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E-ALERT | Health Care

October 27, 2014

OIG PROPOSES UPDATES TO SAFE HARBORS UNDER ANTI-KICKBACK REGIME

On October 3, 2014, HHS's Office of Inspector General (OIG) published a proposed rule that would add several new safe harbors to 42 C.F.R. § 1001.952, codify statutory revisions to the definition of "remuneration" for purposes of imposing civil monetary penalties (CMPs), and codify a CMP provision relating to gainsharing. The proposed rule is available at 79 Fed. Reg. 59717. Some of these amendments would codify protections for types of arrangements that OIG has already looked favorably upon in advisory opinions. This alert summarizes key provisions of the proposed rule.

BACKGROUND

The federal Anti-Kickback Statute establishes both criminal liability and CMPs for soliciting, receiving, offering, or paying any "remuneration" in return for referrals or recommendations for items or services that are covered by federal health care programs.[1] Violations may also result in exclusion from these programs, False Claims Act liability, and other consequences.

Because the scope of the law is extremely broad and potentially covers many otherwise legitimate marketing practices, the Anti-Kickback Statute requires the U.S. Department of Health and Human Services (HHS) to establish safe harbors that protect from enforcement certain practices that are deemed beneficial after taking into account factors such as the effect of a given practice on access to care, quality of care, freedom of choice, and overutilization of services.[2] The current safe-harbor rules, some of which are specifically required by statute and some of which have been promulgated at HHS's discretion, are codified at 42 C.F.R. § 1001.952. Among the most widely known safe harbors are those for discounts, personal services and management contracts, and group purchasing organization fees.

PROPOSED NEW SAFE HARBORS

The new safe harbors are intended to implement certain statutory mandates and to "protect certain services that the industry has expressed an interest in offering and that [OIG] believe[s] could be, if properly structured and with appropriate safeguards, low risk to Federal health care programs."[3] They include:

- **Implementation of the safe harbor created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) for pharmacy waivers of Medicare Part D cost-sharing.**[4] The proposed rule would implement the MMA's safe harbor that protects a pharmacy's waiver of a Medicare Part D beneficiary's co-pay or co-insurance obligation. In order for the cost-sharing waiver to be protected, three conditions must be met: (1) "the waiver is not offered as part of any advertisement or solicitation;" (2) "the [pharmacy] does not routinely waive coinsurance or

[1] 42 U.S.C. §§ 1320a-7a(a)(7), 1320a-7b(b)(1), (2).
[2] *Id.* § 1320a-7d(a).
[3] 79 Fed. Reg. at 59718.
[4] *See* Pub. L. No. 108-173, tit. I, § 101(e), 117 Stat. 2066 (2003).

deductible amounts;" and (3) the pharmacy either "waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need" or "fails to collect coinsurance or deductible amounts after making reasonable collection efforts."[5] If the Part D beneficiary is eligible for the low-income subsidy, the proposed rule would require that only the first condition be met in order to qualify for the safe harbor.

- **Creation of a new safe harbor for waivers of cost-sharing for emergency ambulance services furnished by ambulance-service providers owned by States, their subdivisions, or Indian tribes.** This safe harbor would extend only to ambulance services covered by Medicare Part B. Application of the safe harbor depends on whether the government entity is (a) providing services "free of charge, i.e., without expectation of payment from any source and without regard to the individuals' ability to pay," or is instead (b) "reduc[ing] or waiv[ing] its charges for patients unable to pay, or charg[ing] patients only to the extent of their Medicare and other health insurance coverage."[6] In the first situation, Medicare will not pay for the services,[7] and the safe harbor is inapplicable; in the second, Medicare will pay, and the safe harbor applies. To qualify for the safe harbor, the ambulance supplier must offer the waiver on a uniform basis, "without regard to patient-specific factors," and it "must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare" or others.[8] OIG is soliciting comments on whether to extend this safe harbor to ambulance services covered by Medicaid and other federal health care programs.
- **Implementation of the safe harbor created by the MMA for remuneration between Medicare Advantage (MA) organizations and federally qualified health centers (FQHCs) pursuant to agreements that meet statutory standards.**[9] Under the MMA, MA agreements with FQHCs are required to provide for a level and amount of payment to the FQHC that is not less than the MA plan would pay for such services if the services had been furnished by a similar entity that is not a FQHC.[10] Under these agreements, the FQHC "may collect any amount of cost-sharing permitted under the [agreement]," subject to certain criteria.[11] OIG proposes to codify that remuneration pursuant to allowable agreements is subject to a safe harbor.
- **Implementation of the Affordable Care Act's (ACA's) protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program.**[12] Under the Medicare Coverage Gap Discount Program, branded prescription drug manufacturers must enter into an agreement with HHS to provide discounts on drugs at the point of sale to Part D beneficiaries in the coverage gap (also known as the donut hole). The ACA provides a safe harbor for these discounts, and the proposed regulation would codify the safe harbor.
- **Creation of a new safe harbor for free or discounted local transportation services.** OIG proposes a safe harbor to cover transportation services provided to "established patients (and, if needed, a person to assist the patient) to obtain medically necessary items and services."[13] The safe harbor would apply only to transportation services made available by an "Eligible Entity"—that is, an entity that does not "primarily supply health care items," such as durable medical equipment and pharmaceuticals. OIG is soliciting comments on whether to exclude laboratories (as it is inclined to do), home health care providers, and other entities from the safe harbor's protection.

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[5] 42 U.S.C. § 1320a-7a(i)(6).
[6] CMS Medicare Benefit Policy Manual, Pub. No. 100–02, ch. 16, § 50.3.1.
[7] *See* 42 C.F.R. § 411.8(a).
[8] 79 Fed. Reg. at 59731.
[9] *See* Pub. L. No. 108-173, tit. I, § 237.
[10] 42 U.S.C. § 1395w-27(e)(3).
[11] *Id.*
[12] *See* Pub. L. No. 111-148, tit. III, subtit. D, § 3301, 124 Stat. 119 (2010).
[13] 79 Fed. Reg. at 59722.

The proposed safe harbor would not be available to a practice that offers or provides free or discounted transportation to new patients.[14]

Other criteria for the safe harbor include requirements that: (a) the availability of the services is not determined in a manner related to the past or anticipated volume or value of federal health care program business; (b) the services are not air, luxury, or ambulance-level transportation; (c) the services are not marketed or advertised, and no marketing of health care items or services occurs during the transportation; (d) those who provide or arrange for the transportation are not paid on a per-beneficiary transported basis; (e) transportation is made available only to obtain medically necessary services; (f) the beneficiary is not transported more than 25 miles; and (g) the cost of the transportation is not shifted to a federal health care program.[15] OIG is soliciting feedback on these criteria. It is also seeking comments on whether and how to extend the safe harbor to programs in which hospitals would run shuttles along routes serving hospitals, doctors' offices, and the like.[16]

- **Technical correction to referral services safe harbor.** The proposed rule also makes a technical correction to the existing safe harbor for referral services. This safe harbor requires that any payment to a referral service be "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."[17] The correction would change the italicized language to "for the other party." OIG already made this change in 1999, but inadvertently undid it in 2002.

PROPOSED REVISIONS TO DEFINITION OF "REMUNERATION" FOR CMP PURPOSES

OIG proposes to codify in regulation certain statutory provisions establishing that the following arrangements are not "remuneration" within the meaning of the CMP regime (these provisions do not affect the criminal Anti-Kickback Statute):

- Reductions in copayment amounts for covered hospital outpatient department (OPD) services.[18]
- Remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs. OIG seeks input on this ACA provision and has not yet proposed specific regulatory language.[19]
- Programs in which retailers offer coupons, rebates, or other rewards, provided that they do so "on equal terms available to the general public, regardless of health insurance status" and that the rewards are "not tied to the provision of other items or services reimbursed in whole or in part by [Medicare] or a State health care program."[20] This safe harbor is intended to protect customer-loyalty programs offered by retailers—that is, entities that "sell[] items directly to consumers" (such as "grocery stores, drug stores, [and] 'big-box'" stores)—and it excludes "individuals or entities that primarily provide services (*e.g.*, hospitals or physicians)."[21] OIG is soliciting comments on whether "entities that primarily sell items that require a prescription (*e.g.*, medical equipment stores)" should be considered retailers.[22] The prohibition on tying means that the earning of the reward should not be conditioned on the purchase of goods or services

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[14] *Id.*
[15] *Id.* at 59732.
[16] *Id.* at 59723.
[17] 42 C.F.R. § 1001.952(f)(2) (emphasis added).
[18] *See* Social Security Act (SSA) § 1833(t)(8)(B), 42 U.S.C. § 1395l(t)(8)(B).
[19] *See* 79 Fed. Reg. at 59725.
[20] *Id.* at 59732.
[21] *Id.* at 59726-27.
[22] *Id.* at 59727.

covered by a federal health care program, and that the reward itself should not consist of such goods or services.

- The offer or transfer of items or services for free or less than fair market value, provided that the offer is not "part of any advertisement or solicitation," is "not tied to the provision of other items or services reimbursed in whole or in part by [Medicare] or a State health care program," has a "reasonable connection" to the recipient's medical care, and is made after a good-faith determination that the recipient "is in financial need."[23]

  OIG offers the following examples of transfers of items or services that might qualify as having a "reasonable connection" to the recipient's medical care:

  - [d]istribution of protective helmets and safety gear to hemophiliac children;
  - distribution of pagers to alert patients with chronic medical conditions to take their drugs;
  - provision of free blood pressure checks to hypertensive patients;
  - distribution of free nutritional supplements to malnourished patients with end-stage renal disease (ESRD); . . .
  - provision of air conditioners to asthmatic patients[]; [and] . . .
  - a complimentary download of [an "app" relating to management of blood sugar levels for a diabetic patient].[24]

- Waivers of cost-sharing for the first fill of a generic drug by a Part D plan, "as long as such waivers are included in the benefit design package submitted to CMS."[25] This exception would be effective for coverage years beginning after publication of the final rule.[26]

PROPOSED TREATMENT OF GAINSHARING FOR CMP PURPOSES

The CMP statute penalizes hospitals for making, and doctors for receiving, payments "as an inducement to reduce or limit services" provided to Medicare and Medicaid beneficiaries.[27] OIG now proposes to codify this provision. In doing so, OIG acknowledges the apparent overbreadth of the statutory prohibition, which is not limited "to reductions or limitations of *medically necessary* items or services"; it asserts that "[w]ithout a change in the statute, . . . we cannot read a 'medically necessary' element into the prohibition."[28] In an effort to reconcile the statute to modern medical practice, which now includes "greater emphasis on accountability for providing high quality care at lower costs," OIG proposes to consider a "a narrower interpretation of the term 'reduce or limit services' than we have previously held."[29] Specifically, OIG solicits input on how to "recognize that a change in practice does not necessarily constitute a limitation or reduction of services, but may in fact constitute an improvement in patient care or a reduction in cost without reducing patient care or diminishing its quality."[30]

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[23] Id.
[24] Id. at 59728.
[25] Id. at 59732.
[26] Id.
[27] 42 U.S.C. § 1320a-7a(b).
[28] 79 Fed. Reg. at 59729.
[29] Id.
[30] Id. at 59730.

COMMENT PERIOD

Comments must be delivered to OIG by December 2, 2014. We would be happy to assist with the drafting of any comments you may wish to submit.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

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