

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of Inspector General****42 CFR Parts 1003 and 1005**

RIN 0936-AA04

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules**AGENCY:** Office of Inspector General (OIG), HHS.**ACTION:** Final rule.

SUMMARY: This final rule amends the civil monetary penalty (CMP or penalty) rules of the Office of Inspector General to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on civil money penalties, assessments, and exclusions to improve readability and clarity.

DATES: These regulations are effective on January 6, 2017.

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SUPPLEMENTARY INFORMATION:**I. Executive Summary***A. Purpose of the Regulatory Action*

The Affordable Care Act of 2010 (Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (2010), hereafter the ACA) significantly expanded OIG's authority to protect Federal health care programs from fraud and abuse. The OIG proposed to update its regulations to codify the changes made by the ACA in the regulations. At the same time, OIG proposed updates pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other statutory authorities, as well as technical changes to clarify and update the regulations.

B. Legal Authority

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

1003: 42 U.S.C. 1320a-7(c), 1320a-7a, 1320b-10, 1395w-27(g), 1395w-112(b)(3)(E), 1395w-141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 1396r-

8(b)(3)(B), 1396r-8(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a.
1005: 42 U.S.C. 405(a), 405(b), 1302, 1320a-7, 1320a-7a, and 1320c-5.

C. Summary of Major Provisions

We proposed changes to the Civil Monetary Penalties (CMP) regulations at 42 CFR part 1003 to implement or codify authorities under the ACA and other statutes. The ACA provides for CMPs, assessments, and exclusion for:

- Failure to grant OIG timely access to records;
- ordering or prescribing while excluded;
- making false statements, omissions, or misrepresentations in an enrollment application;
- failure to report and return an overpayment; and
- making or using a false record or statement that is material to a false or fraudulent claim.

These statutory changes are reflected in the proposed regulations.

We also proposed a reorganization of 42 CFR part 1003 to make the regulations more accessible to the public and to add clarity to the regulatory scheme. We proposed an alternate methodology for calculating penalties and assessments for employing excluded individuals in positions in which the individuals do not directly bill Federal health care programs for furnishing items or services. We also clarified the liability guidelines under OIG authorities, including the Civil Monetary Penalties Law (CMPL); the Emergency Medical Treatment and Labor Act (EMTALA); section 1140 of the Act for conduct involving electronic mail, Internet, and telemarketing solicitations; and section 1927 of the Act for late or incomplete reporting of drug-pricing information.

D. Costs and Benefits

There are no significant costs associated with the regulatory revisions that would impose any mandates on State, local, or tribal governments or the private sector. The OIG anticipates that CMP collections may increase in the future in light of the new CMP authorities and other changes proposed in this rule. However, it is difficult to accurately predict the extent of any increase because of a variety of factors, such as budget and staff resources, the number and quality of CMP referrals or other potential cases, and the time needed to investigate and litigate a case. In calendar years 2004-2015, OIG collected annual amounts ranging between \$10.2 million and \$107.3 million in CMP resolutions for a total of over \$309.2 million.

I. Discussion*A. Summary of Revisions and Response to Comments*

In response to the notice of proposed rulemaking, 79 FR 27,080 (May 12, 2014), OIG received 27 public comments from various health care providers and organizations, professional medical societies and associations, and other interested parties. We also received a comment that was filed one day late, which we included in our responses. The comments included both concerns regarding the general factors and more detailed comments on specific CMP provisions.

Set forth below is a discussion of the proposed changes to the regulations at the 42 CFR part 1003, a synopsis of the various comments and recommendations received in response to the proposed rule, our response to those comments and recommendations, and a summary of the specific revisions and clarifications being made to the regulations as a result of the public comments.

B. Background

For over 27 years, OIG has exercised the authority to impose CMPs, assessments, and exclusions in furtherance of its mission to protect Federal health care programs and their beneficiaries from fraud, waste, and abuse. As those programs have changed over the last two decades, OIG has received new fraud-fighting CMP authorities, including new authorities under the ACA. With the addition of new authorities over time, part 1003 has become cumbersome. While adding new authorities, we are also reorganizing part 1003 to improve its readability and clarity and addressing several substantive issues in our existing authorities.

In 1981, Congress enacted the CMPL, section 1128A of the Act (42 U.S.C. 1320a-7a), as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The CMPL authorized the Secretary to impose penalties and assessments on a person, as defined in 42 CFR part 1003, who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMPL also authorized the Secretary to exclude persons from Medicare and all State health care programs (including Medicaid). Congress later expanded the CMPL and the scope of exclusion to apply to all Federal health care programs. The Secretary delegated the CMPL's authorities to OIG. 53 FR 12,993 (April 20, 1988). Since 1981, Congress has

created various other CMP authorities covering numerous types of fraud and abuse. These new authorities were also delegated by the Secretary to OIG and were added to part 1003.

The ACA is the most recent expansion of the CMP provisions and OIG's ability to protect Federal health care programs from fraud and abuse. Sections 6402(d)(2)(A)(iii) and 6408(a) of ACA amended the CMPL by adding new conduct that subjects a person to penalties, assessments, and/or exclusion from participation in Federal health care programs. The new covered conduct includes: (1) Failure to grant OIG timely access to records, upon reasonable request; (2) ordering or prescribing while excluded when the excluded person knows or should know that the item or service may be paid for by a Federal health care program; (3) making false statements, omissions, or misrepresentations in an enrollment or similar bid or application to participate in a Federal health care program; (4) failure to report and return an overpayment; and (5) making or using a false record or statement that is material to a false or fraudulent claim. See the Act, section 1128A(a)(8)–(12). We are codifying these new authorities and remedies at 42 CFR 1003.200(b)(6)–(10), 1003.210(a)(6)–(9), and 1003.210(b)(3).

Section 6408(b)(2) of the ACA amended section 1857(g)(1) of the Act (42 U.S.C. 1395w–27(g)(1)), which relates to Medicare Advantage and Part D contracting organizations. See the Act, section 1860D–12(b)(3)(E) (42 U.S.C. 1395w–112) (incorporating 1857(g) by reference). Through this amendment to the Act, the ACA made several changes to these authorities. First, section 6408(b)(2) of the ACA clarifies that penalties, and, where applicable, assessments, may be imposed against a Medicare Advantage or Part D contracting organization when its employees or agents, or any provider or supplier who contracts with it, engages in the conduct described in the CMP authorities in section 1857(g) of the Act. This statutory change broadens the general liability of principals for the actions of their agents under our existing regulations at § 1003.102(d)(5) (proposed § 1003.120(c)) to include contracting providers and suppliers who may not qualify as agents of the contracting organization. The ACA also provides for penalties and assessments against a Medicare Advantage or Part D contracting organization that: (1) Enrolls an individual without his or her prior consent; (2) transfers an enrollee from one plan to another without his or her prior consent; (3) transfers an enrollee solely for the purpose of earning a

commission; (4) fails to comply with marketing restrictions described in sections 1851(h) or (j) of the Act (42 U.S.C. 1395w–21(h) or (j)) or applicable implementing regulations or guidance; or (5) employs or contracts with any person who engages in the conduct described in section 1857(g)(1) of the Act.

We have codified these new authorities in the proposed regulations at § 1003.400(c) and their corresponding penalties and assessments at § 1003.410. The Centers for Medicare & Medicaid Services (CMS) may also impose sanctions under its authorities related to Medicare Advantage or Part D contracting organizations. Those authorities are at 42 CFR parts 422 and 423.

C. Reorganization of Part 1003

We proposed reorganizing part 1003 to make the regulations more accessible to the public and to add clarity to the regulatory scheme. Except for general and procedural subparts, the reorganized part 1003 groups CMP authorities into subparts by subject matter. This revised structure also clarifies the differences between the various CMP authorities and their respective statutory remedies. For certain CMP authorities, penalties, assessments, and exclusion are authorized. For other CMP authorities, only penalties, or penalties and assessments, are authorized. Each subpart is intended to be self-contained, with all the relevant provisions concerning a particular violation included in the same subpart.

We received no comments on the reorganization and finalize it as proposed.

D. Technical Changes and Clarifications

Because we intended each subpart to be self-contained, we proposed incorporating the exclusion sections, which were found at §§ 1003.105 and 1003.107, into the subparts in which exclusion is available: False Claims; Anti-kickback and Physician Self-Referral; EMTALA; and Beneficiary Inducement. This proposed revision more clearly reflects the statutory scheme, which permits both monetary and exclusion remedies for these violations.

The proposed changes clarify in each subject matter subpart that we may impose a penalty for each individual violation of the applicable provision. As we explained in the notice of proposed rulemaking, and below, the statutory authorities are clear that each act that constitutes a violation is subject to penalties. The proposed revisions to the

regulatory language better reflect this statutory framework.

Throughout part 1003, we proposed replacing references to Medicare and State health care programs with “Federal health care programs” when the provision concerns exclusion to more completely reflect the full scope of exclusion. The proposed changes also remove all references to the penalties and assessments available before 1997 because any conduct prior to 1997 falls outside the CMPL's statute of limitations.

The proposed changes clarify that a principal's liability for the acts of its agents does not limit liability only to the principal. Agents are still liable for their misconduct. In our enforcement litigation, we have encountered the argument that agents are not liable for their misconduct where the principal is liable for the same misconduct. We believed the law provides that the agent remains liable for his or her conduct and may not use the principal as a liability shield. The proposed revision clarifies this point. In addition, we proposed to consolidate § 1003.102(d)(1)–(4), which addressed situations in which multiple parties may have liability for separate CMP provisions. This proposed revision clarifies that each party may be held liable for any applicable penalties and that the parties may be held jointly and severally liable for the assessment.

We received no comments on these topics and finalize the regulation as proposed.

Under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of Pub. L. 114–74, 129 Stat. 599), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890), Federal agencies must make annual adjustments to their CMPs, including the CMPs in the Social Security Act. The Department of Health and Human Services (HHS or the Department) will publish all of the Department's adjusted CMP amounts at 45 CFR part 102. That section will include CMPs that have been delegated to OIG. To ensure transparency, we have added footnotes to subparts B through M stating that the penalty amounts are adjusted for inflation and citing to 45 CFR part 102.

E. Civil Monetary Penalty Authorities

Subpart A—General Provisions

Subpart A contains the general provisions that apply to part 1003. The proposed changes revised the “Basis and Purpose” section to state more succinctly part 1003's purpose and to

include a complete listing of CMPs. We also proposed updates to statutory authority citations at proposed § 1003.100(a)–(b).

We received no comments on these changes and finalize the regulations as proposed.

1003.110 Definitions

The proposed rule included several changes to the “Definitions” section for clarity and readability. First, we proposed to redesignate § 1003.101 as § 1003.110. We proposed to remove terms from this part that duplicate definitions in part 1000 or are no longer used in this part. We also proposed the following changes and additions to the specific definitions.

Claim

We proposed to revise the definition of “claim” by changing the word “to” to “under.” This change more closely aligns the regulations to the CMPL’s definition of “claim” to avoid any misinterpretation that a claim is limited to an application for payment for an item or service made directly to a Federal health care program (e.g., a claim also includes applications for payment to contractors).

Contracting Organization

We proposed to update the definition of “contracting organization” to include all entities covered by sections 1857, 1860D–12, 1876(b) (42 U.S.C. 1395mm(b)), or 1903(m) of the Act.

Item or Service

We proposed revisions to the definition of the term “item or service.” Section 1128A of the Act provides that the term “item or service” “includes” various items, devices, supplies, and services. By using the word “includes” in section 1128A of the Act, Congress created an illustrative statutory definition that is broad enough to capture all the uses of the term in section 1128A of the Act. The term is used in section 1128A of the Act in two different contexts: one, in reference to submitting claims for items and services reimbursed by a Federal health care program, and two, in the definition of “remuneration” to beneficiaries in reference to section 1128A(a)(5) of the Act. We proposed clarifying the definition to ensure that it reflects the broad meaning of “item or service” in both contexts.

Knowingly

We proposed clarifying the definition of “knowingly,” found in the existing regulation at § 1003.102(e), to cover acts as opposed to information. We also

proposed removing the reference to the False Claims Act (FCA) from the definition of “knowingly” because it is unnecessary. As used in part 1003, the term “knowingly” applies only to acts, such as the act of presenting a claim. When a person’s awareness or knowledge of information is at issue, the CMPL and other statutes use either a “knew or should have known” construction. For example, section 1128A(a)(2) of the Act subjects a person to liability when the person knowingly presents, or causes to be presented, a claim that the person knew or should have known is false or fraudulent. Here, the act is presenting the claim or causing the claim to be presented. The information is that the claim was false or fraudulent.

Material

We proposed a definition of “material” that mirrors the FCA definition as “having a tendency to influence, or be capable of influencing, the payment or receipt of money or property.”

Overpayment

We proposed a definition of “overpayment” that is taken from section 1128J(d)(4) of the Act (42 U.S.C. 1320a-7k(d)(4)), as amended by section 6402(a) of the ACA.

Reasonable Request

We proposed a definition of “reasonable request” as part of implementing the new ACA CMP authority for failure to grant OIG timely access to records, as discussed below under § 1003.200, subpart B.

Responsible Official

We proposed a definition of “Responsible Official” as this term relates to the select agent and toxin CMP authority. We proposed to amend the definition of “select agent and toxin” as the term relates to the select agent and toxin CMP authority (42 U.S.C. 262a(i); Act, section 1128A(j)(2)).

Responsible Physician

We also proposed revising the definition of “responsible physician” to more closely conform to statutory intent, as discussed below under § 1003.500, subpart E.

Separately Billable Item or Service and Non-Separately-Billable Item or Service

We also proposed definitions of “separately billable item or service” and “non-separately-billable item or service” to create an alternate method for calculating penalties and

assessments for violations of section 1128A(a)(6) of the Act.

We did not receive comments on the proposed definitions of “claim,” “contracting organization,” “item or service,” “Responsible Official,” “non-separately-billable item or service,” or “separately billable item or service” and are finalizing the definition as proposed. We received comments on the definition of “knowingly,” “should know, or should have known,” “material,” and “timely basis,” which are discussed below. We also received comments on the definitions of “overpayment,” “reasonable request,” and “responsible physician,” which we will address in the discussion of the overpayment, timely access, and EMTALA CMPs respectively.

Comment: One commenter recommended that the definitions of “knowingly” and “should know, or should have known” not include that “no proof of specific intent to defraud is required.” Another commenter recommended that, when applied to § 1003.200(b)(7) for false statements, omissions, or misrepresentations, “knowingly” should include a specific intent to defraud. Both commenters argued that, where there was no specific intent to defraud, a maximum penalty of \$50,000 for a violation of § 1003.200(b)(7) would be unduly harsh.

Response: The definition of “should know” in section 1128A(i)(7) of the Act states that “no proof of specific intent to defraud is required.” Similarly, the existing regulatory definitions of “knowingly” and “should know, or should have known” both state that “no proof of specific intent is required.” We proposed no changes to that language in either definition. As discussed above, our proposal clarified that the use of the term “knowingly” referred to acts, such as submitting a claim, and “should know or should have known” referred to information, such as the claim was false or fraudulent. Further, OIG does not believe it would be unduly harsh to apply up to a \$50,000 penalty where a person acted with reckless disregard when making a material omission on an application, bid, or contract to participate or enroll as a provider or supplier. We are finalizing these terms, as proposed.

Comment: Some commenters disagreed with the proposed definition of “material” and recommended we adopt a definition of “having an actual influence on the payment or receipt of money or property.”

Response: We respectfully disagree with the commenters and finalize the definition, as proposed. The proposed language mirrors the definition of

material in the FCA, 31 U.S.C. 3729(b)(4). In the ACA, Congress added a new CMP cause of action against persons who knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program. This cause of action mirrors a cause of action under the FCA at 31 U.S.C. 3729(a)(1)(B). We believe that the same definition should apply in the CMPL given the similarities with the FCA. In addition, we believe this definition is appropriate for the other CMP causes of action in this part that use the term “material” because those authorities also involve the use of false statements—§§ 1003.200(a)(4)(ii), 1003.200(a)(7), 1003.200(d), and 1003.1100(a).

Comment: One commenter argued that we should change the definition of “timely basis” to the 60-day period from the time the individual or entity knows that the amounts collected violated the Physician Self-Referral Law. The commenter states that it is unreasonable to expect individuals and entities consistently to know, within 60 days of collection, that an amount was collected in violation of the Stark Law, and that it would be unfair to impose penalties, assessments, and exclusions on individuals and entities for failure to return payments that they did not know were collected in violation of the Stark Law.

Response: Because we did not propose changing the language of the definition, only the internal citation, this suggestion is outside the scope of this rulemaking. We are finalizing the definition, as proposed.

Comment: We also received a comment asking that OIG clarify that the provisions of part 1003 applying to Federal health care programs do not apply to Qualified Health Plan Issuers or State-based or Federally facilitated exchanges.

Response: “Federal health care program” is defined in section 1128B(f) of the Act. part 1003 does not include a definition of “Federal health care program” and none was included in our proposed changes to that part. Therefore, this comment is beyond the scope of the rulemaking. That said, the Department stated in an October 30, 2013 letter from the Secretary to Representative Jim McDermott that it does not consider Qualified Health Plans (QHPs) or other programs related to the Federally facilitated marketplace to be federal health care programs, for the purposes of 1128B(f) of the Act.

1003.140 Determinations Regarding the Amount of Penalties and Assessments and the Period of Exclusion

We proposed modifying the provisions relating to the factors considered in determining exclusion periods and the amount of penalties and assessments for violations. The existing structure separately listed factors for certain CMP violations in § 1003.106(a) and provided additional detail on these factors for certain CMP violations in § 1003.106(b) and (d). This structure was cumbersome and potentially confusing for the reader.

To add clarity and improve transparency in OIG’s decision-making, we identified the most common issues among the factors listed and created a single, primary list of factors in the proposed § 1003.140. The primary factors are: (1) The nature and circumstances of the violation, (2) the degree of culpability of the person, (3) the history of prior offenses, (4) other wrongful conduct, and (5) other matters as justice may require. As the fifth factor demonstrates, these are illustrative factors rather than a comprehensive list. These factors would apply to all CMP violations, except as otherwise provided in the subpart relating to a specific subject matter, which may contain additional detail or explanation regarding a factor’s applicability to a specific violation. For example, the aggravating factors listed in § 1003.106(b)(1) related to the nature and circumstances of a violation. Because these factors relate most directly to billing issues, the proposed regulations include them in §§ 1003.220, 1003.320, and 1003.420. We proposed updating the claims-mitigating factor by increasing the maximum dollar amount considered as mitigation from \$1,000 to \$5,000. We believed this updated amount is an appropriate threshold that is consistent with rationale behind the original amount. A dollar threshold as a mitigating factor for CMP purposes differentiates between conduct that could be considered less serious and more serious. Conduct resulting in more than \$5,000 in Federal health care program loss is an indication of more serious conduct. Given the changes in the costs of health care since this regulation was last updated in 2002, we believed the \$1,000 threshold was lower than appropriate. We also proposed revising the claims-aggravating factor that was at 1003.106(b)(1)(iii) by replacing “substantial” with “\$15,000 or more.” We believe that replacing “substantial” with a specific dollar

threshold increases transparency and gives providers better guidance on OIG’s evaluation of this factor. In assigning a dollar value to the aggravating factor, we considered our practices in evaluating conduct for pursuing CMPs and proposed that a loss greater than \$15,000 is an indication of serious misconduct. As discussed in response to comments, we are finalizing the aggravating factor as a loss greater than \$50,000.

The OIG will, however, continue to review the facts and circumstances of a violation on a case-by-case basis. For instance, when considering the nature and circumstances of any case, OIG will consider, among other things and to the extent they are relevant, the period over which the conduct occurred, whether a pattern of misconduct is indicated, the magnitude of the violation, the materiality or significance of a false statement or omission, the number of people involved, the number of victims, and whether patients were or could have been harmed.

The proposed changes also clarify that these factors apply to exclusion determinations made under part 1003 as well as penalty and assessment amount determinations. We are removing § 1003.107(c) in light of this reorganization. The existing regulations stated, at § 1003.107(c), that the guidelines regarding exclusion determinations are not binding. This language was used to emphasize that only the reasonableness of a period of exclusion is reviewable on appeal as opposed to OIG’s decision to impose an exclusion. While OIG’s discretion to exercise its exclusion authority remains unreviewable, the § 1003.107(c) language is no longer necessary under the proposed reorganization. The revisions at § 1003.140 more clearly state that the general guidelines relate to the length of exclusion as opposed to the decision whether to exclude a person.

At § 1003.106(b)(2), the regulations discussed a person’s degree of culpability and listed several aggravating circumstances concerning whether a person had knowledge of the violation. We believed the language was out-of-date in light of all the CMP authorities that have been added to part 1003 over the years. We proposed to consider as an aggravating factor a person’s having a level of intent to commit the violation that is greater than the minimum intent required to establish liability.

Various CMP authorities have different intent or scienter requirements. Some authorities have a “knows or should know” standard consistent with

the FCA standard that includes actual knowledge, deliberate ignorance, or reckless disregard. Some authorities require only negligence and some have no intent requirement. In CMP cases in which the scienter standard required to prove a violation is lower than actual knowledge, having actual knowledge is more egregious. Our existing regulations provide that actual knowledge is an aggravating factor when a respondent knew an item or service was not provided as claimed or if the respondent knew that a claim was false or fraudulent. We intend the general “degree of culpability” factor to encompass this approach and to extend to all CMP authorities that have a scienter standard that is lower than actual knowledge. In response to comments, as summarized below, we are finalizing the rule to provide that it shall be considered an aggravating factor when a person has actual knowledge and the level of intent required to establish liability is less than actual knowledge.

Possessing the lowest level intent to commit a violation is not a defense against liability, a mitigating factor, or a justification for a less serious remedy. Individuals and entities are expected to know the law and Federal health care program rules. While the degree of culpability is relevant in our determination to impose a monetary or exclusion remedy, other factors, such as the nature and circumstances of the violation, may justify a maximum monetary remedy or exclusion to protect Federal health care programs and beneficiaries from fraud, waste, and abuse.

In addition, we proposed to add a mitigating circumstance to the degree-of-culpability factor for taking “appropriate and timely corrective action in response to the violation.” The proposed regulation required that a person, to qualify as taking corrective action, disclose the violation to OIG through the Self-Disclosure Protocol (the Protocol) and fully cooperate with OIG’s review and resolution of the violation. We have long emphasized the importance of compliance programs that result in appropriate action when Federal health care program compliance issues are identified. We continue to believe that appropriate action for potential violations of OIG’s CMP authorities must include self-disclosure and cooperation in the inquiry and resolution of the matter. For most OIG CMP authorities, the person should not qualify for mitigation of the potential monetary or exclusion remedies without self-disclosure through the Protocol (available at—<http://oig.hhs.gov/>

compliance/self-disclosure-info/protocol.asp). In response to comments, which are summarized below, we are finalizing the rule to include self-disclosure to CMS’s Self-Referral Disclosure Protocol for Stark violations. As further discussed in subpart E, we are also including disclosure to CMS for EMTALA violations.

The proposed changes clarified that when we are determining the appropriate remedy against an entity, aggravating circumstances include the prior offenses or other wrongful conduct of: (1) The entity itself; (2) any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act (42 U.S.C. 1320a–3)) in the entity at the time the violation occurred and who knew, or should have known, of the violation; or (3) any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act (42 U.S.C. 1320a–5)) of the entity at the time the violation occurred. For “prior offenses,” we also proposed to change “any other public or private program for reimbursement for medical services” to “in connection with the delivery of a health care item or service.” This proposed change is consistent with the aggravating circumstance “other wrongful conduct.”

Finally, the proposed rule clarified when OIG considers the financial condition of a person in determining penalty or assessment amounts. The regulations discussed financial condition in various sections with varying degrees of specificity: § 1003.106(a)(1)(iv); (a)(3)(i)(F); (a)(4)(iv); (b)(5); and (d)(4). We proposed a more uniform and specific standard to apply after OIG evaluates the facts and circumstances of the conduct and weighs the aggravating and mitigating factors to determine an appropriate penalty and assessment amount. Once OIG proposes this penalty and assessment amount, the person may request that OIG consider its ability to pay the proposed amount. To permit OIG to evaluate a person’s ability to pay, the person must submit sufficient documentation that OIG deems necessary to conduct its review, including, but not limited to, audited financial statements, tax returns, and financial disclosure statements. This ability-to-pay review may also consider the ability of the person to reduce expenses or obtain financing to pay the proposed penalty and assessment. If a person requested a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review would be that which the person submitted to OIG, unless the

Administrative Law Judge (ALJ) finds that extraordinary circumstances prevented the person from providing the financial documentation to OIG in the time and manner requested by OIG prior to the hearing request.

We received the following comments on these proposals. To the extent the comments do not address aspects of these changes, we are finalizing this section of the rule, as proposed.

Comment: Some commenters disagreed with our proposal to include a person’s level of intent as an aggravating factor for several reasons. Some commenters viewed proving, and distinguishing between, different degrees of mental states, such as “actual knowledge,” “deliberate ignorance,” and “reckless disregard,” as subjective. Commenters argued that the proposed rule’s rationale for using degrees of scienter to determine the existence of aggravating circumstances is not sufficient to overcome concerns regarding the subjectivity involved in distinguishing between and proving these highly nuanced mental states. Aside from the statement that “actual knowledge is considered more egregious than a lower level of intent,” commenters expressed concern that the proposed rule does not explain which different scienter requirements carry respectively greater, or lesser, culpability. For example, commenters argued that the proposed rule does not provide if or how scienter requirements, such as “reckless disregard” and “deliberate ignorance,” relate to one another with respect to potential culpability. Commenters were also concerned that the proposed rule does not set forth the evidentiary standards required to prove, and distinguish between, degrees of scienter, (e.g., where a person can be held liable: (1) For *knowingly* presenting an inaccurate claim; or (2) where the person *knew, or should have known*, that the claim was not accurate). Given that legal expertise is typically required to fully interpret and understand these terms, commenters stated that physicians and health care providers may not fully comprehend the changes proposed by the rule and may be disadvantaged when trying to respond to OIG’s determination that an aggravating circumstance is present on the basis of alleged degrees of culpability.

Finally, while commenters acknowledged OIG’s experience in CMP enforcement as the main support for its degree-of-culpability proposal, commenters noted that this rule expands OIG’s authority to new types of conduct under the five new ACA liability bases to its enforcement

authority. These additional bases for CMPs require physicians to understand new authorities and also expands OIG scianter determinations to new areas of the law. Given this expanded scope, commenters urged OIG to reconsider use of this new aggravating factor, especially without providing more detailed guidance distinguishing different mental standards and their applicability to CMPs, assessments, and exclusions.

Response: We have altered the final rule so that in cases in which the scianter standard required to prove a violation is lower than actual knowledge, having actual knowledge will be an aggravating factor. We will continue evaluating each case to determine the appropriate penalties and assessments and whether exclusion is appropriate. In any case in which the scianter standard required to prove a violation is lower than actual knowledge, actual knowledge is more egregious. The OIG's existing regulations provide that actual knowledge is an aggravating factor where a respondent knew an item or service was not provided as claimed or if the respondent knew that a claim was false or fraudulent. In the final rule, OIG is simply extending actual knowledge as an aggravating factor to all cases in which the scianter standard to prove a violation is lower than actual knowledge.

Comment: One commenter expressed concern about OIG's proposed provision that any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors are present. The commenter argued that this proposed change would tilt the balance in favor of the aggravating factors without due consideration to all of the circumstances in each case and could lead to uneven enforcement. The commenter also stated that this concern was compounded by OIG's other proposal to move away from separately listed aggravating factors to a more general, illustrative list of factors that the commenter argues could be applied more broadly. Finally, the commenter also stated that this proposal could discourage mitigating actions (e.g., participating in the Self-Disclosure Protocol).

Response: We believe that the proposed rule accurately reflects the case-by-case analysis that OIG has historically done and that is conducted in the ALJ hearing process. Aggravating and mitigating circumstances require qualitative weighing of facts and circumstances and are, by their nature, dependent on the facts and

circumstances present in the individual case. In this weighing process, it is possible to conclude that one aggravating circumstance should outweigh several mitigating circumstances because of the nature and circumstances of the case. As such, our proposal that any one aggravating circumstance may justify a high penalty or assessment simply reflects this qualitative, fact-driven analysis. The converse is also true, that one mitigating factor could justify a lower penalty. Our proposal is not intended to change OIG's longstanding and repeatedly stated position that appropriate self-disclosure is a critical indication that the provider or supplier has an effective compliance program. We will continue to follow the process outlined in the Self-Disclosure Protocol in resolving Protocol submissions.

Comment: One commenter stated that proposed § 1003.140(d), which provides that OIG should exclude where there are aggravating circumstances, is superfluous because OIG already has the authority to exclude where aggravating circumstances exist. The commenter expressed concern that, if read so as not to be superfluous, the provision would suggest that exclusion is mandated by the rule.

Response: We agree with the commenter that the provision is superfluous. The OIG makes determinations regarding penalties, assessments, and exclusion based on a case-by-case analysis, and for any particular case the presence of aggravating circumstances may support exclusion. Therefore, we are finalizing the rule without this proposed provision.

Comment: A few commenters suggested that a lower level of intent be considered as a mitigating factor. Commenters argued that if a higher level of intent may be viewed as a potential aggravating factor, OIG should consider a lower level of intent as a mitigating factor.

Response: Possessing a lower level of intent to commit a violation is not a defense against liability or a justification for a less serious remedy. Individuals and entities are expected to know the law and Federal health care program rules. While the degree of culpability is relevant in our determination to impose a monetary or exclusion remedy, other factors, such as the nature and circumstances of the violation, may justify a maximum monetary remedy or exclusion to protect the Federal health care programs and beneficiaries. Moreover, if the facts show that the person did not possess the requisite level of intent to violate a particular

statutory or regulatory provision, no monetary penalty or exclusion would apply.

Comment: Several commenters suggested that OIG expand the corrective action that would be considered as a mitigating factor to include more than submissions to the Self-Disclosure Protocol. Commenters argued that limiting the mitigating factor to use of the Self-Disclosure Protocol is overly limited and suggested that the following actions be considered mitigating: Disclosure to the CMS Self-Referral Disclosure Protocol, returning payments to Medicare contractors, internal investigation, and staff retraining. Commenters argued that retaining existing regulatory language, which more generally references corrective steps taken promptly after a problem was discovered, would allow providers and suppliers the flexibility to take the corrective action best fitted to their particular practice settings and is more likely to encourage providers and suppliers to actively take appropriate corrective action.

Response: We have decided to amend our proposal to include use of the CMS Self-Referral Disclosure Protocol (SRDP) as meeting the corrective action requirement for the mitigating factor. We decided to make this change to clarify that appropriately using the SRDP satisfies OIG's goals of encouraging disclosure and recognizes the specific protocol that CMS has created to handle physician self-referral law (Stark Law) compliance issues. Because conduct that implicates only the Stark Law is not eligible for OIG's Self-Disclosure Protocol, we wanted to clarify that using the SRDP for this conduct is appropriate. We do not believe the other actions described above are appropriate for this mitigating factor. Returning overpayments to the appropriate contractor is important. However, this action does not address or eliminate CMP liability if it exists. Put another way, if the conduct involves only overpayments and no CMP liability, there is no penalty at issue to mitigate. Similarly, taking actions such as internal investigations and retraining employees can be important compliance program activities. However, in the absence of a self-disclosure, these actions also do not affect CMP liability.

We are also amending subpart E (EMTALA) to include in this mitigating factor disclosure of the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

Comment: Some commenters stated that, as a practical matter, this proposal

“mandates” disclosure to the Protocol, which would, for many providers and suppliers, limit the availability of this mitigating circumstance. Some commenters viewed participation in the Protocol as time and labor intensive and often necessitating the assistance of an experienced attorney, which may be expensive for smaller providers and suppliers.

Response: This mitigating factor becomes relevant only if the provider or supplier has CMP liability for the conduct at issue. If that is the case, we expect the provider or supplier to appropriately disclose and resolve the conduct in the Protocol. Attorney representation is not necessary to use the Protocol.

Comment: Some commenters posed questions concerning the relationship between the Self-Disclosure Protocol and the proposed rule. For example, the Self-Disclosure Protocol states that “OIG’s general practice is to require a minimum multiplier of 1.5 times the single damages” while the proposed rule contains no discussion concerning the nexus between Protocol settlements and the imposition of monetary penalties, assessments, and exclusion. Commenters asked whether the 1.5 multiplier will be available to those using the Self-Disclosure Protocol if an aggravating factor exists under the proposed rule. Commenters also asked whether OIG would suspend the statutory obligation to report and return an overpayment within 60 days if the provider has appropriately made a disclosure under the Self-Disclosure Protocol and is actively seeking a resolution.

Response: The OIG will continue to follow the process and principles outlined in the Self-Disclosure Protocol in resolving Protocol submissions. Even where aggravating circumstances exist, we will generally apply a 1.5 multiplier in Protocol resolutions, as explained in the Protocol. Regarding the 60-day rule referenced by commenters, CMS has rulemaking authority concerning section 1128J(d) of the Act and published a final rule on February 12, 2016. 81 FR 7654 (February 12, 2016). The regulation adopted by that final rule states: “The deadline for returning overpayments will be suspended when the following occurs: (i) The OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.” 42 CFR 401.305(b)(2)(i).

Comment: Some commenters expressed concerns about the proposed rule’s expansion of the “history of prior offenses” and “other wrongful conduct” aggravating factors. Specifically, these commenters argued that it would be unjust to consider prior offenses or other wrongful conduct of officers or managing employees unless the officer or managing employee knew or should have known of the violation. Accordingly, they urged OIG to, as with individuals with ownership or control interests, limit consideration of prior offenses and other wrongful conduct of officers and managing employees to situations in which the officer or managing employee knew or should have known of the violation.

Response: We are finalizing the rule, as proposed. Officers and managing employees have significant responsibility for an entity’s day-to-day operations. Owners, on the other hand, may be active or passive. Passive owners may have less involvement in daily operations, and consequently may have less culpability in the entity’s conduct that creates CMP liability. As such, the rule specifies that individuals who have a direct or indirect ownership or control interest are considered in these factors only if they knew or should have known of the violation. Moreover, this factor was structured to reflect the exclusion authority under section 1128(b)(15) of the Act. Under section 1128(b)(15)(A)(ii) of the Act, an individual who is an officer or managing employee of an excluded entity can be excluded regardless of whether the officer or managing employee knew or should have known of the action that constituted the basis for the exclusion. In contrast, under section 1128(b)(15)(A)(i) of the Act, an owner of the excluded entity can be excluded only if he or she knew or should have known of the action constituting the basis for the exclusion. We believe that Congress intended this different treatment to account for the greater responsibility of officers or managing employees in the entity’s day-to-day operations.

Comment: One commenter argued that “administrative sanctions” in the “history of prior offenses” aggravating factor should not include actions taken by purely private actors, such as health insurers, because, in such private actions, health care providers may not be given due process protections comparable to those available when a governmental entity is seeking administrative sanctions.

Response: We agree with the commenter that the history of prior offenses aggravating factor encompasses

only situations in which the provider or supplier was held liable for criminal, civil, or administrative sanctions by a governmental entity, such as a Federal or State agency or one of its contractors.

Comment: One commenter expressed concerns with the proposed rule’s increased consideration of wrongful conduct related to the commercial market. The commenter recommended that OIG consider only *fraud* sanctions in the private market to ensure that the wrongful conduct directly relates to the conduct being addressed by OIG.

Response: We are finalizing the language, as proposed. We do not believe the other wrongful conduct needs, in all cases, to be related to fraud generally or to the CMP authority at issue to be relevant. This factor is intended to provide some guidance on the trustworthiness of the individual or entity in question. The OIG will continue to perform an analysis of whether the other wrongful conduct should be considered an aggravating circumstance in any given case.

1003.150 Delegation of Authority

The proposed rule also adds an express delegation of authority from the Secretary to OIG to impose penalties, assessments, and exclusions against persons who violate any of the provisions of part 1003. Several **Federal Register** notices and delegation letters, spanning more than 20 years, delegate various authorities to OIG. Some of these older notices and letters are no longer easily accessible by the public, such as 53 FR 12,993 (April 20, 1988). This provision, at proposed § 1003.150, reiterates OIG’s authority to pursue these matters.

We received no comments on this provision and finalize, as proposed.

1003.160 Waiver of Exclusion

We also proposed changes to part 1003’s exclusion-waiver provisions to clarify the criteria for a waiver request from a State agency. The existing regulations stated that OIG will consider an exclusion waiver request from a State agency for exclusions imposed pursuant to 42 CFR 1003.102(a), (b)(1), and (b)(4) and 1003.105(a)(1)(ii) under certain circumstances. We proposed updating the regulations to permit an administrator of a Federal health care program to request a waiver, similar to the waiver in part 1001. Also, we proposed removing the limitations concerning when a waiver may be requested by such an administrator.

We received no comments on this provision and finalize, as proposed.

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

Subpart B contains most of the provisions that were found in the existing regulations at § 1003.102(a) and several of the provisions that were found in § 1003.102(b). The text of the proposed provisions remains largely unchanged, except for a separate provision we created to address section 1128A(a)(6) of the Act. Section 1128A(a)(6) of the Act subjects persons to liability for arranging or contracting with (by employment or otherwise) a person who the employer or contractor knows or should know is excluded from participation in a Federal health care program for the provision of items or services for which payment may be made under that program. This authority was included in the regulations describing false or fraudulent claims at § 1003.102(a)(2). Because of our desire to improve the clarity of the regulations generally and because of the proposed penalty and assessment provisions discussed below, the proposed regulation addressed section 1128A(a)(6) of the Act in a separate subsection at § 1003.200(b)(4).

On the basis of our experience enforcing section 1128A(a)(6) of the Act, we proposed an alternate methodology for calculating penalties and assessments. This alternate methodology recognizes the variety of ways in which items and services are reimbursed by Federal health care programs and the numerous types of health care professionals and other individuals and entities that contribute to the provision of those items and services.

The proposed regulations addressed how penalties and assessments would be imposed for two distinct types of violations: (1) Instances in which items or services provided by the excluded person may be separately billed to the Federal health care programs and (2) instances in which the items or services provided by the excluded person are not separately billable to the Federal health care programs, but are reimbursed by the Federal health care programs in some manner.

To achieve this distinction, we proposed to define two new terms: “separately billable item or service” and “non-separately-billable item or service.” A “separately billable item or service” is defined as “an item or service for which an identifiable payment may be made under a Federal health care program.” This type of item or service exists when a person provides, furnishes, orders, or

prescribes an identifiable item or service for which a claim for reimbursement may be submitted to a Federal health care program by either the person or another person. Examples include physician office visits and prescribed pharmaceuticals.

A “non-separately-billable item or service” is defined as “an item or service that is a component of, or otherwise contributes to the provision of, an item or service, but is not itself a separately billable item or service.” Non-separately-billable items or services are reimbursed as part of the claim submitted under the applicable payment methodology, *e.g.*, nursing or clerical services associated with a physician office visit, care covered by the skilled nursing facility per diem payment, nursing care covered by a hospital diagnosis-related group (DRG) payment, or radiology technician services associated with a specific procedure.

In instances in which the item or service provided by the excluded person is separately billable, the employing or contracting person would continue to be subject to penalties and assessments based on the number and value of those separately billable items and services. For instances in which the item or service provided by the excluded person is non-separately-billable, we proposed an alternate methodology to calculate penalties and assessments. We proposed that penalties would be based on the number of days the excluded person was employed, was contracted with, or otherwise arranged to provide non-separately-billable items or services. We proposed that assessments would be based on the total costs to the employer or contractor of employing or contracting with the excluded person during the exclusion, including salary, benefits, and other money or items of value. We believe this cost-based assessment achieves the purposes of section 1128A(a)(6) of the Act by capturing the value of the excluded person to the employing or contracting person. As discussed below in our response to comments, we are finalizing the assessments, as proposed, but are finalizing the penalties based on each item or service provided by the excluded person.

As discussed above, the ACA added five new violations and corresponding penalties to the CMPL. These new violations and the corresponding penalties are at proposed §§ 1003.200(b)(6)–(10), 1003.210(a)(6)–(9), and 1003.210(b)(3). In general, the proposed regulatory text closely mirrors the statutory text. However, we supplement the statutory text where appropriate. Section 6402(d)(2)(A) of the

ACA amends the CMPL by adding a violation for knowingly making or causing to be made “any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program.” (Emphasis added.) ACA does not, however, include the word “omission” in its description of the penalty and assessment for this violation. To give full effect to the amendment adding “omission” to the CMPL, we have added the word “omission” in the penalty and assessment sections.

Also, we proposed clarifying the penalty under the CMPL, as amended by section 6402(d)(2) of the ACA, for failure to report and return overpayments. Under the amended section 1128J(d) of the Act, overpayments must be reported and returned by the later of 60 days after the date the overpayment was identified or the date any corresponding cost report is due, if applicable. The new CMPL authority under section 1128A(a)(10) of the Act does not contain a specific penalty amount, but instead uses the default penalty amount in the CMPL, which is up to \$10,000 for each item or service. In this context, we proposed regulatory text interpreting the CMPL’s default penalty as up to \$10,000 for each day a person fails to report and return an overpayment by the deadline in section 1128J(d) of the Act. Because the failure to report and return overpayments within 60 days of identification is based on the 60-day period passing, we believed that the penalty could be interpreted to attach to each following day that the overpayment is retained. However, as we noted in the proposed rule, Congress specified a per day penalty in sections 1128A(a)(4) and (12) of the Act and did not do so for section 1128A(a)(10) of the Act. Thus, we solicited comments on whether to interpret the default penalty of up to \$10,000 for each item or service as pertaining to each claim for which the provider or supplier identified an overpayment. As discussed below in our response to comments, we are finalizing the rule using the default penalty amount in the CMPL, which is up to \$10,000 for each item or service.

Section 6408(a)(2) of the ACA amended the CMPL by adding a violation for failure to grant timely access, upon reasonable request, to OIG for the purpose of audits, investigations, evaluations, or other statutory functions. Section 1128(b)(12) of the Act and 42 CFR 1001.1301 authorize exclusion based on similar, but not identical, conduct — failure to grant immediate

access. We believe Congress expanded OIG's authority to exclude, and created an authority to impose a penalty, in a broader set of circumstances than covered by section 1128(b)(12) of the Act by using the phrase "timely access" in section 6408(a)(2) of the ACA. Thus, we believe conduct that implicates section 1128(b)(12) of the Act is a subset of the conduct implicated by the new CMPL authority created by section 6408(a)(2) of the ACA. In these situations, OIG has the discretion to choose whether to pursue exclusion under section 1128(b)(12) of the Act or penalties and/or exclusion under section 6408(a)(2) of the ACA. In drafting regulations pursuant to section 6408(a)(2) of the ACA, we evaluated the conduct covered by section 1128(b)(12) of the Act to ensure that this proposed rule is consistent with § 1001.1301.

The proposed definitions of "failure to grant timely access" and "reasonable request" give OIG flexibility to determine the period in which a person must respond to a specific request for access, depending on the circumstances. Given the different purposes for which OIG may request access to material, such as audits, evaluations, investigations, and enforcement actions, we believe the best approach is for OIG to specify the date for production or access to the material in OIG's written request. In making this decision, OIG will consider the circumstances of the request, including the volume of material, size and capabilities of the party subject to the request, and OIG's need for the material in a timely way to fulfill its responsibilities. The exception to this approach is a case in which OIG has reason to believe that the requested material is about to be altered or destroyed. Under those circumstances, timely access means access at the time the request is made. This exception is the same as provided in § 1001.1301.

Finally, we proposed revisions to the regulation's aggravating factors for CMPL violations. The aggravating factors listed in proposed § 1003.220 are based on those that apply to the violations in the existing regulations. We proposed moving the aggravating factors to one section and consolidating similar factors into one factor. For instance, the first aggravating factor, *i.e.*, the violations were of several types or occurred over a lengthy period, was found at § 1003.106(b)(1)(i). We interpret the phrase "several types" to include, but not be limited to, billing for services that are covered by different billing codes. The final aggravating factor relates to the amount or type of financial, ownership, or control interest, or the degree of responsibility a person

has in an entity with respect to actions brought under § 1003.200(b)(3). While we will consider whether a person is a CEO or a manager, job titles alone will not guide our consideration of this factor; we will look at the degree of responsibility and influence that a person has in an entity.

We received the following comments on this subpart. To the extent provisions of the proposed rule are not addressed in the comments below, we are finalizing this section of the rule, as proposed.

Comment: We received many comments supporting the creation of the alternate methodology for calculating assessments for employing or contracting with an excluded individual in violation of section 1128A(a)(6) of the Act. Some commenters argued against a per-day penalty. First, commenters argued that the assessment adequately addresses the misconduct and a per-day penalty seems duplicative. Second, commenters argued that liability should be related to the cost of the items and services and may not be rationally related to the number of days an individual was employed by, or contracted with, the entity. Third, commenters argued that a per-day penalty is contrary to the plain language of the Act because Congress created other per-day penalties in the CMPL but did not create one in section 1128A(a)(6) of the Act. Finally, commenters maintained that the proposed method of calculating the assessment for contracting with or employing an excluded individual whose services are not separately billable to Federal health care programs already adequately takes into consideration the length of time of the prohibited relationship. A longer period of the prohibited relationship would result in more salary and benefits paid to the person, and thus would increase the value of the assessment.

Response: After considering the comments, we are withdrawing the proposed per-day penalty for section 1128A(a)(6) of the Act. Instead, we are finalizing a penalty of up to \$10,000 for each item or service provided by the excluded person by removing proposed § 1003.210(a)(4)(ii) and adding "non-separately billable" items or services to proposed § 1003.210(a)(4)(i). This penalty more closely tracks the Act's language.

Comment: Many commenters urged OIG to take into account the Federal health care program payor mix, or percentage of Federal health care program business, when determining the assessment for employing or contracting with an excluded

individual. Commenters argued that using a pro-rata share of the compensation would more fairly capture the portion of time the excluded person likely spent providing items or services to Federal health care program beneficiaries in violation of their exclusion. These commenters noted that OIG outlined this practice in the 2013 Updated Provider Self-Disclosure Protocol.

Response: We are finalizing the rule, as proposed. We continue to believe that the Federal health care program payor mix is appropriate to consider in the context of a self-disclosure, and OIG will continue to consider it in settlements, as appropriate. Nevertheless, we have decided not to require the consideration of payor mix in the regulations. The appropriate way to measure payor mix is not always clear for the many types of providers, suppliers, items, and services at issue in various cases. Further, there may be cases for which a reduction of the assessment based on payor mix is not appropriate. We view our approach to this CMP as analogous to the CMP for violations of the anti-kickback statute. Under § 1003.310(b)(2), OIG may seek damages of up to three times the amount of remuneration regardless of whether some of the remuneration was for a lawful purpose. Nevertheless, in self-disclosures and other settlements, we often collect a multiplier based only on the portion of the remuneration that we determine was for an unlawful purpose. We anticipate continuing a similar approach under this CMP authority.

Comment: Several commenters objected to our proposed reading of the penalty and assessment sections applicable to violations of section 1128A(a)(9) of the Act, as established by section 6402(d)(A) of the ACA, to include "omissions." Those commenters argued that our reading went beyond the authority of the ACA because Congress did not include the term "omissions" in the penalty language.

Response: We respectfully disagree with the commenters. Adopting the commenters' suggested reading would lead to the conclusion that Congress intended to restrict OIG to pursuing an exclusion action only against those who omitted a material fact and intended to permit OIG to choose between pursuing penalties, assessments, and exclusions against those who made a false statement or misrepresentation of a material fact. This reading leads to an absurd result. Instead, we are interpreting this provision consistent with the purpose and intent of the statute.

Comment: Some commenters requested that OIG clarify that liability for omission of a material fact under Section 1128A(a)(9) of the Act apply only to willful omissions so that the regulations not capture clerical errors or omissions where there was no intention to deceive. Specifically, commenters encouraged us to delete the reference to “omissions” or at a minimum use the term “willful omissions” until a greater degree of standardization among Medicare contractors and their processes and interpretations is achieved. Commenters argued that the proposed definitions of “knowingly” and “should know, or should have known” where “no proof of specific intent to defraud is required” may result in a violation based on an error or oversight.

Response: We do not believe the commenters’ suggestion conforms to the statute. To violate section 1128A(a)(9) of the Act, a person must knowingly make a false statement, omission, or misrepresentation of material fact. We believe the commenters’ concerns are addressed by the evidentiary standard OIG must meet to bring such a case. In addition, OIG will continue to evaluate the nature and circumstances of the conduct and exercise discretion in deciding whether to pursue a case. The OIG will not pursue cases under this section based on inadvertent (non-reckless) errors and minor oversights.

Comment: Some commenters urged OIG to further specify the standards it will use to determine penalties, assessments, or exclusion imposed under section 1128A(a)(9) of the Act. Commenters stated that clarification is needed to understand whether this new authority could apply to simple documentation errors. Commenters believed that such mistakes would not be done “knowingly.” According to commenters, documentation errors are common—not because of deliberate physician misrepresentation, but because of frequent changes in the requirements for applications, contracts, and other agreements that may lead to confusion and miscommunications.

Response: We do not believe further guidance is appropriate in this context. We are unable to anticipate all potential factual scenarios in this rulemaking. We believe our traditional evaluation of the nature and circumstances of the conduct and exercise of discretion will inform whether to pursue an individual enforcement action. As previously stated, it is not OIG’s intention to pursue cases under this section for inadvertent (non-reckless) errors or minor oversights.

Comment: One commenter stated that the \$50,000 penalty amount set forth in § 1003.210(a)(6) for knowingly making a false statement, omission, or misrepresentation of a material fact seemed excessive, and should be reconsidered by OIG and that, if levying a heavy penalty is authorized, the application should be as narrow and temperate as possible.

Response: The penalty amount is statutory. We will continue to engage in our traditional evaluation of the nature and circumstances of the conduct and exercise of discretion in deciding to pursue cases and determine appropriate penalty amounts.

Comment: Many commenters disagreed with our proposed per-day penalty for failure to report and return an overpayment in violation of section 1128A(a)(10) of the Act. Commenters noted that Congress has created per-day penalties for two different sections of section 1128A of the Act and did not do so here. One of these two sections, failure to grant timely access to OIG, was enacted as part of the ACA, in which the overpayment authority was also enacted. The commenters argued that if Congress had intended to create a per-day penalty for section 1128A(a)(10) of the Act, it would have expressly done so in the ACA. In addition, some commenters stated that a per-day approach could lead to large penalties that may not be commensurate with the value of the underlying overpayment. Most commenters asserted that the penalty for overpayments should be the CMPL’s default penalty of up to \$10,000 for each item or service. Some commenters recommended a per-claim penalty calculation, rather than a per-day or per item or service calculation. Other commenters argued OIG should consider the lateness and size of overpayment in determining the penalty amount.

Response: After careful consideration, we are finalizing the penalty for section 1128A(a)(10) of the Act as up to \$10,000 for each item or service. This penalty methodology is the statutory default. Where a person fails to return the overpayment for a lengthy period, the general aggravating factor under § 1003.220(b)(1) could be triggered.

Comment: Some commenters encouraged OIG to adopt a penalty scale for violations of section 1128A(a)(10) of the Act that would penalize providers more gravely for more serious violations. Commenters suggest that such a scale could be based on the length of delay, overpayment amount, and the number of claims.

Response: The factors set forth in § 1003.140 and § 1003.220 provide a framework to identify more egregious conduct and determine appropriate penalty amounts. The general factor of nature and circumstances would naturally take into account such factors as the length of time the provider or supplier knew it had received an overpayment and § 1003.220 states that an overpayment in an amount over \$50,000 may be considered as an aggravating circumstance.

Comment: Commenters from pharmacy organizations expressed concerns with the proposed penalty under section 1128A(a)(10) of the Act of \$10,000 per day for each “claim.” Commenters argued that the proposed rule would affect pharmacies more than other providers because pharmacies dispense billions of low-cost medications each year and, therefore, any potential penalty would be disproportional to the injury caused. Instead of a \$10,000 penalty on each prescription, the commenters suggested that OIG examine other alternatives for calculating a penalty for pharmacies and other entities that submit many small “claims.” Examples of potential solutions include calculating the penalty at \$10,000 per day regardless of the number of individual prescription claims involved, or assessing a penalty in proportion to the overall dollar amount of the overpayment.

Response: Based on our evaluation of all the comments on this issue, we are finalizing the penalty as up to \$10,000 for each item or service. In the case of pharmacies, each prescription would be considered an item, and thus pharmacies have exposure of up to \$10,000 for each prescription for which the pharmacy received an overpayment. This is the result compelled by the statute. We will evaluate the facts and circumstances in each case to determine the appropriate penalty amount.

Comment: Some commenters from Part D plan sponsors expressed concerns about the use of per-day, per-claim, or per-item or service penalties in the context of Part D prescription drug claims. Given the huge volume of daily prescription drug events (PDEs), which are not equivalent to final medical claims, commenters believed that the application of CMPs in Part D should focus on the “annual cost report” and not on individual PDEs. According to commenters, Part D drug claims are not final until both the annual reconciliation and the final reopening are completed. Commenters recommended that OIG clarify that, in the context of Part D, determination of the penalty amount should be based on

the “annual cost report” submitted by Part D sponsors and not on individual PDEs. Further, commenters argued that OIG should clarify that a PDE is not a claim until it has gone through reconciliation and the final reopening has been completed.

Response: We are finalizing the penalty for section 1128A(a)(10) of the Act, using the CMPL default of up to \$10,000 for each item or service. This penalty is consistent with the final rule adopted by CMS regarding Part D overpayments. See 79 FR 29,844. In adopting that rule, CMS declined to make the deadline for reporting and returning identified overpayments the “date any corresponding cost report is due” because “Part D sponsors are paid based on their bids, and not based on their actual incurred costs.” 79 FR at 29,920. In determining an overpayment, CMS focuses on the submission of erroneous PDE data, and those data constitute claims for items or services under the CMPL.

Comment: Some commenters suggested that OIG does not recognize CMS’s role in overseeing section 1128J of the Act, as applicable to Part C plans or Part D plan sponsors, pursuant to 42 CFR 422.326 and 423.360. One commenter suggested that OIG defer to CMS on overpayment issues and reserve its authority for instances of egregious behavior.

Response: While CMS oversees Part C plans and Part D plan sponsors under its regulations, OIG has been delegated the authority for enforcement of section 1128A of the Act. Thus, we decline to adopt the commenter’s suggestion.

Comment: Several commenters suggested that for Part C plans and Part D plan sponsors, compliance with CMS’s final rule, 79 FR 29,844 (May 23, 2014), should be deemed compliance with section 1128A(a)(10) of the Act. Specifically, commenters recited the language of that final rule and stated that a Medicare Advantage organization has identified an overpayment when that organization has determined, or should have determined through the exercise of reasonable diligence, that it has received an overpayment. Commenters stated that the phrase “or should have determined through the exercise of reasonable diligence” has caused great concern among health plans because there is no guidance for plans to follow and plans are exposed to potential FCA liability if they do not comply. According to commenters, this lack of clarity means that plans can act in good faith but still be subject to liability if their actions are later found to not meet the “reasonable diligence” test. In light of these uncertainties

regarding compliance with the Part C and Part D rule, commenters requested that OIG’s rule clarify that compliance with such rule will be deemed compliance with OIG requirements.

Response: This suggestion is outside the scope of our rulemaking, which did not propose to interpret the CMS final rule concerning Part C plans and Part D plan sponsors. In the context of section 1128A(a)(10) of the Act, a plan or plan sponsor may be liable if it knows of an overpayment and did not report and return it in accordance with section 1128J of the Act.

Comment: Several commenters asked that OIG clarify the definition of “overpayment.” One commenter suggested that OIG should use CMS’s definition of “funds” in the Part C and D final rule, 79 FR 29,844 (May 23, 2014). One commenter also asked that we clarify the application of section 1128A(a)(10) of the Act in situations in which the plan is not at fault for the overpayment, such as when CMS makes a retroactive change to a member’s low-income status that triggers changes in the low-income subsidy payments for cost sharing and premiums or affects the coverage gap discount program.

Response: We are finalizing the definition, as proposed. The proposed regulatory text simply mirrors the statute. In the context of Parts C and D, CMS has interpreted the meaning of “overpayment,” and we are required to apply the same meaning in an enforcement action against a Part C plan or Part D plan sponsor under section 1128A(a)(10) of the Act. This regulation also applies to Medicare Parts A and B and to Medicaid, so we believe the overpayment definition in our regulations should be broad enough to cover all of the programs. Commenters’ other suggestions are outside the scope of this rulemaking. Plans should refer to CMS’s May 2014 final rule, 79 FR 29,844 (May 23, 2014), in self-assessing their compliance with reporting and returning overpayments.

Comment: Several commenters requested clarification as to when the 60-day period begins. Commenters also requested clarification of the term “identify.” Some commenters suggested that OIG not impose CMPs for overpayments, or alternatively, defer issuance of this final rule, until CMS finalizes its Part A/B overpayment proposed rule, 77 FR 9179 (February 16, 2012), which, among other things, defines when an overpayment has been identified. A few commenters suggested that OIG use the term “confirmed” rather than “identify” because some providers and suppliers have complex billing processes that require

coordination with other providers and suppliers. For example, for air ambulances, additional information and documentation are needed from other providers to determine the correct amount of an overpayment. Commenters encouraged OIG to include in the final rule a clear standard as to when the 60-day period begins and to exercise discretion in enforcing this authority so that providers and suppliers are not harshly penalized when good faith efforts to meet the 60-day rule are made but delays occur because of the action or inaction of entities beyond the providers’ or suppliers’ control.

Response: We will continue to evaluate the nature and circumstances of the conduct and the exercise of discretion when deciding whether to pursue a case. The obligations of section 1128J(d) of the Act became effective upon enactment, without a final rule from CMS. However, CMS published its final rule on February 12, 2016. 81 FR 7654 (February 12, 2016). The comments asking OIG to defer issuance of its final rule are therefore moot. We do not in this regulation provide definitions for or clarify the meaning of “identify” or clarify when the 60-day period begins. These topics are within CMS’s purview and are included in its final rule. 81 FR at 7683.

Comment: Some commenters stated that providers should not be penalized under section 1128A(a)(10) of the Act in cases in which good faith efforts to return overpayments could not be completed because of the inability of government contractors and their payment systems to receive the overpayment. The commenters complained that Medicare, Medicaid, and Medicaid managed care organizations (Medicaid MCOs) have payment process systems that can both cause overpayments and that can prevent providers from promptly returning overpayments. The commenters contended that when a provider discovers an overpayment and attempts to return it to a Medicaid MCO, if the Medicaid MCO has not yet corrected the system error that led to the overpayment, the Medicaid MCO may be unable accept the returned overpayment. The commenters argue that this leaves the provider with no avenue for the prompt return on the overpayment.

Response: As stated above, CMS is responsible for issuing regulations concerning section 1128J(d) of the Act and, thus, these comments are outside the scope of this rulemaking. As they relate to OIG’s enforcement of section 1128A(a)(10) of the Act, we will consider the nature and circumstances

of each alleged violation in determining whether to bring an enforcement action and at what amount to set the penalty and assessment. In situations in which a person attempts to return an overpayment but a Medicare contractor, Medicaid, or a Medicaid MCO rejects the returned overpayment at no fault of the person, it is unlikely that OIG would pursue an action.

Comment: One commenter suggested that, when OIG begins imposing CMPs under section 1128A(a)(10) of the Act, OIG should impose CMPs of not more than \$5,000 until OIG has more experience analyzing violations of that section.

Response: We respectfully disagree with the commenter's suggestion. The obligations under section 1128(d) have been in effect since the statute was enacted in March 2010. As with all other cases, OIG will determine the amount of the penalty and assessment pursuant to the criteria set forth in § 1003.140 and § 1003.220.

Comment: Several commenters suggested that OIG exercise its authority under section 1128A(a)(10) of the Act in coordination with CMS to ensure that: (1) Providers' obligations are uniform across these agencies; and (2) actions by OIG and CMS are undertaken contemporaneously to ensure that the associated administrative burden on providers is minimized.

Response: The OIG coordinates regularly with CMS on various program integrity efforts, including, as appropriate, on OIG administrative enforcement actions. As with many Medicare and Medicaid subject areas, CMS issues regulations on the 60-day repayment rule in section 1128(d) and OIG is authorized to pursue administrative sanctions against those that violate the rule. However, as set forth in § 1003.150, we have been delegated the enforcement responsibility for section 1128A(a)(10) of the Act.

Comment: Two commenters requested that we clarify that penalties for violation of section 1128A(a)(10) of the Act set forth in the rule are the maximum allowed, leaving discretion to OIG to levy smaller penalties, or no penalties, in cases in which providers are acting in good faith or the delays in repayment are beyond the control of the provider.

Response: We believe that the proposed rule's language, which we are finalizing, is clear on this point. All penalties in the proposed rule are described as "not more than" the applicable penalty amount.

Comment: Several commenters requested that OIG clarify that the CMP

at § 1003.200(b)(6), regarding excluded persons who order or prescribe an item or service that will be paid for by a Federal health care program, applies only to the excluded person and not to the person who provides the service. Some of these commenters mentioned the example of an air ambulance provider who, as an emergency responder, responds only at the request of physicians to transport a patient to a different facility, or when called to an accident scene by the Emergency Medical System or other qualified dispatcher. In such an emergent situation, commenters stated it is nearly impossible for transport providers to know the exclusion status of those who ordered or prescribed the transport. One commenter acknowledged that the service itself will likely be considered non-covered, which would result in the provider having received an overpayment, but argued that the imposition of a CMP in addition to the overpayment would be unduly harsh.

Response: We agree that, based on a plain reading of the statutory language, the CMP authority at § 1003.200(b)(6) would be imposed against the excluded person who ordered or prescribed the item or service, not against the person who provided or supplied the items or services that were ordered or prescribed. With regard to emergency services, section 1862 of the Act and § 1001.1901(c)(5) allow payment for emergency items or services not provided in an emergency room of a hospital in certain circumstances. Also, under section 1862 of the Act and § 1001.1901, items and services ordered or prescribed by an excluded person are not payable only if the person furnishing such item or service knew or had reason to know of the exclusion.

Comment: Some emergency transport providers requested clarification that an emergency transport provider would not violate section 1128A(a)(1)(B) of the Act or § 1003.200(a)(2) for presenting a false or fraudulent claim when it relies upon a facially valid order to provide services. According to commenters, because of the emergency situation, there is little time to check the exclusion status of the ordering physician and no ability to refuse to provide the emergency services. Commenters recommended adding specific language to the regulations stating that, in the case of emergency services or transport, the provider or supplier would not be held liable for knowingly presenting such a claim if the ordering or prescribing physician was excluded.

Response: We decline to adopt the commenters' recommendation. If the

provider or supplier knew or had reason to know that the ordering physician was excluded, the provider or supplier also knew or should have known that the claim for those emergency services is not payable. Submitting that claim could subject the provider or supplier to liability under § 1003.200(a)(2). In our experience, we have not seen a case in which an air ambulance provider submitted claims for emergency transportation ordered by an excluded individual and we believe such circumstances would be rare. We will continue to evaluate cases individually and use our discretion in determining which cases to pursue.

Comment: Several commenters expressed concern about the aggravating factor at § 1003.220(b)(3) relating to the amount of program loss. Specifically, the commenters suggested that OIG continue to use the "substantial loss" threshold in applying this aggravating factor instead of the proposed "\$15,000 or more" threshold. The commenters viewed \$15,000 as relatively low and argued that it would unfairly apply more often to providers who bill for expensive items or services. The commenters asserted that a specific overpayment threshold may have no correlation to the number of claims in error or the significance of the issue giving rise to the overpayment, and argued that it should not automatically be considered an aggravating factor in determining the amount of penalties and assessments levied against the provider. Therefore, these commenters suggested that OIG maintain the flexibility to determine, on a case-by-case basis, what is a "substantial loss." Other commenters agreed with the proposal to change "substantial loss" to "\$15,000 or more" because it provided transparency and better guidance to the provider community.

Response: We believe that a specific dollar threshold gives clearer guidance to the provider and supplier community and still permits the traditional case-by-case analysis of the facts and circumstances as discussed above. We agree, however, with those commenters who stated that the proposed \$15,000 threshold is low. We have, instead, raised the "substantial loss" threshold to \$50,000. Based on our experience resolving health care fraud matters, we believe \$50,000 better reflects the threshold amount of loss for when a penalty or period of exclusion should be increased.

Comment: Some commenters opposed the proposed change to the aggravating factor in proposed § 1003.220(b)(4), which would amend existing § 1003.106(b)(1)(iv) to include situations

in which the violation “could have resulted” in patient harm, premature discharge, or a need for additional services or subsequent hospital admission. These commenters complain that the “could have resulted” language requires OIG to establish only the *mere possibility* of harm, regardless of what actually occurred. Commenters believed that this change would vastly expand the application of this aggravating factor and urged OIG to retain the existing language at § 1003.106(b)(1)(iv).

Response: We are finalizing the rule, as proposed. The existing regulation requires proof that the violation actually caused patient harm, premature discharge, or a need for additional services or subsequent hospital admission. This formulation is overly constrained for several reasons. The CMP authorities in this part, as a general matter, aim to redress fraud on the Federal health care programs by recovering funds, protecting the programs and beneficiaries from untrustworthy providers and suppliers, and deterring improper conduct by others. Accordingly, it is highly relevant if the conduct put beneficiaries at risk of patient harm. The requirement that OIG prove causation does not conform to this aim.

Comment: Several commenters objected to the proposed definition of “reasonable request” with respect to § 1003.200(b)(10). Commenters asked OIG to add to the definition that a request is not reasonable unless the recipient has a reasonable period of time to respond, taking into account the recipient’s resources, regular business hours, availability, the location of the records, and the complexity and scope of the request. Commenters also asked OIG to include an objective, minimum period for compliance, such as 2 weeks or 10 days. Some commenters suggested that OIG include an exception to that minimum period when there is a demonstrated need for a faster response. One commenter asked OIG to use discretion when a recipient of a request, acting in good faith, does not meet the specified timelines.

Response: We do not believe a minimum period is necessary or appropriate in this context. Given the different purposes for which OIG may request access to material, such as audits, evaluations, investigations, and enforcement actions, we believe the best approach to defining timely access and reasonable request is for OIG to specify the date for production or access to the material in a written request. In determining the period a provider has to comply with the request, OIG will consider the circumstances of the

request, including the volume of material, size and capabilities of the party subject to the request, and OIG’s need for the material in a timely way to fulfill its responsibilities. The exception to this approach is a case in which OIG has reason to believe that the requested material is about to be altered or destroyed. Under those circumstances, timely access means access at the time the request is made.

Comment: Some commenters noted that a “reasonable request” must be “made by a properly identified agent of OIG during reasonable business hours,” but that the definition does not specify whether it refers to OIG’s or the recipient’s business hours. Commenters urged OIG to clarify that the request must be made during the recipient’s regular business hours and when the recipient’s office is open to the public.

Response: “Reasonable business hours” means the recipient’s business hours. This time includes when the recipient holds itself out to the public as open, such as for appointments or walk-in customers. However, a recipient may also conduct its business outside of the times when it is open to the public. We are finalizing the definition, as proposed.

Comment: One commenter expressed concern about OIG’s authority to exclude a provider under § 1003.200(b)(10), asserting that OIG requests for information could get lost among other mail in light of the number of entities that request medical documentation from providers to validate services and payment. The commenter asked that a single, recognizable standard be put in place to clearly identify a request from OIG or any other auditing entity.

Response: We do not believe that such a single standard needs to be put in place. The OIG requests for information are clearly identifiable as being from OIG. The requests are made in writing, appear on OIG letterhead, and are signed by OIG officials.

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

Subpart C contains the provisions relating to violations of the anti-kickback statute and physician self-referral law, which were found in the existing regulations at § 1003.102(a)(5), (b)(9), (b)(10), and (b)(11). The proposed changes include various technical corrections to improve readability and ensure consistency with the language in the anti-kickback statute and physician self-referral law.

We proposed revising the CMP provisions relating to the physician self-

referral law to incorporate statutory terms that are unique to the physician self-referral law (section 1877 of the Act (42 U.S.C. 1395nn)). These revisions include using “designated health service” instead of “item or service” and “furnished” instead of “provided.” In addition, we proposed revising the authority regarding “cross-referral arrangements” that was in the existing regulations at § 1003.102(b)(10) to more closely reflect the statutory language. Section 1877(g)(4) of the Act provides for CMPs and exclusion against any physician or other person who enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person who, if the physician directly made referrals to such person, would violate the prohibitions of 42 CFR 411.353. The regulations, at § 1003.102(b)(10)(i), contained an example of a cross-referral arrangement whereby the physician-owners of entity “X” refer to entity “Y” and the physician-owners of entity “Y” refer to entity “X” in violation of 42 CFR 411.353. While this is one example of a cross-referral arrangement, such arrangements and circumvention schemes can take a variety of forms. The proposed changes to the regulatory language more closely align the regulations to the statute to avoid any misinterpretation that § 1003.102(b)(10)(i) limited the conduct that circumvents the prohibitions of the physician self-referral law.

The proposed changes also include minor technical corrections to the CMPs related to the anti-kickback statute to improve consistency with the statute. First, we added the phrases “to induce” and “in whole and in part” to § 1003.300(d) to better mirror the statutory language of the anti-kickback statute. The proposed change also clarified that the CMP at section 1128A(a)(7) of the Act permits imposing a penalty for each offer, payment, solicitation, or receipt of remuneration and that each action constitutes a separate violation. In addition, we included the language from the CMPL stating that the calculation of the total remuneration for purposes of an assessment does not consider whether any portion of the remuneration had a lawful purpose.

We received no comments and finalize this subpart, as proposed, except that, for the reasons provided in response to comments to proposed § 1003.220(b)(3), we increased the threshold for the aggravating factor at

§ 1003.302(b)(3) from \$15,000 to \$50,000.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

Subpart D contains the proposed provisions for penalties and assessments against managed care organizations. We proposed several stylistic changes to the existing regulations at § 1003.103(f). We changed the verbs in this subpart from past tense to present tense to conform to the statutory authorities and many other regulations in this part. The proposed regulation also removes superfluous phrases, such as “in addition to” or “in lieu of other remedies available under law.” The proposed regulation replaced references to “an individual or entity” with “a person” because “person” is defined in the general section as an individual or entity. The proposed regulation also removes the phrase “for each determination by CMS.” The OIG may impose CMPs in addition to or in place of sanctions imposed by CMS under its authorities.

We also added to the regulations OIG’s authority to impose CMPs against Medicare Advantage contracting organizations pursuant to section 1857(g)(1) of the Act and against Part D contracting organizations pursuant to section 1860D–12(b)(3) of the Act.

The ACA amended several provisions of the Act that apply to misconduct by Medicare Advantage or Part D contracting organizations. We included these provisions in the proposed regulations. We added the change in section 6408(b)(2)(C) of the ACA regarding assessing penalties against a Medicare Advantage or Part D contracting organization when its employees or agents, or any provider or supplier that contracts with it, violates section 1857 of the Act. We proposed to add the five new violations created in the ACA, and their corresponding penalties, at § 1003.400(c). We also proposed to include the new assessments, which are available for two of the five new violations, at § 1003.410(c). The proposed regulatory text closely mirrors that of the statute.

The violations in this subpart are grouped according to the contracting organizations to which they apply. For instance, § 1003.400(a) violations apply to all contracting organizations. Section 1003.400(b) violations apply to all Medicare contracting organizations, *i.e.*, those with contracts under sections 1857, 1860D–12, or 1876 of the Act. Section 1003.400(c) violations apply to Medicare Advantage and Part D contracting organizations, *i.e.*, those with contracts under sections 1857 or 1860D–12 of the Act. Section

1003.400(d) violations apply to Medicare Advantage contracting organizations, *i.e.*, those with contracts under section 1857 of the Act. Section 1003.400(e) violations apply to Medicaid contracting organizations, *i.e.*, those with contracts under section 1903(m) of the Act.

We also proposed to remove the definition of “violation,” which was found at § 1003.103(f)(6), because throughout this part, violation means each incident or act that violates the applicable CMP authority. We also proposed including aggravating circumstances to be used as guidelines for taking into account the factors listed in proposed § 1003.140. These aggravating circumstances are adapted from those listed in the existing regulations at §§ 1003.106(a)(5) and 1003.106(b)(1) and those published in the **Federal Register** in July 1994. 59 FR 36072 (July 15, 1994).

We received the following comments on the subpart. As discussed in response to the comments, we are finalizing this section of the rule as proposed.

Comment: One commenter argued that certain alleged violations of § 1003.410(d) by a contracting provider or supplier might not entirely be the responsibility of that provider and supplier, but rather the result of pressures from the Part C plans. The commenter asked that OIG not permit Part C plans to avoid responsibility under § 1003.410(d) through indemnity clauses in the plans’ contracts with providers and suppliers.

Response: This comment is outside the scope of our rulemaking. The OIG does not have regulatory authority over the programmatic aspects of the Part C and Part D programs, which would include setting limitations on or requirements for contracting organizations’ relationships with providers and suppliers. CMS has this programmatic authority, which includes, among many other things, implementing the provider indemnification limitations contained in section 1852 of the Act and at 42 CFR 422.212.

Comment: Two commenters expressed concern with the overlapping enforcement authority of OIG and CMS with regard to Part D contracting organizations. The commenters argued that this overlap could subject Part D contracting organizations to duplicative enforcement actions, multiple audits of the same activities, and potentially inconsistent standards and interpretations of regulatory requirements. The commenters recommended that CMS be the sole

enforcement authority with respect to those areas for which OIG and CMS share jurisdiction, except in cases in which OIG’s unique investigative authority is necessary to determine non-compliance. One commenter recommended that OIG state that compliance with the Part D requirements, when assessed by CMS, will be deemed to be compliance with OIG’s enforcement authorities. The commenter argued that, if CMS has already performed audits and other oversight activity, there is no reason for OIG to duplicate this work.

Response: We do not agree with the comments. The OIG and CMS have concurrent jurisdiction in various matters concerning the Medicare program, including this area. CMS and OIG have internal mechanisms in place to ensure that the other agency within the Department is not simultaneously pursuing a CMP for the same or similar conduct. The OIG will continue to coordinate appropriately with CMS on potentially overlapping CMP enforcement actions.

Comment: A commenter requested a change in the new authority at § 1003.400(b)(2) relating to employing or contracting with an excluded person for the provision of health care, utilization review, medical social work, or administrative services, or employing or contracting with an entity for the provision of such services directly or indirectly through an excluded person. Specifically, the commenter requested that a plan’s liability cease with its employees and direct contractors and not extend to the employees or contractors of its contractor, whether a health care provider or otherwise. The commenter accordingly requested that OIG revise § 1003.400(b)(2) by striking the text after the term “administrative services.” To support this recommendation, the commenter noted that plans contract with numerous providers, including health systems, that, in turn, employ or contract vast numbers of persons. The commenter argued that plans would not be able to identify all of the individuals that a health system employs nor the persons with which a health system contracts.

Response: The proposed regulation mirrors the statutory language. Specifically, the ACA created a cause of action against a contracting organization that employs or contracts with an excluded person for the provision of health care, utilization review, medical social work, or administrative services, or employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded person. Accordingly, we are

finalizing this section of the rule, as proposed.

Comment: A commenter also asserted that OIG's proposed reference to "health care, utilization review, medical social work, or administrative services" is overly broad and asked OIG to revise "administrative services" to "administrative services for a Medicare or Medicaid eligible individual."

Response: We believe that the commenter's proposed revision is inappropriately narrow and does not reflect the statutory language. The regulation mirrors the language of the ACA. Second, there may be administrative services related to a Federal health care program that are not for a specific Medicare- or Medicaid-eligible individual.

Comment: A commenter requested clarification on the potential liability of plans for claims submitted by out-of-network providers or suppliers who have no privity of contract with the health plan.

Response: The CMP authority at § 1003.400(b)(2) does not apply to out-of-network providers or suppliers because the plan did not employ or contract with that person.

Subpart E—CMPs and Exclusions for EMTALA Violations

Subpart E contains the penalty and exclusion provisions for violations of EMTALA, section 1867 of the Act (42 U.S.C. 1395dd). EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272. Section 1867 of the Act sets forth the obligations of a Medicare-participating hospital to provide medical screening examinations to individuals who come to the hospital's emergency department and request examination or treatment for a medical condition. EMTALA further provides that, if the individual has an emergency medical condition, the hospital is obligated to stabilize that condition or to arrange for an appropriate transfer to another medical facility where stabilizing treatment can be provided. EMTALA also requires hospitals with specialized capabilities or facilities to accept appropriate transfers of individuals from other hospitals. Finally, EMTALA creates obligations for physicians responsible for the examination, treatment, or transfer of an individual in a participating hospital, including a physician on call for the care of that individual. The CMS regulations related to section 1867 of the Act are found at 42 CFR 489.24.

Under section 1867(d) of the Act, participating hospitals and responsible

physicians may be liable for CMPs of up to \$50,000 (\$25,000 for hospitals with fewer than 100 State-licensed and Medicare-certified beds) for each negligent violation of their respective EMTALA obligations. Responsible physicians are also subject to exclusion for committing a gross and flagrant or repeated violation of their EMTALA obligations. The OIG's regulations concerning the EMTALA CMPs and exclusion are at 42 CFR 1003.102(c), 103(e) and 106(a)(4) and (d).

We proposed several updates to the EMTALA CMP regulations. First, as part of our proposed general reorganization, we have included the EMTALA authorities within a separate subpart. Further, the proposed revision removed outdated references to the pre-1991 "knowing" scienter requirement. We also proposed minor revisions to emphasize that the CMP may be assessed for each violation of EMTALA and that all participating hospitals subject to EMTALA, including those with emergency departments and those with specialized capabilities or facilities, are subject to penalties.

We proposed revising the "responsible physician" definition to clarify that on-call physicians at any participating hospital subject to EMTALA, including the hospital to which the individual initially presented and the hospital with specialized capabilities or facilities that has received a request to accept an appropriate transfer, face potential CMP and exclusion liability under EMTALA.

Section 1867(d) of the Act provides that any physician who is responsible for the examination, treatment, or transfer of an individual in a participating hospital, including any physician on-call for the care of such an individual, and who negligently violates section 1867 of the Act may be penalized under section 1867(d)(1)(B) of the Act. The definition of "responsible physician" also provides for on-call physician liability. We proposed to revise the definition to clarify the circumstances when an on-call physician has EMTALA liability. An on-call physician who fails or refuses to appear within a reasonable time after such physician is requested to come to the hospital for examination, treatment, or transfer purposes is subject to EMTALA liability. This includes on-call physicians at the hospital where the individual presents initially and requests medical examination or treatment as well as on-call physicians at a hospital with specialized capabilities or facilities where the individual may need to be transferred. In addition, an on-call physician at the

hospital with specialized capabilities or facilities may violate EMTALA by refusing to accept an appropriate transfer.

We also proposed revising the factors that were set forth in §§ 1003.106(a)(4) and (d) to improve clarity and better reflect OIG's enforcement policy. First, we proposed clarifying that the factors listed in proposed § 1003.520 will be used in making both CMP and exclusion determinations. Further, we proposed incorporating the general factors listed in § 1003.140 and provide additional guidance on the EMTALA subpart at proposed § 1003.520. Many of the factors that were in § 1003.106(a)(4) and (d) duplicate those general factors.

Finally, we examined the factors that were at § 1003.106(d) in light of our lengthy enforcement experience. Congress enacted EMTALA to ensure that individuals with emergency medical conditions are not denied essential lifesaving services. 131 Cong. Rec. S13904 (daily ed. Oct. 23, 1985) (statement of Sen. David Durenberger); H.R. Rep. No 99-241, pt. 1, at 27 (1986), reprinted 1986 U.S.C.C.A.N. 579, 605. In light of this statutory purpose, the circumstances surrounding the individual's presentation to a hospital are important to determinations about whether and to what extent a CMP or an exclusion is appropriate. Thus, the proposed regulations revised the factors to clarify that aggravating circumstances include: A request for proof of insurance or payment prior to screening or treating; patient harm, unnecessary risk of patient harm, premature discharge, or a need for additional services or subsequent hospital admission that resulted, or could have resulted, from the incident; and whether the individual presented with an emergency medical condition. While we removed the language at § 1003.106(a)(4), we consider these circumstances to be included in the general factors listed at proposed § 1003.140. Thus, while the proposed regulations do not state that OIG will consider "other instances where the respondent failed to provide appropriate medical screening examination, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer," OIG will consider each of these failures when determining a penalty because they relate to a respondent's history.

We concluded that for several reasons, the mitigating factors should be removed. Because of the overall statutory purpose, the fact-specific nature of EMTALA violations, and the CMS certification process, the mitigating factors that were found at

§ 1003.106(d) are not useful in determining an appropriate penalty amount. For example, § 1003.106(d)(5) stated that it should be considered a mitigating circumstance if an individual presented a request for treatment but subsequently exhibited conduct that demonstrated a clear intent to leave the hospital voluntarily. In our enforcement activities, however, we have found situations in which the individual may have demonstrated a clear intent to leave because the hospital failed to properly screen the individual within a reasonable amount of time. We do not believe that in this circumstance, the hospital's penalty should be mitigated. Further, the factor at § 1003.106(d)(6)(A) in the existing regulation is not relevant to mitigation because developing and implementing a corrective action plan is a requirement of the CMS certification process following an investigation of an EMTALA violation. However, in response to comments discussed below, we have determined that certain corrective action could be mitigating. Specifically, it should be considered a mitigating circumstance if a hospital took appropriate and timely corrective action in response to the violation prior to CMS initiating an investigation. That corrective action must include disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

We will continue to evaluate the circumstances of each EMTALA referral to determine whether to exercise our discretion to pursue the violation and to determine the appropriate remedy.

We received the following comments on the subpart. To the extent the provisions of the proposed rule are not addressed in response to the comments below, we are finalizing this section of the rule, as proposed.

Comment: One commenter urged OIG to adopt a regulation that does not impose penalties where the violation of EMTALA is based only on negligence and not on willful conduct.

Response: The suggestion is beyond the scope of the proposed rule and does not reflect the statutory language, which sets the scienter level at negligence.

Comment: Several commenters addressed OIG's changes to the definition of "responsible physician." One commenter requested that OIG clarify that it is not creating a new application of EMTALA to hospitals with specialized capabilities, but simply clarifying that on-call physicians at hospitals with specialized capabilities are considered "responsible physicians." Another commenter asserted that OIG's revised definition is

an expansion of EMTALA to physicians and on-call physicians who fail to accept an appropriate transfer. This commenter argued that the nondiscrimination provisions in section 1867(g) of the Act apply only to participating hospitals and do not create CMP liability for physicians at such hospitals. One commenter noted that assessing whether a responsible physician has neglected his or her responsibilities under EMTALA is a rigorous undertaking. The commenter said that the assessment should include more than whether the on-call physician showed up when called, but also whether the on-call physician was in the operating room when called or whether a community call arrangement existed. Finally, a commenter urged OIG to ensure that its enforcement against a "responsible physician" is consistent with the regulations and guidance promulgated by CMS.

Response: We are finalizing the rule, as proposed. In response to comments, we confirm that OIG is clarifying that on-call physicians at hospitals with specialized capabilities are considered "responsible physicians." The OIG believes this is an appropriate reading of the statute and that the proposed regulation does not expand the application of EMTALA. The OIG recognizes that a determination of potential liability for an on-call physician is fact-intensive and takes into account factors that include a hospital's compliance with CMS regulations and guidance regarding the adoption of written policies governing on-call physicians and an on-call physician's compliance with such policies.

Comment: Several commenters discussed OIG's proposal to remove the mitigating factors related to EMTALA CMPs. Two commenters objected to the removal of the mitigating factor under which an individual presented a request for treatment but subsequently exhibited conduct that demonstrated a clear intent to leave the hospital voluntarily. Another commenter stated that removal of this mitigating factor would remove consideration of a hospital's or physician's attempts to comply with EMTALA's requirements where they were unable to do so because of patient conduct over which they had no control. Further, a commenter asserted that EMTALA is not violated when a patient leaves of his or her free will.

Response: We are finalizing the rule, as proposed. The OIG believes that the evaluation of whether an EMTALA violation occurred when the individual who presented for treatment left the hospital voluntarily is fact- and

circumstance-specific. If no violation is found to have occurred, the lack of the former mitigating factor would be of no consequence. If a violation is found to have occurred, the patient's having left voluntarily should not be a mitigating circumstance.

Comment: A commenter stated that additional mitigating factors, including the implementation of appropriate policies, procedures, training and action against hospital personnel prior to a CMS investigation, are useful and fair factors to distinguish hospitals making good faith and effective efforts to address EMTALA violations.

Response: The OIG agrees and has added as a mitigating factor situations in which a hospital takes appropriate and timely corrective action in response to a violation. For purposes of this mitigating factor, corrective action must be completed prior to CMS initiating an investigation of the hospital for violations of EMTALA and must include disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

Comment: One commenter objected to the proposed removal of the term "clearly" from the existing regulation at § 1003.106(d)(2). The commenter stated that, under proposed § 1003.520(c), an aggravating circumstance would exist even if screenings were applied with optimal consistency and fairness. The commenter asserted that even hospitals' and physicians' best efforts to comply with EMTALA will invariably fail to identify an emergency medical condition and, therefore, physicians and hospitals may be subject to maximum CMPs even in cases in which the violation falls short of negligence.

Response: The OIG is finalizing the proposal. While determination of EMTALA violations are fact- and circumstance-dependent, OIG would not impose a CMP where a physician or hospital did not at least demonstrate negligence in failing to comply with EMTALA. Further, if the hospital complied with EMTALA and still failed to diagnose an emergency medical condition, there would be no violation.

Comment: Several commenters addressed OIG's proposed aggravating factors. One commenter expressed concern with including premature discharge in the aggravating factor at § 1003.520(b) given continually evolving triage proposals and Federal guidelines that support reduction in emergency department use. That commenter further stated that all three of OIG's proposed aggravating factors were vague and subject to widely varying

interpretations. Another commenter expressed concern that the use of the phrase “could have resulted” in § 1003.520(b) would divorce the list of potential aggravating factors from a causal nexus to the EMTALA violation.

Response: In response to the comments, OIG is revising the proposed aggravating factor at § 1003.520(b) to include only patient harm or risk of patient harm that resulted from the incident. However, “risk of patient” harm could, depending on the facts and circumstances of a case, include premature discharge or the need for additional services. The existing regulation requires OIG to prove that patient harm actually resulted from the violation. This formulation is overly constrained. It is highly relevant if the violation put a beneficiary at risk of patient harm. Contrary to the commenter’s assertion that the proposed aggravating factors are vague, OIG considers them to be clear and specific and based on OIG’s lengthy experience pursuing penalties for violations of EMTALA.

Subpart F—CMPs for Section 1140 Violations

Subpart F applies to violations of section 1140 of the Act (42 U.S.C. 1320b–10). The most significant proposed change to this subpart was clarifying the application of section 1140 of the Act to telemarketing, Internet, and electronic mail solicitations. Section 1140 of the Act, as amended by the Bipartisan Budget Act of 2015 (Bipartisan Budget Act, Pub. L. 114–74, section 814(a), 129 stat. 604 (2015)), prohibits the use of words, letters, symbols, or emblems of HHS, CMS, Medicare, or Medicaid in connection with “an *advertisement, solicitation, circular, book, pamphlet, or other communication (including any Internet or other electronic communication), or a play, motion picture, broadcast, telecast, or other production*” in a manner that could reasonably be interpreted as conveying the false impression that HHS, CMS, Medicare, or Medicaid has approved, endorsed, or authorized such use. (Emphasis added.)

We previously defined conduct that constituted a violation for (1) direct or printed mailing solicitations or advertisements and (2) broadcasts or telecasts. The proposed regulations were updated to also reflect telephonic and Internet communications. Under a plain reading of the Act, telemarketing solicitations, email, and Web sites fall within the statutory terms emphasized above. In fact, since the publication of the proposed rule, the Bipartisan Budget

Act of 2015 amended section 1140(a)(1) of the Act to expressly include Internet and other electronic communications. We believe telephonic and Internet communications are analogous to, and therefore proposed imposing penalties that would apply in the same manner as, those for direct mail and other printed materials. The number of individuals who received direct mail and other printed materials can be more easily quantified than the number of individuals who saw a television commercial or heard a radio commercial. Telemarketing calls, electronic messages, and Web page views can be similarly quantified. Thus, we proposed subjecting telemarketing, email, and Web site violations to the same \$5,000 penalty as printed media. Each separate email address that received the email, each telemarketing call, and each Web page view would constitute a separate violation. This proposal is further supported by the Bipartisan Budget Act of 2015, which amended section 1140(b) of the Act to state that, for violations involving the Internet or other electronic communications, “each dissemination, viewing, or accessing of such communication . . . shall represent a separate violation.” Bipartisan Budget Act of 2015, section 814(b).

The final rule includes changes from the proposed rule to reflect the Bipartisan Budget Act of 2015. We changed “electronic message” and “electronic mail” to “electronic communication.” We also state “each dissemination, viewing, or accessing of the electronic communication,” as opposed to “each separate email address that received the email message,” will constitute a violation. The proposed rule used email addresses as a way to determine the number of disseminations, views, or accessing of the communication. Because not all “electronic communications” involve an “email address,” we believe “each dissemination, viewing, or accessing of the electronic communication” is a more appropriate description of potential violations of the rule.

We received no comments on this subpart and finalize, as proposed, except as explained above.

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

Subpart H covers violations for failing to report payments in settlement of a medical malpractice claim in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131); failing to report adverse actions pursuant to section 221 of Public Law 104–191 as set forth in section 1128E of the Act (42

U.S.C. 1320a–7e); or improperly disclosing, using, or permitting access to information reported in accordance with Part B of Title IV of Public Law 99–660 (42 U.S.C. 11137).

The language in proposed subpart H remains largely unchanged from the existing regulations at §§ 1003.102(b)(5)–(6) and § 1003.103(c), (g). We proposed to remove the reference to the Healthcare Integrity and Protection Data Bank (HIPDB) in conformity with section 6403(a) of the ACA, which removed the reference from section 1128E of the Act. The relevant reporting requirements, violation, and penalties would remain unchanged. Under section 1128E of the Act, providers must still report the same information. Once the HIPDB is phased out pursuant to section 6403(a) of ACA, the information will be collected and stored in the National Practitioner Data Bank established pursuant to the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 *et seq.*). In the penalty section, we proposed to clarify that a CMP may be imposed for each failure to report required information or adverse action and for each improper disclosure, use, or permitting of access to information.

We received no comments on this subpart and finalize, as proposed.

Subpart I—CMPs for Select Agent Program Violations

Subpart I contains penalties for violations involving select agents, found in the existing regulations at § 1003.102(b)(16) and § 1003.103(l). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002), Public Law 107–188, provides for the regulation of certain biological agents and toxins (referred to below as “select agents and toxins”) by HHS. The regulations created pursuant to the Bioterrorism Act of 2002 are found at 42 CFR part 73. The regulations set forth requirements for the possession and use in the United States, receipt from outside the United States, and transfer within the United States of the select agents and toxins. For each violation of 42 CFR part 73, OIG is authorized to impose CMPs of up to of \$250,000 in the case of an individual, and \$500,000 in the case of an entity.

Proposed subpart I explains that the CMP may be assessed for each individual violation of 42 CFR part 73. The Bioterrorism Act of 2002 states that any person who violates “any provision” of the regulations is subject to the maximum statutory penalty. The plain meaning of “any provision” means that any single violation can

subject a person to the maximum penalty. Thus, we proposed amending the regulation to add “each individual” before “violation” to clarify our longstanding interpretation of this section to mean that each violation subjects a person to a CMP up to the maximum amount.

In addition, proposed subpart I includes several aggravating circumstances to guide our penalty determinations. Aggravating factors include: (1) The Responsible Official participated in or knew or should have known of the violation; (2) the violation was a contributing factor, regardless of proportionality, to an unauthorized individual’s access to or possession of a select agent or toxin, an individual’s exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from the person’s physical location as identified on the person’s certificate of registration; and (3) the person previously received a statement of deficiency from HHS or the Department of Agriculture for the same or substantially similar conduct. In the final rule, we removed “regardless of proportionality” from the second aggravating factor. Such proportionality would be relevant to our qualitative weighing of the aggravating factor, but it would not be relevant to the applicability of the aggravating factor. We also added “observation” and “finding” to previous “statements of deficiency” in the third aggravating factor to better reflect the terminology used by HHS and the Department of Agriculture in Facility Inspection Reports.

We received no comments on this subpart and, except as noted above, finalize, as proposed.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

Subpart J covers two statutory provisions concerning beneficiary inducement violations. We proposed moving the existing regulation, § 1003.102(b)(13), concerning the beneficiary inducement provision in the CMPL (section 1128A(a)(5) of the Act), to this subpart. We also proposed regulatory language for the authority at section 1862(b)(3)(C) of the Act. The statutory authority is self-implementing and does not require a regulation. We proposed adding the regulatory language at this time in light of the general reorganization. Under section 1862(b)(3)(C) of the Act, a penalty of up to \$5,000 may be imposed against any person who offers any financial or other incentive for an individual entitled to benefits under Medicare not to enroll, or

to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A) of the Act. The proposed regulatory text closely follows the language of the statute.

We proposed to incorporate the general factors listed in § 1003.140 for determining amounts of penalties and assessments for violations in this subpart and to clarify that we will consider the amount of remuneration, other financial incentives, or other incentives. This provision was in the existing regulations at § 1003.106(a)(1)(vii).

We changed the basis for penalties for violations of § 1003.1000(a) in the final rule to reflect the statute, which uses the CMPL default of penalties for each item or service.

We received the following comment on this subpart. As the comment was outside the scope of this rulemaking, we are finalizing this subpart, as proposed, except as explained above.

Comment: A commenter urged OIG to include in proposed § 1003.1000(a) the current exceptions to the beneficiary inducement prohibition. As examples, the commenter included gifts or free services to beneficiaries that do not exceed \$10 per item and \$50 annually, and services or other remuneration permissibly furnished to financially needy beneficiaries.

Response: Any exceptions to liability under § 1003.1000(a) would be appropriately located in the definition of “remuneration,” which is at § 1003.101, not in § 1003.1000(a) itself. Any proposed amendments to the definition of “remuneration” are outside the scope of this rulemaking. The OIG proposed changes to that definition in a separate notice of proposed rulemaking, 79 FR 59,717 (October 3, 2014). The OIG plans to address the dollar limits discussed in this comment as part of that other rulemaking. Moreover, the examples raised by the commenter do not clearly fall within any of the exceptions set forth at § 1128A(i)(6) of the Act.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

Subpart K covers violations relating to the sale of Medicare supplemental policies. The statutory authority is self-implementing and does not require a regulation. Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, section 4354(c), 104 Stat. 3327 (1990); 42 U.S.C. 1395ss(d). However, we proposed adding the regulatory

language at this time in light of the general reorganization.

The OIG may impose a penalty against any person who it determines has violated section 1882(d)(1) of the Act (42 U.S.C. 1395ss(d)(1)) by knowingly and willfully making or causing to be made or inducing or seeking to induce the making of any false statement or representation of material fact with respect to the compliance of any policy with Medicare supplemental policy standards and requirements or with respect to the use of the Secretary’s emblem (described at section 1882(a)(1) of the Act (42 U.S.C. 1395ss(a)(1))) indicating that a policy has received the Secretary’s certification. We proposed to add this violation at § 1003.1100(a).

The OIG may impose a penalty against any person who it determines has violated section 1882(d)(2) of the Act (42 U.S.C. 1395ss(d)(2)) by falsely assuming or pretending to be acting, or misrepresenting in any way that he is acting, under the authority of or in association with, Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands or obtains money, paper, documents or anything of value. We proposed to add this violation at § 1003.1100(b).

The OIG may also impose a penalty against any person who it determines has violated section 1882(d)(4)(A) of the Act (42 U.S.C. 1395ss(d)(4)(A)) by mailing or causing to be mailed any matter for advertising, soliciting, offering for sale, or the delivery of Medicare supplemental insurance policy that has not been approved by the State commissioner or superintendent of insurance. We proposed to add this violation at § 1003.1100(c).

The OIG may impose a penalty against any person who it determines has violated section 1882(d)(3)(A)(i) of the Act (42 U.S.C. 1395ss(d)(3)(A)) by issuing or selling to an individual entitled to benefits under Part A or enrolled in Part B (including an individual electing a Medicare Part C plan): (1) A health insurance policy with the knowledge that the policy duplicates Medicare or Medicaid health benefits to which the individual is otherwise entitled; (2) a Medicare supplemental policy to an individual who has not elected a Medicare Part C plan where the person knows that the individual is entitled to benefits under another Medicare supplemental policy; (3) a Medicare supplemental policy to an individual who has elected a Medicare Part C plan where the person knows that the policy duplicates health

benefits to which the individual is otherwise entitled under the Medicare Part C plan or under another Medicare supplemental policy; and (4) a health insurance policy (other than a Medicare supplemental policy) with the knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law. We proposed to add this violation at § 1003.1100(d).

The OIG may also impose a penalty against any person who violated section 1882(d)(3)(A)(vi)(II) of the Act (42 U.S.C. 1395ss(d)(3)(A)(vi)(II)) by issuing or selling a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III) of the Act) to an individual entitled to benefits under Part A or enrolled under Part B who is applying for a health insurance policy without furnishing a disclosure statement (described at section 1882(d)(3)(A)(vii) of the Act). We proposed to add this violation at § 1003.1100(e).

The OIG may also impose a penalty against any person who it determines has violated section 1882(d)(3)(B)(iv) of the Act (42 U.S.C. 1395ss(d)(3)(B)(iv)) by issuing or selling a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Part B without obtaining the written statement from the individual or written acknowledgement from the seller required by section 1882(d)(3)(B) of the Act (42 U.S.C. 1395ss(d)(3)(B)). We proposed to add this violation at § 1003.1100(f).

For violations of section 1882(d)(1), (d)(2), and (d)(4)(A) of the Act, OIG may impose a penalty of not more than \$5,000 for each violation. We proposed to add this penalty at § 1003.1110(a). For violations of section 1882(d)(3)(A) and (B) of the Act, OIG may impose a penalty of not more than \$25,000 for each violation by a seller that is also the issuer of the policy and a penalty of not more than \$15,000 for each violation by a seller that is not the issuer of the policy. We proposed to add these penalties at §§ 1003.1110(b) and (c). In determining the amount of the penalty in accordance with proposed subpart K, OIG would consider the factors listed in the proposed § 1003.140.

We received the following comment on this subpart. As discussed below, we are finalizing this subpart, as proposed.

Comment: A commenter requested that OIG defer adopting the proposed § 1003.1100(d), which relates to the issuance or sale of duplicative coverage, until the application of the prohibitions in that section to QHPs and State and

Federally facilitated exchanges are better understood. The commenter stated that questions arose during the 2013 open enrollment period for exchange-based health insurance coverage as to individuals eligible for or enrolled in Medicare and exchange-based health insurance coverage. According to the commenter, some exchanges did not inquire as to a beneficiary's Medicare status prior to instructing plans to enroll these individuals into QHPs. The commenter asserted that exchanges are best-positioned to verify an individual's Medicare status and that it would be inappropriate to penalize QHPs under this CMP authority.

Response: We respectfully disagree with the suggestion to defer issuance of the regulation and are finalizing the rule, as proposed. The CMP authorities covered in this subpart have existed in statute for many years and should be added to part 1003 at this time in light of our reorganization. In addition, the concerns raised by the commenter appear to be addressed by the fact that § 1003.1100(d)(1) and (2) apply only when a health insurance policy is issued with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled.

Subpart L—CMPs for Drug Price Reporting

Subpart L contains the CMPs for drug-price reporting found in section 1927(b)(3)(B)–(C) of the Act (42 U.S.C. 1396r–8(b)(3)(B)–(C)). Although the statutory authority is self-implementing and does not require a regulation, we proposed adding the regulatory language at this time in light of the general reorganization. The proposed regulation text closely mirrors the language of the statute.

Section 1927(a) of the Act implements a drug-pricing program in which manufacturers that sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. Under section 1927(a) of the Act, manufacturers must provide certain statutorily mandated discounts to covered entities. Section 1927(b)(3)(A) of the Act requires manufacturers with Medicaid Drug Rebate Agreements to provide specified drug-pricing and product information to the Secretary, including, but not limited to, average manufacturer price (AMP), average sales price (ASP), wholesale acquisition cost, and best price. Labelers are required to certify each product and pricing data submission made to CMS.

Manufacturers submit the product and pricing information required by

section 1927 of the Act using the National Drug Code (NDC) product identifier. The OIG proposed calculating CMPs under section 1927(b)(3)(C) of the Act at the NDC level. For example, a manufacturer that fails to provide the information required by section 1927(b)(3)(A) of the Act for five separate NDCs may be penalized for each NDC, in an aggregate amount of not more than \$50,000 per day for each day that the information is not provided. If, after 2 days, the manufacturer in this example submitted information for two of the missing NDCs, the manufacturer would be subject to an aggregate penalty of not more than \$30,000 per day for each additional day that information was not provided for the remaining three NDCs. The OIG believes that this interpretation is supported by the statutory text, which refers to NDCs, and by the reporting systems employed by CMS, under which manufacturers are required to report AMP and ASP product and pricing data using NDCs.

Section 1927(b)(3)(B) of the Act provides for verification surveys of AMPs and establishes that a penalty of not more than \$100,000 may be imposed against a wholesaler, direct seller, or manufacturer that directly distributes its covered outpatient drugs for refusing a request for information by, or for knowingly providing false information to, the Secretary about charges or prices in connection with such a survey.

Pursuant to section 1927(b)(3)(C) of the Act, OIG may impose a penalty of not more than \$100,000 against any manufacturer with an agreement under section 1927 of the Act that knowingly provides false information for each item of false information.

We received the following comments on this subpart. To the extent provisions of the proposed rule are not addressed in our response to the comments below, we are finalizing this section of the rule, as proposed.

Comment: One commenter expressed concern with OIG's proposal to calculate penalties at the NDC level instead of per late report. The commenter argued that, where one report contained multiple NDCs, imposing multiple penalties per day instead of one penalty per day would be unduly harsh.

Response: The OIG is finalizing the rule, as proposed. The OIG believes that this interpretation is supported by the statutory text, which refers to NDCs, and by the reporting systems employed by CMS, under which manufacturers are required to report AMP and ASP product and pricing data using NDCs.

Comment: One commenter expressed concern with OIG's proposal to

calculate penalties at the 9-digit NDC level. The commenter suggested that OIG avoid establishment of a bright-line rule that would rigidly define products at the 9-digit NDC level for the purposes of calculating penalties. This commenter noted that the preamble language in which OIG proposed calculating penalties at the 9-digit NDC level is not reflected in the regulation text.

Response: We agree that OIG should have discretion to determine the appropriate NDC level at which to calculate penalties based on the particular requirements and submissions for each manufacturer. Neither section 1927(b)(3)(C) of the Act nor the regulation dictates which NDC level must be used in calculating the penalties. Therefore, we have not included the discussion of 9-digit and 11-digit NDC levels in the text of the final rule. To the extent the commenter may have been recommending that OIG not use NDCs to calculate penalties, OIG believes that the use of NDCs is appropriate based on the statutory text and the reporting systems employed by CMS.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

In subpart M, we proposed to add regulations providing for CMPs for notifying a skilled nursing facility (SNF), nursing facility (NF), home health agency (HHA), or a community care setting of the date or time of a survey. The statutory authority for these CMPs is self-implementing and does not require a regulation. Sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), 1929(i)(3)(A); 42 U.S.C. 1395i–3(g)(2)(A), 1396r(g)(2)(A), 1395bbb(c)(1), 1396t(i)(3)(A) of the Act. However, we proposed adding the regulatory language at this time in light of the general reorganization. The proposed regulation text closely mirrors the language of the statute.

SNFs, NFs, HHAs, and community care settings are subject to State compliance surveys without any prior notice. Sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), and 1929(i)(3)(A) of the Act provide for imposing a penalty of not more than \$2,000 against any individual who notifies, or causes to be notified, a SNF, NF, home health agency, or community care setting of the time or date on which a survey is scheduled to be conducted.

The OIG will consider the general factors listed in § 1003.140 when determining the amount of the penalties to be imposed under this subpart.

We received no comments on this subpart and finalize, as proposed.

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

Subpart O contains the procedural provisions that apply to part 1003. We proposed several clarifying changes to procedures in this subpart. We proposed amending the methods permitted for service of a notice of a proposal of a penalty, assessment, or exclusion under part 1003. Section 1003.109 required service by certified mail, return receipt requested. Section 1128A(c)(1) of the Act, however, permits service by any method authorized by Rule 4 of the Federal Rules of Civil Procedure (FRCP), which has been amended to authorize various service methods depending on whether the recipient is a domestic or foreign individual or corporation. Therefore, we are amending our regulation at §§ 1003.1500(a) and 1003.1510 to permit service under any means authorized by FRCP Rule 4. By referencing the rule, the regulation would reflect any future amendments to Rule 4 automatically.

We also proposed technical changes to the judicial review provision at § 1003.127 in the existing regulation and redesignated as § 1003.1540 to better conform to the statutory scheme requiring a person to exhaust his or her administrative remedies before filing a claim in Federal court. Exhaustion of administrative remedies is a well-settled legal principle, particularly concerning section 405(g) of the Act (42 U.S.C. 205(g)). Consistent with existing law, the proposed regulations clarify that a person may not bring a claim in Federal court without first raising that claim at every applicable stage within the administrative process, including any administrative appeal process. In the context of part 1003, that administrative process consists of making a timely request for a hearing before an ALJ pursuant to 42 CFR 1005.2 and, if the respondent loses at the ALJ level, timely filing an appeal of the ALJ decision to the Appellate Division of the Departmental Appeals Board. Only after the Departmental Appeals Board makes a final decision under 42 CFR 1005.21(j) is the respondent eligible to file an action in Federal court.

We also proposed a technical change to the regulatory language to clarify the statutory limit on issues eligible for judicial review. Section 1128A(e) of the Act provides that “[n]o objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of

extraordinary circumstances.” We interpret this to mean that a person is precluded from making arguments or raising issues in Federal court that were not first raised during the administrative process, unless the court finds that extraordinary circumstances prevented raising those arguments or issues. We interpret “extraordinary circumstances” to mean that those arguments or issues were beyond the authority of the administrative process.

We received no comments on this subpart and finalize, as proposed.

Other Changes in Part 1003

The OIG has authority to impose CMPs against endorsed sponsors under the Medicare Prescription Drug Discount Card Program that knowingly commit certain violations. The discount card program has been defunct since January 1, 2006, when Medicare Part D went into effect. We proposed to remove this CMP from the regulations as the statute of limitations has expired for any conduct that might implicate this CMP.

We received no comments on removing this CMP and finalize, as proposed.

F. Appeals of Exclusions, Civil Monetary Penalties, and Assessments

We proposed changes to OIG regulations at 42 CFR part 1005 to correct an internal inconsistency in § 1005.4(c). The regulation states at § 1005.4(c)(5)–(6) that an ALJ is not authorized to (1) review the exercise of discretion by OIG to exclude an individual or entity under section 1128(b) of the Act, (2) determine the scope or effect of the exclusion, or (3) set a period of exclusion at zero when the ALJ finds that the individual or entity committed an act described in section 1128(b) of the Act. Section 1005.4(c)(7) stated that an ALJ is not authorized to review the exercise of discretion by OIG to impose a CMP, an assessment, or an exclusion under part 1003. The second and third limits on ALJ authority with respect to exclusions under section 1128(b) of the Act should also apply to exclusions imposed under part 1003. To correct this inconsistency, we proposed to clarify that when reviewing exclusions imposed pursuant to part 1003, an ALJ is not authorized to (1) review OIG’s exercise of discretion to exclude an individual or entity, (2) determine the scope or effect of the exclusion, or (3) set a period of exclusion at zero if the ALJ finds that the individual or entity committed an act described in part 1003. We believe that this requirement is consistent with congressional intent in enacting the statutes providing authority for part

1003 that explicitly provide for exclusion as an appropriate remedy for the commission of any of the acts specified in those statutes. Thus, in every case in which OIG has exercised its discretion to impose an exclusion and when the ALJ decides that a violation did occur, exclusion is appropriate.

We received the following comment on this proposal. As discussed in response to the comment, we are finalizing this section of the rule, as proposed.

Comment: A commenter asked OIG to reconsider our proposal to limit an ALJ's authority in the absence of a specific legislative mandate.

Response: We respectfully disagree with the commenter's suggestion and finalize the rule, as proposed. The rule ensures consistency in the ALJ review of discretionary exclusions imposed under sections 1128(b) and 1128A of the Act.

III. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132. Executive Order Nos. 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. A regulatory impact analysis must be prepared for major rules with economically significant effects, *i.e.*, \$100 million or more in any given year. This is not a major rule as defined at 5 U.S.C. 804(2); it is not economically significant because it does not reach that economic threshold.

This proposed rule is designed to codify in regulations new statutory provisions, including new CMP authorities. This proposed rule is also designed to clarify the intent of existing statutory requirements and to reorganize CMP regulation sections for ease of use. The vast majority of providers, suppliers, and other persons participating in Federal health care programs would be minimally affected, if at all, by these proposed revisions.

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

Regulatory Flexibility Act

The Regulatory Flexibility Act (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 if they have revenues of \$5 million to \$25 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities.

The aggregate effect of the changes to the CMP provisions would be minimal.

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

In addition, section 1102(b) of the Act (42 U.S.C. 1302) requires us to prepare a regulatory impact analysis if a rule under Titles XVIII or XIX or section B of Title XI of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to section 604 of the RFA. Only one proposed change has been made under the relevant title, the amendments to the Medicare Contracting Organization Rule at proposed § 1003.400, *et seq.* This rule applies only to Medicare contracting organizations, not to rural hospitals, and would have no effect on rural hospitals. Thus, an analysis under section 1102(b) is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million or more. As indicated above, these proposed revisions comport with statutory amendments and clarify existing law. We believe that as a result, there would be no significant costs associated with these proposed revisions that would impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of \$110 million or more (adjusted for inflation) in any given year and that a full analysis

under the Unfunded Mandates Reform Act is not necessary.

Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

IV. Paperwork Reduction Act

These proposed changes to parts 1003 and 1005 impose no new reporting requirements or collections of information. Therefore, a Paperwork Reduction Act review is not required.

List of Subjects

42 CFR Part 1003

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

42 CFR Part 1005

Administrative practice and procedure, Fraud, Investigations, Penalties.

For the reasons set forth in the preamble, the Office of the Inspector General, Department of Health and Human Services, amends 42 CFR chapter V, subchapter B as follows:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

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

Authority: 42 U.S.C. 262a, 1302, 1320-7, 1320a-7a, 1320b-10, 1395u(j), 1395u(k), 1395cc(j), 1395w-141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

- 2. Designate §§ 1003.100 through 1003.135 as subpart A, and add a heading for subpart A to read as follows:

Subpart A—General Provisions

- 3. Revise § 1003.100 to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1140, 1819(b)(3)(B), 1819(g)(2)(A), 1857(g)(2)(A), 1860D-12(b)(3)(E), 1860D-31(i)(3), 1862(b)(3)(C), 1867(d)(1), 1876(i)(6), 1877(g), 1882(d),

1891(c)(1); 1903(m)(5), 1919(b)(3)(B), 1919(g)(2)(A), 1927(b)(3)(B), 1927(b)(3)(C), and 1929(i)(3) of the Social Security Act; sections 421(c) and 427(b)(2) of Public Law 99-660; and section 201(i) of Public Law 107-188 (42 U.S.C. 1320a-7(c), 1320a-7a, 1320b-10, 1395i-3(b)(3)(B), 1395i-3(g)(2)(A), 1395w-27(g)(2)(A), 1395w-112(b)(3)(E), 1395w-141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm(i)(6), 1395nn(g), 1395ss(d), 1395bbb(c)(1), 1396b(m)(5), 1396r(b)(3)(B), 1396r(g)(2)(A), 1396r-8(b)(3)(B), 1396r-8(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a(i)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments and exclusions against persons who have committed an act or omission that violates one or more provisions of this part and

(2) Sets forth the appeal rights of persons subject to a penalty, assessment, and exclusion.

§§ 1003.102 through 1003.110, 1003.114, 1003.126 through 1003.129, and 1003.132 through 1003.135 [Removed]

■ 4. Remove §§ 1003.102 through 1003.110, 1003.114, 1003.126 through 1003.129, and 1003.132 through 1003.135.

§ 1003.101 [Redesignated as § 1003.110]

■ 5. Redesignate § 1003.101 as § 1003.110.

■ 6. Amend newly designated § 1003.110 by:

- a. Removing the definitions of “Act”, “Adverse effect”, and “ALJ”;
- b. Revising the definitions of “Assessment” and “Claim”;
- c. Removing the definition of “CMS”;
- d. Revising the definitions of “Contracting organization” and “Enrollee”;
- e. Removing the definitions of “Department”, “Exclusion”, “Inspector General”, and “Item or service”;
- f. Adding in alphabetical order definitions for “Items and services or items or services”, “Knowingly”, and “Material”;
- g. Removing the definition of “Medicaid”;
- h. Revising the definition of “Medical malpractice claim or action”;
- i. Removing the definition of “Medicare”;
- j. Adding in alphabetical order definitions for “Non-separately-billable item or service”, and “Overpayment”;
- k. Revising the definitions of “Participating hospital”, “Penalty”, and “Physician incentive plan”;
- l. Adding in alphabetical order definitions for “Reasonable request”, and “Responsible Official”;

- m. Revising the definition of “Responsible physician”;
- n. Removing the definition of “Secretary”;
- o. Revising the definition of “Select agents and toxins”;
- p. Adding in alphabetical order a definition for “Separately billable item or service”;
- q. Revising the definitions of “Should know, or should have known” and “Social Services Block Grant Program”;
- r. Removing the definitions of “State” and “State health care program”;
- s. Revising the definition of “Timely basis”; and
- t. Removing the definition of “Transitional assistance”.

The revisions and additions read as follows:

§ 1003.110 Definitions.

* * * * *

Assessment means the amounts described in this part and includes the plural of that term.

Claim means an application for payment for an item or service under a Federal health care program.

* * * * *

Contracting organization means a public or private entity, including a health maintenance organization, Medicare Advantage organization, Prescription Drug Plan sponsor, or other organization that has contracted with the Department or a State to furnish, or otherwise pay for, items and services to Medicare or Medicaid beneficiaries pursuant to sections 1857, 1860D-12, 1876(b), or 1903(m) of the Act.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization.

* * * * *

Items and services or items or services includes without limitation, any item, device, drug, biological, supply, or service (including management or administrative services), including, but not limited to, those that are listed in an itemized claim for program payment or a request for payment; for which payment is included in any Federal or State health care program reimbursement method, such as a prospective payment system or managed care system; or that are, in the case of a claim based on costs, required to be entered in a cost report, books of account, or other documents supporting the claim (whether or not actually entered).

Knowingly means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard

of the act, and no proof of specific intent to defraud is required.

Material means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

* * * * *

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician’s, dentist’s, or other health care practitioner’s provision of, or failure to provide, health care services and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

* * * * *

Non-separately-billable item or service means an item or service that is a component of, or otherwise contributes to the provision of, an item or a service, but is not itself a separately billable item or service.

Overpayment means any funds that a person receives or retains under Medicare or Medicaid to which the person, after applicable reconciliation, is not entitled under such program.

Participating hospital means either a hospital or a critical access hospital, as defined in section 1861(mm)(1) of the Act, that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in this part and includes the plural of that term.

* * * * *

Physician incentive plan means any compensation arrangement between a contracting organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

* * * * *

Reasonable request, with respect to § 1003.200(b)(10), means a written request, signed by a designated representative of the OIG and made by a properly identified agent of the OIG during reasonable business hours. 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 timely access” under part 1003, the deadline by which the OIG requests access, and the amount of the civil money penalty or assessment that could be imposed 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.

* * * * *

Responsible Official means the individual designated pursuant to 42 CFR part 73 to serve as the Responsible Official for the person holding a certificate of registration to possess, use, or transfer select agents or toxins.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department requesting examination or treatment, including any physician who is on-call for the care of such individual and fails or refuses to appear within a reasonable time at such hospital to provide services relating to the examination, treatment, or transfer of such individual.

Responsible physician also includes a physician who is responsible for the examination or treatment of individuals at hospitals with specialized capabilities or facilities, as provided under section 1867(g) of the Act, including any physician who is on-call for the care of such individuals and refuses to accept an appropriate transfer or fails or refuses to appear within a reasonable time to provide services related to the examination or treatment of such individuals.

* * * * *

Select agents and toxins is defined consistent with the definition of "select agent and/or toxin" and "overlap select agent and/or toxin" as set forth in 42 CFR part 73.

Separately billable item or service means an item or service for which an identifiable payment may be made under a Federal health care program, e.g., an itemized claim or a payment under a prospective payment system or other reimbursement methodology.

Should know, or should have known, means that a person, with respect to information, either acts in deliberate ignorance of the truth or falsity of the information or acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant Program means the program authorized under Title XX of the Act.

* * * * *

Timely basis means, in accordance with § 1003.300(a) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

* * * * *

■ 7. Add §§ 1003.120, 1003.130, 1003.140, 1003.150, and 1003.160 to subpart A to read as follows:

Sec.

* * * * *

1003.120 Liability for penalties and assessments.

1003.130 Assessments.

1003.140 Determinations regarding the amount of penalties and assessments and the period of exclusion.

1003.150 Delegation of authority.

1003.160 Waiver of exclusion.

§ 1003.120 Liability for penalties and assessments.

(a) In any case in which it is determined that more than one person was responsible for a violation described in this part, each such person may be held liable for the penalty prescribed by this part.

(b) In any case in which it is determined that more than one person was responsible for a violation described in this part, an assessment may be imposed, when authorized, against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(c) Under this part, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of his or her agency. This provision does not limit the underlying liability of the agent.

§ 1003.130 Assessments.

The assessment in this part is in lieu of damages sustained by the Department or a State agency because of the violation.

§ 1003.140 Determinations regarding the amount of penalties and assessments and the period of exclusion.

(a) Except as otherwise provided in this part, in determining the amount of any penalty or assessment or the period of exclusion in accordance with this part, the OIG will consider the following factors—

(1) The nature and circumstances of the violation;

(2) The degree of culpability of the person against whom a civil money penalty, assessment, or exclusion is proposed. It should be considered an aggravating circumstance if the respondent had actual knowledge where a lower level of knowledge was required to establish liability (e.g., for a provision that establishes liability if the respondent "knew or should have known" a claim was false or fraudulent, it will be an aggravating circumstance if the respondent knew the claim was false or fraudulent). It should be a mitigating circumstance if the person took appropriate and timely corrective action

in response to the violation. For purposes of this part, corrective action must include disclosing the violation to the OIG through the Self-Disclosure Protocol and fully cooperating with the OIG's review and resolution of such disclosure, or in cases of physician self-referral law violations, disclosing the violation to CMS through the Self-Referral Disclosure Protocol;

(3) The history of prior offenses. Aggravating circumstances include, if at any time prior to the violation, the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or in connection with the delivery of a health care item or service;

(4) Other wrongful conduct. Aggravating circumstances include proof that the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to a government program or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance; and

(5) Such other matters as justice may require. Other circumstances of an aggravating or mitigating nature should be considered if, in the interests of justice, they require either a reduction or an increase in the penalty, assessment, or period of exclusion to achieve the purposes of this part.

(b)(1) After determining the amount of any penalty and assessment in accordance with this part, the OIG considers the ability of the person to pay the proposed civil money penalty or assessment. The person shall provide, in a time and manner requested by the OIG, sufficient financial documentation,

including, but not limited to, audited financial statements, tax returns, and financial disclosure statements, deemed necessary by the OIG to determine the person's ability to pay the penalty or assessment.

(2) If the person requests a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review is that which the person provided to the OIG during the administrative process, unless the ALJ finds that extraordinary circumstances prevented the person from providing the financial documentation to the OIG in the time and manner requested by the OIG prior to the hearing request.

(c) In determining the amount of any penalty and assessment to be imposed under this part the following circumstances are also to be considered—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by this part to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum permitted by this part to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should not be less than double the approximate amount of damages and costs (as defined by paragraph (e)(2) of this section) sustained by the United States, or any State, as a result of the violation.

(4) The presence of any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors is present.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including, but not limited to, the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this part limits the authority of the Department or the OIG to settle any issue or case as provided by § 1003.1530 or to compromise any exclusion and any penalty and assessment as provided by § 1003.1550.

(4) Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties, assessments, or other sanctions prescribed by law.

§ 1003.150 Delegation of authority.

The OIG is delegated authority from the Secretary to impose civil money penalties and, as applicable, assessments and exclusions against any person who has violated one or more provisions of this part. The delegation of authority includes all powers to impose and compromise civil monetary penalties, assessments, and exclusion under section 1128A of the Act.

§ 1003.160 Waiver of exclusion.

(a) The OIG will consider a request from the administrator of a Federal health care program for a waiver of an exclusion imposed under this part as set forth in paragraph (b) of this section. The request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) If the OIG subsequently obtains information that the basis for a waiver no longer exists, the waiver will cease and the person will be fully excluded from the Federal health care programs for the remainder of the exclusion period, measured from the time the full exclusion would have been imposed if the waiver had not been granted.

(c) The OIG will notify the administrator of the Federal health care program whether his or her request for a waiver has been granted or denied.

(d) If a waiver is granted, it applies only to the program(s) for which waiver is requested.

(e) The decision to grant, deny, or rescind a waiver is not subject to administrative or judicial review.

■ 8. Add subparts B through F to read as follows:

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

Sec.

1003.200 Basis for civil money penalties, assessments, and exclusions.

1003.210 Amount of penalties and assessments.

1003.220 Determinations regarding the amount of penalties and assessments and the period of exclusion.

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

1003.300 Basis for civil money penalties, assessments, and exclusions.

1003.310 Amount of penalties and assessments.

1003.320 Determinations regarding the amount of penalties and assessments and the period of exclusion.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

1003.400 Basis for civil money penalties and assessments.

1003.410 Amount of penalties and assessments.

1003.420 Determinations regarding the amount of penalties and assessments.

Subpart E—CMPs and Exclusions for EMTALA Violations

1003.500 Basis for civil money penalties and exclusions.

1003.510 Amount of penalties.

1003.520 Determinations regarding the amount of penalties and the period of exclusion.

Subpart F—CMPs for Section 1140 Violations

1003.600 Basis for civil money penalties.

1003.610 Amount of penalties.

1003.620 Determinations regarding the amount of penalties.

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

§ 1003.200 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, assessment, and an exclusion against any person who it determines has knowingly presented, or caused to be presented, a claim that was for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that was part of a pattern or practice of claims based on codes that the person knew, or should have known, would result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent;

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was presented;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified by a medical specialty board when he or she was not so certified; or

(5) An item or service that a person knew, or should have known was not

medically necessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty; an exclusion; and, where authorized, an assessment against any person who it determines—

(1) Has knowingly presented, or caused to be presented, a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1) of the Act; or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act;

(2) Has knowingly given, or caused to be given, to any person, in the case of inpatient hospital services subject to section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital;

(3) Is an individual who is excluded from participating in a Federal health care program under section 1128 or 1128A of the Act, and who—

(i) Knows, or should know, of the action constituting the basis for the exclusion and retains a direct or indirect ownership or control interest of 5 percent or more in an entity that participates in a Federal health care program or

(ii) Is an officer or a managing employee (as defined in section 1126(b) of the Act) of such entity;

(4) Arranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in Federal health care programs for the provision of items or services for which payment may be made under such a program;

(5) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under a Federal health care program if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act or violates the requirements for such an arrangement;

(6) Orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program, in the case when the person knows, or should know, that a claim for such medical or other item or service will be made under such a program;

(7) Knowingly makes, or causes to be made, any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program, including contracting organizations, and entities that apply to participate as providers of services or suppliers in such contracting organizations;

(8) Knows of an overpayment and does not report and return the overpayment in accordance with section 1128J(d) of the Act;

(9) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(10) Fails to grant timely access to records, documents, and other material or data in any medium (including electronically stored information and any tangible thing), upon reasonable request, to the OIG, for the purpose of audits, investigations, evaluations, or other OIG statutory functions. Such failure to grant timely access means:

(i) Except when the OIG reasonably believes that the requested material is about to be altered or destroyed, 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, by the deadline specified in the OIG's written request, and

(ii) When the OIG 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.

(c) The OIG may impose a penalty against any person who it determines, in accordance with this part, is a physician and who executes a document falsely by certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements in section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(d) The OIG may impose a penalty against any person who it determines knowingly certifies, or causes another individual to certify, a material and false statement in a resident assessment

pursuant to sections 1819(b)(3)(B) and 1919(b)(3)(B).

§ 1003.210 Amount of penalties and assessments.

(a) *Penalties.*¹ (1) Except as provided in this section, the OIG may impose a penalty of not more than \$10,000 for each individual violation that is subject to a determination under this subpart.

(2) The OIG may impose a penalty of not more than \$15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.200(b)(2).

(3) The OIG may impose a penalty of not more than \$10,000 per day for each day that the prohibited relationship described in § 1003.200(b)(3) occurs.

(4) For each individual violation of § 1003.200(b)(4), the OIG may impose a penalty of not more than \$10,000 for each separately billable or non-separately-billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity.

(5) The OIG may impose a penalty of not more than \$2,000 for each bill or request for payment for items and services furnished to a hospital patient in violation of § 1003.200(b)(5).

(6) The OIG may impose a penalty of not more than \$50,000 for each false statement, omission, or misrepresentation of a material fact in violation of § 1003.200(b)(7).

(7) The OIG may impose a penalty of not more than \$50,000 for each false record or statement in violation of § 1003.200(b)(9).

(8) The OIG may impose a penalty of not more than \$10,000 for each item or service related to an overpayment that is not reported and returned in accordance with section 1128J(d) of the Act in violation of § 1003.200(b)(8).

(9) The OIG may impose a penalty of not more than \$15,000 for each day of failure to grant timely access in violation of § 1003.200(b)(10).

(10) For each false certification in violation of § 1003.200(c), the OIG may impose a penalty of not more than the greater of—

(i) \$5,000; or

(ii) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a

¹ The penalty amounts in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74). Annually adjusted amounts are published at 45 CFR part 102.

physician, as prohibited by section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(11) For each false certification in violation of § 1003.200(d), the OIG may impose a penalty of not more than—

(i) \$1,000 with respect to an individual who willfully and knowingly falsely certifies a material and false statement in a resident assessment; and

(ii) \$5,000 with respect to an individual who willfully and knowingly causes another individual to falsely certify a material and false statement in a resident assessment.

(b) *Assessments.* (1) Except for violations of § 1003.200(b)(4), (5), and (7), and § 1003.200(c) and (d), the OIG may impose an assessment for each individual violation of § 1003.200, of not more than 3 times the amount claimed for each item or service.

(2) For violations of § 1003.200(b)(4), the OIG may impose an assessment of not more than 3 times—

(i) The amount claimed for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity or

(ii) The total costs (including salary, benefits, taxes, and other money or items of value) related to the excluded individual or entity incurred by the person that employs, contracts with, or otherwise arranges for an excluded individual or entity to provide, furnish, order, or prescribe a non-separately-billable item or service.

(3) For violations of § 1003.200(b)(7), the OIG may impose an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement, omission, or misrepresentation of material fact.

§ 1003.220 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in § 1003.140—

(a) It should be considered a mitigating circumstance if all the items or services or violations included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or violations, and the total amount claimed or requested for such items or services was less than \$5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items or services or violations (or the nature and

circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services, or the amount of the overpayment was \$50,000 or more;

(4) The violation resulted, or could have resulted, in patient harm, premature discharge, or a need for additional services or subsequent hospital admission; or

(5) The amount or type of financial, ownership, or control interest or the degree of responsibility a person has in an entity was substantial with respect to an action brought under § 1003.200(b)(3).

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

§ 1003.300 Basis for civil money penalties, assessments, and exclusions.

The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines in accordance with this part—

(a) Has not refunded on a timely basis, as defined in § 1003.110, amounts collected as a result of billing an individual, third party payer, or other entity for a designated health service furnished pursuant to a prohibited referral as described in 42 CFR 411.353.

(b) Is a physician or other person who enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person that, if the physician directly made referrals to such person, would be in violation of the prohibitions of 42 CFR 411.353.

(c) Has knowingly presented, or caused to be presented, a claim that is for a payment that such person knows, or should know, may not be made under 42 CFR 411.353;

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

§ 1003.310 Amount of penalties and assessments.

(a) *Penalties.*² The OIG may impose a penalty of not more than—

(1) \$15,000 for each claim or bill for a designated health service, as defined

in § 411.351 of this title, that is subject to a determination under § 1003.300(a) or (c);

(2) \$100,000 for each arrangement or scheme that is subject to a determination under § 1003.300(b); and

(3) \$50,000 for each offer, payment, solicitation, or receipt of remuneration that is subject to a determination under § 1003.300(d).

(b) *Assessments.* The OIG may impose an assessment of not more than 3 times—

(1) The amount claimed for each designated health service that is subject to a determination under § 1003.300(a), (b), or (c).

(2) The total remuneration offered, paid, solicited, or received that is subject to a determination under § 1003.300(d). Calculation of the total remuneration for purposes of an assessment shall be without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose.

§ 1003.320 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in § 1003.140:

(a) It should be considered a mitigating circumstance if all the items, services, or violations included in the action brought under this part were of the same type and occurred within a short period of time; there were few such items, services, or violations; and the total amount claimed or requested for such items or services was less than \$5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items, services, or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services or the amount of the remuneration was \$50,000 or more; or

(4) The violation resulted, or could have resulted, in harm to the patient, a premature discharge, or a need for additional services or subsequent hospital admission.

² The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

§ 1003.400 Basis for civil money penalties and assessments.

(a) *All contracting organizations.* The OIG may impose a penalty against any contracting organization that—

(1) Fails substantially to provide an enrollee with medically necessary items and services that are required (under the Act, applicable regulations, or contract with the Department or a State) to be provided to such enrollee and the failure adversely affects (or has the substantial likelihood of adversely affecting) the enrollee;

(2) Imposes a premium on an enrollee in excess of the amounts permitted under the Act;

(3) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by beneficiaries whose medical condition or history indicates a need for substantial future medical services, except as permitted by the Act;

(4) Misrepresents or falsifies information furnished to a person under sections 1857, 1860D–12, 1876, or 1903(m) of the Act;

(5) Misrepresents or falsifies information furnished to the Secretary or a State, as applicable, under sections 1857, 1860D–12, 1876, or 1903(m) of the Act;

(6) Fails to comply with the requirements of 42 CFR 417.479(d) through (i) for Medicare and 42 CFR 417.479(d) through (g) and (i) for Medicaid regarding certain prohibited incentive payments to physicians; or

(7) Fails to comply with applicable requirements of the Act regarding prompt payment of claims.

(b) *All Medicare contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1857, 1860D–12, or 1876 of the Act that—

(1) Acts to expel or to refuse to reenroll a beneficiary in violation of the Act; or

(2) Employs or contracts with a person excluded, under section 1128 or 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services, or employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded person.

(c) *Medicare Advantage and Part D contracting organizations.* The OIG may impose a penalty, and for § 1003.400(c)(4) or (5), an assessment,

against a contracting organization with a contract under section 1857 or 1860D–12 of the Act that:

(1) Enrolls an individual without the individual's (or his or her designee's) prior consent, except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1) of the Act;

(2) Transfers an enrollee from one plan to another without the individual's (or his or her designee's) prior consent;

(3) Transfers an enrollee solely for the purpose of earning a commission;

(4) Fails to comply with marketing restrictions described in subsection (h) or (j) of section 1851 of the Act or applicable implementing regulations or guidance; or

(5) Employs or contracts with any person who engages in the conduct described in paragraphs (a) through (c) of this section.

(d) *Medicare Advantage contracting organizations.* The OIG may impose a penalty against a contracting organization with a contract under section 1857 of the Act that fails to comply with the requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii) of the Act.

(e) *Medicaid contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1903(m) of the Act that acts to discriminate among individuals in violation of the Act, including expulsion or refusal to reenroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals with the contracting organization whose medical condition or history indicates a need for substantial future medical services.

§ 1003.410 Amount of penalties and assessments for Contracting Organization.

(a) *Penalties.*³ (1) The OIG may impose a penalty of up to \$25,000 for each individual violation under § 1001.400, except as provided in this section.

(2) The OIG may impose a penalty of up to \$100,000 for each individual violation under § 1003.400(a)(3), (a)(5), or (e).

(b) *Additional penalties.* In addition to the penalties described in paragraph (a) of this section, the OIG may impose—

(1) An additional penalty equal to double the amount of excess premium charged by the contracting organization for each individual violation of

§ 1003.400(a)(2). The excess premium amount will be deducted from the penalty and returned to the enrollee.

(2) An additional \$15,000⁴ penalty for each individual expelled or not enrolled in violation of § 1003.400(a)(3) or (e).

(c) *Assessments.* The OIG may impose an assessment against a contracting organization with a contract under section 1857 or 1860D–12 of the Act (Medicare Advantage or Part D) of not more than the amount claimed in violation of § 1003.400(a)(4) or (a)(5) on the basis of the misrepresentation or falsified information involved.

(d) The OIG may impose a penalty or, when applicable, an assessment, against a contracting organization with a contract under section 1857 or 1860D–12 of the Act (Medicare Advantage or Part D) if any of its employees, agents, or contracting providers or suppliers engages in any of the conduct described in § 1003.400(a) through (d).

§ 1003.420 Determinations regarding the amount of penalties and assessments.

In considering the factors listed in § 1003.140, aggravating circumstances include—

(a) Such violations were of several types or occurred over a lengthy period of time;

(b) There were many such violations (or the nature and circumstances indicate a pattern of incidents);

(c) The amount of money, remuneration, damages, or tainted claims involved in the violation was \$15,000 or more; or

(d) Patient harm, premature discharge, or a need for additional services or subsequent hospital admission resulted, or could have resulted, from the incident; and

(e) The contracting organization knowingly or routinely engaged in any prohibited practice that acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization.

Subpart E—CMPs and Exclusions for EMTALA Violations

§ 1003.500 Basis for civil money penalties and exclusions.

(a) The OIG may impose a penalty against any participating hospital with an emergency department or specialized capabilities or facilities for each negligent violation of section 1867 of the Act or § 489.24 (other than § 489.24(j)) of this title.

³ The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

⁴ This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(b) The OIG may impose a penalty against any responsible physician for each—

(1) Negligent violation of section 1867 of the Act;

(2) Certification signed under section 1867(c)(1)(A) of the Act if the physician knew, or should have known, that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(3) Misrepresentation made concerning an individual's condition or other information, including a hospital's obligations under section 1867 of the Act.

(c) The OIG may, in lieu of or in addition to any penalty available under this subpart, exclude any responsible physician who commits a gross and flagrant, or repeated, violation of this subpart from participation in Federal health care programs.

(d) For purposes of this subpart, a "gross and flagrant violation" is a violation that presents an imminent danger to the health, safety, or well-being of the individual who seeks examination and treatment or places that individual unnecessarily in a high-risk situation.

§ 1003.510 Amount of penalties.

The OIG may impose⁵—

(a) Against each participating hospital, a penalty of not more than \$50,000 for each individual violation, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed \$25,000 for each violation, and

(b) Against each responsible physician, a penalty of not more than \$50,000 for each individual violation.

§ 1003.520 Determinations regarding the amount of penalties and the period of exclusion.

In considering the factors listed in § 1003.140,

(a) It should be considered a mitigating circumstance if a hospital took appropriate and timely corrective action in response to the violation. For purposes of this subpart, corrective action must be completed prior to CMS initiating an investigation of the hospital for violations of section 1867 of the Act and must include disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

(b) Aggravating circumstances include:

(1) Requesting proof of insurance, prior authorization, or a monetary payment prior to appropriately screening or initiating stabilizing treatment for an emergency medical condition, or requesting a monetary payment prior to stabilizing an emergency medical condition;

(2) Patient harm, or risk of patient harm, resulted from the incident; or

(3) The individual presented to the hospital with a request for examination or treatment of a medical condition that was an emergency medical condition, as defined by § 489.24(b) of this title.

Subpart F—CMPs for Section 1140 Violations

§ 1003.600 Basis for civil money penalties.

(a) The OIG may impose a penalty against any person who it determines in accordance with this part has used the words, letters, symbols, or emblems as defined in paragraph (b) of this section in such a manner that such person knew, or should have known, would convey, or in a manner that reasonably could be interpreted or construed as conveying, the false impression that an advertisement, a solicitation, or other item was authorized, approved, or endorsed by the Department or CMS or that such person or organization has some connection with or authorization from the Department or CMS.

(b) Civil money penalties may be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department, or its programs, for misuse of—

(1) The words "Department of Health and Human Services," "Health and Human Services," "Centers for Medicare & Medicaid Services," "Medicare," or "Medicaid" or any other combination or variations of such words;

(2) The letters "DHHS," "HHS," or "CMS," or any other combination or variation of such letters; or

(3) A symbol or an emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under Title II, or envelopes or other stationery used by the Department or CMS) or any other combination or variation of such symbols or emblems.

(c) Civil money penalties will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that uses any symbol or emblem or any words or letters that specifically identify that agency or instrumentality of the State or political subdivision.

§ 1003.610 Amount of penalties.

(a) The OIG may impose a penalty of not more than⁶—

(1) \$5,000 for each individual violation resulting from the misuse of Departmental, CMS, or Medicare or Medicaid program words, letters, symbols, or emblems as described in § 1003.600(a) relating to printed media;

(2) \$5,000 for each individual violation in the case of such misuse related to an electronic communication, Web page, or telemarketing solicitation;

(3) \$25,000 for each individual violation in the case of such misuse related to a broadcast or telecast.

(b) For purposes of this paragraph, a violation is defined as—

(1) In the case of a direct mailing solicitation or advertisement, each separate piece of mail that contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a);

(2) In the case of a printed solicitation or advertisement, each reproduction, reprinting, or distribution of such item related to a determination under § 1003.600(a);

(3) In the case of a broadcast or telecast, each airing of a single commercial or solicitation related to a determination under § 1003.600(a);

(4) In the case of an electronic communication, each dissemination, viewing, or accessing of the electronic communication that contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a);

(5) In the case of a Web page accessed by a computer or other electronic means, each instance in which the Web page was viewed or accessed and that Web page contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a); and

(6) In the case of a telemarketing solicitation, each individual unsolicited telephone call regarding an item or service under Medicare or Medicaid related to a determination under § 1003.600(a).

§ 1003.620 Determinations regarding the amount of penalties.

(a) In considering the factors listed in § 1003.140, the following circumstances are to be considered—

(1) The nature and objective of the advertisement, solicitation, or other communication and the degree to which it had the capacity to deceive members of the public;

⁵The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

⁶The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(2) The frequency and scope of the violation and whether a specific segment of the population was targeted; and

(3) The prior history of the individual, organization, or entity in its willingness or refusal to comply with a formal or informal request to correct violations.

(b) The use of a disclaimer of affiliation with the United States Government, the Department, or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with § 1003.600(a).

Subpart G—[Reserved]

■ 9. Add reserved subpart G.

■ 10. Add subparts H through M to read as follows:

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

Sec.

- 1003.800 Basis for civil money penalties.
- 1003.810 Amount of penalties.
- 1003.820 Determinations regarding the amount of penalties.

Subpart I—CMPs for Select Agent Program Violations

- 1003.900 Basis for civil money penalties.
- 1003.910 Amount of penalties.
- 1003.920 Determinations regarding the amount of penalties.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

- 1003.1000 Basis for civil money penalties, assessments, and exclusions.
- 1003.1010 Amount of penalties and assessments.
- 1003.1020 Determinations regarding the amount of penalties and assessments and the period of exclusion.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

- 1003.1100 Basis for civil money penalties.
- 1003.1110 Amount of penalties.
- 1003.1120 Determinations regarding the amount of penalties.

Subpart L—CMPs for Drug Price Reporting

- 1003.1200 Basis for civil money penalties.
- 1003.1210 Amount of penalties.
- 1003.1220 Determinations regarding the amount of penalties.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

- 1003.1300 Basis for civil money penalties.
- 1003.1310 Amount of penalties.
- 1003.1320 Determinations regarding the amount of penalties.

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

§ 1003.800 Basis for civil money penalties.

The OIG may impose a penalty against any person (including an insurance company) who it determines—

(a) Fails to report information concerning—

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

(2) An adverse action required to be reported under section 1128E, as established by section 221 of Public Law 104-191.

(b) Improperly discloses, uses, or permits access to information reported in accordance with Part B of Title IV of Public Law 99-660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with Part B of Title IV in response to a subpoena or a discovery request is considered an improper disclosure in violation of section 427 of Public Law 99-660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered an improper disclosure in violation of section 427 of Public Law 99-660.)

§ 1003.810 Amount of penalties.

The OIG may impose a penalty of not more than ⁷—

(a) \$11,000 for each payment for which there was a failure to report required information in accordance with § 1003.800(a)(1) or for each improper disclosure, use, or access to information in accordance with a determination under § 1003.800(b); and

(b) \$25,000 against a health plan for each failure to report information on an adverse action required to be reported in accordance with section 1128E of the Act and § 1003.800(a)(2).

§ 1003.820 Determinations regarding the amount of penalties.

In determining the amount of any penalty in accordance with this subpart,

⁷The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

the OIG will consider the factors listed in § 1003.140.

Subpart I—CMPs for Select Agent Program Violations

§ 1003.900 Basis for civil money penalties.

The OIG may impose a penalty against any person who it determines in accordance with this part is involved in the possession or use in the United States, receipt from outside the United States or transfer within the United States, of select agents and toxins in violation of sections 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73.

§ 1003.910 Amount of penalties.

For each individual violation of section 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73, the OIG may impose a penalty of not more than \$250,000 in the case of an individual, and not more than \$500,000 in the case of any other person.⁸

§ 1003.920 Determinations regarding the amount of penalties.

In considering the factors listed in § 1003.140, aggravating circumstances include:

(a) The Responsible Official participated in or knew, or should have known, of the violation;

(b) The violation was a contributing factor to an unauthorized individual's access to or possession of a select agent or toxin, an individual's exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from the person's physical location as identified on the person's certificate of registration; or

(c) The person previously received an observation, finding, or other statement of deficiency from the Department or the Department of Agriculture for the same or substantially similar conduct.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

§ 1003.1000 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines offers or transfers remuneration (as defined in § 1003.110) to any individual eligible for benefits under Medicare or a State health care program that such person knows, or should know, is likely to influence such individual to order or to receive from a particular provider, practitioner, or supplier, any item or

⁸The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(b) The OIG may impose a penalty against any person who it determines offered any financial or other incentive for an individual entitled to benefits under Medicare not to enroll, or to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A) of the Act.

§ 1003.1010 Amount of penalties and assessments.

The OIG may impose a penalty of not more than⁹—

(a) \$10,000 for each item or service for which payment may be made, in whole or in part, under Medicare or a State health care program, ordered by or received from a particular provider, practitioner, or supplier for a beneficiary who was offered or received remuneration in violation of § 1003.1000(a) that was likely to influence the beneficiary to order or receive the item or service from the provider, practitioner, or supplier, and an assessment of not more than 3 times the amount claimed for each such item or service and

(b) \$5,000 for each individual violation of § 1003.1000(b).

§ 1003.1020 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In determining the amount of any penalty or assessment or the period of exclusion under this subpart, the OIG will consider the factors listed in § 1003.140, as well as the amount of remuneration or the amount or nature of any other incentive.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

§ 1003.1100 Basis for civil money penalties.

The OIG may impose a penalty against any person who—

(a) Knowingly and willfully makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact with respect to—

(1) The compliance of any policy with the standards and requirements for Medicare supplemental policies set forth in section 1882(c) of the Act or in promulgating regulations, or

(2) The use of the emblem designed by the Secretary under section 1882(a)

of the Act for use as an indication that a policy has received the Secretary's certification;

(b) Falsely assumes or pretends to be acting, or misrepresents in any way that he or she is acting, under the authority of or in association with Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands, or obtains money, paper, documents, or anything of value;

(c) Knowingly, directly, or through his or her agent, mails or causes to be mailed any matter for the advertising, solicitation, or offer for sale of a Medicare supplemental policy, or the delivery of such a policy, in or into any State in which such policy has not been approved by the State commissioner or superintendent of insurance;

(d) Issues or sells to any individual entitled to benefits under Part A or enrolled under Part B of Medicare—

(1) A health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under Medicare or Medicaid,

(2) A health insurance policy (other than a Medicare supplemental policy) with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law,

(3) In the case of an individual not electing a Part C plan, a Medicare supplemental policy with knowledge that the individual is entitled to benefits under another Medicare supplemental policy, or

(4) In the case of an individual electing a Part C plan, a Medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Part C plan or under another Medicare supplemental policy;

(e) Issues or sells a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III)) to any individual entitled to benefits under Medicare Part A or enrolled under Medicare Part B who is applying for a health insurance policy and fails to furnish the appropriate disclosure statement described in section 1882(d)(3)(A)(vii); or

(f) Issues or sells a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Medicare Part B without obtaining the written statement or the written acknowledgment described in section 1882(d)(3)(B) of the Act.

§ 1003.1110 Amount of penalties.

The OIG may impose a penalty of not more than¹⁰—

(a) \$5,000 for each individual violation of § 1003.1100(a), (b), or (c).

(b) \$25,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is also the issuer of the policy; and

(c) \$15,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is not the issuer of the policy.

§ 1003.1120 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart L—CMPs for Drug Price Reporting

§ 1003.1200 Basis for civil money penalties.

The OIG may impose a penalty against—

(a) Any wholesaler, manufacturer, or direct seller of a covered outpatient drug that—

(1) Refuses a request for information by, or

(2) Knowingly provides false information to, the Secretary about charges or prices in connection with a survey being conducted pursuant to section 1927(b)(3)(B) of the Act; and

(b) Any manufacturer with an agreement under section 1927 of the Act that—

(1) Fails to provide any information required by section 1927(b)(3)(A) of the Act by the deadlines specified therein, or

(2) Knowingly provides any item information required by section 1927(b)(3)(A) or (B) of the Act that is false.

§ 1003.1210 Amount of penalties.

The OIG may impose a penalty of not more than¹¹—

(a) \$100,000 for each individual violation of § 1003.1200(a) or § 1003.1200(b)(2); and

(b) \$10,000 for each day that such information has not been provided in violation of § 1003.1200(b)(1).

§ 1003.1220 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart,

¹⁰The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

¹¹The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

⁹The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

the OIG will consider the factors listed in § 1003.140.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

§ 1003.1300 Basis for civil money penalties.

The OIG may impose a penalty against any individual who notifies, or causes to be notified, a skilled nursing facility, nursing facility, home health agency, a community care setting, of the time or date on which a survey pursuant to sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), or 1929(i) of the Act is scheduled to be conducted.

§ 1003.1310 Amount of penalties.

The OIG may impose a penalty of not more than \$2,000 for each individual violation of § 1003.1300.¹²

§ 1003.1320 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart N—[Reserved]

- 11. Add reserved subpart N.
- 12. Add subpart O to read as follows:

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

Sec.

- 1003.1500 Notice of proposed determination.
- 1003.1510 Failure to request a hearing.
- 1003.1520 Collateral estoppel.
- 1003.1530 Settlement.
- 1003.1540 Judicial review.
- 1003.1550 Collection of penalties and assessments.
- 1003.1560 Notice to other agencies.
- 1003.1570 Limitations.
- 1003.1580 Statistical sampling.
- 1003.1590 Effect of exclusion.
- 1003.1600 Reinstatement.

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

§ 1003.1500 Notice of proposed determination.

(a) If the OIG proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in all Federal health care programs, as applicable, in accordance with this part, the OIG must serve on the respondent, in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure, written notice

of the OIG's intent to impose a penalty, an assessment, and an exclusion, as applicable. The notice will include—

(1) Reference to the statutory basis for the penalty, assessment, and exclusion;

(2) A description of the violation for which the penalty, assessment, and exclusion are proposed (except in cases in which the OIG is relying upon statistical sampling in accordance with § 1003.1580, in which case the notice shall describe those claims and requests for payment constituting the sample upon which the OIG is relying and will briefly describe the statistical sampling technique used by the OIG);

(3) The reason why such violation subjects the respondent to a penalty, an assessment, and an exclusion,

(4) The amount of the proposed penalty and assessment, and the length of the period of proposed exclusion (where applicable);

(5) Any factors and circumstances described in this part that were considered when determining the amount of the proposed penalty and assessment and the length of the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of the respondent's right to a hearing and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment, and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the respondent's provider agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the OIG has proposed the imposition of a penalty, an assessment, or an exclusion may appeal such proposed penalty, assessment, or exclusion to the Departmental Appeals Board in accordance with 42 CFR 1005.2. The provisions of 42 CFR part 1005 govern such appeals.

(c) If the respondent fails, within the time period permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

§ 1003.1510 Failure to request a hearing.

If the respondent does not request a hearing within 60 days after the notice prescribed by § 1003.1500(a) is received, as determined by 42 CFR 1005.2(c), by the respondent, the OIG may impose the proposed penalty, assessment, and exclusion, or any less severe penalty,

assessment, or exclusion. The OIG shall notify the respondent in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of any penalty, assessment, and exclusion that have been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, an assessment, or an exclusion with respect to which he or she has not made a timely request for a hearing under 42 CFR 1005.2.

§ 1003.1520 Collateral estoppel.

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

(b) In a proceeding under this part, a person is estopped from denying the essential elements of the criminal offense if the proceeding—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action.

§ 1003.1530 Settlement.

The OIG has exclusive authority to settle any issues or case without consent of the ALJ.

§ 1003.1540 Judicial review.

(a) Section 1128A(e) of the Act authorizes judicial review of a penalty, an assessment, or an exclusion that has become final. The only matters subject to judicial review are those that the respondent raised pursuant to 42 CFR 1005.21, unless the court finds that extraordinary circumstances existed that prevented the respondent from raising the issue in the underlying administrative appeal.

(b) A respondent must exhaust all administrative appeal procedures established by the Secretary or required by law before a respondent may bring an action in Federal court, as provided in section 1128A(e) of the Act, concerning any penalty, assessment, or exclusion imposed pursuant to this part.

(c) Administrative remedies are exhausted when a decision becomes final in accordance with 42 CFR 1005.21(j).

§ 1003.1550 Collection of penalties and assessments.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the

¹²This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

case of the Maternal and Child Health Services Block Grant Program, in which the collection will be the responsibility of the Public Health Service (PHS); in the case of the Social Services Block Grant program, in which the collection will be the responsibility of the Administration for Children and Families; and in the case of violations of subpart I, collection will be the responsibility of the Program Support Center (PSC).

(b) A penalty or an assessment imposed under this part may be compromised by the OIG and may be recovered in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The amount of penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States Government or a State agency to the person against whom the penalty or assessment has been assessed.

(d) Matters that were raised, or that could have been raised, in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 1003.1560 Notice to other agencies.

(a) Whenever a penalty, an assessment, or an exclusion becomes final, the following organizations and entities will be notified about such action and the reasons for it: The appropriate State or local medical or professional association; the appropriate quality improvement organization; as appropriate, the State agency that administers each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies);

and the long-term-care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

(b) When the OIG proposes to exclude a nursing facility under this part, the OIG will, at the same time the facility is notified, notify the appropriate State licensing authority, the State Office of Aging, the long-term-care ombudsman, and the State Medicaid agency of the OIG's intention to exclude the facility.

§ 1003.1570 Limitations.

No action under this part will be entertained unless commenced, in accordance with § 1003.1500(a), within 6 years from the date on which the violation occurred.

§ 1003.1580 Statistical sampling.

(a) In meeting the burden of proof in 42 CFR 1005.15, the OIG may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment, as described in this part, that were presented, or caused to be presented, by the respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment, as described in this part.

(b) Once the OIG has made a prima facie case, as described in paragraph (a) of this section, the burden of production shall shift to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The OIG will then be given the opportunity to rebut this evidence.

§ 1003.1590 Effect of exclusion.

The effect of an exclusion will be as set forth in 42 CFR 1001.1901.

§ 1003.1600 Reinstatement.

A person who has been excluded in accordance with this part may apply for

reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of 42 CFR 1001.3001 through 1001.3004.

PART 1005—[AMENDED]

■ 13. The authority citation for part 1005 continues to read as follows:

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

■ 14. Section 1005.4 is amended by republishing paragraph (c) introductory text and revising paragraphs (c)(5) and (6) to read as follows:

§ 1005.4 Authority of the ALJ.

* * * * *

(c) The ALJ does not have the authority to—

* * * * *

(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act or under part 1003 of this chapter, or determine the scope or effect of the exclusion;

(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero, in any case in which the ALJ finds that an individual or entity committed an act described in section 1128(b) of the Act or under part 1003 of this chapter; or

* * * * *

Dated: August 3, 2016.

Daniel R. Levinson,
Inspector General.

Approved: August 4, 2016.

Sylvia M. Burwell,
Secretary.

Note: This document was received by the Office of the Federal Register on November 18, 2016.

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