

SIGNIFICANT PROPOSED CHANGES TO THE ANTI-KICKBACK STATUTE AND THE CIVIL MONETARY PENALTIES LAW

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Introduction

On October 3, 2014, the Office of Inspector General (“OIG”) published a proposed rule¹ (“Proposed Rule”) to amend the safe harbors under the Anti-Kickback Statute (“AKS”), codify the changes to the Civil Monetary Penalties’ (“CMP”) definition of “remuneration” from the Patient Protection and Affordable Care Act (“PPACA”), and add a gainsharing provision under the CMP. If adopted, several provisions of the Proposed Rule would have a major impact on the AKS and CMP regulations. Numerous portions of the Proposed Rule do not include proposed or definitive regulatory text. Rather, the OIG invited comments on regulatory text while discussing concepts and considerations related to fraud and abuse. Comments on the Proposed Rule had to be submitted by December 2, 2014.

Changes to the Safe Harbor Provisions of the AKS

The AKS² is a criminal statute that prohibits individuals and entities from knowingly and willfully (even if there is no specific knowledge of, or intent to violate, the AKS) offering, paying, soliciting or receiving remuneration to induce the referral of federal healthcare program business. The OIG has adopted a number of “safe harbors” that protect against prosecution under the AKS. Under the Proposed Rule, the OIG intends to: (i) make a technical correction to the existing “referral services” safe

harbor;³ (ii) add new provisions to the “waiver of beneficiary coinsurance and deductible amounts” safe harbor⁴ for cost-sharing waivers by pharmacies under Medicare Part D and for certain emergency ambulance services; (iii) codify a safe harbor for Medicare Advantage payments to Federally Qualified Health Centers (“FQHCs”); (iv) codify a safe harbor for discounts in the price of certain drugs under the Medicare Coverage Gap Discount Program; and (v) add a safe harbor for free or discounted local transportation.

Referral Services

At the outset of the Proposed Rule, the OIG proposes a technical correction to one of the four factors required to meet the “referral services” safe harbor at 42 C.F.R. § 1001.952(f). The current language of 42 C.F.R. § 1001.952(f)(2) reads:

Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by **either party for the referral service** for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. (Emphasis added.)

Under the Proposed Rule, the bolded language above will be replaced by the language found in the 1999 final rule,⁵ which clarified that any payment made to a referral service may not be based on “the volume or value of referrals to, or business otherwise generated by, *either party for the other party*.”⁶ The OIG claims that this language was inadvertently changed during revisions in 2002, and the OIG intends to revert to the 1999 language to correct such error.

Cost-Sharing Waivers

The OIG emphasizes its longstanding concern that blanket waivers of cost-sharing amounts have a high potential for abuse and may violate the AKS and CMP. However, the OIG proposes two new provisions for cost-sharing waivers that, according to the OIG, pose a low risk of harm.

Part D Cost-Sharing Waivers by Pharmacies

The OIG seeks to add a new subparagraph (3) under the “waiver of beneficiary coinsurance and deductible amounts” safe harbor found at 42 C.F.R. § 1001.952(k). The provision originates from the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) and would protect waivers or reductions by pharmacies of any cost-sharing imposed under Medicare Part D. To be entitled to protection, three criteria must be met: (i) the waiver or reduction must not be advertised; (ii) the pharmacy must not routinely waive the cost-sharing; and (iii) before waiving the cost-sharing, the pharmacy either must determine in good faith that the beneficiary has a financial need or fail to collect the cost-sharing amount only after making a reasonable effort to collect. However, conditions (ii) and (iii) are not required if the waiver or reduction is made on behalf of a subsidy-eligible individual.⁷

Cost-Sharing Waivers for Emergency Ambulance Services

The OIG proposes to add an additional subparagraph to the “waiver of beneficiary coinsurance and deductible amounts” safe harbor at 42 C.F.R. § 1001.952(k)(4) for certain emergency ambulance services. By way of brief background, through the years the OIG has issued many favorable advisory opinions approving of the reduction or

waiver of cost-sharing amounts for emergency ambulance services to an ambulance supplier that is owned and operated by a state or political subdivision of a state.⁸ Nevertheless, the OIG notes that it continues to receive requests for advisory opinions on this topic each year.⁹ Therefore, the OIG proposes to add the new subparagraph to clarify the OIG's position on, and provide safe harbor protection for, these types of cost-sharing waivers.

First, to receive protection under the new provision, the ambulance provider or supplier would need to be the Medicare Part B provider or supplier of the emergency ambulance services and must be owned by a state, a political subdivision of a state, or a federally recognized Indian tribe. The OIG advises that the protection **would not** extend to situations where the governmental unit owns but does not operate the ambulance provider or supplier (e.g., where the governmental unit contracts with outside ambulance providers or suppliers). Second, protection would be limited to services that are not paid for directly or indirectly by a government entity (i.e., the government entity furnishes the services free of charge without expectation of payment), subject to certain exceptions.¹⁰ Third, the ambulance provider or supplier would need to offer the reduction or waiver on a uniform basis, without regard to patient-specific factors. Fourth, the reduction or waiver would need to be borne by the ambulance provider or supplier and not claimed as bad debt for payment purposes or otherwise shifted to Medicare or other payors.

Under the proposal, the OIG intends to define "ambulance provider or supplier" as "a provider or supplier of ambulance transport services that furnishes emergency ambulance services," but not one that furnishes only nonemergency transport services.¹¹ Additionally, the OIG intends to define "emergency ambulance services" in accordance with the definition found

in the "ambulance replenishing" safe harbor.¹² Lastly, the OIG is soliciting comments regarding whether to protect reductions or waivers of cost-sharing amounts owed under other federal healthcare programs, such as Medicaid.

FQHCs and Medicare Advantage Organizations

The OIG proposes to codify an additional statutory safe harbor at 42 C.F.R. § 1001.952(z), which originates from the MMA and would protect any remuneration between an FQHC¹³ and a Medicare Advantage organization¹⁴ pursuant to a written agreement under 42 U.S.C. § 1395w-23(a)(4). Further, the Proposed Rule would codify the MMA requirement that the written agreement provide that the Medicare Advantage organization "will pay the contracting FQHC no less than the level and amount of payment that the plan would make for the same services if the services were furnished by another type of entity."¹⁵

Medicare Coverage Gap Discount Program

Under the Medicare Coverage Gap Discount Program, established by PPACA, prescription drug manufacturers provide certain beneficiaries access to point-of-sale discounts on drugs.¹⁶ The Proposed Rule would add protection for these discounts provided by manufacturers who participate in and are in full compliance with all requirements of the Medicare Coverage Gap Discount Program. Specifically, the new safe harbor would protect a discount in the price of an "applicable drug" furnished to an "applicable beneficiary," as those terms are defined in 42 U.S.C. § 1395w-114A. The Proposed Rule would add the new safe harbor at 42 C.F.R. § 1001.952(aa).

Local Transportation

The OIG proposes to add a new safe harbor at 42 C.F.R. § 1001.952(bb) to protect free or discounted local transportation services provided to federal healthcare program beneficiaries. The OIG notes that the CMP law's

legislative history reveals that Congress did not intend to preclude the provision of complimentary local transportation of nominal value.¹⁷ Currently, the OIG interprets "nominal value" to mean "no more than \$10 per item or service or \$50 in the aggregate over the course of a year."¹⁸ However, the OIG is concerned that this definition is overly restrictive. The proposal would protect not only certain free local transportation but also certain discounted local transportation services as long as specific requirements are met. The OIG notes that any safe harbor offering protection under the AKS would exempt the same practice from the definition of "remuneration" under the CMP law. In fact, transportation services have recently been the subject of numerous favorable advisory opinions issued by the OIG.¹⁹

First, the safe harbor would protect transportation services provided to the patient (and, if necessary, someone to assist the patient) only to obtain medically necessary items or services within the local area (25 miles) of the healthcare provider or supplier. However, protection **would not** extend to laboratories or to individuals and entities that primarily supply healthcare items that are heavily dependent on practitioner prescription and referrals, such as DME suppliers, and the OIG is soliciting comments on whom else to exclude from protection. For example, the OIG is concerned that the protection of free or discounted transportation by home healthcare providers to physician offices may result in unnecessary physician visits or serve as an inducement to physicians to refer to the home healthcare provider.²⁰

Additionally, protection would be available for the transportation of established patients only. This restriction is intended to reduce the risk that a provider or supplier could use the safe harbor to inappropriately induce referrals of new patients from other providers. Similarly, the provider or supplier would not be protected if: (i) the transportation is limited to patients

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who were referred by a particular referral source; or (ii) the transportation is contingent on a patient seeing a particular provider or supplier who may be a referral source. Further, a provider or supplier would be able to restrict the offer of free or discounted transportation to patients whose conditions require frequent or critical appointments. However, the provider or supplier **would not** be allowed to restrict the offer to patients receiving expensive treatments that are lucrative for the provider or supplier offering the transportation.

Other scenarios that the OIG said would not be protected under the proposed safe harbor include: (a) transportation by air, luxury transportation (e.g., limousine), or ambulance-level transportation; (b) transportation involving payment to the transporter on a per-beneficiary basis (as opposed to an hourly or mileage basis); (c) transportation services that are publicly advertised to patients or potential referral sources; and (d) transportation that includes the marketing of healthcare items and services during the transportation (not including signage on the vehicle designating the source of the transportation).²¹ These exclusions are not surprising because they are consistent with the OIG's longstanding guidance on these issues as addressed in numerous advisory opinions and OIG notices of intent to develop regulations.²²

More so than any other provision in the Proposed Rule, the OIG spends significant time discussing numerous fact scenarios related to patient transportation. This is likely due to the number of factors that must be considered in order to adequately protect against fraud and abuse when free or discounted transportation is offered to patients.²³ The OIG is soliciting comments on the proposed safe harbor, including whether it should require providers and suppliers to document beneficiary eligibility criteria,

such as documenting a "need" for free or discounted transportation, and whether the protection should apply to transportation for non-medical care (e.g., counseling or social services).

Changes to the Definition of Remuneration Under the Beneficiary Inducement CMP Provisions

The CMP law,²⁴ among other things, prohibits the offer or transfer of remuneration to Medicare or Medicaid beneficiaries that the offeror knows or should know is likely to influence the beneficiary to order or receive items or services from a particular provider or supplier paid for by federal or state healthcare programs. For this reason, the CMP law is often referred to as the "beneficiary inducement" or "patient inducement" law.

First, the Proposed Rule amends the CMP definition of "remuneration" related to the beneficiary inducement CMP by adding a self-implementing exception that was enacted in the Balanced Budget Act of 1997, but was never codified in the regulations due to a purported oversight. This amendment would add subparagraph (5) to the CMP definition of "remuneration" found in 42 C.F.R. § 1003.101,²⁵ which states that a "reduction in the copayment amount for covered OPD services under section 1833(t)(8)(B) of the [Social Security] Act" would be excluded from the CMP definition of "remuneration."²⁶

Second, the Proposed Rule would codify four new exceptions to the CMP law's definition of "remuneration," which emanate from PPACA, by adding subparagraphs (6)-(9) to the definition of "remuneration" found in 42 C.F.R. § 1003.101.²⁷ The OIG explains that the new exceptions are "intended to protect certain arrangements that offer beneficiaries

incentives to engage in their wellness or treatment regimens or that improve or increase beneficiary access to care," while at the same time reducing the potential for abuse if beneficiaries receive inducement to obtain unnecessary, expensive, or poor quality services.²⁸

Promoting Access to Care

The first of the new proposed exceptions would protect remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs. The OIG defines "promotes access to care" as remuneration that "improves a particular beneficiary's ability to obtain medically necessary health care items and services."²⁹ The OIG seeks comments on whether to interpret this exception more broadly to include, for example: (i) beneficiaries from a designated population instead of a "particular beneficiary"; (ii) care that is non-clinical but related to medical care, such as social services; or (iii) encouraging patients to access care or making access to care more convenient for patients.

Additionally, the OIG defines "low risk of harm" to mean that the remuneration: (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to federal healthcare programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns.³⁰ In fact, these concerns are the driving force behind the AKS.³¹

Further, the OIG emphasizes that it views the offering of valuable gifts in connection with marketing activities and rewards for compliance with treatment regimens as activities with a high potential for abuse. However, the OIG recognizes that there may be beneficial incentives for compliance with treatment regimens that should be included in the exception; it is

seeking comments on this issue and what safeguards it must put into place to lower the risk of abuse. Lastly, the OIG does not propose regulatory text for this exception and is soliciting proposals for the language to be included at 42 C.F.R. § 1003.101³² under subparagraph (6) of the CMP definition of “remuneration.”

Retailer Rewards Programs

In the Proposed Rule, the OIG explains that retailer rewards programs, through which retailers “attempt to incentivize and reward customer loyalty by providing benefits to shoppers,” have “proliferated in recent years at grocery stores, drug stores, ‘big-box,’ and other retailers.”³³ Many of these retailers have pharmacies selling items or services reimbursable by federal healthcare programs. The OIG acknowledges that many retailer reward programs have specifically excluded federal healthcare program beneficiaries from participation in these programs, perhaps out of fear that offering this type of remuneration will violate the informal “inexpensive gifts” limitation currently set at \$10 individually and \$50 annually per patient.³⁴ The OIG believes that creating an exception for these programs will increase the chance that retailers will include federal healthcare program beneficiaries in their rewards programs. Therefore, the OIG intends to codify the provision of PPACA that excludes retailer rewards programs from the CMP definition of “remuneration” at subparagraph (7) of 42 C.F.R. § 1003.101.³⁵

Financial Need-Based Exception

The OIG proposes to codify the new exception to the CMP definition of “remuneration” that allows for the offer or transfer of free or less than fair-market value items or services to a beneficiary in financial need. The new exception would be found in subparagraph (8) of the CMP definition of “remuneration” at 42 C.F.R. 1003.101.³⁶ The OIG notes that “items or services” do not include “cash or instruments convertible to cash.”³⁷

Under the Proposed Rule, the items or services would be provided only after a good-faith determination that the individual is in financial need. Moreover, protection would only apply to items or services that are not advertised, are not tied to other services reimbursed by federal or state healthcare programs, and are “reasonably connected” to the individual’s medical care.

As guidance, the OIG provides examples of certain items and services that it may consider to be “reasonably connected” to medical care, including: (i) safety gear for hemophiliac children; (ii) pagers to alert patients with chronic medical conditions to take their drugs; (iii) free blood pressure checks to hypertensive patients; (iv) free nutritional supplements to malnourished patients with end-stage renal disease; and (v) air conditioners to asthmatic patients. However, the OIG notes that, in order for these items or services to qualify for the exception, the item or service must be medically indicated. In order to better advise the public on this exception, the OIG seeks comments on the concepts of “medically indicated” and “reasonably connected.”

Waivers of Cost-Sharing for the First Fill of a Generic Drug

The OIG proposes to exempt from the CMP definition of “remuneration” waivers of any copayment for the “first fill” of a generic drug if the waiver is by an authorized PDP sponsor³⁸ or Medicare Advantage organization. The purpose of this exception is to encourage the use of lower cost generic drugs, and it would be found at subparagraph (9) of the CMP definition of “remuneration” under 42 C.F.R. § 1003.101.³⁹ While this proposed regulation will not be effective until a future date, the Centers for Medicare & Medicaid Services (“CMS”) already permits similar waivers. For that reason, the OIG advises that it will not “exercise [its] enforcement authority against plans complying with CMS requirements for these waivers in the interim.”⁴⁰

The CMP’s Gainsharing Provisions

The CMP’s gainsharing provisions⁴¹ prohibit “hospitals and critical access hospitals from knowingly paying a physician to induce the physician to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the physician’s direct care.”⁴² However, the OIG observes that there is a shift in healthcare to accountable and high-quality care at lower costs. Therefore, along with codifying the CMP’s previous gainsharing guidance in a regulation, the OIG seeks comments on an appropriate definition for the term “reduce or limit services” in order to allow programs to improve patient care or reduce costs without reducing patient care or diminishing its quality.

After reciting the numerous favorable gainsharing guidance that has been issued,⁴³ the OIG enumerates its thoughts and solicits comments on potential rules. In particular, the OIG poses the following questions:

- Should the prohibition on payments to reduce or limit *services* include payments to limit *items*?
- Should a hospital’s decision to standardize certain items constitute reducing or limiting care? What if the hospital simply encouraged the use of standardized items, but other items remained available?
- Should a hospital’s decision to rely on protocols based on objective quality metrics for certain procedures constitute reducing or limiting care?
- Should it require a hospital that wants to standardize items or processes as part of a gainsharing program to establish certain thresholds based on historical experience or clinical protocols, beyond which participating physicians could not share in cost savings?
- Should the regulation include a requirement that the hospital or

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physician participating in a gain-sharing program notify potentially affected patients about the program in order to ensure that the payments were for legitimate purposes and not for the purpose of reducing or limiting care?

The Proposed Rule does not offer any text for the definition of “reduce or limit services,” which will allow the OIG time to receive and digest comments on the above-mentioned issues before ultimately issuing regulatory text.

Conclusion

Attorneys representing providers and suppliers should stay tuned for the final rule, which will have a large impact on the AKS safe harbors and CMP regulations. In a number of instances, the OIG refrained from proposing regulatory text on the topics laid out in the Proposed Rule, and is instead soliciting comments on regulatory text for the same. The OIG has shown flexibility in certain areas under the Proposed Rule, while also being hesitant to adopt new rules that may have a broad impact without heavy analysis and lengthy requirements intended to protect the Medicare program. In light of the many comments the OIG is likely to receive, and the nebulous nature of much of the Proposed Rule, there may be an extended wait before the OIG publishes the final rule.



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Endnotes

- 1 79 Fed. Reg. 59717 (Oct. 3, 2014).
- 2 42 U.S.C. § 1320a-7b(b).
- 3 42 C.F.R. § 1001.952(f).
- 4 42 C.F.R. § 1001.952(k).
- 5 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999).
- 6 79 Fed. Reg. 59717, 59720.
- 7 42 U.S.C. 1395w-114(a)(3)(A) defines a “subsidy eligible individual” as “a part D eligible individual who (i) is enrolled in a prescription drug plan or [Medicare Advantage prescription drug] plan; (ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and (iii) meets the resources requirement described in subparagraph (D) or (E) [of 42 U.S.C. 1395w-114(a)(3)].”
- 8 79 Fed. Reg. 59717, 59720. *See, for example*, OIG Advisory Opinion No. 03-09 (issued April 17, 2003; posted April 25, 2003).
- 9 79 Fed. Reg. 59717, 59720.
- 10 *See* 42 C.F.R. 411.8(b). *See also* CMS Medicare Benefit Policy Manual, Pub. No. 100-02, ch. 16, § 50.3.1, which states that a “facility which reduces or waives its charges for patients unable to pay, or charges patients only to the extent of their Medicare and other health insurance coverage, is not viewed as furnishing free services and may therefore receive program payment.”
- 11 79 Fed. Reg. 59717, 59721.
- 12 The “ambulance replenishing” safe harbor defines “ambulance provider” as “a provider or supplier of ambulance transport services that provides emergency ambulance services. The term does not include a provider of ambulance transport services that provides only non-emergency transport services.” 42 C.F.R. § 1001.952(v)(4)(iv).
- 13 The requirements to qualify as an FQHC are listed in 42 U.S.C. 1395x(aa)(4).
- 14 A Medicare Advantage Organization is generally defined as a “public or private entity organized and licensed by a state as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the Medicare Advantage contract requirements.” Medicare Advantage is the managed care plan offered by the United States government to eligible individuals. *See* CMS Medicare Managed Care Manual, Pub. No. 100-16, ch. 1, § 20.
- 15 79 Fed. Reg. 59717, 59721.
- 16 *See*, 42 U.S.C. 1395w-114A.
- 17 79 Fed. Reg. 59717, 59721 (*citing*, H.R. Conf. Rep. No. 104-736 at 255 (1996)).
- 18 79 Fed. Reg. 59717, 59721.
- 19 *See, for example*, OIG Advisory Opinions No. 09-01 (issued March 6, 2009; posted March 13, 2009); No. 11-01 (issued January 3, 2011; posted January 10, 2011); No. 11-02 (issued March 17, 2011; posted March 24, 2011); and

No. 11-16 (issued November 8, 2011; posted November 13, 2011).

²⁰ 79 Fed. Reg. 59717, 59722.

²¹ *Id.* at 59723-59724.

²² See n. 19. See also, 67 Fed. Reg. 72892 (Dec. 9, 2002).

²³ This article merely provides a summary of the main issues raised in the Proposed Rule; therefore, attorneys representing providers and suppliers offering or considering offering patient transportation should review the specific factual scenarios addressed in the Proposed Rule.

²⁴ 42 U.S.C. § 1320a-7a(a)(5).

²⁵ Note that the OIG proposes to re-designate the current 42 C.F.R. § 1003.101 to 42 C.F.R.

§ 1003.110.

²⁶ 79 Fed. Reg. 59717, 59732. OPD services are outpatient department services as defined in 42 U.S.C. 1395l(t)(1)(B).

²⁷ See n. 24.

²⁸ 79 Fed. Reg. 59717, 59725.

²⁹ *Id.*

³⁰ *Id.*

³¹ See Office of Public Affairs, U.S. Department of Health & Human Services, Office of Inspector General, Fact Sheet November 1999, Federal Anti-Kickback Law and Regulatory Safe Harbors.

³² See n. 24.

³³ 79 Fed. Reg. 59717, 59726.

³⁴ *Id.*

³⁵ See n. 24.

³⁶ See n. 24.

³⁷ 79 Fed. Reg. 59717, 59727.

³⁸ A prescription drug plan (“PDP”) sponsor is a nongovernmental entity certified under, and meeting the requirements and standards of, Medicare Part D (i.e., part D of Title XVIII of the Social Security Act). See 42 U.S.C. 1395w-151(a)(13).

³⁹ See n. 24.

⁴⁰ 79 Fed. Reg. 59717, 59728.

⁴¹ 42 U.S.C. § 1320a-7a(b).

⁴² 79 Fed. Reg. 59717, 59729.

⁴³ *Id.* at 59729-59730.

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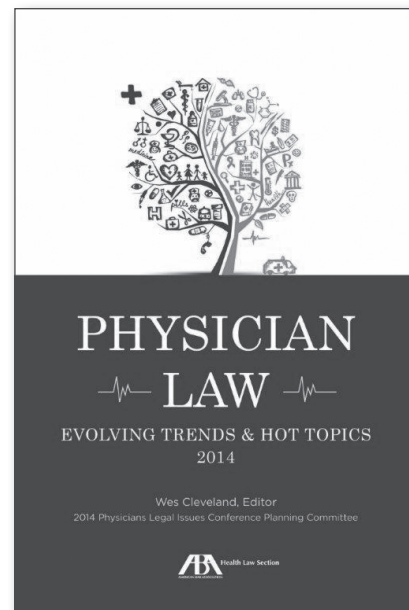
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