



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Inspector General**

**42 CFR Parts 1000, 1001, 1002, and 1006**

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

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

**ACTION:** Final rule.

**SUMMARY:** This final 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 final rule incorporates statutory changes, early reinstatement provisions, and policy changes, and clarifies existing regulatory provisions.

**DATES:** These regulations are effective on [OFR: INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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**SUPPLEMENTARY INFORMATION:**

**I. Statutory Background**

The Affordable Care Act of 2010 (the 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)) (ACA) expanded the Secretary's authority to exclude various individuals and entities from participation in Federal health care programs under section 1128 of the Social Security Act (Act). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended the Secretary's authority to waive certain exclusions under section 1128 of the Act. The Secretary's authority under section 1128 of the Act has been delegated to the Department's Office of Inspector General. The changes in this Final Rule were proposed at 79 Federal Register 26810 (May 9, 2014).

## **II. Legal Authority**

The legal authority for this regulatory action is found in the Act, as amended by MMA and ACA. The legal authority for the proposed changes is listed by the parts of Title 42 of the Code of Federal Regulations (CFR) 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.

### **III. Summary of the Proposed Rule**

On May 9, 2014, we published a proposed rule (79 FR 26810) addressing new and revised exclusion authorities in accordance with ACA and MMA, as well as a number of proposed technical, policy, and clarifying changes to 42 CFR 1000, 1001, 1002, and 1006. We received 19 comments on the May 9, 2014, proposed rule. Commenters included industry associations and organizations, beneficiary and other advocacy groups, and health insurance plans. The commenters generally supported our proposals. Set forth below is a brief summary of the regulatory provisions contained in that proposed rule.

#### ***Part 1000***

The proposed regulation made a number of technical changes to the definitions found in section 1000.10 of the regulations. These included changes to the definitions of "Directly," "Furnished," and "Indirectly" that would more clearly incorporate newer payment methodologies into these definitions. The proposed regulation also moved numerous definitions from parts 1001 and 1003 into part 1000 to make them applicable to the entire subchapter and to consolidate the definitions in the

subchapter. Lastly, it removed definitions that were specific to Medicare and Medicaid from sections 1000.20 and 1000.30 because those definitions are not applicable to OIG's authorities.

### **Part 1001**

The proposed regulation reflected the expansion of OIG's exclusion authority in MMA and ACA and also proposed numerous technical and policy changes. First, ACA expanded the permissive exclusion authority found in section 1128(b)(2) of the Act to reach all individuals and entities who were convicted for the interference with or obstruction of both investigations and audits related to the use of funds received from a Federal health care program. Next, the proposal reflected an expansion of the permissive exclusion authority found in section 1128(b)(11) of the Act. After ACA, section 1128(b)(11) of the Act provides for exclusion of any individual or entity *furnishing, ordering, referring for furnishing, or certifying the need for* items and services for which payment may be made under Medicare or Medicaid that fails to provide certain payment information to the Secretary (emphasis added). The change made by ACA to section 1128(b)(11) of the Act expanded the categories of individuals and entities that are subject to exclusion under this section to those who *refer patients or certify* the need for items or services they themselves do not provide.

Third, ACA added a permissive exclusion authority at section 1128(b)(16) of the Act for knowingly making or causing to be made any false statement, omission, or misrepresentation of 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. The proposed regulation corresponding to this authority, at § 1001.1751 (in the final rule as § 1001.1552), proposed to describe the sources OIG will consider in determining whether section 1128(b)(16) of the Act applies, including information from the Centers for Medicare and Medicaid Services, State Medicaid agencies, fiscal agents or contractors, private insurance companies, State or local licensing or certification authorities, and law enforcement agencies.

Lastly, in § 1001.1801 the proposal reflected the expansion of OIG's authority to grant waivers of certain exclusions in accordance with ACA and MMA. MMA amended the Act to allow waiver requests to come from administrators of Federal health care programs, rather than just State health care programs, and to apply OIG's waiver authority to sections 1128(a)(3) and (a)(4) of the Act as well as section 1128(a)(1) of the Act. ACA further amended section 1128 of the Act to allow an administrator to request a waiver if the administrator determines that the exclusion would impose a hardship on any

beneficiary. The proposal reflected both MMA's and ACA's changes.

The proposed regulation also included numerous changes that reflect OIG's policies and practices. We proposed to narrow the scope of providers excluded under sections 1128(a)(4) and (b)(3) for convictions related to controlled substances to those who were convicted for offenses that occurred during the time they were employed in the health care industry. We also proposed to update the dollar amounts in the aggravating and mitigating factors that take financial harm into account to \$15,000 from \$5,000 (and under § 1001.701(d)(2)(iv), \$1,500). We proposed to remove: (1) the aggravating factor related to the receipt of overpayments from Medicare or Medicaid; (2) all of the aggravating and mitigating factors for loss of health care licenses and Federal health care program sanctions; and (3) the mitigating factor found throughout the regulations related to whether alternative sources of health care are not available.

We also proposed to add a process for early reinstatement where a health care license has been lost and has not been reinstated, which included numerous factors that OIG would consider under such a process. We proposed to include a provision at § 1001.901(c) stating that no period of limitations exists with respect to exclusions under section 1128(b)(7) of the Act. We proposed to add loan repayment programs as the

bases for exclusions under section 1128(b)(14) of the Act. We proposed to expand the "pay the first claim rule" to Parts C and D of Medicare. We proposed to give individuals and entities excluded under new section 1128(b)(16) of the Act the right to an oral argument in front of an OIG official prior to exclusion, and we proposed to remove the requirement that OIG send a notice of intent to exclude in cases under section 1128(b)(7) of the Act.

The proposed regulation also made numerous technical and clarifying changes. We proposed reorganizing § 1001.1001 to clarify the authority and to move all the definitions in § 1001.1001 to § 1001.2. This proposal would also create a new definition of "ownership or control interest," which mirrors existing regulatory language at § 1001.1001(a)(1)(ii). Next, we proposed separating the two concepts in the aggravating factor related to "Other Offenses and Adverse Actions" to clarify that the first portion relates to additional convictions, and the second portion relates to adverse actions by government agencies and boards.

We also proposed revising the language requiring that individuals convicted of previous offenses be excluded for a longer minimum period to reflect the statutory language, which considers "previous" convictions instead of "other" convictions. We proposed to revise the language related to immediate access

requirements to include technical clarifications and access to electronically stored documents under the Inspector General Reform Act of 2008.

Lastly, we proposed a clarification to the regulation pertaining to exclusions under section 1128(b)(15) of the Act that would state that the length of an individual's exclusion under section 1128(b)(15) of the Act is the same length as the exclusion of an excluded entity on which the individual's exclusion is based.

***Part 1002***

The proposed rule included several clarifying and technical changes, including clarifying Medicaid agencies' right to refuse to enter into a provider agreement because of a criminal conviction related to any Federal health care program, renumbering certain sections, changing headings, adding clarifying language to the section describing payment prohibitions, and clarifying circumstances for exclusion of managed care entities that are related to sanctioned entities.

***Part 1006***

Consistent with ACA, the proposed regulation reflected OIG's new authority to issue testimonial subpoenas in investigations of potential cases involving the exclusions statute.

#### **IV. Response to Comments and Summary of Revisions**

In response to the Notice of Proposed Rulemaking, OIG received 19 filed public comments from various health care providers and organizations, professional medical societies and organizations, and other interested parties. In the next section below, we address the comments we received to particular proposals. The final rule makes certain non-substantive technical changes that were not included in the proposed rule. First, the final rule implements a reorganization of certain subparts of part 1001. Specifically, § 1001.1051, which corresponds to the exclusion authority found at section 1128(b)(15) of the Act, is moved to new § 1001.1551, after § 1001.1501. The new exclusion authority in section 1128(b)(16), which was proposed at § 1001.1751, is moved to new § 1001.1552. These changes were made to put the regulatory authorities in the same order as the underlying exclusion authorities in section 1128 of the Act. Because of the non-substantive nature of these changes, we believe it is appropriate to include them in this final rule.

Next, the final rule moves the definition of "Federal health care program" from § 1001.2 to § 1000.10. The final rule also modifies the definition slightly to mirror the statutory definition in section 1128B(f) of the Act. While these changes were not proposed, they are technical corrections only and do not change the meaning or effect of the regulations. The final

rule's definition of Federal health care program mirrors the statutory definition of the phrase and varies only grammatically from the prior regulatory definition (we changed "providing health care benefits" to "provides health benefits" and, because we believe our regulatory definition unintentionally did not mirror the statutory definition, we changed it from "whether directly through insurance or otherwise" to "whether directly, through insurance, or otherwise"). OIG has always interpreted this phrase according to the statutory definition at section 1128B(f) of the Act.

The reason we are moving the definition of Federal health care program from part 1001 to part 1000 is to reflect the statute and OIG's existing regulatory interpretation that this definition applies throughout Chapter V of Title 42, wherever the term may appear. The term "Federal health care program" appears only in parts 1001 and 1003. Part 1003 sometimes refers to the statutory definition (see § 1003.101), and sometimes does not (see § 1003.102(a)(3), (a)(15)). The move clarifies that one definition, mirroring the statute, applies to both part 1001 and part 1003, but does not change the meaning of any provision in Chapter V.

The final rule also spells out "civil money penalties" in § 1001.1001(a)(2), replacing an instance of the term "CMPs." This change does not affect the substance of § 1001.1001.

## **General Comments**

*Section 1001.901 and 951: Period of limitations on affirmative exclusions*

*Comments:* Thirteen commenters objected to OIG's proposal to clarify that there is no time limitation to exclusions imposed under section 1128(b)(7) of the Act. Some objected on legal grounds, arguing that even if a statute is silent regarding a period of limitations, courts have often applied some period of limitations and not deferred to an agency's interpretation of the period of limitations.

Others highlighted that although the preamble discussed this proposal with respect to all exclusions under section 1128(b)(7) of the Act, the proposed regulatory text only included this language for exclusions pursued under 42 CFR 1001.901 and not for those pursued under 42 CFR 1001.951. Some commenters were concerned that the proposed clarification regarding the limitations period would create an administrative burden because they felt that providers would be required to indefinitely retain all documentation that could be relevant to OIG's authorities. Other commenters suggested that OIG should toll the limitations period for exclusion in individual cases rather than finalize the language as proposed.

*Response:* The proposal stated that there is no time limitation on OIG's initiating an exclusion action under section 1128(b) (7) of the Act. As a result of the comments we received, OIG has decided not to finalize the rule as proposed and to instead codify a ten-year limitations period.

The proposal was based on the plain language and purpose of section 1128 of the Act and its interaction with the False Claims Act (FCA), the Federal Government's primary civil remedy for health care fraud. Section 1128, which includes no period of limitations, authorizes exclusions as prospective remedial actions to protect Federal health care programs and their beneficiaries from untrustworthy individuals and entities. Almost every Federal health care program fraud actionable under the FCA can also form the basis for exclusion under section 1128(b) (7) of the Act. Because of the volume of health care FCA cases, most of which are qui tam matters initiated by private parties on behalf of the Government, most section 1128(b) (7) matters considered by OIG are related to FCA cases. The FCA allows for complaints to be filed up to 10 years after the conduct. The filing of the qui tam complaint stops the running of the FCA statute of limitations and allows the Government to investigate the FCA allegations without the risk of losing any civil claims based on time. OIG closely coordinates with DOJ and generally considers and resolves exclusions in conjunction

with FCA settlements. Because many FCA cases are not resolved until many years after the claims at issue, any limitations period on section 1128(b)(7) exclusions may force OIG to either initiate administrative proceedings while the FCA matter is proceeding or lose the ability to protect the programs and beneficiaries through an exclusion. Litigating FCA and exclusion actions on parallel tracks wastes Government (both administrative and judicial) and private resources.

We believe we should administer the section 1128(b)(7) exclusion authority in a way that protects the programs and beneficiaries while reducing the risk of wasting resources. We also recognize that older conduct is less relevant to current trustworthiness. We have balanced the commenters' concerns with our policy goal of protecting Federal health care programs and beneficiaries and OIG's experience administering the exclusion statute. We have chosen to adopt a 10-year limitations period for exclusions initiated under 42 CFR 1001.901 or 42 CFR 1001.951.

The 10-year limitations period addresses the commenters' concerns about administrative burden and courts' historical favoring of an enumerated limitations period. Providing for a 10-year limitations period for exclusion under section 1128(b)(7) of the Act will better align the resolution of FCA

and section 1128(b)(7) remedies. The FCA allows the filing of an action up to 10 years after the conduct. Once an FCA action is filed by a qui tam relator or the Government, the FCA statute of limitations is tolled while the Government investigates the matter through any resulting litigation. Based on past experience, we expect to still confront situations in which FCA litigation is ongoing as we are forced to either initiate an exclusion or lose the ability to bring such an action; such situations will be less frequent with a 10-year period than with a shorter period. The 10-year period is grounded in the FCA period of limitations, provides certainty to the industry, and better protects OIG's ability to protect the programs and individuals from untrustworthy persons identified in FCA cases or otherwise.

When determining whether to seek exclusion of a defendant in an FCA case, OIG considers factors that cannot be determined until the case is resolved. In litigated FCA cases, OIG is in the best position to consider exclusion after there is a judgment, which will either provide a strong basis for exclusion (if the judgment is in favor of the Government) or make an exclusion case difficult or impossible (if the judgment is in favor of the defendant). When a case settles, OIG can consider all the relevant factors, including the defendant's willingness to agree to appropriate compliance terms, when determining

whether to seek exclusion. A longer limitations period will better allow OIG to consider all of the relevant factors before making an exclusion decision and expand the number of cases in which resolution of an FCA matter will not occur after OIG's period of limitations has ended. The 10-year limitations period will also reduce the risk of OIG litigating an exclusion action while FCA litigation is pending. In OIG's experience, it is difficult for all parties when two sets of concurrent litigation are ongoing. A 10-year limitations period will allow for conservation of both Government and private resources in these instances.

We believe that recent acts are more indicative of trustworthiness than acts in the distant past. However, in our experience, exclusion can be necessary to protect the Federal health care programs even when the conduct is up to 10 years old. We intend to exercise this authority to preserve our ability to protect the programs when it is impracticable for OIG to pursue exclusion closer in time to the fraudulent conduct. A 10-year limitations period balances the need to provide the defendant certainty and also allow OIG to adequately evaluate exclusion in light of the fraudulent conduct.

As commenters noted, OIG provided notice of the relevant changes to exclusions under 1128(b)(7) of the Act but inadvertently provided only a text change for 42 CFR 1001.901.

We have updated the final rule to add the relevant language to both 42 CFR 1001.901 and 42 CFR 1001.951. Commenters' concerns about the length of the limitations period in 42 CFR 1001.901 are equally applicable to 42 CFR 1001.951, and we have considered those concerns in the context of both sections.

Some commenters suggested that OIG toll its statute of limitations in situations where certain conduct would lead to exclusion but OIG has not learned of the conduct until years after the conduct. We have used tolling agreements in certain appropriate matters and will continue to do so where it is needed to preserve our ability to protect the Federal health care programs. However, we do not believe that OIG seeking a tolling agreement in specific cases is an efficient way to preserve OIG's authorities in these cases. As mentioned above, the Government's FCA remedies are tolled with the filing of a complaint. The complaint does not toll OIG's exclusion remedy. Given the volume of FCA complaints that are being investigated at any point in time, it would be inefficient for OIG to seek to negotiate a tolling agreement in each of these cases. In addition, a defendant who is litigating with the United States is unlikely to agree to toll OIG's authorities. A defendant's refusal to agree to toll the statute of limitations leaves OIG in the position of having to choose between (i) filing a concurrent action while the United States is in FCA litigation

or (ii) losing the ability to protect the programs and beneficiaries through an exclusion. Therefore, we do not believe that seeking individual tolling agreements applicable to exclusion authorities would be an effective or efficient way to address the protection of OIG's authorities in all cases.

***Specific Comments***

*Section 1000.10: Definitions of "Directly," "Furnished," and "Indirectly"*

*Comment:* One commenter suggested that the proposed language would be confusing for providers. Specifically, the commenter noted that OIG's proposed change from "submit claims to" to "request or receive payment from" would confuse providers trying to avoid liability because of the uncertainty about what "requesting" or "receiving" payment means. As an example, the commenter cited capitation payment methodologies, which the commenter stated sometimes "sever the direct link between the items/services that a payment is expected to cover and the items/services that the payment actually ends up covering." The commenter also stated that our reference to the False Claims Act was inappropriate.

*Response:* We continue to believe that the regulations should be updated to more clearly reflect that Federal health care programs make payments through methods other than the submission of fee-for-service claims, and that individuals and entities who

request or receive such payment, directly or indirectly, are subject to exclusion. The prior regulations discussed these concepts in the context of claims for items and services being submitted to Federal health care programs. The proposed definitions more clearly include situations in which payment is made by a Federal health care program without a traditional fee-for-service claim, *i.e.*, where the program makes payments through some other mechanism.

We believe the plain meaning of the words "request" and "receive" can be applied in this context without undue confusion. Funds are requested and received in many different forms from Federal health care programs, and the breadth of these terms is necessary to include current and potential future payment methodologies.

The terms include payment methodologies that have been implemented in the years since the regulations were last amended. By way of example only, some new payment models involve Federal health care programs issuing shared savings payments or performance-based payments (e.g., reflecting quality improvements) to individuals and entities. These individuals and entities therefore may receive payments from Federal health care programs that are not tied exclusively to claims for specific services that were provided. In another example, in managed care or other models, capitated payments may be received

by individuals and entities from managed care organizations or the Federal health care programs to pay for health care provided to Federal health care program beneficiaries, but the individuals and entities may not be submitting claims directly to the Federal health care programs for particular items and services. As a final example, diagnosis resource groups that are used to determine payments for inpatient Medicare stays may assume the use of medical devices in certain procedures, but the provider does not submit a claim requesting payment for the particular item used in the procedure.

Over time, more Federal health care program payments for items and services furnished to its beneficiaries are not directly connected to submitted fee-for-service claims. The regulation should clearly encompass such circumstances within the reach of the exclusion remedy. In applying its authorities, OIG carefully considers all relevant facts and circumstances in each case before taking action.

We referenced the False Claims Act's broad definition of "claim" to illustrate that other sections of the United States Code recognize that payment from the Federal Government is requested in many different ways. The statutory intent of recent amendments to that act apply its penalties without limitations imposed by changing payment methodologies. The FCA now extends to a broader category of payment methodologies and

fraud schemes than it did prior to its amendment. Because the underlying conduct triggering an exclusion action is comparable to that pursued under the FCA, it would be incongruous to limit the exclusion statute's reach to outdated payment methodologies and not extend it to newer fraud schemes.

*Section 1001.101 and 1001.401: Application of certain exclusions to health care providers*

*Comment:* One commenter stressed that the temporal change proposed by OIG would not protect beneficiaries from individuals who left employment in the health care industry before committing an offense leading to conviction, and then re-entered the health care industry after their conviction.

*Response:* We agree with the commenter that the proposed change would not cover individuals who left the health care industry before they committed an offense. Accordingly, we are not including the proposed change in the final rule.

*Sections 1001.102(b)(1), 201(b)(2), 301(b)(2)(viii), and 701(d)(2)(iv): Financial loss aggravating factors*

*Comment:* A commenter expressed concern that OIG's proposal to increase the financial loss aggravating factors used to determine the length of an exclusion from \$5,000 and \$1,500 to \$15,000 does not sufficiently increase the loss amount. The commenter stated that this amount would encompass many, if not

all, exclusions and, therefore, would not be useful in determining trustworthiness. The commenter suggested further increasing the financial loss amount to reflect that most health care fraud cases result in much greater losses than \$15,000. Another commenter agreed with OIG that the financial loss aggravating factor should be increased to the proposed amount of \$15,000.

*Response:* We partially agree with the commenters with respect to the increase in financial loss aggravating factor. In the final rule, we have increased the amount of the financial loss aggravating factors listed at §§ 1001.102(b)(1), 1001.201(b)(2)(i), 1001.301(b)(2)(viii) to \$50,000. We believe that this increase better reflects the threshold amount when a period of exclusion should be increased on the basis of our experience resolving health care fraud matters. Because exclusions under section 1128(b)(6) are not derivative of convictions and are focused on unnecessary or substandard care, we disagree that \$15,000 is an insufficient amount of loss to trigger the financial loss aggravating factor under § 1001.701(d)(2)(iv) and have finalized the proposal to increase that amount to \$15,000.

*Comment:* One commenter suggested that OIG retain the financial loss aggravating factors used to determine the length of an

exclusion at \$5,000 and \$1,500 based on a concern that an increase in the amount of the aggravating factor could reduce exclusion periods for untrustworthy providers.

*Response:* While we agree that any loss from health care fraud is troubling, the purpose of the aggravating factor is to provide for an additional period of exclusion for those cases that involve high losses relative to other cases. In order for it to be a meaningful tool, the financial loss aggravating factor used to determine the length of an exclusion must be a realistic marker for differentiating conduct that is more serious because it involves a relatively significant amount of loss. In the current health care fraud environment, the \$5,000 and \$1,500 financial aggravating factor thresholds do not reflect unusual or relatively high losses. In order to best reflect the current trends in health care fraud cases, we believe that an increase in amount is appropriate.

*Section 1001.102(c)(1): Mitigating factor relating to misdemeanor offenses and loss to Government programs*

*Comment:* One commenter supported OIG's proposal to raise the loss amount in this factor to \$5,000.

*Response:* We have finalized the rule as proposed.

*Sections 1001.201, 301, 401, 501, 601, 701, 801, 951, 1101, 1201, 1601, and 1701: Alternative sources mitigating factor*

*Comment:* Two commenters suggested OIG retain the mitigating factor of whether alternative source of the type of health care items or services furnished by the individual or entity being excluded are unavailable. One commenter stated that removal of this factor would impair access to care. Another commenter was concerned that OIG's consideration of this factor prior to determining whether to impose an exclusion, rather than as a mitigating factor, could cause confusion.

*Response:* Exclusion of an individual or entity can have an impact on access to care as soon as an exclusion is effective. Therefore, it is more appropriate to consider whether exclusion will impact access to care in determining whether to impose a permissive exclusion rather than to determine the length of exclusion. In all permissive exclusions, OIG sends a notice of intent to exclude or a notice of proposal to exclude, giving the individual or entity the opportunity to present information about potential access to care issues. This opportunity to present information should clarify to individuals and entities that OIG will consider access to care issues before imposing an exclusion. OIG will continue to consider the issue of beneficiary access before excluding an individual or entity under OIG's permissive exclusion authorities.

*Section 1001.301: Expanded application of a specific permissive exclusion authority to include obstruction of audits*

*Comment:* One commenter urged OIG not to put audits, which the commenter characterized as informal, on a par with investigations, which the commenter characterized as formal. The commenter suggested that the addition of audits to this permissive exclusion authority could cause providers to devote excessive time and funds to substantiate their compliance in audit situations, which could restrict access to care. Another commenter was pleased that OIG is expanding its permissive exclusion authority to include obstruction of audits and pointed out that obstructing an audit is as dishonest and untrustworthy as obstructing an investigation.

*Response:* First, we note that the expansion of this authority is statutory and therefore OIG must expand the regulations to cover audits. Next, OIG continues to believe this regulation is necessary. Contrary to the commenter's characterizations, audits by governmental entities or contractors are formal in nature, similar to investigations. Compliance with audit processes and requests is integral to fraud prevention and detection by payors and by law enforcement. It is appropriate for providers to devote resources to compliance with such audits.

*Comment:* Several commenters noted that it would be helpful for OIG to define "audit" in the regulations reflecting this statutory change. For example, one commenter questioned whether the Medicare survey and certification process qualifies as an audit.

*Response:* The term "audit" has a general meaning that is clear based on dictionary definitions. Such definitions include the words "official," "inspection," "verification," and "examination." We believe it is appropriate to apply the general, commonsense meaning to the word "audit" for the purpose of section 1128(b)(2) of the Act, and that a definition is not necessary in the regulatory text. To address the commenter's example, the Medicare survey and certification process is implemented for the purpose of inspecting facilities for compliance with Medicare health and safety standards. Where Government entities or contractors conduct an official inspection for the purpose of verifying compliance with Government program standards, we believe the term "audit" would include such actions for purposes of the exclusion authority at section 1128(b)(2) of the Act. Government entities, including OIG, often conduct "inspections" in which information is requested from members of the public for the purpose of evaluating compliance with the law. An "examination" by the Internal Revenue Service is synonymous with an "audit" by that

agency. In this way, official inspections and examinations are similar to Government audits. A conviction for obstruction of a Government inspection or examination is an indication of a lack of trustworthiness and should not result in a disparate application of the exclusions statute (if the Government action relates to Federal health care programs). Further, the permissive nature of the exclusion authority at section 1128(b)(2) of the Act allows OIG to exercise discretion and analyze the facts and circumstances of each relevant conviction before using the authority.

*Sections 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 did not receive comments on this proposal, which would have removed the aggravating and mitigating factors related to exclusions imposed under sections 1128(b)(4) and 1128(b)(5) of the Act. The reasoning for the proposal was that the lengths of these exclusions are consistent with the periods of suspension or exclusion by the licensing boards and health care programs. However, we have reconsidered this proposal and now believe that it is appropriate, in some cases, for OIG to impose longer or

shorter periods of exclusion than the license suspension or revocation periods, or the health care program exclusions, based on aggravating and mitigating factors that may be present. For this reason, we are not including this proposal in the final rule.

*Section 1001.501: Early reinstatement*

*Comment:* Several commenters supported OIG's proposed early reinstatement regulation, because it would facilitate beneficiary access and promote employment of individuals who obtain a new license or seek employment in non-licensed positions.

*Response:* We appreciate the comments.

*Comment:* Several commenters urged OIG not to subject individuals seeking employment in unlicensed positions to a 5-year presumption against reinstatement. The commenters suggested that unlicensed individuals have a less direct role, and less authority, in furnishing or billing for items and services than licensed individuals.

*Response:* We agree with the comments, and in the final rule we change the presumption against reinstatement to 3 years for individuals without any health care licenses seeking reinstatement under § 1001.501. We apply one exception for

cases in which the licensing board that took the action leading to the exclusion has assigned a term of years to the license revocation or suspension that is longer than 3 years. This is because the intent behind early reinstatement is to address situations in which an individual may not be precluded by the licensing board from trying to re-obtain the lost license but is choosing (because of practicality, financial resources, lack of interest, etc.) not to attempt to regain the license. If the licensing board has affirmatively assigned a term of years that is longer than 3 years, the individual will not be eligible for early reinstatement into the Federal health care programs until the term set by the licensing board has elapsed.

While unlicensed individuals employed in health care settings can have a significant impact on the programs and beneficiaries, we believe that, if all the other factors weigh in favor of reinstatement, 3 years is a sufficient presumption given the 3-year benchmark exclusion period for some other permissive exclusions, including those based on criminal convictions.

*Comment:* One commenter objected to OIG's inclusion of the proposed factor at 1001.501(c)(2)(viii) (the reason the individual is seeking reinstatement). The commenter stated that the factor is highly subjective and likely to lead to arbitrary application.

*Response:* We agree with the comment. We believe it is more appropriate to consider the potential impact on Federal health care programs and beneficiaries of reinstatement. For the same reason, we have also removed the factor we proposed related to whether the individual is seeking employment in an unlicensed health care position.

*Comment:* One commenter asked OIG to clarify the proposed factor at 1001.501(c)(1)(vii) and (c)(2)(vii) (any ongoing investigations of the individual). The commenter suggested that this factor should be limited to investigations that pertain to OIG or Federal health care programs.

*Response:* In order to best protect the Federal health care programs, OIG will consider a broad range of investigations even if those investigations do not directly impact the programs in order to properly assess the integrity and trustworthiness of individuals seeking reinstatement into the programs.

Investigations by private insurers or third parties may have a direct bearing on OIG's assessment of trustworthiness even though they do not involve the Federal health care programs.

*Comment:* One commenter asked that OIG provide more information regarding the relative weight to be given to each factor.

*Response:* Consistent with other regulations in which OIG considers various factors, we believe it is appropriate for OIG to retain discretion in determining which factors are most relevant to any individual case, and to consider the relative weight of each factor. Similar to when OIG considers aggravating and mitigating factors to determine length of exclusion, OIG will look at the facts and circumstances individually to determine whether reinstatement is appropriate. In the proposed rule, we stated that we would consider "alternative approaches, and solicit comments on these and any additional factors that should be considered." In the interest of providing additional transparency regarding our assessment of factors, we have added a factor at § 1001.501(c)(1)(ii) regarding whether the second licensure authority is in a State that is not the individual's primary place of practice. If a licensure board granting a license is not in the individual's primary place of practice, this would affect our assessment of the potential risks associated with reinstatement and the weight given to the second licensure. This factor is important in certain cases, based on our experience, in which a second licensing board may not take action simply because an individual does not practice in that State anymore. In such cases, reinstatement may not be appropriate based solely on the second licensing board's position.

We proposed numerous factors related to OIG's consideration of the facts surrounding the action or lack of action by a second licensing authority, and this additional factor is consistent with these proposed factors. Moreover, OIG already has the discretion to consider the primary place of practice of an applicant based on other factors in the regulation, such as the benefits and risks to the programs of early reinstatement, evidence that the second licensing authority was aware of the circumstances surrounding the basis for the exclusion, and the circumstances that formed the basis for the exclusion. Therefore, the addition of this factor does not change what OIG is already able to consider under the regulations, but instead provides transparency for members of the public who may want to apply for early reinstatement.

*Comment:* One commenter asked OIG to prevent early reinstatement of individuals who lost their licenses for reasons related to abuse or neglect.

*Response:* We agree that it is important to protect beneficiaries from individuals who have lost their licenses due to reasons related to patient abuse or neglect. Therefore, in the final rule, early reinstatement will not be available to these individuals. Instead, individuals who have lost their health care licenses for reasons related to patient abuse and neglect will be required to obtain the license that they lost,

in the State where they lost it, before OIG will consider a reinstatement application. While consideration of abuse or neglect could have been considered by OIG under other proposed factors, the final rule eliminates discretion in these cases. We believe this change to eliminate discretion is consistent with the inclusion of proposed factors related to the facts and circumstances of the underlying exclusion, the risks to Federal health care programs, and the resolution of underlying problems that led to the exclusion.

*Section 1001.1001: Exclusion of entities owned or controlled by a sanctioned person*

*Comment:* Section 1001.1001 allows OIG to exclude entities under certain circumstances, one of which is in a situation in which a person transfers his or her ownership or control interest to an immediate family member or a member of the person's household in anticipation of a conviction, civil monetary penalty (CMP), or exclusion. One commenter suggested that OIG allow for exceptions where (1) the excluded person was sanctioned on the basis of actions that did not involve the entity and where (2) the transfer was justified on the basis of business or legal considerations independent of exclusion.

*Response:* We do not believe it is necessary to add exceptions to this permissive exclusion authority, because of the

permissive nature of the authority. The statute's language allows OIG to carefully consider all relevant facts and circumstances in each individual case before imposing exclusion under section 1128(b) (8) of the Act.

*Section 1001.1051 (in the final rule as Section 1001.1551):*

*Exclusion of individuals with ownership or control interest in sanctioned entities*

*Comment:* Two commenters stated that the proposed language would have the effect of expanding the basis for exclusions under section 1128(b) (15) beyond the statutory authority.

Specifically, the commenters argued that adding the words "or had" with respect to the relationship between the excluded entity and the individual being excluded would allow OIG to exclude individuals who terminated their relationships with a sanctioned entity before being excluded. One commenter also noted that the individual should not remain excluded after termination of the relationship with the entity.

*Response:* The intent of this proposal was to clarify that an individual who has been excluded under section 1128(b) (15) of the Act will be excluded for the same period as the entity, regardless of whether the individual terminates his or her relationship with the entity after he or she has been excluded. We have modified the proposed language in the final rule to

simply read “[i]f the entity has been excluded, the length of the individual’s exclusion will be for the same period as that of the sanctioned entity.” OIG believes that the statute allows the length of an exclusion under section 1128(b)(15) to be for the same term as the exclusion of the sanctioned entity. The final regulatory language specifies that once an individual has been excluded under section 1128(b)(15), the exclusion will remain in effect for as long as the term of the entity’s exclusion.

*Comment:* One commenter argued that OIG should not make the period of exclusion consistent between the entity and the individual because the individual may not have the knowledge or participation level in the wrongdoing to warrant an exclusion that is the same length as the entity’s exclusion.

*Response:* We believe it is appropriate to determine the individual’s exclusion length consistent with the entity’s exclusion length. This is consistent with the statute, which creates this authority in order to protect the programs and beneficiaries from individuals that OIG deems to be untrustworthy. The determination of untrustworthiness is made based on the conduct of the entity and the individual’s position with respect to the entity. The statute places responsibility for the conduct on the individuals in certain positions. OIG

exercises its discretion under section 1128(b)(15) of the Act in accordance with factors we published in 2011 to ensure that the authority is used only when appropriate. As a result, when OIG has determined that an individual is untrustworthy based on the conduct of an entity, it is appropriate to exclude him or her for the same period for which the entity is excluded.

*Comment:* Several commenters argued that OIG should not exclude individuals under section 1128(b)(15) of the Act unless specific findings are made regarding the individual's wrongdoing or knowledge of wrongdoing.

*Response:* We believe that requiring specific findings outside of those listed in section 1128(b)(15) of the Act would be inconsistent with the clear language of the statute. The statute only requires evidence of knowledge to support the exclusion of individuals with an ownership or control interest in a sanctioned entity under section 1128(b)(15)(A)(i). There is no requirement to demonstrate knowledge of wrongdoing in order to exclude officers or managing employees under section 1128(b)(15)(ii). OIG published factors in 2011 that are used in determining whether to exercise discretion under this section. Those factors consider, among other things, the seriousness of the misconduct, the individual's role in the misconduct, and the individual's actions in response to the misconduct. Because the

statute articulates a broad permissive exclusion authority to be implemented by OIG under section 1128(b)(15) of the Act, we continue to believe that our subregulatory guidance on this topic is the appropriate mechanism for applying OIG's authority under section 1128(b)(15), and that regulations limiting the statutory authority are not appropriate.

*Section 1001.1201: Broadened scope of a permissive exclusion authority*

*Comment:* Commenters suggested that the proposal to expand the authority to individuals who refer for furnishing or certify the need for services could result in providers being unfairly excluded. The commenters noted that as a referring provider an individual may not know whether a patient is a beneficiary of Federal health care programs.

*Response:* While we understand that referring physicians may not know whether a patient is a Federal health care program beneficiary, this regulatory change is consistent with the change made to the statutory exclusion authority by section 6406(c) of ACA. Further, the exclusion is for a failure to supply payment information when requested by Federal health care programs and does not require a physician's knowledge of how the referred or certified services might be paid.

*Section 1001.1301: Exclusion for failure to grant immediate access*

*Comment:* A commenter suggested that in order to protect those providing access to information, and their patients, OIG should implement privacy precautions that would apply to OIG and other agencies requesting electronic material under section 1128(b)(12) of the Act, and suggested that those precautions should mirror those found in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) applicable to business associates. The commenter also suggested that OIG perform due diligence on other authorized entities that may be requesting information under section 1128(b)(12) of the Act, and that OIG require entities and agencies with access to the data to compensate individuals and entities who are harmed by any unauthorized access or use of the requested information.

*Response:* Although OIG is not subject to the HIPAA Privacy and Security Rules, existing Federal laws and directives provide similar protections for personally identifiable information (PII) in OIG's possession. OIG, like all Federal executive branch agencies, is required to protect PII from unauthorized disclosures by the Privacy Act and Office of Management and Budget (OMB) directives (for example, OMB Circular A-130 and OMB Memoranda M-06-15 and M-06-16 of June 23, 2006). Additionally, HHS has requirements for the protection of PII and for reporting

security breaches that OIG must follow in addition to OIG's internal policies and procedures.

All Federal agencies, including OIG, are required by the Federal Information Security Management Act of 2002 (FISMA; 44 U.S.C. § 3541 et seq.), and OMB Memoranda M-07-19 of May 22, 2007; M-07-19 of July 25, 2007; and M-06-19 of July 12, 2006, to report all security incidents (suspected or confirmed) involving PII to the U.S. Computer Emergency Readiness Team (US-CERT), located within the Department of Homeland Security.

*Comment:* A commenter asked OIG to clarify OIG's 24-hour deadline and what constitutes a compelling reason for failure to produce information within this deadline.

*Response:* We believe that the regulations regarding immediate access requests are sufficiently clear to put individuals and entities on notice that they must comply with requests within 24 hours. In addition, the statute gives OIG authority to determine whether a failure to produce requested information is the result of a compelling reason, and the regulations that are in place at section 1001.1301 reflect the broad intent of the statute.

*Section 1001.1501: Default on health education loans or scholarship obligations*

*Comment:* Several commenters argued that OIG should not expand its exclusion authority to loan repayment programs given the spike in loan defaults since 2008, as documented by the Department of Education. One commenter stated that OIG should not include Indian Health Service (IHS) scholarship and loan repayment programs in the proposed expansion of the loan default regulations, because it will make it more difficult for IHS providers to retain qualified staff.

*Response:* Section 1128(b)(14) of the Act requires that IHS scholarships and loans be included in OIG's authority to exclude. Because IHS is a division of HHS, these are "scholarship obligations or loans in connection with health professions education made or secured . . . by the Secretary." Exclusion has proven to be a successful remedy to incentivize individuals in loan default to repay the obligations owed to the Department. OIG's discretionary authority, including the change to include loan repayment programs, appropriately includes IHS scholarships and obligations.

*Section 1001.1552 (proposed as Section 1001.1751): Establishment of a new permissive exclusion authority pursuant to section 1128(b)(16) of the Act*

*Comment:* One commenter requested that we define "material" as "having an actual influence on the decision to deny or approve applications for enrollment."

*Response:* We continue to believe that our proposed definition of "material," of "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," is reasonable. The broad statutory language does not limit the application of this authority to cases in which the false statement in fact influenced the decision to deny or approve enrollment. The proposed definition is also consistent with the statutory definition of "material" in the False Claims Act (31 U.S.C. § 3729(b)), as applied with respect to the submission of false records and statements material to a false or fraudulent claim. In addition, the permissive nature of the authority allows OIG to consider all relevant facts and circumstances in each case before taking action.

*Comment:* One commenter asked OIG to restrict the sources it will consider to an enumerated list for transparency and clarity.

*Response:* The sources listed in the proposed regulation provide transparency for purposes of giving individuals and entities

notice of the information OIG will consider. We believe it is also reasonable for OIG to retain the right to consider appropriate sources other than those listed, should they become relevant.

*Comment:* One commenter asked OIG to restrict prior wrongdoing considered in determining the length of exclusion to wrongdoing related to health care and to disregard wrongdoing that is in the distant past.

*Response:* The inclusion of this factor is consistent with OIG's considerations in other permissive exclusions (see §§ 1001.601, .701, .1601, and .1701). In applying this factor, OIG will weigh the relevance of conduct that is aged or is unrelated to health care as appropriate.

*Comment:* One commenter suggested that OIG require entities to develop safeguards to ensure quality, accuracy, and integrity, and to compensate individuals and entities harmed by the submission of inaccurate information.

*Response:* The addition of this statutory authority should deter entities and individuals from misstating or falsifying information on enrollment applications, and incentivize providers to create safeguards to prevent fraud, waste, and abuse. We do not believe it is within the scope of the statute

for OIG to require entities to compensate individuals and entities harmed by the submission of inaccurate information.

*Comment:* One commenter stated that the terms “knowingly” and “material” are subjective and can be applied inconsistently. The commenter asked that OIG state an objective standard that won’t penalize providers who are trying to accurately respond on enrollment documents but make “simple documentation errors.”

*Response:* The words “knowingly” and “material” appear in the statute. We believe that the applicable definition adds clarity to the section. In addition, OIG will continue to evaluate the nature and circumstances of the conduct and exercise discretion in deciding whether to impose an exclusion. It is not OIG’s intention to pursue exclusion under section 1128(b)(16) of the Act based on inadvertent errors and minor oversights.

*Comment:* One commenter asked OIG to eliminate its consideration of the actual or potential repercussions of the false statement from the list of factors used to determine the length of exclusion, and instead use that factor to determine whether to exclude. Another commenter suggested OIG should publish a more specific list of factors to be considered in determining the periods of exclusion and objected to the factor considering actual or potential repercussions of the false statement as too

vague, potentially arbitrary, and failing to provide sufficient notice and guidance for physicians. The commenter suggested alternative factors: the nature of the false statement, omission, or misrepresentation; the provider type involved; the enrollment risk tier assigned to the provider; whether the Federal health care program would have accepted the enrollment if the false statement had not occurred; the amount of control the provider was able to exercise over a third party assisting in the enrollment process; and whether the provider furnished medically necessary services to Federal health care program beneficiaries.

*Response:* We continue to believe that the actual and potential impact of the false statement or omission is relevant to the length of the exclusion, and that the statutory language allows OIG to exclude under this permissive authority even where no repercussions resulted from a false statement. However, we agree that the proposed actual or potential repercussions factor is vague and that a more specific list of factors is appropriate. In the final rule, we replace the proposed factor “[w]hat were the actual or potential repercussions of the false statement, omission, or misrepresentation of a material fact” with two factors that more specifically describe what factors OIG will consider regarding the repercussions of the false statement. These factors in the final rule expand upon and

clarify the proposed factor that the public commented upon. The factors are: the nature and circumstances of the false statement and whether and to what extent payments were requested or received from the Federal health care programs under the application, agreement, bid, or contract on which the false statement was made.

The nature and circumstances of the false statement are facts that OIG would necessarily consider in determining whether the conduct had actual or potential repercussions. Under this new factor, OIG will consider, among other things, how, when, why, to whom, and by whom the statement was made.

The second new factor, whether any payments were requested or received, similarly informs whether there were actual or potential repercussions of the conduct; if no payments were made, a shorter exclusion length may be appropriate.

However, we do not agree that the commenter's other suggested factors are appropriate. We do not believe that the type of provider or the enrollment risk tier should be relevant to OIG's determination of untrustworthiness and, thus, length of exclusion. Instead, OIG may consider whether exclusion of the relevant type of provider would impact Federal health care program beneficiaries' access to care in determining whether an entity or individual should be excluded. The commenter also suggested that we add a factor considering whether the program

would have enrolled the applicant if the false statement had not been made. This potential factor considers whether the false statement was material to the program's decision to accept the application; if the application had contained the truth (for example, that a person had a former name that was not reported on the application) and the program would have nonetheless granted enrollment, then the fact that was subject to the false statement was likely not material to the program's decision. Because section 1128(b)(16) of the Act contains a requirement of materiality to exclude, this factor is relevant to whether OIG should exclude under section 1128(b)(16), but not for how long.

We do not believe that the amount of control a provider had over a third party in the enrollment process is relevant to the length of the exclusion. Whether a provider had control over the actions of a third party engaged to assist in completing an enrollment application, agreement, bid, or contract to participate in a Federal health care program will inform the analysis of whether the false statement was made knowingly. OIG will carefully consider all the circumstances surrounding the false statement before taking action under section 1128(b)(16).

Lastly, we will not consider whether the provider furnished medically necessary services, because it is not relevant to the misconduct of making a false statement on an enrollment application. We instead focus on the egregiousness of the

conduct, relevant past behavior, and the potential impact of the false statement.

We provide the following list of factors, which closely track and respond to comments we received.

*(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) The nature and circumstances surrounding the false statement;*

*(2) Whether and to what extent payments were requested or received from the Federal health care program under the application, agreement, bid, or contract on which the false statement, omission, or misrepresentation was made; and*

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

*Section 1001.1901(c): Scope and effect of exclusion*

*Comment:* One commenter stated that OIG's proposal to allow Medicare to pay claims submitted by an enrollee for items or services furnished by an excluded person is inconsistent with 42 CFR 423.12(c)(5) and (6). Those regulations require Medicare Part D sponsors and pharmacy benefit managers to deny claims for items from a pharmacy when the prescribing physician does not

have an active and valid individual prescriber NPI, including if the prescribing physician is excluded.

*Response:* The proposed change to section 1001.1901(c) was intended to update the regulations to conform with the current payment framework relevant to section 1862(e)(2) of the Act. We recognize that our proposal may not be operationally clear in light of the regulatory changes made under 42 CFR 423.12(c)(5) and (6). Therefore, we have not included the proposal in the final rule and intend to work with our partners in HHS to ensure that section 1862(e)(2) of the Act is implemented both on a regulatory and on an operational level.

*Comment:* One commenter urged OIG not to expand the exception in section 1001.1901(c) to parts C and D. It appears that the commenter opposed an expansion of OIG's exclusion authority to parts C and D, rather than the expansion of the "pay the first claim" rule to parts C and D. The commenter reasoned that the expansion would restrict access to care and expand exclusion authorities.

*Response:* The proposal was to expand a statutory *exception* to the general prohibition on payment for items or services ordered, prescribed, or provided by an excluded individual or entity, and would have expanded Part C and D beneficiary access to items and services where they had no reason to know that a

provider had been excluded. Nevertheless, as described above, we have withdrawn the proposal because operation of the proposed changes would have been unclear given regulatory changes to part 423.

*Comment:* Several commenters suggested that excluded providers could assist program enrollees in submitting claims so that they could more easily submit claims either online or at the excluded provider's facility by adding the following language to section 1001.1901(c)(1): "[i]n cases where the excluded individual or entity's submission of claims would invalidate payment for an emergency item or service or one that the enrollee cannot reasonably obtain from a non-excluded individual or entity, the provider may assist the enrollee in submitting the claim directly."

*Response:* This comment is outside our proposal and is not responsive to our solicitation for comments on how to protect Part D enrollees who cannot fill a prescription due to the exclusion of a physician. We are concerned that allowing an excluded provider to assist in the submission of claims by an enrollee creates risk for the program, as the excluded provider is still involved in billing for its services. Additionally, we believe that an emergency situation would be better covered under section 1001.1901(c)(5)(i). The intent of section

1001.1901(c)(1) is to implement by regulation the statutory exception provided for in section 1862(e)(2) of the Act. There is already a statutory exception that covers emergency items and services in section 1862(e) of the Act and a regulatory framework for emergency situations under section 1001.1901(c)(5)(i). We have decided to withdraw our proposal at this time.

*Comment:* Several commenters suggested that the emergency exception to the prohibition on payment for items and services provided by an excluded individual be expanded outside emergency services and specifically that the payment prohibition exception apply to patients who have a geographic or financial inability to obtain medically necessary services from a non-excluded provider, or in other circumstances within the scope of a provider's professional judgment.

*Response:* This comment is outside our proposal and is not responsive to our solicitation for comments on how to protect Part D enrollees who cannot fill a prescription due to a prescriber's exclusion. We understand the commenters' point that there may be difficulties for certain individuals to obtain care from non-excluded providers, including geographic barriers. Section 1862(e) of the Act does not allow for additional exceptions to address such circumstances. OIG will continue to

consider access to care when deciding whether to impose permissive exclusions and/or to grant waivers under sections 1128(c)(3)(B) of the Act and § 1001.1801, where appropriate.

*Comment:* One commenter suggested allowing the filling pharmacy to inform the enrollee of the exclusion, fill the prescriptions presented, and bill Medicare Part D for those prescriptions on a one-time basis.

*Response:* Because the pharmacy would be the entity submitting the claim, we believe that this suggestion falls beyond the scope of OIG's regulatory authority and would be better suited for consideration in the relevant payment rules.

*Comment:* One commenter suggested requiring as a condition of participation that all providers and suppliers inform their patients of an exclusion and arrange for a transfer to a provider or supplier who is not excluded.

*Response:* OIG does not have the authority to regulate conditions of participation. Although we have withdrawn our proposal, we will continue to work with our partners in HHS to ensure that enrollees are protected in the event that they need to fill a prescription written by an excluded provider.

*Section 1001.2001: Notice of Intent to Exclude-opportunity to present oral argument in cases under section 1128(b) (16)*

*Comment:* One commenter asked whether the Departmental Appeals Board (DAB) has capacity to hear appeals of exclusions under section 1128(b) (16) of the Act.

*Response:* The proposed opportunity is for an oral argument to an OIG official prior to exclusion, not an appeal before the DAB. OIG does have capacity to hear these oral arguments.

*Comment:* One commenter requested that OIG also provide an opportunity for oral argument if it proposes to exclude an individual or entity under section 1128(b) (7) of the Act. The commenter argued that OIG must make factual findings or determinations in section 1128(b) (7) cases that are similar to those under section 1128(b) (16) of the Act.

*Response:* While we agree that OIG must make factual determinations in cases under each of these sections, the processes under these sections are different. Under sections 1128(b) (6) and 1128(b) (16), the exclusion goes into effect 20 days after receipt of OIG's Notice of Exclusion, issued under section 1001.2002, and before a hearing before an administrative law judge (ALJ). In section 1128(b) (7) cases, if appealed, the exclusion does not go into effect until after a determination by an ALJ. In such cases, the respondent may present its arguments

to OIG in writing after receiving the Notice of Intent to Exclude. We believe this, coupled with an ALJ hearing, gives sufficient opportunity for argument in section 1128(b)(7) cases. In practice, OIG also contacts potential subjects of section 1128(b)(7) exclusions, often through "pre-demand letters" or other means, to give defendants the opportunity to respond to OIG before formal proceedings are initiated.

*Section 1001.2001: Notice of Intent to Exclude - Exception for section 1128(b)(7) cases*

*Comment:* One commenter stated that the proposal to eliminate the notice of intent to exclude when OIG has determined to exclude an individual or entity under sections 1128(b)(7), 1842(j)(1)(D)(4), or 1842(k)(1) of the Act would deprive individuals of their right to receive notice and a meaningful opportunity to respond. The commenter also believed that this was particularly important considering OIG's reliance on U.S. mail to send these notices.

*Response:* We continue to believe that the notice of proposal to exclude provides a sufficient opportunity for individuals and entities to receive and respond to OIG's proposals to exclude under section 1128(b)(7) of the Act. In these cases, it is OIG's longstanding practice to contact and initiate discussions with potential subjects, often through a "pre-demand letter,"

before initiating formal proceedings under part 1001. OIG's practices give potential respondents an opportunity to respond to OIG's concerns in advance of formal proceedings. The proposal also aligns OIG's processes under section 1128(b)(7) of the Act with those under the Civil Monetary Penalties Law (CMPL), which is referenced by section 1128(b)(7) of the Act. That law and its implementing regulations do not require a notice of intent before OIG initiates formal proceedings. The final rule is consistent with the process required under the CMPL.

We have made some clarifying changes in the final rule from the proposal. The regulations require that three notices be sent to potential defendants: a notice of intent to exclude under § 1001.2001, a notice of exclusion under § 1001.2002, and a notice of proposal to exclude under § 1001.2003. The final rule removes the requirements for both the notice of intent to exclude and the notice of exclusion.

This change eliminates an ambiguity as to when an exclusion goes into effect under these notice requirements. Specifically, § 1001.2003(a) states that an exclusion under section 1128(b)(7) of the Act goes into effect 60 days after the receipt of the notice of proposal to exclude unless appealed. Section 1001.2003(b)(1), however, also requires OIG to send a notice of exclusion as described in §1001.2002 if the individual or entity

does not request a hearing within 60 days. The regulations under § 1001.2002 indicate that an exclusion will go into effect 20 days from the date of the notice of exclusion. Although our longstanding policy has been to read these regulations together so that the exclusion, if it was not appealed, goes into effect on the earlier of the two dates, the final rule clarifies the language to state that a proposed exclusion under section 1128(b)(7) of the Act becomes effective, if not appealed, 60 days of the date of the Notice of Proposal to Exclude.

In addition, as we stated in the proposed rule, it has been and remains OIG's practice and policy to send notices under part 1001 by regular mail.

*Section 1001.2006: Notice of exclusion by HHS*

*Comment:* One commenter noted that in the preamble OIG included a reference to a proposal to require indirect providers to notify their customers of their exclusion.

*Response:* This proposal was not contained in the proposed regulation text. The reference to the proposal was included in error. As a result, the proposed changes to the headings in sections 1001.2004, .2005, and .2006 are unnecessary. We withdraw the proposals to rename those headings.

*Section 1001.3005: Withdrawal of exclusion*

*Comment:* One commenter approved of OIG's proposal to clarify that OIG will withdraw exclusions that are derivative of convictions that are reversed or vacated on appeal. Another commenter suggested that OIG should withhold exclusions until appeals are exhausted in order to protect individuals and entities from unjust financial, reputational, and career damage that the commenter believes would be caused by an exclusion that is later withdrawn after a conviction is reversed or vacated on appeal.

*Response:* Section 1128(a) of the Act requires OIG to exclude individuals and entities based on certain convictions, and section 1128(b) of the Act grants OIG the authority to exclude based on other convictions. Section 1128(i)(1) of the Act specifically includes in the definition of "conviction" situations in which an appeal of the conviction is pending. As a result of this definition of conviction, OIG does not have the authority to delay the imposition of exclusions until after appeals are exhausted. In addition, timely exclusions of convicted providers, regardless of pending appeals, best protects Federal health care program beneficiaries from untrustworthy providers. Based on our experience of excluding thousands of individuals and entities based on criminal convictions, very few of these convictions are reversed or vacated on appeal. The existing and proposed regulation makes

it clear that should a conviction be reversed or vacated on appeal, OIG will withdraw the exclusion. The effect of a withdrawal is that reinstatement will be retroactive to the effective date of the exclusion. If the individual or entity provided items or services to beneficiaries of Federal health care programs while the appeal was pending, payment may be made by Federal health care programs for items and services provided during that period of time in accordance with the payor's policies.

*Comment:* One commenter asked that HHS provide notice of withdrawn exclusions to State agencies, State licensing agencies, and the public.

*Response:* As a matter of policy, OIG provides notice of withdrawals and reinstatements to the same State agencies that were notified of the exclusion. We do not believe it is necessary, or required by the law, for us to include this policy in the regulations. OIG's notification to the public is by monthly update to OIG's List of Excluded Individuals and Entities, or LEIE. OIG also works with providers to communicate with payors when issues arise as the result of a reinstatement.

*Section 1006.1: Testimonial subpoena authority in section 1128 cases*

*Comment:* One commenter stated that OIG should only use the new testimonial subpoena authority where there is an objective, reasonable basis to believe that the conduct that has occurred warrants permissive exclusion.

*Response:* The proposed changes to section 1006.1 were made to reflect statutory changes made in section 6402(e) of ACA. As always, OIG intends to use its testimonial subpoena authority only when it has the authority to do so and when appropriate to gather facts relevant to a possible administrative action.

*Comment:* One commenter stated that OIG has sufficient subpoena authority and that there is no need to expand authority in this area.

*Response:* The change made to the regulations reflects a statutory change, so we have finalized the provision as proposed.

## **V. Regulatory Impact Statement**

We have examined the impact of this final 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 final rule will implement new statutory provisions, including new exclusion authorities. It is also designed to clarify the intent of existing statutory requirements and promote transparency by publishing OIG policies. The vast majority of providers and Federal health care programs will be minimally impacted, if at all, by these revisions. The changes to the exclusion regulations will 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 formal proceedings for affirmative exclusion cases have been initiated. Thus, we believe that any aggregate economic effect of the exclusion regulatory provisions will 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 falls under the \$100 million threshold. Accordingly, we believe that the likely aggregate economic effect of these regulations will 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 1 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 will be minimal. The rule directly impacts small entities that may be excluded by clarifying how OIG determines exclusion lengths, waivers, reinstatement, and affirmative exclusion. It also codifies exclusion authorities added to section 1128 of the Act by MMA and ACA, adding clarity for members of the health care community regarding the scope of OIG's actions. Because the rule adds transparency to OIG's

process and implements exclusion authorities designed to protect Federal health care programs and their beneficiaries from untrustworthy individuals and entities, we believe any resulting impact will be a positive one on the health care community. In summary, we have concluded that this final rule will 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 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million or more. As indicated above, these proposed revisions comport with statutory amendments and clarify existing law. As a result, we believe that the regulations would not impose any mandates on State, local, or tribal governments or the private sector that will result in expenditures 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 final rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

#### **VI. Paperwork Reduction Act**

These 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  
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 republishing the introductory  
text and by revising the definition of "Directly", "Furnished",  
"Indirectly", "QIO", and "Secretary" and by adding the  
definitions of "ALJ", "Exclusion", "Federal health care  
program", "State", and "State health care program" in  
alphabetical order to 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 OIG.

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

\* \* \* \* \*

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 or 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 50 States, 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**

4. 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).

5. Section 1001.2 is amended by removing the definitions of "Exclusion", "Federal health care program", "OIG", "QIO", and "State health care program", and by adding introductory text and the definitions of "Agent", "Immediate family member", "Indirect ownership interest", "Managing employee", "Member of household", "Ownership interest", and "Ownership or control interest" in alphabetical order to 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.

\* \* \* \* \*

6. Section 1001.101 is amended by revising paragraphs (d) (1) and  
(2) to read as follows:

**§ 1001.101 Basis for liability.**

\* \* \* \* \*

(d) \* \* \*

(1) Is, or has ever been, a health care practitioner, provider, or supplier or furnished or furnishes items or services;

(2) Holds, or has held, 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, director, agent, or managing employee of such an entity; or

\* \* \* \* \*

7. Section 1001.102 is amended as follows:

- a. Revise paragraph (b) (1);
- b. Remove paragraph (b) (7);
- c. Redesignate paragraphs (b) (8) and (9) as paragraphs (b) (7) and (8);
- d. Revise newly designated paragraphs (b) (7) and (8);
- e. Add new paragraph (b) (9);
- f. Revise paragraph (c) (1); and
- g. Revise paragraph (d).

The revisions to read as follows:

**§ 1001.102 Length of exclusion.**

\* \* \* \* \*

(b) \* \* \*

(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 \$50,000 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) \* \* \*

(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) For 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.

8. Section 1001.201 is amended as follows:

- a. Revise paragraphs (b) (2) (i) and (vi);
- b. Add paragraph (b) (2) (vii); and
- c. Revise paragraphs (b) (3) (i) and (ii).

The revisions and addition to read as follows:

**§ 1001.201 Conviction relating to program or health care fraud.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(i) The acts resulting in the conviction, or similar acts, caused or reasonably could have been expected to cause, a financial loss of \$50,000 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) \* \* \*

(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, emotional, or physical condition, before or during the commission of the offense, that reduced the individual's culpability; or

\* \* \* \* \*

9. Section 1001.301 is amended as follows:

- a. Revise the section heading and paragraph (a);
- b. Revise paragraphs (b) (1) and (b) (2) (i), (ii), and (vi);
- c. Add paragraphs (b) (2) (vii) and (viii); and
- d. Revise paragraph (b) (3) (i).

The revisions and additions to 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.

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

(2) \* \* \*

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

(ii) The interference or obstruction had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

\* \* \* \* \*

(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 \$50,000 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) \* \* \*

(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

\* \* \* \* \*

10. Section 1001.401 is amended as follows:

- a. Revise paragraphs (a) introductory text, (a) (1) and (2);
- b. Republish the heading of paragraph (c);
- c. Revise paragraphs (c) (1), (c) (2) introductory text, (c) (2) (iv), and (v);
- d. Add paragraph (c) (2) (vi); and
- e. Revise paragraph (c) (3).

The revisions and addition to 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, or has ever been, a health care practitioner, provider, or supplier or furnished or furnishes items or services;

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

\* \* \* \* \*

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

\* \* \* \* \*

(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: the individual's or entity's cooperation with Federal or State officials resulted in-

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

(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.

11. Section 1001.501 is amended by revising paragraphs (b) (1), (3), and (4); and by 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.

\* \* \* \* \*

(3) Only if any of the aggravating factors listed in paragraph (b) (2) of this section justifies a longer exclusion may a mitigating factor be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b) (1) of this section. Only the following factor may be considered mitigating: The individual's or entity's cooperation with a State licensing authority resulted in-

- (i) The sanctioning of other individuals or entities, or
- (ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses.

(4) 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 health care license or has decided to take no adverse action as to a currently held health care 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) Whether the second licensing authority is in a state that is not the individual's primary place of practice;

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

(iv) 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;

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

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

(vii) Any additional or pending license actions in any State;

(viii) Any ongoing investigations involving the individual; and

(ix) 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 this 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 paragraph (c)(2) of this section if the person has been excluded for less than 3 years; however, if the revocation or suspension on which the exclusion is based was for a set period longer than 3 years, the presumption against early reinstatement will be coterminous with the period set by the licensing board;

(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 any State;

(vii) Any ongoing investigations involving the individual; and

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

(3) Notwithstanding paragraphs (c)(1) and (2) of this section, if an individual's license revocation or suspension was for reasons related to patient abuse or neglect, the OIG will not consider an application for early reinstatement.

(4) 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.

12. Section 1001.601 is amended by revising paragraphs (b) (3) and (4) to read as follows:

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

\* \* \* \* \*

(b) \* \* \*

(3) Only if any of the aggravating factors listed in paragraph (b) (2) of this section justifies a longer exclusion may a mitigating factor be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b) (1) of this section. Only the following factor may be considered mitigating: The individual's or entity's cooperation with Federal or State officials resulted in—

(i) The sanctioning of other individuals or entities, or

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

(4) If the individual or entity is eligible to apply for reinstatement in accordance with § 1001.3001 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.

13. Section 1001.701 is amended by republishing the headings for paragraphs (a) and (c); and by revising paragraphs (d) (2) (iv), and (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, or 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.

14. Section 1001.801 is amended as follows:

- a. Revise the paragraph (a) introductory text;
- b. Remove paragraph (c) (3) (ii); and

- c. Redesignate paragraph (c) (3) (iii) as new paragraph (c) (3) (ii).

The revision to read as follows:

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

(a) Circumstances for exclusion. The OIG may exclude an entity—

\* \* \* \* \*

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

**§ 1001.901 False or improper claims.**

\* \* \* \* \*

(c) Limitations. The OIG may not impose an exclusion under this section more than 10 years after the date when an act which is described in section 1128A of the Act occurred.

16. Section 1001.951 is amended by revising paragraph (b) (2) and adding paragraph (c) 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.

(c) Limitations. The OIG may not impose an exclusion under this section more than 10 years after the date when an act which is described in section 1128B(b) of the Act occurred.

17. Section 1001.1001 is amended by revising paragraph (a) 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 State health care program, 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, imposition of a civil money penalty or assessment under section 1128A of the Act, or imposition of an exclusion.

\* \* \* \* \*

**§ 1001.1051 [Redesignated § 1001.1551]**

18. Section 1001.1051 is redesignated as § 1001.1551.

19. Section 1001.1101 is amended as follows:

- a. Revise paragraph (b) (4);
- b. Remove paragraph (b) (5); and
- c. Redesignate paragraph (b) (6) as new paragraph (b) (5).

The revisions read as follows:

**§ 1001.1101 Failure to disclose certain information.**

\* \* \* \* \*

(b) \* \* \*

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

\* \* \* \* \*

20. Section 1001.1201 is amended as follows:

- a. Revise paragraph (a) introductory text;
- b. Revise paragraphs (b) (3) and (4); and
- c. Remove paragraph (b) (5).

The revisions to 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) \* \* \*

(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).

21. 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--

(i) 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, or

(ii) 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 an 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.

\* \* \* \* \*

22. Section 1001.1501 is amended by revising paragraphs (a) (1), (a) (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.

23. Newly designated § 1001.1551 is amended by revising paragraph (c)(1) to read as follows:

**§ 1001.1551 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.

\* \* \* \* \*

24. Section 1001.1552 is added to subpart C to read as follows:

**§1001.1552 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, 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. 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) The nature and circumstances surrounding the false statement;

(2) Whether and to what extent payments were requested or received from the Federal health care program under the application, agreement, bid, or contract on which the false statement, omission, or misrepresentation was made; and

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

25. Section 1001.1601 is amended as follows:

- A. Republish paragraph (b)(1) introductory text;
- B. Revise paragraphs (b)(1)(iii) and (iv); and
- C. Remove paragraph (b)(1)(v).

The republications and revisions to read as follows:

**§ 1001.1601 Violations of the limitations on physician charges.**

\* \* \* \* \*

(b) \* \* \*

(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).

\* \* \* \* \*

26. Section 1001.1701 is amended as follows:

- A. Republish paragraph (c)(1) introductory text;
- B. Revise paragraphs (c)(1)(iv) and (v); and
- C. Remove paragraph (c)(1)(vi).

The republications and revisions to read as follows:

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

\* \* \* \* \*

(c) \* \* \*

(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).

\* \* \* \* \*

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

\* \* \* \* \*

28. Section 1001.1901 is amended by revising paragraph (b) 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.

\* \* \* \* \*

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

**§ 1001.2001 Notice of intent to exclude.**

\* \* \* \* \*

(b) If the OIG intends to exclude an individual or entity under the provisions of § 1001.701, § 1001.801, or § 1001.1552, 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, paragraph (a) of this section will not apply.

\* \* \* \* \*

30. Section 1001.2003 is amended by revising paragraphs (a) and (b) to read as follows:

**§ 1001.2003 Notice of proposal to exclude.**

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with § 1001.901, § 1001.951, § 1001.1601, or § 1001.1701, it will send a written notice of proposal to exclude to the affected individual or entity. The written notice will provide the same information set forth in § 1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the receipt of the notice (as defined in § 1005.2 of this chapter) unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth-

- (1) The specific issues or statements in the notice with which the individual or entity disagrees;
- (2) The basis for that disagreement;
- (3) The defenses on which reliance is intended;
- (4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b) If the individual or entity makes a timely written request for a hearing and the OIG has determined that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant immediate exclusion, an exclusion will only go into effect as of the date of the ALJ's decision, if the ALJ upholds the decision to exclude.

\* \* \* \* \*

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

\* \* \* \* \*

32. 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—

\* \* \* \* \*

33. 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—PROGRAM INTEGRITY—STATE-INITIATED EXCLUSIONS FROM MEDICAID**

34. 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).

35. 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 Federal financial

participation (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]**

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

37. 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.

38. 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.

\* \* \* \* \*

39. 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]**

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

**§ 1002.211 [Redesignated as § 1002.6]**

41. Section 1002.211 is redesignated as § 1002.6 and transferred from subpart C to subpart A.

42. 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), (4) and (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.

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

**Subpart B—State Exclusion of Certain Managed Care Entities**

44. 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 § 1001.1551 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 § 1001.1551 of this chapter.

\* \* \* \* \*

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

**Subpart C—Procedures for State-Initiated Exclusions**

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

**§ 1002.210 General authority.**

\* \* \* \* \*

**§ 1002.211 [Removed and Reserved]**

47. Section 1002.211 is removed and reserved.

**PART 1006—INVESTIGATIONAL INQUIRIES**

48. 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.

49. 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).

\* \* \* \* \*

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**Daniel R. Levinson**

Inspector General

APPROVED: August 4, 2016.

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**Sylvia M. Burwell**

Secretary

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