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Proposed OIG Rules Amending Regulations Governing Exclusion and Civil Monetary Penalties: More Than Meets the Eye?



By Howard Young, Holly Barker and Jake Harper

The Department of Health and Human Services Office of Inspector General proposed to amend its exclusion and Civil Monetary Penalties Law regulations. After five years of hearing the OIG's firm message that it will use its sanction authorities to hold health-care executives, owners and other individuals accountable, the two proposed rulemakings appear to shore up OIG's arsenal to do just that.

The Exclusion Proposed Rule[1] and CMPL Proposed Rule[2] (collectively, the Proposed Rules) are principally aimed at implementing certain Affordable Care Act (ACA) provisions and elaborating on OIG interpretation of its current authorities.

[1] 79 Fed. Reg. 26810 (May 9, 2014).
[2] 79 Fed. Reg. 27080, 27081 (May 12, 2014).

Young (hyoung@morganlewis.com is a partner at Morgan, Lewis & Bockius LLP, Washington; Barker (hbarker@morganlewis.com) and Harper (jharper@morganlewis.com) are associates.

When taken together, the Proposed Rules would expand OIG's authority to impose administrative sanctions, but also provide OIG with greater discretion and flexibility in the exercise of its program integrity functions. The Proposed Rules may also show evidence of OIG's desire to bolster its enforcement reach and hold individuals and industry participants accountable.

Although much of the proposed rulemaking is focused on ACA regulatory implementation and "good housekeeping" reorganization to make the regulations better organized and more readable, there are certain proposals, such as dispensing with a statute of limitations for affirmative exclusion actions, that merit closer attention, as discussed below.

OIG notes in its CMPL Proposed Rule that the separate rulemakings stand on their own, inviting comment on each rulemaking, but there is clear overlap in subject matter and sanctionable conduct between the Proposed Rules. Accordingly, those who wish to comment on the Proposed Rules may wish to understand and address them together. Public comments are due July 8 on the Exclusion Proposed Rule and on July 11 on the CMPL Proposed Rule.

The table below shows the various ACA exclusion and CMPL provisions for which OIG proposes new regulations.

Changes Mandated by ACA	
Exclusion	**CMPs**
Permissive exclusion authorized for: ■ Conviction of an offense in connection with obstruction of an audit (ACA § 6408(c); 42 CFR § 1001.301[3]); ■ Failure to supply payment information by ordering, re-	CMPs authorized for: ■ Failure to grant OIG timely access to records (ACA § 6408(a); 42 CFR 1003.200(b)(10)); ■ Ordering or prescribing while excluded (ACA

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Changes Mandated by ACA	
Exclusion	**CMPs**
ferring, or certifying physicians (ACA § 6406(c); 42 CFR § 1001.1201); ■ Knowingly making, or causing to be made, any false statement, omission, or misrepresentation of a material fact on a Federal health care program application (ACA § 6402(d); 42 CFR § 1001.1751).	§ 6402(d)(2)(A); 42 CFR § 1003.200(b)(6)); ■ Knowingly making, or causing to be made, any false statement, omission, or misrepresentation of a material fact on a Federal health care program application (ACA § 6408(d)(2)(A); 42 CFR § 1003.200(b)(7)); ■ Failure to timely report and return an identified overpayment (ACA § 6402(d)(2)(A); 42 CFR § 1003.200 (b)(8)); ■ Making or using a false record or statement material to a false or fraudulent claim. (ACA § 6408(a); 42 CFR § 1003.200(b)(9)).
OIG may issue testimonial subpoenas in exclusion actions (ACA § 6402(e); 42 CFR § 1006.1).	Penalties and assessments may be imposed against an MA or Part D contracting organization for acts of its providers/suppliers, significantly broadening general liability of principals for actions of their agents and contractors (ACA § 6408(b)(2); 42 CFR § 1003.400).
Expansion of OIG waiver authorities to consider impact on all Federal health care program beneficiaries (ACA § 6402(k); 42 CFR § 1001.1801).	Penalties and assessments may be imposed against an MA or Part D contracting organization for enrollment/transfer violations. (ACA § 6408(b)(2); 42 CFR § 1003.400).

[3] CFR citations are those designated in the Proposed Rules.

A. Expanded Exclusion Authority

In addition to the new authorities set out in the table above, the Exclusion Proposed Rule implements ACA's expansion of OIG authority to issue testimonial subpoenas in exclusion investigations (similar to DOJ's testimonial Civil Investigative Demands and OIG's own authority in CMPL investigations).[4]

This expanded investigative tool will assist OIG's agents to gather and assess evidence in its exclusion investigations of individuals. For instance, in its Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act, related to officers or managing employees of an entity that has been excluded or convicted of certain offenses, OIG stated when there is evidence that an owner, officer or a managing employee knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion, but must gather evidence on what the individual knew or should have known.[5]

In this Guidance, the agency further explains that OIG and its law enforcement partners will focus on developing effective investigative plans to address this need to obtain further supportive evidence of knowledge.[6] The current Exclusion Proposed Rule makes clear OIG's continued desire to hold individuals more accountable for their actions, even if an investigation had resulted in action against a corporate organization.

Additional noteworthy proposed regulatory changes relate to (1) early reinstatement of individuals excluded in connection with license revocation or suspension; (2) expansion of the OIG's authority to waive exclusion where in the program or beneficiaries' interest; and (3) some modest changes to aggravating and mitigating factors.

Finally, and perhaps most significantly, OIG also announced its intention to eliminate the statute of limitations with respect to permissive exclusions under SSA § 1128(b)(7) (for fraud, false claims and kickback violations), creating an enhanced risk for individuals affiliated with entities that have been subject to False Claims Act ("FCA") investigations and settlements.

OIG's Proposal to Eliminate the Period of Limitations for SSA § 1128(b)(7) Exclusions

OIG has made no bones about its interest to hold health-care executives and owners accountable under its exclusion authority. It must also be remembered that, based upon regulations crafted by OIG in 1992, Administrative Law Judges (ALJs) have no authority to question OIG's exercise of its discretion to exclude.[7]

Consequently, any proposed expansion of OIG's exclusion authority or its interpretation of those authorities must be understood in the context of an enforcement agency that can exercise its permissive exclusion authority (intended as a remedial tool, but with a distinctly punitive flavor) in a substantially unfettered manner. In general, ALJs may consider only (1) whether there was an underlying violation for which exclusion is authorized or (2) the length of exclusion.[8]

Perhaps motivated by a desire to reduce impediments to exclude more individuals arising from alleged FCA violations, including managing employees, executives and owners, OIG seeks in this proposed rulemaking to eliminate any statute of limitations for exclusion cases involving false claims. Following a Departmental Appeals Board decision in 1999, the OIG has applied a 6 year statute of limitations on its affirmative exclusion actions for false claims under SSA § 1128(b)(7).[9]

In 2000, OIG had proposed rulemaking clarifying its interpretive view that no statute of limitations for exclu-

[4] 79 Fed. Reg. at 26810.

[5] Office of Inspector General, *Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act*, (Oct. 2010) *available at* https://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

[6] *Id.*

[7] 57 Fed. Reg. 3330 (Jan. 29, 1992).

[8] *See* 42 CFR § 1001.2007.

[9] *See In Wesley J. Hammer v. IG*, DAB 1693 (1999).

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sions would apply to (b)(7) exclusions.[10] However, based on limited public comment, OIG determined in 2002 not to finalize that proposal.[11] Now, a dozen years later, OIG appears to have changed its mind.

Based upon preamble language in its 2002 rulemaking, OIG was persuaded to respect a statute of limitations for affirmative exclusions because of potential concerns about difficulty in gathering evidence after many years and the assertion that old conduct may not bear on a person's current trustworthiness.[12] But in its current Exclusion Proposed Rule, OIG asserts that those factors are outweighed by other factors that OIG now believes favor its interpretation that a limitless period of time to bring exclusion actions for false claims.

While OIG concedes that more recent acts are ''more indicative of current trustworthiness than acts that took place in the distant past,'' conduct more than 6 years old may form a proper basis to exclude a person.[13] OIG asserts the age of the conduct is but one factor to consider and, somewhat remarkably, a long passage of time from when the conduct occurred to an exclusion action will not prejudice the subject of the exclusion.[14]

OIG notes that SSA § 1128(b)(7) exclusions often arise out of civil FCA proceedings, where investigations can persist for years and can result in settlements of conduct well over 6 years old. OIG asserts it is helpful before deciding on exclusion to wait to see if a case is settled or if there is a civil judgment, and if restitution is made.[15] Under a current 6 year statute of limitations construct, in order to preserve its exclusion authority, OIG contends it may need to initiate an exclusion action prematurely to toll the statute of limitations, which can be disruptive to FCA cases.[16]

However, there are other factors and realities to consider. DOJ and federal judges are pushing for quicker intervention decisions, so FCA *qui tams* do not linger under seal for years. Conversely, DOJ is increasingly asserting its 10 year statute of limitations under the FCA and so the conduct at issue can be, in some instances, considerably older.

For conduct a decade ago or older, will an exclusion defendant be prejudiced by the ''one-sided discovery'' that manifests itself in most FCA investigations and settlements? Although almost all civil FCA settlements contain no admission of liability, will OIG try to use the settlement as a form of admission before an ALJ in an administrative proceeding in which the Federal Rules of Evidence do not necessarily apply?

OIG could also use allegations in an FCA complaint, even if not fully investigated or substantiated, as potential evidence the individual engaged in the knowing submission of false or improper claims or illegal kickbacks. With no statute of limitations, exclusion defendants may be at a distinct evidentiary disadvantage in demonstrating they should not be excluded.

If OIG adopts this ''no period of limitations'' interpretation, what might this mean as a practical matter? Individual employees, executives or former owners may find themselves defending against individual exclusion actions some years after the conduct at issue or years after a FCA settlement. It may mean that FCA litigants will feel the need to extend discovery before settlement discussions to establish a more robust and balanced record of why there was no FCA violation so as not to give OIG an opportunity to develop an exclusion case built on one-sided investigative files where the exclusion defendant had no meaningful opportunity to engage in discovery to establish exculpatory evidence. Most likely it will mean that parties settling FCA matters will push harder for individual exclusion releases.

Currently, OIG is loath to grant any individual exclusion releases in FCA settlements, but the prospect of exclusion actions many years later may well change the calculus of parties willing to settle, especially when the employees or executives who were involved (through commission or omission) in the alleged misconduct remain with the organization at the time of the settlement.

OIG Revises Exclusion Aggravating & Mitigating Factors: Pyrrhic Victory for Defendants

OIG has proposed certain modifications to the list of aggravating and mitigating factors it uses to determine the length of an exclusion.[17] Specifically, OIG has increased the dollar value thresholds for individuals or entities causing losses to Federal health care programs for which it will consider shortening or lengthening exclusions.

Under the proposed rule, a mitigating factor would exist if damages did not exceed $5,000 (up from $1,500) and an aggravating factor would exist if damages exceeded $15,000 (up from $5,000).[18] Moreover, OIG plans to remove all aggravating and mitigating factors from exclusions under 1128(b)(4) and (b)(5), since the length of exclusion for these sections is keyed to the underlying conduct (and thus aggravating and mitigating factors are generally irrelevant).[19]

While OIG's attempt to provide a more reasonable approach to balancing these factors is a good start, the practical application of the factors that OIG has modified may be fairly minimal. As may be readily discerned, the dollar values in nearly every matter OIG reviews will often exceed the threshold for aggravating factors ($15,000).

Furthermore, a number of other aggravating factors, including whether another governing entity at the federal, state, or local level has taken an adverse action against the individual or entity for the same conduct, remain intact without appropriate mitigating factors to balance them out. As far back as 1998, when OIG promulgated many of these factors, opponents identified a number of inequities and potential for misuse of the exclusion authority.[20]

Despite this criticism to develop a legitimate set of mitigating factors that might effectively balance out OIG's aggravating factors, OIG has declined to do so. With an opportunity to make meaningful changes to the aggravating and mitigating factor framework, OIG instead proposes largely cosmetic changes that will quickly trigger aggravating factors with a low likelihood of triggering mitigating factors.

OIG Offers Early Reinstatement for the Most Common Basis for Exclusion

[10] 65 Fed. Reg. 63035, 63035 (Oct. 20, 2000).
[11] 67 Fed. Reg. 11928, 11929 (Mar. 18, 2002).
[12] *Id.*
[13] 79 Fed. Reg. 26810, 26815.
[14] *Id.*
[15] *Id.*
[16] *Id.* at 26815-26816.
[17] *Id.* at 26813-814.
[18] *Id.*
[19] *Id.* at 26814.
[20] 63 Fed. Reg. 46676, 46680 (Sept. 2, 1998).

In a proposal that should offer helpful relief to many individuals on the OIG exclusion list, OIG intends to revise its approach for SSA § 1128(b)(4) exclusions (for license revocation or suspension)—currently the most common basis for exclusion. The length of exclusion for this basis was originally tied to the period a state board revoked or suspended a health care provider's license. However, OIG has observed that, in many instances, individuals have sought and obtained licensure either from boards from another state for the same profession or from a board from the original state for a different profession.[21]

Under the original regulations, these providers could not be reinstated for participation in Federal health care programs because the original licensing authority had not reinstated the individual's license. Under the Exclusion Proposed Rule, OIG plans to allow possible ''early reinstatement'' for those providers who have successfully obtained licensure after fully and accurately disclosing the circumstances of the original conduct to a different licensing authority.[22]

B. Expanded Authority to Impose Civil Monetary Penalties

The second of the two proposed rules, the CMPL Proposed Rule addresses OIG's authority to impose CMPs. Like the Exclusion Proposed Rule, it implements ACA provisions that expand OIG's enforcement authority and establishes new grounds upon which OIG may seek CMPs: (1) failing to grant OIG timely access to records; (2) ordering or prescribing (not just furnishing) health care items or services while excluded; (3) failing to report and return an overpayment within 60 days; (4) making a false statement, omission, or misrepresentation on an enrollment application; and (5) making or using a false claim material to payment.[23]

The proposed rule consolidates existing provisions and establishes a single list of factors to be taken into account in determining the severity of CMPs for any given violation.[24] While provisions addressing certain prohibited conduct may provide additional detail, under the CMPL Proposed Rule, the list of factors is meant to be universally applied to all CMPL violations.[25] Substantive changes to aggravating and mitigating factors include (1) increasing from $1,000 to $5,000 the dollar value cap to identify less serious offenses (a mitigating factor) and establishing a dollar threshold of $15,000 to identify more serious offenses (an aggravating factor);[26] (2) establishing levels of intent as a proxy for culpability;[27] and (3) expanding the prior conduct OIG may consider in imposing administrative sanctions.[28]

In the regulatory preamble, OIG clarifies that it may impose a penalty for each individual violation under any given provision that, despite the imposition of CMPs against a principal, an ''agent remains liable for his conduct and may not use the principal as a liability shield,'' and that joint and several liability applies when OIG imposes CMPs.[29] These ''clarifications'' seem to reiterate OIG's message to the industry that individuals will be held accountable for their conduct.

OIG is also expanding its authority with respect to Medicare Advantage (''MA'') Plans and Part D Sponsors, in part, by making them liable for actions of agents, such as network providers and suppliers. Under the CMPL Proposed Rule, MA Plans and Part D Sponsors could be subject to CMPs and assessments based on the same legal theory of agent-principle liability, in that network providers are acting on behalf of the Plan or Sponsor in furnishing items or services to Federal health care program beneficiaries. Because of this broadening of potential liability and in keeping with flow-down contracting principles, MA Plans and Sponsors may likely seek to revise their contracts to account for this added exposure.

OIG proposes a new methodology for calculating and applying penalties and assessments arising from employing, or contracting with, an excluded person or entity for the provision of items or services payable under a Federal health care program.[30] The CMPL Proposed Rule distinguishes between those items and services that may be separately billed (e.g., an outpatient prescription drug or physician service) and those that may not be separately billed (e.g., a bundled payment such as a hospital inpatient DRG payment), and includes two new definitions for ''separately billable item or service'' and ''non-separately-billable item or service.''[31]

CMPs Associated With Employing/Contracting With Excluded Persons

OIG proposes an approach to calculating penalties to account for situations where it would be excessive and punitive to deny payment for the entirety of the claim – *i.e.*, situations where the value of the service or item cannot be wholly attributed to a single excluded individual.[32] Specifically, OIG proposes for ''non-separately-billable items or services'' a per-day penalty for the number of days an excluded person was employed or under contract and assessments based on the total costs to the employer or contractor of the contractual relationship (e.g., salary plus fully loaded benefits).[33]

An example of this is per diem payments made to skilled nursing facilities under Medicare's prospective payment system. Many individuals participate in providing care to a resident in a skilled nursing facility; OIG believes it would be excessively punitive to prohibit the entire payment because one excluded individual participated in the provision of care. The authors agree.

That said, although granting itself with regulatory discretion to apply penalties and assessments for excluded persons involved in furnishing non-separately-billable items or services is helpful in seeking a proportional resolution, applying the new proposed methodology could represent an upward departure for OIG from the settlement methodology it has often applied in the past when it used a ''salary and benefits'' measure to settle excluded persons matters and not a per-day employment penalty on top of that. For separately billable items or services, OIG notes that its CMP calculation

[21] 79 Fed. Reg. at 26814.
[22] *Id.*
[23] *See* authors' table at 1, ''Changes Mandated by ACA,'' for corresponding ACA and CFR citations.
[24] 79 Fed. Reg. at 27082, 27094.
[25] *See Id.*
[26] *Id.* at 27082.
[27] *Id.* at 27082, 27094.
[28] *Id.* at 27082-3, 27094.
[29] *Id.* at 27083.
[30] *Id.* at 27084.
[31] *Id.* at 27085, 27093, 27096.
[32] *Id.* at 27085.
[33] *Id.* at 27085, 27096.

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would continue to be based simply on the number and value of those distinct items and services furnished or ordered by the excluded individual.[34]

In its discussion of the proposed calculation methodology in the regulatory preamble, OIG emphasizes that ''each person who is in the supply chain or who has a role in the process that leads to an item or a service being provided'' is capable of tainting, so to speak, a claim for an item or service, if that person or entity is excluded.[35] CMP liability (jointly or severally) will attach to the person that submits the claim, where that person knows or should have known of the excluded individual.[36]

That knowledge standard provides some limitation on liability, but leaves open the question of what suffices for reasonable inquiry (so that you discover what you should know and can avoid liability altogether). After well over a decade of touting the importance of exclusion screening and making its List of Excluded Individuals and Entities more accessible, OIG readily takes the position that any Medicare and/or Medicaid participating provider or supplier should know if one of its employees or contractors is excluded, even in the absence of a direct legal requirement to screen for excluded persons.

Pushing that broad ''strict liability'' knowledge standard down the supply chain to distributors and manufacturers and other indirect industry participants is more challenging as a practical matter. For example, to what end does a diagnostic lab have to go to in order to vet the supplier that provides a reagent it needs to run a particular test? Is a strong ''excluded person'' representation and warranty in a vendor agreement sufficient?

The CMPL Proposed Rule preamble also reiterates OIG's position that a prescription drug is a separately billable item and if an excluded pharmacist dispenses that prescription, the dispensing fee and payment for the drug (item) are not payable.[37] But this analysis may be overly simplistic as, for example, a pharmacist may be involved in only one of multiple steps leading to the dispensing of a prescription drug. Interestingly, as an example of a ''non-separately-billable item or service'' OIG uses an example of ''radiology technician services associated with a specific procedure.''[38]

For CMP liability purposes associated with excluded persons, it is difficult to distinguish meaningfully between a pharmacist who, for example, only conducts a drug utilization review check at a computer terminal (leaving other dispensing acts to other pharmacists and technicians) and a radiology technician who performs the test but leaves a professional interpretation to others.

With its grant of considerable discretion, hopefully OIG would consider all such factors and not apply a mathematical formula for CMP liability assessment based simply on the number and value of separately billable items. Obviously, in ratcheting up CMPs and assessments for excluded persons, the value of effective exclusion screening for health care organizations becomes even greater.

[34] *Id*.
[35] *Id*. at 27085.
[36] *Id*. at 27084-85, 27095.
[37] *Id.* at 27085.
[38] *Id.*

CMP Liability Arising From Failure to Return Overpayment

ACA § 6402(a) imposes an obligation to report and refund identified Medicare and Medicaid overpayments within 60 days or by the date any corresponding cost report is due. The Secretary had proposed a regulation on the reporting and refund of Medicare Part A and Part B identified overpayments on February 16, 2012[39] that garnered considerable attention, including its proposed 10-year lookback period.

The Secretary has not finalized that proposed rule, perhaps in part due to the complex issues inherent in the statutory obligation. On January 10, 2014, the Secretary proposed a rule for the reporting and refund of Medicare Advantage and Part D Sponsor overpayments, with a six-year lookback period.[40] With considerable regulatory uncertainty arising from CMS's proposed rules regarding ACA § 6402 refund and reporting obligations, the authors wonder whether CMPL rulemaking relating to that violation is perhaps premature.

The ACA authorized CMPs for certain knowing failures to report and return an overpayment[41]; it did not, however, provide any guidance as to how such CMPs were to be calculated. OIG has proposed to apply the default CMP penalty of up to $10,000 as applied to each day a person fails to report and return an identified overpayment beyond the 60-day deadline.[42] It has solicited comments on this interpretation.

In addition, OIG solicited comments on whether it might be more appropriate to apply the up-to-$10,000 penalty to each item or service as pertaining to each claim for which the provider identified an overpayment.[43] Citing two other provisions where daily penalties are provided for explicitly, OIG suggests that if Congress had meant for a daily penalty to apply, it could have said so explicitly.[44] Under either calculation methodology, the potential CMP liability could mount quickly.

Aggravating/Mitigating Factors

As previously noted, to enhance the readability of its regulations and for consistency, OIG has created a single consolidated list of potentially aggravating or mitigating factors to be considered for purposes of determining the severity of penalties to be applied. Significantly, the CMPL Proposed Rule also clarifies that the same list is to be used for determining whether or not exclusion is appropriate in the first instance.[45]

[39] Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179 (Feb. 16, 2012)
[40] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918 (Jan. 10, 2014).
[41] ACA § 6402(d).
[42] 79 Fed. Reg. at 27086.
[43] *Id.*
[44] *Id.* (''However, we note that Congress specified a per day penalty in sections 1128(a)(4) and (12) and did not do so for section 1128(a)(10). Thus, we also solicit 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.'')
[45] *Id.* at 27082 (''the proposed changes also clarify that these factors apply to both exclusion determinations made under part 1003 as well as penalty and assessment amount determinations'').

In addition to consolidating the aggravating and mitigating factors into a single list, OIG proposes making a few substantive changes.

First, OIG proposes to increase the threshold dollar amount that corresponds to the seriousness of the offense; the changes mirror those made for purposes of determining the length of exclusion.[46]

Second, OIG defines the levels of intent (depending on the underlying scienter requirement for the offense) that indicate an individual's culpability.[47] Third, it expands the scope of prior conduct that may be considered in imposing administrative sanctions;[48] for example, an offense in connection with a commercial program may now be weighed against someone in an OIG enforcement action related to Federal health care programs.

As a mitigating factor, OIG will consider appropriate and timely corrective action; however, OIG will not consider corrective action unless the violation was disclosed to OIG utilizing its Self-Disclosure Protocol (''SDP'').[49] The narrow scope of this mitigating factor raises important questions insofar as this would seem to preclude any benefit associated with legitimate disclosures to other enforcement or regulatory bodies, including the Department of Justice, a state Attorney General, CMS or its contractors and Medicaid agencies.

Particularly when CMS and state Medicaid agencies have encouraged voluntary disclosures through their development of forms and processes of voluntary reporting of overpayments, the authors question why OIG would not grant itself the discretion to consider as a mitigating factor a bona fide disclosure that was made through channels other than the OIG SDP.

All told, the proposed changes to the aggravating and mitigating factors provide little practical benefit to potential CMP defendants. Notably, if a single aggravating circumstance is present, the highest penalties and assessments may be applied and the person could also be excluded.[50]

Ability to Pay

OIG's CMPL Proposed Rule requires production of ''sufficient financial documentation, including audited financial statements, tax returns, and financial disclosure statements,'' and provides that aggravating and mitigating factors will be considered in assessing ability to pay.[51] The CMPL Proposed Rule provides that, in general, penalties and assessments should, in aggregate, be at least double the amount of damages and costs sustained by the government.[52] (This is in contrast to OIG's rule of thumb for self disclosures under its SDP when OIG often applies a 1.5x damages multiplier.) Under the CMPL Proposed Rule, if the defendant requests an appeal, no new evidence of ability to pay may be submitted, unless the ALJ finds ''extraordinary circumstances'' prevented the person from providing the information to OIG sooner. [53]

In light of OIG's expanded authority to impose CMPs and its apparent intent to exercise its enforcement authority more aggressively, the specter and leverage associated with extraordinarily high CMPs could result in a significantly enhanced enforcement tool for OIG. If it comes down to ability to pay, a defendant should be thorough and should identify all of its financial risks and liabilities.

If possible, a working dialogue is helpful to ensuring that all of OIG's questions on ability to pay are answered completely, so that if the defendant is faced with appealing an ability to pay finding before an ALJ, it is working from a complete and well-developed record.

C. Conclusion

The Proposed Rules implement the required elements of ACA, but the OIG has also used this rulemaking opportunity to assert expansion of its authorities. OIG proposes to make certain concessions as well, such as relaxed exclusion waivers and early reinstatement for narrow circumstances.

However, through the use of its testimonial subpoena power and a perhaps endless look-back period for affirmative exclusions under SSA § 1128(b)(7), OIG could focus more intensely on individuals they believe lack present trustworthiness or are to blame for sanctionable conduct.

We expect that this will result in continued focus on individual accountability at the corporate and board levels, consistent with OIG's recent exclusion efforts in *Purdue*[54] and lengthy exclusion agreements it has negotiated recently with owners and executives of health care businesses.

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[46] *Id.*

[47] *Id.* at 27082, 27094.

[48] *Id.*

[49] *Id.*

[50] *Id.* at 27084 (''if any single aggravating circumstance is present: (1) the imposition of a penalty and assessment at or close to the maximum amount may be justified and (2) if exclusion is available, the person should be excluded'').

[51] *Id.* at 27083, 27094.

[52] *Id.* at 27094.

[53] *Id.* at 27083.

[54] *Friedman v. Sebelius*, 2012 BL 190046, No. 11-5028 (D.C. Cir. July 27, 2012).

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