ReedSmith

The business of relationships.SM

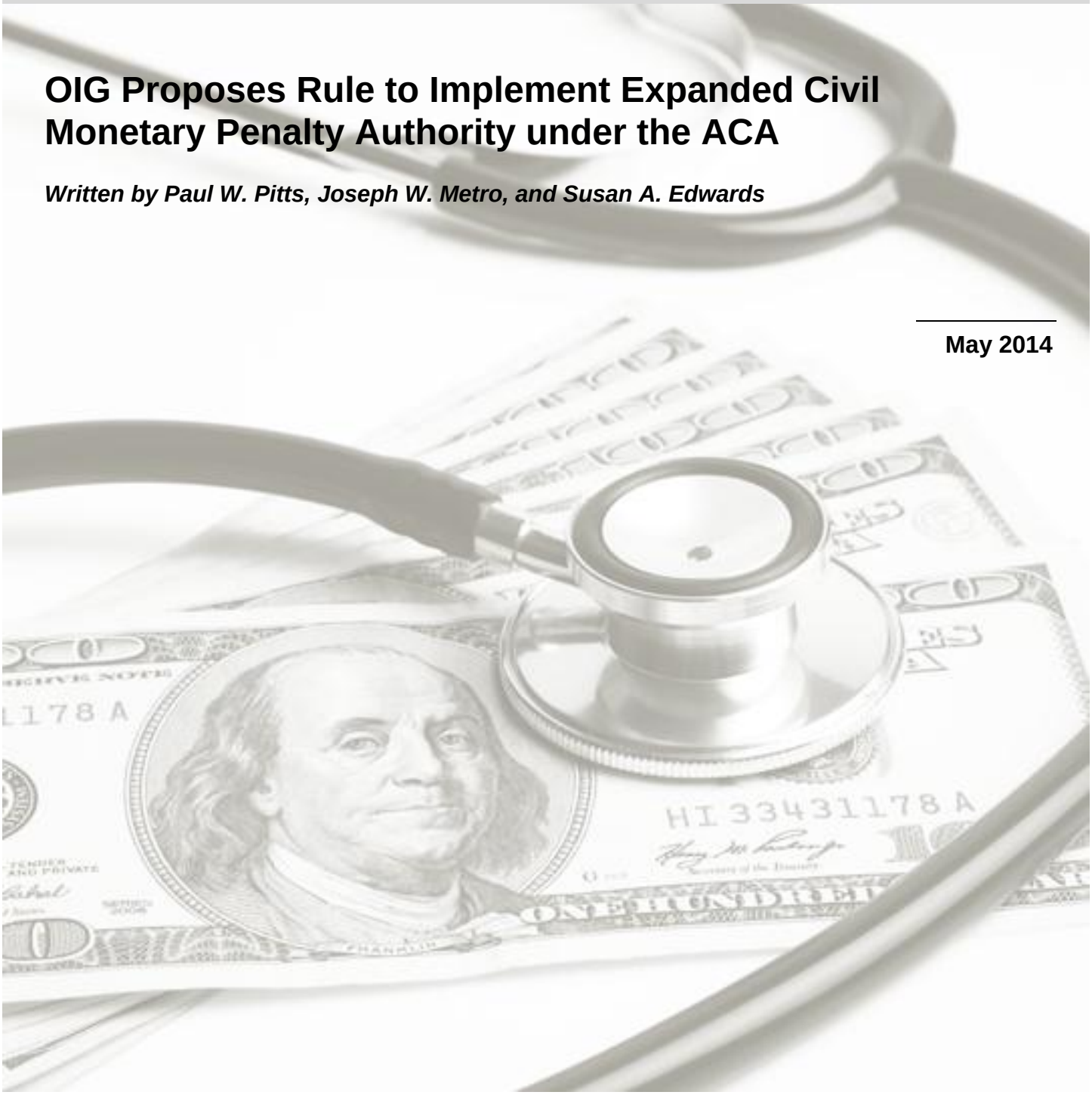
Client Alert

Life Sciences Health Industry Group

OIG Proposes Rule to Implement Expanded Civil Monetary Penalty Authority under the ACA

Written by Paul W. Pitts, Joseph W. Metro, and Susan A. Edwards

May 2014



ReedSmith

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

Paul W. Pitts
Partner, San Francisco
+1 415 659 5971
ppitts@reedsmith.com

Joseph W. Metro
Partner, Washington, D.C.
+1 202 414 9284
jmetro@reedsmith.com

Susan A. Edwards
Associate, Washington, D.C.
+1 202 414 9261
saedwards@reedsmith.com

…or the Chair of the Life Sciences Health Industry Group

Carol C. Loepere
Partner, Washington, D.C.
+1 202 414 9216
cloepere@reedsmith.com

Table of Contents

Page

ReedSmith

OIG Proposes Rule to Implement Expanded Civil Monetary Penalty Authority under the ACA

Written by Paul W. Pitts, Joseph W. Metro, and Susan A. Edwards

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) has published a proposed rule that would amend the health care program civil monetary penalty (CMP) regulations (Proposed Rule).[1] Notably, the Proposed Rule would codify the OIG's expanded statutory authority under the Affordable Care Act (ACA) to impose CMPs on providers and suppliers and would allow for significant penalties in a variety of scenarios. For example, the Proposed Rule would permit the OIG to impose $10,000 *per day* penalties on providers and suppliers who fail to timely report and return an identified overpayment. Furthermore, the Proposed Rule would allow the OIG to impose $10,000 *per day* penalties—at the 9-digit NDC level—on drug manufacturers who fail to timely report and certify drug-pricing data. Such proposals could increase the OIG's ability to leverage substantial penalties beyond that which is permitted under current regulations. Likewise, the OIG would codify its expanded authority under the ACA to permit CMPs for conduct including:

- Failure to grant OIG timely access to records, upon reasonable request;
- 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;
- Making false statements, omissions, or misrepresentations in an enrollment or similar bid or application to participate in a federal health care program; and
- Making or using a false record or statement that is material to a false or fraudulent claim.

In addition, the OIG proposes to reorganize and clarify current regulations the agency describes as "cumbersome" and "confusing." The OIG estimates that the Proposed Rule would increase the government's CMP collections, which have ranged from $10.2 million to $26.2 million per year over the past decade. Comments on the Proposed Rule are due *July 11, 2014*. Our analysis of major provisions of the Proposed Rule follows.

Note that the OIG published the Proposed Rule on the heels of another OIG proposal related to the agency's exclusion authorities; Reed Smith has prepared a separate client alert analyzing the exclusion authority proposed rule.

---

[1] 79 Fed. Reg. 27,080 (May 12, 2014).

Overpayments

Under the ACA, a person who receives an overpayment must report and return the overpayment to CMS, the state, an intermediary, a carrier, or a Medicare Administrative Contractor (MAC), as appropriate. The ACA defines "overpayment" as any fund that a person receives or retains under the Medicare or Medicaid program to which the person, after applicable reconciliation, is not entitled. A "person" who receives an overpayment is defined broadly to encompass individuals and entities, including any provider or supplier of items and services under the federal health care programs. When returning an overpayment the person must provide, to whomever the overpayment was returned, written notification of the reason for the overpayment.

The ACA established the deadline for reporting and returning overpayments as the later of 60 days after identification of the overpayment or by the date that the corresponding cost report is due (as applicable). However, the ACA left unanswered what constitutes "identification" of an overpayment. Because of the complexity of billing for some items and services, Medicare and Medicaid providers and suppliers are, at times, faced with a difficult challenge in determining (or "identifying") whether or not a particular claim caused an overpayment. Without clarifying *when* an identification of an overpayment occurs, the Proposed Rule would impose a significant monetary penalty on anyone retaining an overpayment after the 60-day period or cost report due date, as applicable. While the ACA modified the Social Security Act (SSA) to permit a $10,000 penalty for failing to report and return overpayments on a timely basis, the statute states that such penalty may be applied "for each item or service."[2] Under the Proposed Rule, the OIG would interpret such statutory penalty as up to $10,000 for *each day* a person fails to report and return an overpayment by the applicable deadline. The OIG is seeking public comment on its proposal to allow a per day assessment of the penalty. Due to the significance and potential magnitude of the proposed penalties and the frequency with which providers and suppliers face potential overpayments, the industry should consider recommending an alternative methodology for calculating potential penalties for failing to report and return an overpayment.

Access to Records

The OIG proposes adding a penalty not to exceed $15,000 per day for failing to grant timely access to records, upon reasonable request, to OIG for the purpose of audits, investigations, evaluations, or other statutory functions, as authorized by the ACA. A failure to grant timely access would primarily arise under one of two circumstances: (1) failing to produce the requested material by the deadline specified in the OIG's written request; or (2) failing to provide immediate access to the requested materials when the OIG asserts that it has reason to believe the material is about to be altered or destroyed. Any penalties for failing to grant timely access

[2] 42 U.S.C. § 1320a–7a(a).

would be in addition to the OIG's existing authority to exclude a person from the federal health care programs for failing to grant access under 42 C.F.R. § 1001.1301.

The Proposed Rule would give the OIG wide latitude to specify the date on which the responding party must provide access to the requested materials. The OIG proposes to define the term "reasonable request" as "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" and would include, among other details, the deadline by which the OIG requests access.[3] In the preamble, the OIG indicates that in setting the deadline it would consider the circumstances of the request, including the volume of material, size and capabilities of the party subject to the request, and the OIG's need for the material in a timely way to fulfill its responsibilities. However, nothing in the Proposed Rule guarantees a responding party a minimum amount of time in which to provide a response.

Ordering or Prescribing While Excluded

The Proposed Rule would permit the OIG to penalize persons who order or prescribe items or services 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. The OIG would be permitted to impose an assessment of not more than three times the amount for each item or service wrongfully claimed, in accordance with statute.

False Statements

The Proposed Rule would authorize the OIG to impose a penalty not to exceed $50,000 for each false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier under a federal health care program. The OIG is proposing to broaden, in a material way, the authority for this penalty as granted by the ACA. While the ACA authorized penalties for false statements and misrepresentations of material fact, it did not include the word "omission" in describing the penalty. In the preamble to the Proposed Rule, the OIG simply asserts that including "omission" is necessary "to give full effect to the amendment."

Making or Using a False Record or Statement

As mandated by the ACA, the OIG proposes adding a penalty not to exceed $50,000 for each false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal health care program.

---

[3] 79 Fed. Reg. 27,080, 27,093 (May 12, 2014).

Penalties for Employing Excluded Individuals

The SSA currently permits penalties for arranging or contracting with an individual or entity excluded from a federal health care program (such as Medicare or Medicaid) for the provision of items or services which may be paid by a federal health care program.[4] In the Proposed Rule, the OIG restates its broad view that "the provision of items or services" includes every person or entity involved in any way in the furnishing of the item or services that are billed to the federal health care program:

> Thus, an excluded pharmacist furnishes or provides every prescription that he or she fills. Each prescription is separately billable, and under the [Civil Monetary Penalties Law], OIG may collect the full amount of each prescription the pharmacist fills while excluded. This analysis extends to each person who is in the supply chain or who has a role in the process that leads to an item or a service provided. For example, a manufacturer, a wholesaler, and a distribut[o]r have all participated in providing an item or a service.[5]

The OIG recognizes, however, that individuals and entities may be involved in the provision of items and services in a variety of ways, and thus delineates between: (1) the furnishing, providing, ordering, or prescribing of *separately billable* items or services (*e.g.*, a physician office visit identifying a specific physician furnishing the services and a diagnostic test ordered by a physician); and (2) the provision of items or services included as *a component* of a separately billable item or service (*e.g.*, a nurse in a physician's office who contributes to a patient's office visit and the services furnished by a radiology technician during a procedure).[6]

For items and services that are separately billable, the Proposed Rule would permit the OIG to impose a penalty of not more than $10,000 for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual, plus an assessment of not more than three times the amounts billed for such items or services.[7] This is the same methodology currently employed by the OIG. For excluded persons where the items and services are *not* separately billable, however, the OIG would determine a penalty based upon the number of days the person was employed or contracted with the provider, and assessments would be based upon the

---

4 42 U.S.C. § 1320a–7a(a)(6).

5 79 Fed. Reg. 27,080, 27,085 (May 12, 2014).

6 Specifically, the Proposed Rule would define "non-separately-billable item or service" as "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." The OIG would define "separately billable item or service" as "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." *See* proposed 42 C.F.R. § 1003.110; 79 Fed. Reg. 27,080, 27,093 (May 12, 2014).

7 *See* proposed 42 C.F.R. § 1003.210(a)(4)(i); 42 C.F.R. § 1003.210(b)(2)(i) (79 Fed. Reg. 27,080, 27,093 (May 12, 2014)).

worker's total compensation, including salary, benefits, and other money or items of value. The OIG contends that this framework "would achieve the purposes of section 1128A(a)(6) of the Act by penalizing the act of employing or otherwise contracting with the excluded person in proportion to the number of days the prohibited relationship with the excluded person existed."[8]

This proposal is slightly different than the methodology the OIG has used informally—and articulates in its 2013 Updated Provider Self-Disclosure Protocol (SDP) —because it does not take into account the pro rata amount of federal health care program billings. Specifically, under the OIG's proposal, the *total* amount of the excluded person's compensation would have to be repaid, even if a portion of his or her time were not involved in federal health care program items or services. In the Updated SDP's "Calculating Damages" section, on the other hand, the OIG explains that:

> For purposes of resolving SDP matters involving such non-separately-billable items or services, we use the disclosing party's total costs of employment or contracting during the exclusion to estimate the value of the items and services provided by that excluded individual. . . . *This total amount should be multiplied by the disclosing party's revenue-based Federal health care program payor mix for the relevant time period*. . . . The resulting amount will be used, for purposes of compromising OIG's CMP authorities in a settlement, as a proxy for the amount paid and the single damages to the Federal health care programs resulting from the employment of the excluded individual.[9]

Because the OIG proposes a different methodology than it has previously articulated and applied, we believe commenters may wish to point out this disparity and that the proposal does not properly account for a provider's or supplier's payor mix.

Drug-Price Reporting

The OIG proposes to add CMP regulations related to drug-price reporting as part of its general reorganization of the regulations. Under the statute,[10] manufacturers are required to submit monthly and quarterly data on the average manufacturer price (AMP) of their products, and quarterly data on the average sales price (ASP), "Best Price," and other sales information on their products. The Centers for Medicare & Medicaid Services (CMS) uses this data to establish Medicaid rebate liability, as well as to establish payment levels for Part B drugs and generic drugs under Medicaid. As explained by the OIG in the Proposed Rule, the statute provides for penalties of not

---

8 79 Fed. Reg. 27,080, 27,085 (May 12, 2014).

9 OIG, OIG's Provider Self-Disclosure Protocol (Apr. 17, 2013), http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf.

10 42 U.S.C. § 1396r-8.

more than $10,000 per day for each day a manufacturer with a Medicaid Drug Rebate Agreement fails to submit or certify timely or complete drug-pricing and product information.[11] The Proposed Rule would parallel such statutory provision. In addition, the Proposed Rule would mirror statutory language permitting the OIG to impose $100,000 penalties on: (1) wholesalers, manufacturers, or direct sellers of a covered outpatient drug for refusing a request for information by or knowingly providing false information to the government relating to government pricing data; or (2) any manufacturer with a Medicaid Drug Rebate Agreement that knowingly provides false drug-pricing information to the government.

With respect to the late reporting penalties, the OIG issued a Special Advisory Bulletin in 2010 cautioning drug manufacturers about late reporting and advising the industry that it would be working closely with CMS to consider appropriate cases for penalties, in light of prior OIG studies indicating that late reporting occurred with relative frequency. Two modest settlements of $100,000 and $230,000 have been reported in connection with this initiative. In the preamble discussion, however, the OIG has proposed to interpret the statute in a way that could provide the OIG with significantly greater latitude and leverage to impose larger penalties. Specifically, the OIG proposes to calculate such penalties "at the 9-digit NDC level for both AMP and ASP data," such that a penalty could be applied for each day that any individual 9-digit NDC was late. Thus, for example, if a single report were late, but that report contained data with respect to five different 9-digit NDC products, the OIG could seek penalties of up to $50,000 per day, rather than $10,000 per day.[12] Thus, the proposed standard could effectively authorize draconian penalties for manufacturers with large product portfolios, even though only a single "error" would lie at the core of the late reporting. Moreover, the Proposed Rule does not provide for any potential "cut-off" date for penalties, such as one tied to the month or quarter in which the data might be used, although the statute contemplates that a failure to report in excess of 90 days may lead to the suspension of a Medicaid rebate program agreement.

Anti-Kickback and Physician Self-Referral Violations

The OIG proposes to make certain "technical" corrections to the regulations regarding the penalties, assessments, and exclusions resulting from anti-kickback statute and physician self-referral (Stark Law) violations. Such technical revisions include using "furnished" instead of "provided" when referring to Stark Law violations, to mirror the terms used in the Stark Law's statutory and regulatory language, and clarifying that a penalty for an anti-kickback statute violation may be imposed for each offer, payment, solicitation, or receipt of remuneration.

---

[11] 42 U.S.C. § 1396r–8(b)(3)(A).

[12] 79 Fed. Reg. 27,080, 27,090 (May 12, 2014).

Misconduct by a Managed Care Organization (MCO)

The OIG also would make minor, stylistic revisions to the existing regulation that permits the OIG to impose penalties and assessments against MCOs that contract with the federal or a state government to furnish services to Medicare or Medicaid beneficiaries. In addition, the Proposed Rule would codify ACA provisions that allow the OIG to assess penalties on Medicare Advantage Organizations and Medicare Part D contracting organizations that commit certain marketing violations such as enrolling an individual in a plan without the prior consent of the individual or a designee, except as permitted by law.

Emergency Medical Treatment & Labor Act (EMTALA) Violations

EMTALA obligates Medicare-participating hospitals to (1) provide medical screening exams to individuals who come to the hospital's emergency department and request an exam or treatment; and (2) provide stabilizing treatment to a patient who presents with an emergency medical condition (or arrange for appropriate transfer of the patient). In addition, if a hospital has specialized capabilities or facilities, EMTALA requires such hospital to accept appropriate transfers. Lastly, EMTALA imposes certain obligations on physicians, including on-call physicians, in Medicare-participating hospitals.

The Proposed Rule would modify the regulations that impose penalties on hospitals and physicians when they do not fulfill EMTALA's requirements. The Proposed Rule would also clarify that the OIG may impose a penalty for each EMTALA violation and that all hospitals—including hospitals with specialized capabilities or facilities—are subject to penalties. In addition, the Proposed Rule would make clear that an on-call physician may face EMTALA liability if, after a request from the hospital to conduct an examination, furnish treatment, or provide for a transfer, he or she fails or refuses to appear after a reasonable period. Under the Proposed Rule, such liability would be imposed regardless of whether the physician was on-call at the presenting hospital or the hospital with specialized capabilities or facilities.

The Proposed Rule also would delineate certain "aggravating circumstances" to be used when determining the amount of a penalty, such as requesting proof of insurance, prior authorization, or monetary payment prior to screening or treatment. In addition, the Proposed Rule would delete the mitigating factors currently included in the EMTALA-related CMP regulations because, in the OIG's view, these factors are "not useful in determining an appropriate penalty amount."[13]

[13] 79 Fed. Reg. 27,080, 27,088 (May 12, 2014).

Telemarketing, Email and Website

The Medicare statute[14] prohibits the use of words, letters, symbols or emblems of HHS, CMS, Medicare, or Medicaid in a manner that communicates that the government has approved, endorsed, or authorized such use. Current regulations establishing penalties for violations of this prohibition narrowly reference "printed media" and "broadcast or telecast." The Proposed Rule would update the regulations to reflect communications through the internet and by telephone. Specifically, the OIG proposes that each email address that receives an email communication, each telemarketing call, and each webpage view including the misuse of words, letters, symbols or emblems, would constitute a violation, with a $5,000 penalty attached to each violation. Notably, under the Proposed Rule, penalties could add up quickly from, for example, an email marketing blast.

The OIG also solicits comments regarding how to interpret the statute in the context of social media (*e.g.*, Twitter, Facebook, and LinkedIn).

Adverse Action Reporting and Disclosure

Because the ACA removed the statutory reference to the Healthcare Integrity and Protection Data Bank (HIPDB), the OIG proposes to do the same in the Proposed Rule.

Biological Agents and Toxins

The Proposed Rule would clarify the OIG's authority to assess penalties for violations of regulations promulgated pursuant to the Bioterrorism Act of 2002.[15] Under the Proposed Rule, the OIG could impose a penalty of $250,000 against an individual and $500,000 against an entity for *each individual violation* of these regulations, which, according to the OIG, represents the "plain meaning" of the statutory provision.

The Proposed Rule also includes a section listing "several aggravating circumstances" that would guide the OIG's penalty determinations with respect to select agents and toxin violations.

Beneficiary Inducements

The Proposed Rule would codify a statutory penalty provision for offering incentives to a Medicare beneficiary to encourage the beneficiary to disenroll from or terminate benefits in a group health plan that acts as the beneficiary's primary plan (making Medicare the secondary payor). The proposed rule would provide that in determining the amounts of penalties, assessments, and the period of exclusion for violating the beneficiary

---

[14] 42 U.S.C. § 1320b–10.

[15] 42 C.F.R. § 73.1 *et seq*.

inducement provisions, the OIG would consider the factors listed in the proposed § 1003.140, currently listed in § 1003.106, which would include: (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 well as the amount of remuneration or the amount or nature of any other incentive offered or transferred to the Medicare or other federal health program beneficiary.

Medicare Supplemental Policies

The OIG proposes new regulatory language related to violations resulting from the marketing and sale of Medicare supplemental policies. The proposed regulations stem from a self-implementing statutory provision,[16] and largely mirror the statutory language. For example, the Proposed Rule would parallel statutory language that permits the imposition of penalties for knowingly mailing or causing to be mailed marketing materials for Medicare supplemental policies or the delivery of such policy in a state where the policy has not been approved by the respective state's Department of Insurance.

Disclosure of Pending Compliance Surveys

The Proposed Rule would codify a $2,000 CMP that the OIG may impose on any individual who notifies, or causes to be notified, a skilled nursing facility, nursing facility, home health agency, or community care setting of the date and time of a scheduled state compliance survey. The SSA requires such surveys to occur without prior notice to the provider.

Conclusion

The Proposed Rule would bolster the OIG's ability to impose penalties on providers and suppliers and would permit the OIG to impose significant penalties in certain situations. The comment period affords providers and suppliers with an opportunity to shape the OIG's imposition of penalties, through, for example, recommending alternative methodologies than those included in the Proposed Rule.

---

[16] 42 U.S.C. § 1395ss.

multi-jurisdictional and other high-stakes matters; deliver regulatory counsel; and execute the full range of strategic domestic and cross-border transactions. Reed Smith is a preeminent advisor to industries including financial services, life sciences, health care, advertising, technology and media, shipping, energy and natural resources, real estate, manufacturing, and education. For more information, visit reedsmith.com.