it should state "the aggravating or

mitigating factors listed in paragraphs (c) (2) and (c) (3) of this section."

1001.501 and 1001.601 Aggravating and Mitigating Factors Relating to Exclusions Based on the Loss of a Health Care License or Suspension or Exclusion by a Federal or State Health Care Program

We propose removing all the aggravating and mitigating factors found at §§ 1001.501(b) and 601(b), which permit OIG to lengthen periods of exclusion based on the loss of an individual's or entity's health care license and exclusion or suspension from a Federal or State health care program. Because exclusions under sections 1128(b) (4) and (b) (5) of the Act are derivative of a licensing board action or Federal or State health care program action, respectively, OIG generally imposes exclusions under these sections for the same period as that of the licensing board's or agency's action. As a result, individuals are generally eligible for reinstatement once they regain their health care licenses or are allowed to participate in the Federal or State health care program. Our proposed removal of these aggravating and mitigating factors would make the regulations consistent with OIG's general practice under these sections. In addition, because exclusions under § 1001.601 are based on actions by either a Federal or a

State health care program, we would clarify § 1001.601(b) by adding references to Federal health care programs. Therefore, we propose to revise §§ 1001.501(b) and 1001.601(b) accordingly.

1001.501 Early Reinstatement

For several reasons, we are considering instituting a process for early reinstatement for individuals excluded under section 1128(b)(4) of the Act. OIG has discretionary authority to exclude individuals or entities under section 1128(b) of the Act. Specifically, section 1128(b)(4) of the Act permits OIG to exclude individuals from participation in all Federal health care programs because of the loss of their health care licenses for reasons bearing on their professional competence, professional performance, or financial integrity.

Prior to the enactment of section 1128(c)(3)(E) of the Act, the regulations allowed for reinstatement when an individual who had been excluded under section 1128(b)(4) of the Act due to the loss of a health care license in one State fully and accurately disclosed the circumstances surrounding this action to a licensing authority of a different State and when that State granted the individual or entity a new license or took no significant adverse action as to a currently held license. However, upon the

enactment of section 1128(c)(3)(E) of the Act in 1997, this provision was removed from the regulations. Thus, under current regulations, an individual excluded under section 1128(b)(4) of the Act is not eligible to be reinstated to Federal health care programs until the license that was originally lost, in the same State where it was lost, has been restored.

Section 1128(g) of the Act allows an excluded individual to apply for reinstatement in the manner specified by the Secretary in regulations and at the minimum period of exclusion provided under paragraph (c)(3) and "at such other times as the Secretary may provide." Moreover, courts have held that the purpose and effect of the exclusion period is remedial and is intended to protect the Federal health care programs from fraud and abuse and to protect citizens who rely on the integrity of program participants.

OIG excludes a significant number of individuals under section 1128(b)(4) of the Act. Many of these individuals either lose their licenses permanently, move to another State and obtain a license there, or do not intend to seek reinstatement of their health care license. Under current regulations, the excluded individuals may never become eligible for reinstatement even though the exclusion may no

longer be necessary to protect patients or the programs. For example, we have seen many cases in which a medical board permanently revoked a physician's license, making that physician permanently ineligible for reinstatement. This permanent ineligibility exists under current regulations even though another State or another licensing board subsequently granted the physician a license. In addition, we regularly are contacted by individuals who have changed professions and never intend to regain their original licenses but for whom the exclusion is a permanent obstacle to practicing a new health-care related profession.

In contrast, OIG is required to exclude individuals or entities convicted of certain health-care-related offenses under section 1128(a) of the Act for a minimum of 5 years. Absent any aggravating factors, exclusions under the mandatory provisions of the Act require only a 5-year period of exclusion. Many permissive exclusions under section 1128(b)(4) of the Act result in permanent exclusions, even though the individuals were never charged with or convicted of criminal offenses. To serve the remedial purpose and intent of the statute, we are considering an alternative reinstatement process.

For special instances, such as when OIG imposes a permissive exclusion on the basis of a licensing board action and subsequently determines that the individual poses little or no threat to patients or the programs and when license reinstatement by the original licensing board is extremely unlikely, OIG is considering a process for "early reinstatement" pursuant to OIG's authority under section 1128(g) of the Act and the discretion inherent in the permissive exclusion provisions in section 1128(b) of the Act. Thus, we propose to amend the regulations to allow for early reinstatement, and to include a list of factors OIG will consider in determining whether early reinstatement is appropriate. Specifically, we would add a section entitled "(c) Early Reinstatement," which would have two subparts. The first subpart would allow an excluded individual to request early reinstatement if, after fully and accurately disclosing the circumstances surrounding the original license action that formed the basis for the exclusion, the individual obtained a health care license, was allowed to retain a health care license in another State, or retained a different health care license in the same State. The second subpart would allow an excluded individual to request early reinstatement if he or she did not have a valid health care license of any kind

provided that the individual could demonstrate that he or she would no longer pose a threat to Federal health care programs and their beneficiaries. In proposed § 1001.501, we state a number of factors OIG would consider in making this determination. We are also considering alternative approaches, and solicit comments on these and any additional factors that should be considered. For example, we are considering applying the same 3-year benchmark exclusion period that applies to other permissive exclusions under sections 1128(b)(1), (2), and (3) of the Act for exclusions under section 1128(b)(4) of the Act. The excluded individual would be eligible to apply for reinstatement when the 3-year period ends or when the individual regains his or her health care license, whichever comes first. We solicit comments on whether this approach would appropriately protect Federal health care programs and their beneficiaries.

1001.701, 1001.801, and 1001.1701 Correction of Subsection Headings

Throughout the regulations, the paragraph headings are italicized. However, in §§ 1001.701, 1001.801, and 1001.1701, paragraph headings were not italicized. We therefore propose to correct this omission. For example,

paragraph heading (a) in all three sections would now be italicized and read as: "(a) Circumstance for exclusion."
1001.901(c) Period of Limitations on Affirmative Exclusions

To address questions regarding whether a limitations period applies to exclusions imposed under section 1128 of the Act, we propose adding paragraph (c) to § 1001.901, which would provide that there is no time limitation to exclusions imposed under this authority, even when the exclusion is based on violations of another statute that might have a specific limitations period. In 2002, we issued a final rule stating that we had proposed a regulation stating that there would be no time limitation on OIG's imposition of a program exclusion, that we had received comments on this proposal, and that the comments led us not to finalize the proposed regulation. See 67 FR 11928, 11929 (March 18, 2002).

We believe strong policy and legal justifications support our interpretation that there is no limitations period applicable to exclusions imposed under section 1128(b)(7) of the Act. The 2002 comments raised concerns that (1) if an exclusion is based on a violation of another statute, the individual or entity could be excluded for conduct that occurred years before and that does not bear on the person's current trustworthiness or integrity and

(2) after the passage of significant time, evidence becomes difficult or impossible to gather. However, it is significant that no limitations period is specified in section 1128 of the Act. In addition, we do not believe that the reference in section 1128(b)(7) of the Act to other sections of the Act means that a limitations period applicable to another section of the Act should be incorporated into section 1128(b)(7). The referenced sections, which describe acts for which CMPs and criminal prosecutions may be pursued, do not include periods of limitations. Instead, section 1128A(c) sets forth a period of limitations for CMP actions and states that the "Secretary may not initiate an action under this section" more than 6 years after the underlying conduct. The criminal actions in section 1128B of the Act are limited by a period of limitations applicable to Federal noncapital criminal cases in 18 U.S.C. 3282.

We agree that, as a general matter, recent acts are more indicative of current trustworthiness than acts that took place in the distant past. Nevertheless, we believe that conduct that is more than 6 years old may sometimes form a proper basis to conclude that a person should be excluded. The age of the conduct is a factor in determining the weight the conduct should be afforded, not

whether the exclusion should be imposed at all. We do not believe the passage of time will prejudice the person subject to exclusion. For example, exclusions under section 1128(b)(7) of the Act often arise in the context of related civil False Claims Act proceedings, because the elements of the False Claims Act are essentially identical to false claims provisions of section 1128A. Many False Claims Act cases are resolved through settlement or litigation significantly later than 6 years after the underlying conduct. In most cases, the OIG determines whether to seek an exclusion only when the settlement terms are set or there is a judgment. In most cases, the settlement resolves both False Claims Act and section 1128(b)(7) liability simultaneously in one settlement agreement. When determining whether to seek an exclusion under section 1128(b)(7), the OIG considers whether the provider has agreed to pay appropriate restitution, fines, or penalties and whether it will agree to appropriate compliance measures. See 62 Federal Register 67392 (December 24, 1997). Until a settlement agreement is reached, the OIG cannot know whether the provider will agree to make such payments or subject itself to appropriate compliance measures. Therefore, in most cases it makes sense for the OIG to decide whether to impose an

exclusion based on the facts and circumstances at the time of the potential settlement. If the case does not settle and there is litigation under the False Claims Act, the OIG generally waits to see what the civil findings are before determining whether to seek an exclusion.

If section 1128(b)(7) is subject to a six year statute of limitations, then the OIG will often be forced to file exclusion actions prematurely. In False Claims Act cases where the conduct is 6 years old, the OIG may need to file a notice of proposed exclusion in order to toll the statute of limitations. Such an action would need to be taken without the benefit of knowing whether the defendant would agree to a settlement including appropriate payment and compliance measures. It may result in the exclusion of providers who otherwise might be deemed by the OIG to be trustworthy enough to participate in the programs. The filing of exclusion actions while False Claims Act cases are still pending would require the OIG, the defendant, and the DAB to devote resources to cases that would otherwise settle. Further, the filing of exclusion actions during the pendency of a False Claims Act investigation or settlement discussion may disrupt the civil case. Therefore, we believe that in such cases, it is appropriate

for us to consider exclusion based on conduct that is more than 6 years old.

1001.1001 Exclusion of Entities Owned or Controlled by a Sanctioned Person

As described above, we propose to move all the definitions in § 1001.1001 to § 1001.2 to create a definition of "ownership or control interest" that applies to both the exclusions and CMP regulations. As a result of this removal, we propose to remove §§

1001.1001(a)(1)(ii)(A) and (B) and revise paragraph (a)(2)

to read as follows: "(2) such a person has a direct or indirect ownership or control interest in the entity or formerly held an ownership or control interest in the entity, but no longer holds an ownership or control interest because of a transfer of the interest to an immediate family member or a member of the person's household in anticipation of or following a conviction, assessment of a CMP, or imposition of an exclusion."

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

With regard to exclusions imposed under section 1128(b)(15) of the Act, we propose clarifying the circumstances pertaining to the length of exclusion imposed on individuals with ownership or control interests in

sanctioned entities to make the regulations more consistent with the statute. Specifically, we propose amending § 1001.1051(c)(1) to state that the length of the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has or had the prohibited relationship. We believe this proposed clarification would be consistent with the intent of the statute, which allows OIG to exclude individuals who have ownership or control interests in sanctioned entities. The proposed change would clarify that if an individual terminated the relationship with the sanctioned entity after it has been excluded, the individual would nonetheless remain excluded for the same period that the sanctioned entity is excluded.

1001.1201 Broadened Scope of a Permissive Exclusion Authority

Section 1128(b)(11) of the Act permits OIG to exclude an individual or entity "furnishing items or services for which payment may be made" under Medicare or a State health care program that fails to supply certain payment information as required by the Secretary or the State agency. Section 6406(c) of ACA broadened the scope of the permissive exclusion under section 1128(b)(11) of the Act by revising the first phrase as follows: "Any individual

or entity furnishing, ordering, referring for furnishing, or certifying the need for items or services”

Accordingly, we would amend § 1001.1201 by adding the phrase “orders, refers for furnishing, or certifies the need for” after “furnishes.”

1001.1301 Exclusion for Failure to Grant Immediate Access

We propose several technical changes to this section. First, we clarify that OIG may request access to materials other than paper documents, such as electronically stored data, including any tangible thing upon which data is stored. This change conforms to clarifications made to the Inspector General’s authorities in section 9 of the Inspector General Reform Act of 2008, P. L. 110-409. Second, we propose several technical changes to make the terms used in the regulation more consistent.

1001.1501 Exclusion for Default on Health Education Assistance Loans (HEAL Loans)

We propose to amend this section in two ways. First, it has come to OIG’s attention that a significant amount of the health education-related financial assistance available to physicians, dentists, nurses, and other health care professionals from HHS is in the form of loan repayment programs (LRP). Under these programs, some of which are administered by the Indian Health Service, the National

Health Service Corps, and the National Institutes of Health (NIH), a health care professional agrees to the service obligations required by the LRP in return for the repayment by the program of outstanding loan obligations incurred by the individual in connection with his or her health education. Although section 1128(b)(14) does not specifically refer to loan repayment programs, we have concluded that these programs fall within the scope of the statute. They are essentially a type of scholarship awarded by HHS after an individual's health education is completed rather than in advance, a scholarship in the form of loan repayment rather than an upfront payment of tuition. We believe that this interpretation is consistent with the broad language of the statute and with congressional intent in enacting section 1128(b)(14), which was to provide HHS with a significant remedy when those who have received health education assistance from an HHS program default on their repayment obligations. To clarify that section 1128(b)(14) also applies to those who default on LRP obligations, we propose to amend the regulation to specifically reference them.

In addition, we propose a technical amendment to this regulatory provision. The regulations currently reference the Public Health Service (PHS) as the organization

responsible for determining whether an individual is in default on his or her loans or scholarship obligations. However, other HHS organizations, such as the Indian Health Service and NIH, also administer health education loans, scholarship programs, and loan repayment programs. Therefore, we propose amending the regulation to make it consistent with the broad language of the statute by replacing "PHS" with "the administrator of the health education loan, scholarship, or loan repayment program," where applicable.

1001.1751 Establishment of a New Permissive Exclusion Authority

Section 6402(d) of ACA granted a new permissive exclusion authority to the Secretary under section 1128(b) of the Act. Under the newly enacted section 1128(b)(16) of the Act, the Secretary may exclude any individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program. Accordingly, we propose adding a new section at § 1001.1751 entitled "Making false statements or misrepresentation of material facts." Under this proposal, we would determine whether to

impose an exclusion under this section on the basis of information from various sources, including, but not limited to, the Centers for Medicare & Medicaid Services (CMS), Medicaid State agencies, fiscal agents or contractors, private insurance companies, State or local licensing or certification authorities, and law enforcement agencies. In determining the period of exclusion, we propose to consider what the repercussions of the false statement are and whether the individual or entity has a documented history of criminal, civil, or administrative wrongdoing.

1001.1801 Expansion of Waiver Provisions in MMA and ACA

Prior to MMA, OIG could consider waiver requests made under section 1128(c)(3)(B) of the Act and § 1001.1801 of the regulations for exclusions imposed under section 1128(a)(1) of the Act if the Secretary determined that the individual or entity was the sole community physician or sole source of essential specialized services in a community. Congress originally limited the possibility of waiver to those excluded under section 1128(a)(1) because the only other mandatory exclusion authority was section 1128(a)(2), which applied to convictions related to patient abuse or neglect. The legislative history indicates that

Congress did not intend for exclusions imposed under section 1128(a)(2) to be waived.

HIPAA added sections 1128(a)(3) and (a)(4) of the Act, two new 5-year mandatory exclusion authorities. Section 949 of MMA updated the waiver provision of the Act to allow waiver requests for exclusions under sections 1128(a)(3) and 1128(a)(4) of the Act. In addition, section 949 of MMA permitted the administrator of a Federal health care program who determines that the exclusion would impose a hardship on a Medicare beneficiary to request a waiver. Section 6402(k) of ACA amended this hardship provision to permit the administrator of a Federal health care program to request a waiver if the administrator determines that exclusion would impose a hardship on any beneficiary eligible to receive items or services under a Federal health care program, thus removing MMA's requirement that an exclusion could be waived only if it imposed a hardship on Medicare beneficiaries.

The regulations have not been revised since before the enactment of MMA. In accordance with section 949 of MMA and section 6402(k) of ACA, we propose to revise § 1001.1801 to reflect these changes. With respect to individuals authorized to make a waiver request, we would remove references to the administrator of State health care

programs and replace them with the administrator of "Federal health care programs." In addition, we would amend § 1001.1801 to reflect the statutory change in MMA, which allows waiver requests to be made on behalf of individuals or entities excluded under sections 1128(a)(1), (a)(3), or (a)(4) of the Act. Lastly, we would amend § 1001.1801 to reflect that a Federal health care program administrator may request a waiver if the administrator determined that the exclusion would impose a hardship on any beneficiaries. Finally, we propose removing § 1001.1801(g) as it is no longer applicable.

1001.1901 Scope and Effect of Exclusion

Section 1862(e)(1) of the Act (42 U.S.C. 1395y(e)(1)) states that "[n]o payment may be made under this title with respect to any item or service . . . furnished -- (A) by an individual or entity during the period when such individual or entity is excluded . . . from participation in the program under this title; or (B) at the medical direction or on the prescription of a physician during the period when he is excluded . . . from participation in the program under this title and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after notice has been furnished to the person)." We propose to renumber §

1001.1901(b) to more closely track the numbering of section 1862(e)(1) of the Act.

We also propose to amend § 1001.1901(c) to make it more consistent with section 1862(e)(2) of the Act. Section 1862(e)(2) authorizes CMS to pay claims submitted by a Medicare enrollee, if otherwise payable, when the items or services are furnished by an excluded individual if the enrollee does not know or have reason to know of the exclusion. The statute requires Medicare to notify the enrollee and not to pay claims after a reasonable time after such notification. By its terms, the statute applies this exception to "individual[s] eligible for benefits under this title." The current regulation, § 1001.1901(c), limits this payment exception to enrollees in Medicare Part B. This is most likely because at the time the regulation was promulgated, Parts C and D of Medicare had not been enacted and because enrollees do not submit claims under Medicare Part A. We propose to amend the regulation to make it applicable to enrollees in Parts C and D, as well as Part B.

While the statute was designed to provide some protection to Medicare enrollees who received items or services from a physician not knowing that the physician was excluded, we realize that the practical reach of the

statute is quite limited since enrollees rarely submit claims directly to Medicare. Instead, claims are normally submitted by providers or suppliers, who then receive reimbursement directly from Medicare contractors. We are aware that Part D enrollees have at times been unable to refill prescriptions written by an excluded physician when the enrollee was unaware of the exclusion. However, since the pharmacy, not the enrollee, is submitting the claim for reimbursement to the Medicare Part D plan sponsor, we believe that section 1862(e)(1)(B) bars Medicare payments to the pharmacy for items prescribed by an excluded physician after a reasonable time period after notice to the pharmacy of the physician's exclusion. This statutory prohibition appears to apply regardless of whether the enrollee is aware of the exclusion. We realize that there are times when an enrollee whose prescription was written by a physician who was subsequently excluded may urgently need a prescription refill (for example, for blood pressure medication or insulin) and may be unable to see another physician quickly. We are concerned that in some cases, the resulting delay in getting medication could pose a risk to the enrollee's health. For this reason, we are soliciting comments on how, within the law, we could craft

a regulation that would protect the enrollees in this limited circumstance.

1001.2001(b) Opportunity To Present Oral Argument

We propose allowing individuals or entities whom OIG proposes to exclude under the newly enacted section 1128(b)(16) of the Act to request an opportunity to present oral argument to an OIG official prior to imposition of the exclusion. This process is currently available to individuals who are considered for exclusion under section 1128(b)(6) of the Act and is set forth at § 1001.2001(b). Section 1128(b)(16) of the Act is similar to section 1128(b)(6) of the Act in that it requires OIG to make factual findings or determinations; therefore, we propose to also allow these individuals and entities to present oral argument. For this reason, we propose to amend § 1001.2001(b) to add a reference to § 1001.1751, the proposed regulation section for section 1128(b)(16) of the Act.

1001.2001 - 1001.2003 Notice of Intent To Exclude and Notice of Exclusion

Under the current regulations, when OIG proposes to exclude an individual or entity under sections 1128(b)(7), 1842(j)(1)(D)(iv) (42 U.S.C. 1395u(j)(1)(D)(iv)), or 1842(k)(1) of the Act, OIG is required to send both a

written notice of its intent to exclude under § 1001.2001 and a notice of proposal under § 1001.2003. The notice of intent to exclude and the notice of proposed exclusion both allow the individual or entity to respond to OIG with written argument concerning whether the exclusion is warranted before the exclusion goes into effect. Because the notice of proposed exclusion allows the individual or entity to request a hearing with an ALJ, we believe it would be sufficient in these cases for OIG to issue only a notice of proposed exclusion. As a result, we propose modifying § 1001.2001 to eliminate the requirement that OIG send a written notice of intent to exclude prior to sending a notice of proposal to exclude. Correspondingly, we would add §§ 1001.901, 1001.951, 1001.1601, and 1001.1701, the applicable regulation sections pertaining to these exclusions, to the list of exceptions to the notice of intent to exclude in § 1001.2001(c).

In addition, consistent with longstanding practice, OIG will continue to mail the notices of intent to exclude and all other notices relating to the imposition of exclusion via first-class mail.

Section 1001.2001 currently uses the word "proposes" in connection with the notice of intent to exclude. We propose clarifying the language in § 1001.2001 to make it

clear that the notice of intent to exclude under that paragraph is different from the notice of proposal to exclude under § 1001.2003 by replacing the word proposes with the word intends.

Finally, we propose to begin sending notices of intent to exclude individuals pursuant to section 1128(b)(14) of the Act. Section 1128(b)(14) provides that in determining whether to exclude a physician, OIG will consider access of beneficiaries to physician services. Thus, to allow physicians the opportunity to provide information about beneficiary access to physician services before the proposed exclusion goes into effect, we propose removing the reference to § 1001.1501, the applicable regulation section pertaining to exclusions under section 1128(b)(14) of the Act, from the list of exceptions in § 1001.2001(c).

As a result of these changes, § 1001.2001(c) would read as follows: "(c) Exception. If OIG proposes to exclude an individual or entity under the provisions of §§ 1001.901, 1001.951, 1001.1301, 1001.1401, 1001.1601, or 1001.1701 of this part, paragraph (a) will not apply."
1001.2004-1001.2006 Notice of Exclusion by HHS

We propose clarifying that HHS will notify State agencies, State licensing agencies, and the public about the exclusion actions it takes. In light of the following

proposed revision requiring indirect providers, such as companies that manufacture or distribute pharmaceuticals or devices, to notify their customers of their exclusion, we propose clarifying that §§ 1001.2004 through 1001.2006 pertain to notice by HHS. Therefore, we propose renaming the headings to include the phrase "Notice . . . by HHS."

1001.3001 Reinstatement Procedures

Earlier in the preamble, we discussed our proposal to add, at § 1001.501(b) and § 1001.501(c), early reinstatement procedures for individuals excluded under section 1128(b)(4) of the Act. We therefore propose to add references to these regulation sections to the reinstatement procedures at § 1001.3001(a)(1) to accurately reflect all reinstatement procedures. Lastly, we propose renumbering § 1001.3001. Currently, subparagraphs (3) and (4) are placed under paragraph (a), which relates to timing of reinstatement, but subparagraphs (3) and (4) relate to method of request. We propose redesignating current subparagraphs (3) and (4) as new paragraphs (b) and (c) and redesignating the current paragraph (b) as paragraph (d).

1001.3002 Criteria for Reinstatement

We propose to clarify that the factors OIG will consider for a reinstatement determination, set forth at § 1001.3002(b), will be considered under § 1001.3002(a). We

propose to add the following underlined language to § 1001.3002(b): “In making the reinstatement determination described in paragraph (a) of this section, OIG will consider” In addition, we propose amending the current language in § 1001.3002(b)(6) and renumbering it as § 1001.3002(b)(5) to clarify that even when an individual or entity has received a program provider number while excluded, OIG, in deciding whether to reinstate the individual or entity, may consider the fact that the individual or entity submitted claims or caused claims to be submitted while excluded.

1001.3005 Withdrawal of Exclusion

We propose clarifying that OIG will withdraw exclusions that are derivative of convictions that are later reversed or vacated on appeal. The reinstatement procedures currently provide for reinstatement in such situations, but our proposed change to § 1001.3005(a) would make clear that these reinstatements would be the result of OIG’s withdrawal of the exclusion.

3. Changes to Part 1002

1002.1 Scope and Purpose

We propose to revise the list of authorities currently at § 1002.1 to clarify the statutory basis and scope of these regulations. In addition, we propose to add a new §

1002.2 to identify related Federal regulations that establish disclosure requirements for providers and State agencies and exclusion requirements for managed care organizations. This would require a renumbering of the current §§ 1002.2 and 1002.3 as §§ 1002.3 and 1002.4, respectively. Finally, we propose to simplify the description of Federal health care programs in § 1002.3(a) by removing the reference to Medicare and Medicaid, because both programs are included in the definition of "Federal health care program."

1002.4 Disclosure by Providers and State Medicaid Agencies

We propose to renumber § 1002.3 as § 1002.4 and amend it to clarify that the Medicaid agency may refuse to enter into or renew a provider agreement because of a criminal conviction related to any Federal health care program listed at section 1128 of the Act, not just to Medicare, Medicaid, or Title XX programs.

1002.5 State Plan Requirement

We propose to move the provisions currently found in § 1002.100 to a new section, § 1002.5.

1002.6 Payment Prohibitions

We propose to move the provisions currently found in § 1002.211 to a new section, § 1002.6, and to rename the new

section "Payment Prohibitions," which more accurately describes its contents.

1002.6(a) Conforming Change To Mirror Scope and Effect of Exclusion Section

We propose to amend new § 1002.6(a) to clarify that payment is prohibited for items or services furnished at the medical direction or on the prescription of an excluded physician or other authorized individual. This revision conforms more closely to the language in revised § 1001.1901(b) defining the scope and effect of exclusion.

Subpart B - Rename as "State Exclusion of Certain Managed Care Entities"

We propose to rename Subpart B of part 1002 (currently "Mandatory Exclusion") as "State Exclusion of Certain Managed Care Entities" to clarify that it pertains only to State exclusion of certain managed care entities and not more broadly to mandatory exclusions in general.

1002.203 Mandatory Exclusion

We propose to clarify that Federal regulations require States to exclude managed care organizations or entities that have ownership or control interests that could subject them to Federal exclusion by OIG. We also propose to update § 1002.203 by replacing the term "HMO" with the term "managed care organization" to more closely conform to the

language of the Act at section 1902(p)(2) (42 U.S.C. 1396a(p)(2)). The BBA changed the terminology in Title XIX, using the term "managed care organization" to refer to entities previously labeled "health maintenance organizations" (HMOs).

Subpart C - Rename as "Procedures for State-Initiated Exclusions"

We propose to rename Subpart C (currently "Permissive Exclusions") as "Procedures for State-Initiated Exclusions" to clarify that it pertains to procedures for State-initiated exclusions.

4. Changes to Part 1006

1006.1 Testimonial Subpoena Authority in Section 1128 Cases

Section 6402(e) of ACA granted the Secretary testimonial subpoena authority in investigations of section 1128 cases at section 1128(f)(4) of the Act. Prior to the enactment of ACA, OIG's testimonial subpoena authority was limited to cases in which OIG was pursuing CMPs under section 1128A of the Act. The expanded testimonial subpoena authority gives OIG an additional investigative tool under section 1128 of the Act for pursuing exclusions for conduct such as submitting improper claims.

In accordance with section 6402(e) of ACA, we propose to revise § 1006.1 of these proposed regulations to include a reference to the newly enacted section 1128(f)(4) of the Act and add "section 1128" to § 1006.1(b) to reflect that OIG may issue testimonial subpoenas in investigations of potential cases involving the exclusion statute.

III. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

Executive Order Nos. 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. A regulatory impact analysis must be prepared for major rules with economically significant effects, i.e., \$100

million or more in any given year. This is not a major rule as defined at 5 U.S.C. 804(2); it is not economically significant because it does not reach that economic threshold.

This proposed rule is designed to propose implementation of new statutory provisions, including new exclusion authorities. It is also designed to clarify the intent of existing statutory requirements. The vast majority of providers and Federal health care programs would be minimally impacted, if at all, by these proposed revisions.

The proposed changes to the exclusion regulations would have little economic impact. On average, OIG excludes approximately 3,500 health care providers per year. Historically, fewer than 10 waivers of exclusion have been granted in any given year, and fewer than two falls affirmative exclusion cases are filed in court. Thus, we believe that any aggregate economic effect of the proposed exclusion regulatory provisions would be minimal. Additionally, over the past 3 fiscal years, OIG has on average returned approximately \$16.6 million per year to the Medicare Trust Fund. This return under the \$100 million threshold.

Accordingly, we believe that the likely aggregate economic effect of these regulations would be significantly less than \$100 million.

Regulatory Flexibility Act

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require 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 providers are considered small entities by having revenues of \$5 million to \$25 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities.

The aggregate economic impact of the exclusion provisions on small entities would be minimal, directly affecting only those limited number of excluded individuals and entities that are sole community physicians or sole sources of essential specialized services in the community. We believe any resulting impact would be a positive one on the health care community.

In summary, we have concluded that this proposed rule should not have a significant impact on the operations of a substantial number of small providers and that a regulatory flexibility analysis is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4, requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal Governments, in the aggregate, or by the private sector, of \$110 million. As indicated above, these proposed revisions comport with statutory amendments and clarify existing law. As a result, we believe that there would be 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 \$110 million or more (adjusted for inflation) per year and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or 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 proposed rule would not

significantly affect the rights, roles, and responsibilities of State or local Governments.

IV. Paperwork Reduction Act

These proposed changes to Parts 1000, 1001, 1002 and 1006 impose no new reporting requirements or collections of information. Therefore, a Paperwork Reduction Act review is not required.

List of Subjects

42 CFR Part 1000

Administrative practice and procedure, Grant programs-health, Health facilities, Health professions, Medicaid, Medicare

42 CFR Part 1001

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

42 CFR Part 1002

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

42 CFR Part 1006

Administrative practice and procedure, Fraud, Investigations, Penalties.

Accordingly, 42 CFR parts 1000, 1001, 1002, and 1006 are proposed to be amended as set forth below:

PART 1000—INTRODUCTION: GENERAL DEFINITIONS

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

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

2. Section 1000.10 is amended by:

- a. Republishing the introductory text
- b. Adding a definition of "ALJ";
- c. Revising the definition of "Directly";
- d. Adding a definition of "Exclusion";
- e. Revising the definitions of "Furnished", "Indirectly", "QIO", and "Secretary"; and
- f. Adding definitions of "State" and "State health care program".

The additions and revisions read as follows:

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

* * * * *

ALJ means an Administrative Law Judge.

* * * * *

Directly, as used in the definition of "furnished" in this section, means the provision or supply of items and services by individuals or entities (including items and services provided or supplied by them, but manufactured, ordered, or prescribed by another individual or entity) who request or receive payment from Medicare, Medicaid, or other Federal health care programs.

* * * * *

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

* * * * *

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity.

* * * * *

Indirectly, as used in the definition of "furnished" in this section, means the provision or supply of items and services manufactured, distributed, supplied, or otherwise provided by individuals or entities that do not directly request or receive payment from Medicare, Medicaid, or

other Federal health care programs, but that provide items and services to providers, practitioners, or suppliers who request or receive payment from these programs for such items and services.

* * * * *

QIO means a quality improvement organization as that term is used in section 1152 of the Act (42 U.S.C. § 1320c-1) and its implementing regulations.

Secretary means the Secretary of the Department or his or her designees.

* * * * *

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means:

(1) A State plan approved under Title XIX of the Act (Medicaid),

(2) Any program receiving funds under Title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program),

(3) Any program receiving funds under subtitle A of Title XX of the Act or from any allotment to a State under

such subtitle (Block Grants to States for Social Services),
or

(4) A State child health plan approved under Title XXI
(Children's Health Insurance Program).

* * * * *

§§ 1000.20 and 1000.30 [Removed]

3. Sections 1000.20 and 1000.30 are removed.

**PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE
PROGRAMS**

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

Authority: 42 U.S.C. 1302; 1320a-7; 1320a-7b;
1395u(j); 1395u(k); 1395w-104(e)(6), 1395y(d); 1395y(e);
1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv),
1842(k)(1), and sec. 2455, Pub.L. 103-355, 108 Stat. 3327
(31 U.S.C. 6101 note).

6. Section 1001.2 is amended by:

- a. Adding introductory text;
- b. Adding a definition of "Agent";
- c. Redesignating paragraphs (a) and (b) under "Controlled
substance" as paragraphs (1) and (2), paragraphs (a)
through (d) under "Convicted" as paragraphs (1) through (4)
(and (a)(1) and (2) as (1)(i) and (ii));

- d. Removing the definition of "Exclusion";
- e. Adding definitions of "Immediate family member", "Indirect ownership interest", "Managing employee", "Member of household";
- f. Removing the definition of "OIG";
- g. Adding definitions of "Ownership interest" and "Ownership or control interest"; and
- h. Removing the definitions of "QIO" and "State health care program".

The additions read as follows:

§ 1001.2 Definitions.

For purposes of this part:

Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

* * * * *

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

* * * * *

Indirect ownership interest includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10-percent ownership interest in the entity at issue if he or she has a 20-percent ownership interest in a corporation that wholly owns a subsidiary that is a 50-percent owner of the entity in issue.)

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

Member of household means, with respect to a person, any individual with whom the person is sharing a common abode as part of a single family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.

* * * * *

Ownership interest means an interest in:

(1) The capital, the stock, or the profits of the entity, or

(2) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

Ownership or control interest means, with respect to an entity, a person who

(1) Has a direct or an indirect ownership interest (or any combination thereof) of 5 percent or more in the entity,

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

(3) Is an officer or a director of the entity;

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

(5) Is an agent of the entity; or

(6) Is a managing employee of the entity.

* * * * *

7. Section 1001.101 is amended by republishing the introductory text and by revising paragraph (d) to read as follows:

§ 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

* * * * *

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

(1) Is now, or was at the time of the offense, a health care practitioner, provider, or supplier or furnished or furnishes items or services;

(2) Holds, or held at the time of the offense, a direct or an indirect ownership or control interest in an entity that furnished or furnishes items or services or is, or has ever been, an officer, a director, an agent or a managing employee of such an entity; or

(3) Is now, or was at the time of the offense, employed in any capacity in the health care industry.

8. Section 1001.102 is amended by:

- a. Republishing paragraph (b) introductory text;
- b. Revising paragraph (b) (1);
- c. Removing paragraph (b) (7);

- d. Redesignating paragraph (b) (8) as paragraph (b) (7);
- e. Redesignating paragraph (b) (9) and paragraph (b) (8) and revising it;
- f. Adding new paragraph (b) (9);
- g. Republishing paragraph (c) introductory text;
- h. Revising paragraph (c) (1); and
- i. Revising paragraph (d).

The revisions 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, caused, or were intended to cause, a financial loss to a government agency or program or to one or more other entities of \$15,000 or more. (The entire amount of financial loss to such government agencies or programs or to other entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);

* * * * *

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

(8) The individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion; or

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

* * * * *

(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) In the case of an exclusion under §1001.101(a), whether the individual or entity was convicted of three 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 \$5,000;

* * * * *

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

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

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

9. Section 1001.201 is amended by:

- a. Republishing paragraph (b) (1) introductory text;
- b. Revising paragraphs (b) (2) (i) and (vi);
- c. Adding paragraph (b) (2) (vii);
- d. Republishing paragraph (b) (3) introductory text;
- e. Revising paragraphs (b) (3) (i) through (iii); and

f. Removing paragraph (b) (3) (iv).

The revisions and addition read as follows:

§ 1001.201 Conviction relating to program or health care fraud.

* * * * *

(b) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b) (2) and (b) (3) of this section form a basis for lengthening or shortening that period.

(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, caused or reasonably could have been expected to cause, a financial loss of \$15,000 or more to a government agency or program or to one or more other entities or had a significant financial impact on program beneficiaries or other individuals. (The entire 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);

* * * * *

(vi) Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion; or

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

(3) Only 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 three or fewer offenses, and the entire amount of financial loss (both actual loss and reasonably expected loss) to a government agency or program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than \$5,000;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, an emotional, or a physical condition, before or during the commission of the offense, that reduced the individual's culpability; or

(iii) The individual's or entity's cooperation with Federal or State officials resulted in-

(A) Others being convicted or excluded from Medicare, Medicaid, or any other Federal health care program;

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

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

10. Section 1001.301 is amended by:

- a. Revising the section heading
- b. Revising paragraph (a);
- c. Republishing paragraphs (b) (1) and (2);
- d. Revising paragraphs (b) (2) (i), (ii), and (vi);
- e. Adding paragraphs (b) (2) (vii) and (viii);
- f. Republishing the paragraph (b) (3) introductory text;
- g. Revising paragraphs (b) (3) (i) and (ii); and
- h. Removing (b) (3) (iii).

The revisions and addition read as follows:

§ 1001.301 Conviction relating to obstruction of an investigation or audit.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has been convicted, under Federal

or State law, in connection with the interference with or obstruction of any investigation or audit related to:

(1) Any offense described in § 1001.101 or § 1001.201;

or

(2) The use of funds received, directly or indirectly, from any Federal health care program (as defined in section 1128(B)(f) of the Act).

(b) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

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

(i) The interference or obstruction caused the expenditure of significant additional time or resources;

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

* * * * *

(vi) Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion;

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

(viii) The acts resulting in the conviction, or similar acts, caused, or reasonably could have been expected to cause, a financial loss of \$15,000 or more to a government agency or program or to one or more other entities or had a significant financial impact on program beneficiaries or other individuals. (The entire amount of financial loss or intended loss identified in the investigation or audit 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 to be mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings, including sentencing documents, demonstrates that the court

determined that the individual had a mental, emotional, or physical condition, before or during the commission of the offense, that reduced the individual's culpability or

(ii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs;

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

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

11. Section 1001.401 is amended by:

- a. Revising paragraph (a);
- b. Revising paragraphs (c) introductory text and (c) (2) (iv) and (v);
- c. Adding paragraph (c) (2) (vi); and
- d. Revising paragraph (c) (3).

The revisions and addition read as follows:

§ 1001.401 Conviction relating to controlled substances.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity convicted under Federal or State law of a misdemeanor relating to the unlawful manufacture,

distribution, prescription, or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

(1) Is now, or was at the time of the offense, a health care practitioner, provider, or supplier or furnished or furnishes items or services;

(2) Holds, or held at the time of offense, a direct or indirect ownership or control interest in an entity that is a health care provider or supplier; or

(3) Is now, or was at the time of the offense, employed in any capacity in the health care industry.

* * * * *

(c) Length of exclusion. (1) An exclusion imposed in accordance with this section will be for a period of 3 years unless aggravating or mitigating factors listed in paragraphs (c) (2) and (3) of this section form a basis for lengthening or shortening that period.

(2) * * *

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

(v) Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion; or

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

(3) Only the following factor may be considered to be mitigating and to be a basis for shortening the period of exclusion--Whether the individual's or entity's cooperation with Federal or State officials resulted in--

(i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs;

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

(iii) The imposition of a civil money penalty against others.

12. Section 1001.501 is amended by revising paragraphs (b) (1) and (2) and adding paragraph (c) to read as follows:

§ 1001.501 License revocation or suspension.

* * * * *

(b) * * *

(1) Except as provided in paragraph (b) (2) of this section, an exclusion imposed in accordance with this

section will not be for a period of time less than the period during which an individual's or entity's license is revoked, suspended, or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with § 1001.3001 if:

(i) The individual or entity obtains the license in the State where the license was originally revoked, suspended, surrendered, or otherwise lost or

(ii) The individual meets the conditions for early reinstatement set forth in paragraph (c) of this section.

(c) Consideration of early reinstatement. (1) If an individual or entity that is excluded in accordance with this section fully and accurately discloses the circumstances surrounding the action that formed the basis for the exclusion to a licensing authority of a different State or to a different licensing authority in the same State and that licensing authority grants the individual or entity a new license or has decided to take no adverse action as to a currently held license, the OIG will consider a request for early reinstatement. The OIG will consider the following factors in determining whether a

request for early reinstatement under this paragraph (c) (1) will be granted:

(i) The circumstances that formed the basis for the exclusion;

(ii) Evidence that the second licensing authority was aware of the circumstances surrounding the action that formed the basis for the exclusion;

(iii) Whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(iv) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(v) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) Any additional or pending license actions in the same State or in any other State;

(vii) Any ongoing investigations involving the individual; and

(viii) All the factors set forth in § 1001.3002(b).

(2) If an exclusion has been imposed under this section and the individual does not have a valid health care license of any kind in any State, that individual may request the OIG to consider whether he or she may be

eligible for early reinstatement. The OIG will consider the following factors in determining whether a request for early reinstatement under paragraph (c)(2) will be granted:

(i) The length of time the individual has been excluded. The OIG will apply a presumption against early reinstatement under this paragraph (c)(2) if the person has been excluded for less than 5 years;

(ii) The circumstances that formed the basis for the exclusion;

(iii) Whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(iv) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(v) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) Any additional or pending license actions in the same State or in any other State;

(vii) Any ongoing investigations involving the individual;

(viii) The reasons the individual is seeking reinstatement;

(ix) Whether the individual is seeking, or intends to seek, employment in an unlicensed health care position; and

(x) All the factors set forth in 1001.3002(b).

(3) Except for § 1001.3002(a)(1)(i), all the provisions of Subpart F (§§ 1001.3001 through 1001.3005) apply to early reinstatements under this section.

13. Section 1001.601 is amended by revising paragraph

(b)(2) to read as follows:

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

* * * * *

(b) * * *

(2) If the individual or entity is eligible to apply for reinstatement in accordance with § 1001.3001 of this part and the sole reason why the State or Federal health care program denied reinstatement to that program is the existing exclusion imposed by the OIG as a result of the original State or Federal health care program action, the OIG will consider a request for reinstatement.

* * * * *

14. Section 1001.701 is amended by revising the headings for paragraphs (a) and (c) and revising paragraphs

(d)(2)(iv) and (d)(3) to read as follows:

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) Circumstance for exclusion. * * *

* * * * *

(c) Exceptions. * * *

(d) * * *

(2) * * *

(iv) The violation resulted in financial loss to Medicare, Medicaid and any other Federal health care program of \$15,000 or more; or

* * * * *

(3) Only the following factor may be considered mitigating and a basis for reducing the period of exclusion--Whether there were few violations and they occurred over a short period of time.

15. Section 1001.801 is amended by revising the heading for paragraph (a), removing paragraph (c) (3) (ii), and redesignating paragraph (c) (3) (iii) as paragraph (c) (3) (ii).

The revision reads as follows:

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

(a) Circumstance for exclusion. * * *

* * * * *

16. Section 1001.901 is amended by adding paragraph (c) to read as follows:

§ 1001.901 False or improper claims.

* * * * *

(c) An exclusion under this section is neither time barred nor subject to any statute of limitations period, even when the exclusion is based on violations of another statute that may have a specified limitations period.

17. Section 1001.951 is amended by revising paragraph (b) (2) to read as follows:

§ 1001.951 Fraud and kickback and other prohibited activities.

* * * * *

(b) * * *

(2) It will be considered a mitigating factor if—

(i) The individual had a documented mental, emotional, or physical condition before or during the commission of the prohibited act(s) that reduced the individual's culpability for the acts in question; or

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the—

- (A) Sanctioning of other individuals or entities, or
- (B) Imposition of a civil money penalty against others.

18. Section 1001.1001 is amended by revising paragraph (a) introductory text, (a)(1), and (a)(2) to read as follows:

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

(a) Circumstance for exclusion. The OIG may exclude an entity:

(1) If a person with a relationship with such entity—

(i) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2), or (3) of the Act;

(ii) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(iii) Has been excluded from participation in Medicare or any of the State health care programs and

(2) Such a person has a direct or indirect ownership or control interest in the entity, or formerly held an ownership or control interest in the entity, but no longer holds an ownership or control interest because of a transfer of the interest to an immediate family member or a member of the person's household in anticipation of or

following a conviction, assessment of a CMP, or imposition of an exclusion.

* * * * *

19. Section 1001.1051 is amended by revising paragraph (c) (1) to read as follows:

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

* * * * *

(c) * * *

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

* * * * *

20. Section 1001.1101 is amended by republishing paragraph (b) introductory text, revising paragraph (b) (4), removing paragraph (b) (5), and redesignating paragraph (b) (6) as paragraph (b) (5).

The revision reads as follows:

§ 1001.1101 Failure to disclose certain information.

* * * * *

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

* * * * *

(4) Any other facts that bear on the nature or seriousness of the conduct; and

* * * * *

21. Section 1001.1201 is amended by revising paragraph (a) introductory text, republishing paragraph (b) introductory text, revising paragraphs (b) (3) and (4), and removing paragraph (b) (5).

The revisions read as follows:

§ 1001.1201 Failure to provide payment information.

(a) Circumstance for exclusion. The OIG may exclude any individual or entity that furnishes, orders, refers for furnishing, or certifies the need for items or services for which payment may be made under Medicare or any of the State health care programs and that:

* * * * *

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

* * * * *

(3) The amount of the payments at issue; and

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

* * * * *

22. Section 1001.1301 is amended by revising paragraphs

(a)(1)(iii) and (a)(3) to read as follows:

§ 1001.1301 Failure to Grant Immediate Access

(a) * * *

(1) * * *

(iii) The OIG for reviewing records, documents, and other material or data in any medium (including electronically stored information and any tangible thing) necessary to the OIG's statutory functions; or

* * * * *

(3) For purposes of paragraphs (a)(1)(iii) and

(a)(1)(iv) of this section, the term-

Failure to grant immediate access means:

(A) The failure to produce or make available for inspection and copying the requested material upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request, except when the OIG or State Medicaid Fraud Control Unit

(MFCU) reasonably believes that the requested material is about to be altered or destroyed, and

(B) When the OIG or MFCU has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.

Reasonable request means a written request, signed by a designated representative of the OIG or MFCU and made by a properly identified agent of the OIG or a MFCU during reasonable business hours, where there is information to suggest that the person has violated statutory or regulatory requirements under Titles V, XI, XVIII, XIX, or XX of the Act. The request will include a statement of the authority for the request, the person's rights in responding to the request, the definition of "reasonable request" and "failure to grant immediate access" under part 1001, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

* * * * *

23. Section 1001.1501 is amended by revising paragraphs (a)(1) and (2) and (b) to read as follows:

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) * * *

(1) Except as provided in paragraph (a)(4) of this section, the OIG may exclude any individual that the administrator of the health education loan, scholarship, or loan repayment program determines is in default on repayments of scholarship obligations or loans, or the obligations of any loan repayment program, in connection with health professions education made or secured in whole or in part by the Secretary.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine that the administrator of the health education loan, scholarship, or loan repayment program has taken all reasonable administrative steps to secure repayment of the loans or obligations. When an individual has been offered a Medicare offset arrangement as required by section 1892 of the Act, the OIG will find that all reasonable steps have been taken.

* * * * *

(b) Length of exclusion. The individual will be excluded until the administrator of the health education loan, scholarship, or loan repayment program 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.

21. Section 1001.1601 is amended by republishing paragraph (b) (1) introductory text, revising paragraphs (b) (1) (iii) and (iv), and removing paragraph (b) (1) (v).

The revisions read as follows:

§ 1001.1601 Violations of the limitations on physician charges.

(b) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

* * * * *

(iii) The amount of the charges that were in excess of the maximum allowable charges; and

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

* * * * *

25. Section 1001.1701 is amended by republishing paragraph (c)(1) introductory text, revising paragraphs (c)(1)(iv) and (v), and removing paragraph (c)(1)(vi).

The revisions read as follows:

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

* * * * *

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

* * * * *

(iv) Whether approval for the use of an assistant was requested from the QIO or carrier; and

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

* * * * *

26. Section 1001.1751 is added to subpart C to read as follows:

§ 1001.1751 Making false statements or misrepresentation of material facts.

(a) Circumstance for exclusion. The OIG may exclude any individual or entity that it determines has knowingly made or caused to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program (as defined in section 1128B(f)), including Medicare Advantage organizations under part C of Medicare, prescription drug plan sponsors under part D of Medicare, Medicaid managed care organizations, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans.

(b) Definition of "material." For purposes of this section, the term "material" means having a natural tendency to influence or be capable of influencing the decision to approve or deny the request to participate or enroll as a provider of services or supplier under a Federal health care program.

(c) Sources of information. The OIG's determination under paragraph (a) of this section will be made on the basis of information from the following sources:

- (1) CMS;
- (2) Medicaid State agencies;

(3) Fiscal agents or contractors, or private insurance companies;

(4) Law enforcement agencies;

(5) State or local licensing or certification authorities;

(6) State or local professional societies; or

(7) Any other sources deemed appropriate by the OIG.

(d) Length of exclusion. In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors--

(1) What were the actual or potential repercussions of the false statement, omission, or misrepresentation of a material fact and

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

24. Section 1001.1801 is amended by revising paragraphs (a) and (b) and by removing paragraph (g).

The revisions read as follows:

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from the administrator of a Federal health care program (as defined in section 1128B(f) of the Act) 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 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), (c), or (d), a request from a Federal health care program for a waiver of the exclusion will be considered only if the Federal health care program administrator determines that:

(1) The individual or entity is the sole community physician or the sole source of essential specialized services in a community; and

(2) The exclusion would impose a hardship on beneficiaries (as defined in section 1128A(i)(5) of the Act) of that program.

* * * * *

25. Section 1001.1901 is amended by revising paragraphs (b), (c) introductory text, (c)(1), (c)(2), and (c)(4) to read as follows:

§ 1001.1901 Scope and effect of exclusion.

* * * * *

(b) Effect of exclusion on excluded individuals and entities. (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid, and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, including Medicare Advantage and Prescription Drug Plans, Medicaid, or any other Federal health care program for any item or service furnished, on or after the effective date specified in the notice -

(i) By an excluded individual or entity; or

(ii) At the medical direction or on the prescription of a physician or an authorized individual who is excluded when the person furnishing such item or service knew, or had reason to know, of the exclusion.

(2) This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(3) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(4) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil

money penalty liability under section 1128A(a)(1)(D) of the Act and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made, for items or services furnished, ordered, or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

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

If a Medicare enrollee submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or authorized individual, after the effective date of exclusion, CMS, a Medicare Advantage Plan, or a Prescription Drug Plan will pay such claim submitted by the enrollee and will immediately notify the enrollee of the exclusion.

(2) CMS, Medicare Advantage Plans, and Prescription Drug Plans will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual, more than 15 days after the date on the notice to the enrollee.

* * * * *

(4) CMS will not pay any claims submitted by a supplier for items or services ordered or prescribed by an excluded provider for dates of service 15 days or more after the notice of the provider's exclusion was mailed to the supplier.

* * * * *

29. Section 1001.2001 is amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG intends to exclude an individual or entity in accordance with subpart C or this part, or in accordance with subpart B of this part where the exclusion is for a period exceeding five years, it will send a written notice of its intent, the basis for the proposed exclusion and the potential effect of exclusion. Within 30 days of receipt of notice, which can be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If the OIG intends to exclude an individual or entity under the provisions of § 1001.701, § 1001.801, or § 1001.1751, in conjunction with the submission of documentary evidence and written argument, an individual or

entity may request an opportunity to present oral argument to an OIG official.

(c) Exception. If the OIG intends to exclude an individual or entity under the provisions of § 1001.901, § 1001.951, § 1001.1301, § 1001.1401, § 1001.1601, or § 1001.1701 of this part, paragraph (a) of this section will not apply.

* * * * *

30. Section 1001.2004 is amended by revising the section heading to read as follows:

1001.2004 Notice to State agencies by HHS.

* * * * *

31. Section 1001.2005 is amended by revising the section heading to read as follows:

1001.2005 Notice to State licensing agencies by HHS.

* * * * *

32. Section 1001.2006 is amended by revising the section heading to read as follows:

1001.2006 Notice to others regarding exclusion by HHS.

* * * * *

33. Section 1001.3001 is amended by revising paragraphs (a)(1) and (2) and redesignating paragraphs (a)(3), (a)(4), and (b) as paragraphs (b), (c), and (d), respectively.

The revisions read as follows:

§ 1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraph (a)(2) of this section or in § 1001.501(b)(2), § 1001.501(c), or § 1001.601(b)(4) of this part, an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion. Obtaining a program provider number or equivalent does not reinstate eligibility.

(2) An entity excluded under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in § 1001.3002(c) have been met.

* * * * *

34. Section 1001.3002 is amended by revising paragraphs (a), (b), and (c) introductory text to read as follows:

§ 1001.3002 Basis for reinstatement.

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

- (1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

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

(b) In making the reinstatement determination described in paragraph (a) of this section, the OIG will consider—

(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;

(2) Conduct of the individual or entity after the date of the notice of exclusion;

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

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

(5) Whether the individual or entity has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by any Federal health care program, for items or services the excluded party furnished, ordered, or prescribed, including health care administrative services. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated; and

(c) If the OIG determines that the criteria in paragraphs (a) (2) and (3) of this section have been met, an entity excluded in accordance with § 1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion, or civil money penalty was the basis for the entity's exclusion—

* * * * *

35. Section 1001.3005 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 1001.3005 Withdrawal of exclusion for reversed or vacated decisions.

(a) An exclusion will be withdrawn and 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—

* * * * *

PART 1002—[AMENDED]

36. The authority citation for part 1002 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a-3, 1320a-5, 1320a-7, 1396(a)(4)(A), 1396a(p), 1396a(a)(39), 1396a(a)(41), and 1396b(i)(2).

37. Section 1002.1 is revised to read as follows:

§ 1002.1 Basis and scope.

(a) Statutory basis. This part implements sections 1902(a)(4), 1902(a)(39), 1902(a)(41), 1902(p), 1903(i)(2), 1124, 1126, and 1128 of the Act.

(1) Under authority of section 1902(a)(4) of the Act, this part sets forth methods of administration and procedures the State agency must follow to exclude a provider from participation in the State Medicaid program. State-initiated exclusion from Medicaid may lead to OIG exclusion from all Federal health care programs.

(2) Under authority of sections 1124 and 1126 of the Act, this part requires the Medicaid agency to obtain and disclose to the OIG certain provider ownership and control information, along with actions taken on a provider's application to participate in the program.

(3) Under authority of sections 1902(a)(41) and 1128 of the Act, this part requires the State agency to notify the OIG of sanctions and other actions the State takes to limit a provider's participation in Medicaid.

(4) Section 1902(p) of the Act permits the State to exclude an individual or entity from Medicaid for any reason the Secretary can exclude and requires the State to exclude certain managed care entities that could be excluded by the OIG.

(5) Sections 1902(a)(39) and 1903(i)(2) of the Act prohibit State payments to providers and deny FFP in State expenditures for items or services furnished by an individual or entity that has been excluded by the OIG from participation in Federal health care programs.

(b) Scope. This part specifies certain bases upon which the State may, or in some cases must, exclude an individual or entity from participation in the Medicaid program and the administrative procedures the State must follow to do so. These regulations specifically address the

authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. In addition, this part delineates the States' obligation to obtain certain information from Medicaid providers and to inform the OIG of information received and actions taken.

§§ 1002.2 and 1002.3 [Redesignated as §§ 1002.3 and 1002.4]

38. Sections 1002.2 and 1002.3 are redesignated as § 1002.3 and 1002.4, respectively.

39. A new § 1002.2 is added to read as follows:

§ 1002.2 Other applicable regulations.

(a) Part 455, subpart B, of this title sets forth requirements for disclosure of ownership and control information to the State Medicaid agency by providers and fiscal agents.

(b) Part 438, subpart J, of this title sets forth payment and exclusion requirements specific to Medicaid managed care organizations.

40. Newly designated § 1002.3 is amended by revising paragraph (a) to read as follows:

§ 1002.3 General authority.

(a) In addition to any other authority it may have, a State may exclude an individual or entity from

participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in Federal health care programs under sections 1128, 1128A or 1866(b)(2) of the Act.

* * * * *

41. Newly designated § 1002.4 is amended by revising paragraph (c)(1) to read as follows:

§ 1002.4 Disclosure by providers and State Medicaid agencies.

* * * * *

(c) * * *

(1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest, or who is an agent or managing employee of the provider, in the provider has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid, Title V, Title XX, or Title XXI of the Act.

* * * * *

§ 1002.100 [Redesignated as § 1002.5]

42. Section 1002.100 is redesignated as § 1002.5 in subpart A.

§ 1002.211 [Redesignated as § 1002.6]

43. Section 1002.211 is redesignated as § 1002.6 in subpart A.

44. Newly designated §1002.6 is revised to read as follows:

§ 1002.6 Payment prohibitions.

(a) Denial of payment by State agencies. Except as provided for in §§ 1001.1901(c)(3), (c)(4), and (c)(5)(i) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice:

(1) by an individual or entity excluded by the OIG or

(2) at the medical direction or on the prescription of a physician or other authorized individual who is excluded by the OIG when a person furnishing such item or service knew, or had reason to know, of the exclusion.

(b) Denial of Federal financial participation (FFP).

FFP is not available for any item or service for which the State agency is required to deny payment under paragraph (a) of this section. FFP will be available for items and services furnished after the excluded individual or entity is reinstated in the Medicaid program.

45. The subpart heading for subpart B is revised to read as follows:

Subpart B—State Exclusion of Certain Managed Care Entities

46. Section 1002.203 is amended by revising the section heading and paragraph (a) to read as follows:

§ 1002.203 State exclusion of certain managed care entities.

(a) The State agency, in order to receive FFP, must provide that it will exclude from participation any managed care organization (as defined in section 1903(m) of the Act), or entity furnishing services under a waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Has a prohibited ownership or control relationship with any individual or entity that could subject the managed care organization or entity to exclusion under § 1001.1001 or § 1001.1051 of this chapter or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under § 1001.1001 or § 1001.1051 of this chapter.

* * * * *

47. The subpart heading for subpart C is revised to read as follows:

Subpart C—Procedures for State-Initiated Exclusions

48. Section 1002.210 is amended by revising the section heading to read as follows:

§ 1002.210 General authority.

* * * * *

§ 1002.211 [Removed and Reserved]

49. Section 1002.211 is removed and reserved.

PART 1006—[AMENDED]

50. The authority citation for part 1006 is revised to read as follows:

Authority: 42 U.S.C. 405(d), 405(e), 1302, 1320a-7, and 1320a-7a.

51. Section 1006.1 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1006.1 Scope.

(a) The provisions in this part govern subpoenas issued by the Inspector General, or his or her delegates, in accordance with sections 205(d), 1128A(j), and 1128(f)(4) of the Act and require the attendance and testimony of witnesses and the production of any other evidence at an investigational inquiry.

(b) Such subpoenas may be issued in investigations under section 1128 or 1128A of the Act or under any other section of the Act that incorporates the provisions of sections 1128(f)(4) or 1128A(j).

* * * * *

DATED: January 7, 2014_____

Daniel R. Levinson
Inspector General

APPROVED: _January 16, 2014____

Kathleen Sebelius
Secretary

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