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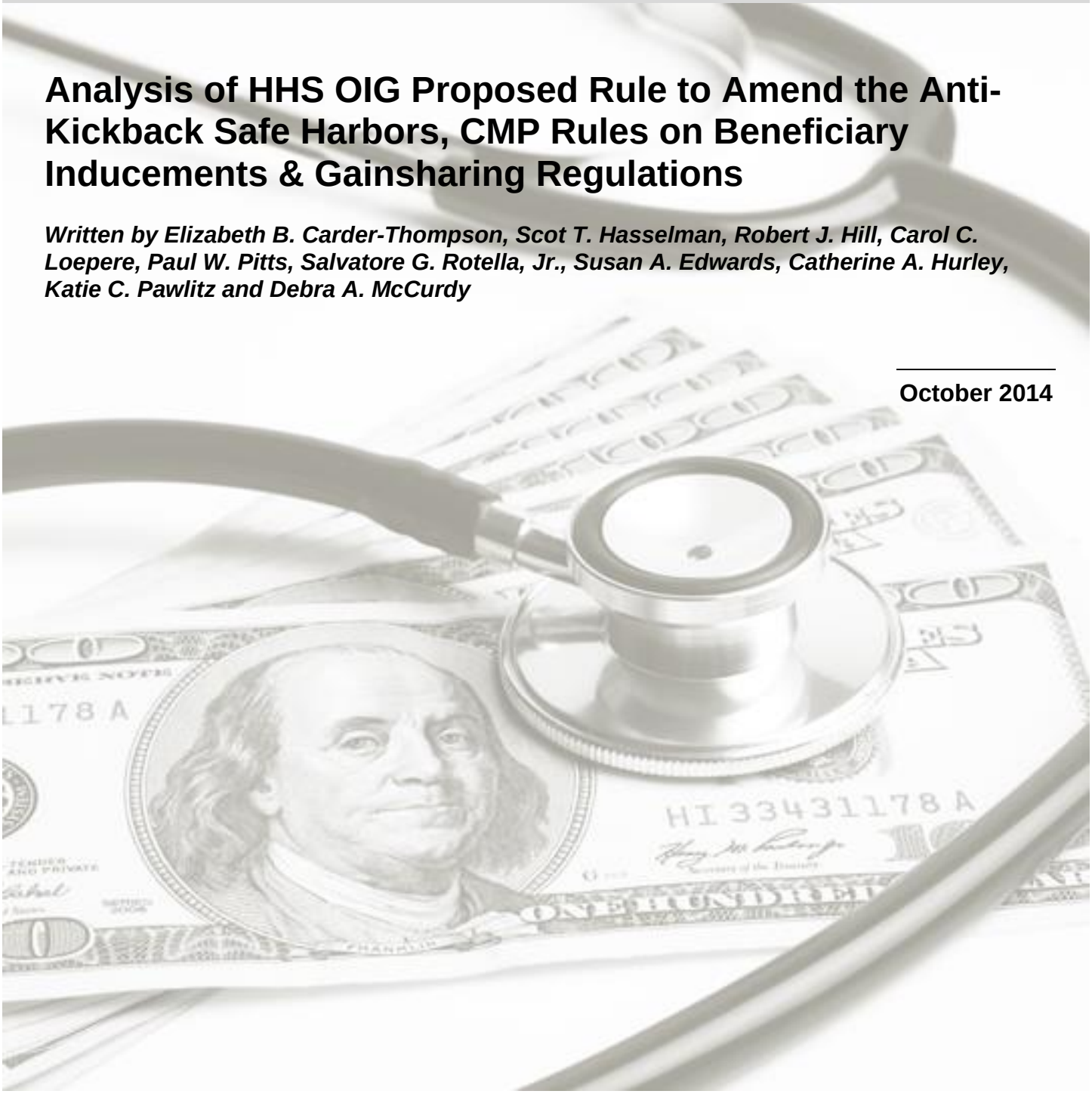
Analysis of HHS OIG Proposed Rule to Amend the Anti-Kickback Safe Harbors, CMP Rules on Beneficiary Inducements & Gainsharing Regulations

Written by Elizabeth B. Carder-Thompson, Scot T. Hasselman, Robert J. Hill, Carol C. Loepere, Paul W. Pitts, Salvatore G. Rotella, Jr., Susan A. Edwards, Catherine A. Hurley, Katie C. Pawlitz and Debra A. McCurdy



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On October 3, 2014, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published a major proposed rule that would amend the safe harbors to the Anti-Kickback Statute (AKS) and the Civil Monetary Penalty (CMP) rules to protect certain payment practices and business arrangements from criminal prosecution or civil sanctions under the AKS ("Proposed Rule").[1] The OIG will accept comments on the Proposed Rule through December 2, 2014.

With regard to the AKS, the OIG proposes:

- A technical correction to the existing safe harbor for referral services;
- Protection for certain cost-sharing waivers, including: pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries, and waivers of cost-sharing for emergency ambulance services furnished by state- or municipality-owned ambulance services;
- Protection for certain remuneration between Medicare Advantage organizations and federally qualified health centers;
- Protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and
- Protection both under the AKS and the statutory prohibition on beneficiary inducement for free or discounted local transportation services that meet specified criteria.

The OIG also proposes to amend the definition of "remuneration" in the CMP regulations at 42 CFR 1003 by adding certain statutory exceptions for:

- Copayment reductions for certain hospital outpatient department services;
- Certain remuneration that poses a low risk of harm and promotes access to care;
- Coupons, rebates, or other retailer reward programs that meet specified requirements;
- Certain remuneration to financially needy individuals; and
- Copayment waivers for the first fill of generic drugs.

[1] 79 Fed. Reg. 59,717 (Oct. 3, 2014). *Available at* http://www.gpo.gov/fdsys/pkg/FR-2014-10-03/pdf/2014-23182.pdf.

The OIG observes that the proposed safe harbors and exceptions generally would "facilitate providers' ability to provide important health care and related services to communities in need."

In addition, the OIG proposes to codify the "gainsharing" CMP rule set forth in section 1128A(b) of the Social Security Act, which prohibits a hospital or a critical access hospital from knowingly paying a physician to reduce or limit services provided to Medicare or Medicaid beneficiaries. In the preamble to the Proposed Rule, the OIG states that it lacks statutory authority to create a new exception, but it nevertheless invites comments on what constitutes reducing and limiting services, and also on what safeguards should be put in place to protect patients and the Medicare program from abuse.

The following is our analysis of the Proposed Rule, highlighting areas where the OIG is seeking public comment. In the last section, we provide our views on the OIG's overall approach.

Proposed Amendments to the AKS Safe Harbors

Local Transportation Services

In 2002, the OIG sought comments from industry regarding the establishment of an exception to the definition of "remuneration" under the statutory beneficiary inducement prohibition that would allow for the provision of complimentary local transportation of a nominal value.[2] As explained in that solicitation for comments and this Proposed Rule, Congress did not intend that the statutory prohibition would preclude free, local transportation of a nominal value.[3] Twelve years after the OIG's 2002 comment solicitation, the agency has now proposed a regulatory safe harbor for free and discounted local transportation. Under the Proposed Rule, any arrangements protected by the safe harbor would also be excluded from the definition of "remuneration" under the beneficiary inducement prohibition.[4]

The Proposed Rule would largely codify a series of OIG Advisory Opinions related to complimentary transportation that the agency has issued over the years.[5] The proposed safe harbor would include the following requirements:

- The provider's or supplier's provision of free or discounted local transportation services are not determined in a manner related to the past or anticipated volume or value of federal health care program business;

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[2] 67 Fed. Reg. 72,892 (Dec. 9, 2002).

[3] H.R. Conf. Rep. No. 104–191 at 255 (1996).

[4] 79 Fed. Reg. 59,717, 59,722; 42 U.S.C. § 1320a–7a(i)(6)(B).

[5] The OIG has issued a variety of Advisory Opinions discussing providers furnishing free transportation services to patients and their friends and family, such as OIG Advisory Opinion Nos.: 00-7, 07-02, 09-01, 11-01, 11-02, and 11-16. In addition, the OIG published a letter regarding complimentary local transportation programs on December 9, 2002, *available at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/sabgiftsandinducements.pdf.

- The free or discounted local transportation services do not take the form of luxury or ambulance-level transportation (i.e., limousines, airline tickets, or ambulance transports);
- The transportation services are not marketed or advertised, the driver does not market health care items and services during the transport, and drivers are not compensated on a per-beneficiary basis;
- The "Eligible Entity" that makes the free or discounted transportation available furnishes the services only:
    - To an established patient (and, if needed, someone to assist the patient) to obtain medically necessary items or services, and
    - Within the local area of the provider or supplier; and
- The cost for such transportation services is not shifted to federal health care programs, or other payors or individuals.

Under the Proposed Rule, transportation would be deemed to be "local" if it is within 25 miles of the provider or supplier. However, the OIG seeks comments on whether this should be a strict limit instead of a "deemed" distance and whether more expansive distances should apply under certain circumstances. In addition, the Proposed Rule defines "Eligible Entity" as "any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items."

Established Patients:

The OIG proposes to limit the safe harbor to "established patients," but it does not define that term or solicit comments on which patients that would include in practice. In the Proposed Rule's preamble, the OIG gives an example that "once a patient has selected an oncology practice and has attended an appointment with a physician in the group," furnishing free transportation would be permissible, but furnishing free transportation to a "new patient" would not be permissible.[6] This example is not particularly illuminating and could be read to impose overly restrictive requirements that would prevent the safe harbor from protecting various potential transportation arrangements. For instance, under the Proposed Rule, it is unclear whether an "established patient" would include a patient being discharged from a hospital who had selected a skilled nursing facility but not officially signed the admission agreement or if the safe harbor would only apply to patients already admitted to the facility.

Eligible Entities:

Citing fraud and abuse concerns, the OIG proposes a narrow definition of "Eligible Entity." The OIG explains in the preamble that "Eligible Entity" would not include durable medical equipment (DME) suppliers "or pharmaceutical companies," though it does not explain the latter term. Also, while not clear in the text of the Proposed Rule, the preamble notes that the agency also proposes to exclude laboratories from the definition of "Eligible Entity." The OIG's stated rationale is that these entities would use transportation to generate business

[6] 79 Fed. Reg. 59,717, 59,722.

for themselves, and in any case would seem to have less need to engage in transportation services than hospitals and other entities with broader patient care responsibilities. The OIG seeks comments on whether other providers or suppliers should be excluded from the "Eligible Entity" definition, and particularly questions whether it should omit home health agencies from the definition of "Eligible Entity." The Proposed Rule's broad exclusion of these suppliers and providers may unfairly penalize legitimate entities which should be able to furnish free or discounted transportation services on the same multiple terms as others in the industry.

Other Areas for Comment:

The OIG requests comments from industry regarding a variety of other potential requirements, such as whether to require that eligible entities maintain documented beneficiary eligibility criteria, such as financial need or risks to the beneficiary from failing to comply with the treatment regimen; whether the agency should impose additional safeguards for free or discounted transportation services provided to the premises of a health care provider; and whether free or discounted transportation should be available for non-health care-related trips, e.g., to obtain social services, visit food banks, etc. The OIG also requests comments regarding whether it should separately protect shuttle or van transportation services provided by an "Eligible Entity."

Someone to Assist Patient:

Finally, while not addressed in great detail in the preamble, the proposed safe harbor would permit a provider or supplier to provide free or discounted transportation services to "someone to assist the patient" to obtain medically necessary items or service (if needed). Notably, the proposed safe harbor's language here appears to be more restrictive than the arrangement permitted by the OIG in Advisory Opinion No. 09-01, which involved a nursing home's provision of free transportation to friends and family members of its residents.

Remuneration Between Medicare Advantage Organizations and Federally Qualified Health Centers

The Proposed Rule incorporates into the AKS regulations, at a new 42 C.F.R. § 1001.952(z), a statutory exception to the AKS created by Section 237 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA). Previously, Section 237 of the MMA added a provision to the then-existing statute governing contracting with Medicare Advantage (MA) organizations to the effect that any agreement between such an organization and a federally qualified health center (FQHC) must require "a level and amount of payment" for services by the MA plan to the FQHC "that is not less than the level and amount of payment" the MA plan would pay to another, non-FQHC entity for similar services. Section 237 also added a provision to the then-existing version of the AKS itself that excluded from the scope of that statute's prohibitions "any remuneration between a [FQHC] (or an entity controlled by such a health center) and a MA organization pursuant to a written agreement" described in the existing statute governing payment to MA organizations.

The Proposed Rule codifies the statutory exclusion from potential AKS enforcement of any remuneration between an MA organization and a FQHC that meets the foregoing requirements – i.e., that is pursuant to a written agreement between the two requiring the MA plan to pay the FQHC at rates no lower than those the plan pays to other types of providers for similar services. In recognition of the key role FQHCs play in serving the poor and medically underserved, federal law requires the Centers for Medicare & Medicaid Services (CMS) to make supplemental payments to such centers for services they render to MA plan members to cover the portion of the center's costs not covered by the MA plan's reimbursement. The proposed new regulatory exclusion furthers the policy goal of supporting FQHCs by limiting their potential AKS liability, while also ensuring that MA plans cover their fair share of the cost of operating such centers, which otherwise would become the responsibility of CMS under the supplemental FQHC payment program.

Manufacturer Discounts Under Part D Coverage Gap Discount Program

The 2010 health reform law, the Patient Protection and Affordable Care Act (ACA), included a statutory exception to the AKS for discounts provided by pharmaceutical manufacturers under the Medicare Part D Coverage Gap Discount Program (CGDP). Under this program, manufacturers agree with CMS to provide discounted prices to certain Medicare beneficiaries at the point of sale, while they are in the so-called "donut hole." OIG has proposed to codify this exception in the safe harbor regulations at 42 C.F.R. § 1001.952(aa). While there can be little question that an AKS exception is appropriate for these statutorily-mandated discounts, manufacturers might take issue with the fact that OIG has drafted the safe harbor to apply only to discounts provided to "applicable beneficiaries" on "applicable drugs" (each as defined under the CGDP), since manufacturers do not control the provision of the discounts—rather, they must pay the amounts invoiced to them for CGDP discounts by CMS's third-party administrator, subject to limited audit and appeal rights.

Technical Correction to Referral Services Safe Harbor

The OIG proposes a technical correction to the referral services safe harbor at 42 C.F.R. § 1001.952(f), which provides that payments (or other exchanges of value) between a participant (i.e., the person or entity that receives referrals through the arrangement) and a referral service (i.e., the person or entity that is making referrals to the participant) are not remuneration for purposes of the AKS, provided that the arrangement meets the safe harbor's four requirements. The second of these four requirements currently is that "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." 42 C.F.R. § 1001.952(f)(2)(emphasis added). Because the phrase "for the referral service" is a source of confusion, the OIG would change the safe harbor to clarify that the volume or value of referrals or business otherwise generated "*by either party for the other party*" cannot affect the referral service's fee to participants. The OIG previously

made this same change in 1999, but then inadvertently undid the change in 2002. *See* 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999); 67 Fed. Reg. 11928, 11929 and 11934 (Mar. 18, 2002).

Cost-Sharing Waivers

The AKS may be implicated by the reduction or waiver of Medicare or other federal health care program cost-sharing amounts, and the OIG has consistently expressed concerns regarding providers and suppliers that routinely waive Medicare cost-sharing amounts unrelated to individualized, good faith assessments of financial hardship. The OIG has long maintained that such waivers may constitute prohibited remuneration to induce referrals under the AKS or beneficiary inducements prohibited under the CMP.

Nonetheless, certain waivers arguably pose a low risk of harm to federal health care programs while benefiting patients and enhancing the efficient and effective delivery of health care. Recognizing this, the OIG has proposed modifying 42 C.F.R. § 1001.952(k) to protect certain cost-sharing waivers related to Part D and emergency ambulance services.

Part D Cost-Sharing Waivers by Pharmacies

The MMA included a statutory exception to the AKS for waivers of Part D cost-sharing by pharmacies that meet certain requirements. The OIG has proposed to add a regulatory safe harbor at 42 C.F.R. § 1001.952(k)(3) reflecting the statutory exception. The basic requirements would be (i) that the waiver not be offered as part of an advertisement or solicitation, (ii) that the pharmacy does not routinely waive cost-Part D sharing, and (iii) that the waiver is provided only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing despite making reasonable collection efforts. However, consistent with the statutory exception, requirements (ii) and (iii) would not apply with respect to waiver of cost-sharing for Part D low-income subsidy-eligible individuals. The OIG stresses that the proposed provisions would protect only against AKS liability and beneficiary inducements CMPs (pursuant to a cross-reference set forth at Section 1128A(i)(6)(B) of the Social Security Act) – a particular practice could still violate CMS program rules (e.g., those set forth at Section 30.4 of Chapter 5 of the Prescription Drug Benefit Manual).

Emergency Ambulance Services Cost-Sharing Waivers by Certain Ambulance Providers and Suppliers

In multiple advisory opinions, the OIG has approved the reduction or waiver of coinsurance or deductible amounts owed for emergency ambulance services to an ambulance supplier that is owned and operated by a state or political subdivision of the state. However, no current safe harbor expressly protects such arrangements. The OIG now proposes to establish a new safe harbor at 42 C.F.R. § 1001.952(k)(4) to protect such arrangements if the following requirements are met:

(i) the coinsurance or deductible amounts are owed to an ambulance provider or supplier for emergency ambulance services (as opposed to nonemergency transport services) for which Medicare pays under a fee-for-service payment system;

(ii) the ambulance provider or supplier is owned and operated by a state, a political subdivision of a state, or a federally recognized Indian tribe (this would not include contractual arrangements with outside ambulance providers and suppliers);

(iii) the ambulance provider or supplier is the Medicare Part B provider or supplier of the emergency ambulance services;

(iv) the reduction or waiver is not considered to be the furnishing of free services paid for directly or indirectly by a government entity;

(v) the reduction or waiver is offered on a uniform basis, without regard to patient-specific factors;[7] and

(vi) the ambulance provider or supplier does 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, a state health care program, other payers, or individuals.

42 C.F.R. § 1001.952(k) and the new proposed cost-sharing waivers above would be limited to reductions or waivers of Medicare and state health care program beneficiary cost-sharing. The agency is considering expanding this safe harbor to protect waivers under all federal health care programs (e.g., Medicaid) and solicits comments regarding the same.

Proposed CMP Rule Exceptions

Beneficiary Inducement CMP – ACA Exclusions

Under section 1128A(a)(5) of the Social Security Act, enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for CMPs of up to $10,000 for each wrongful act. The ACA added four statutory exclusions to the definition of "remuneration" for purposes of the beneficiary inducement prohibition, applicable to arrangements offering beneficiaries incentives to promote wellness or treatment or that improve or increase access to care, including better care coordination. In the Proposed Rule, the OIG seeks to strike a balance between promoting access to care and wellness programs

[7] By the express terms, this subsection of the proposed regulation, this requirement would only apply to ambulance "suppliers" and not ambulance "providers." This appears to be an unintended drafting error, as the preamble discussion notes that this requirement applies to both ambulance providers and suppliers, and all other subsections reference both providers and suppliers.

while minimizing the potential for federal health care program abuse. In this regard, the OIG notes that it is mindful of the "significant potential for abusive arrangements that offer vulnerable beneficiaries (or, in some cases, cooperating beneficiaries) remuneration … to obtain items or services … that may be unnecessary, too expensive, or of poor quality."

Promotes Access to Care and Presents a Low Risk of Harm to Beneficiaries and Federal Health Care Programs

To implement the ACA exception, the OIG proposes to define the phrases "promotes access to care" and "low risk of harm." With regard to the latter phrase, the OIG distinguishes between potentially beneficial arrangements (e.g., hospitals providing lodging assistance to patients when the assistance is necessary to obtaining care) from potentially harmful ones (e.g., offering beneficiaries valuable gifts in connection with direct or indirect marketing activities), In addition, the OIG seeks comments on various types of programs that would meet the purpose of this new statutory exception. Notably, the OIG does not propose regulatory text, but seeks input on language as well as specific examples of the types of remuneration that would further access to care and have minimal fraud and abuse risk. The OIG states that the statutory exception only applies to otherwise-prohibited remuneration that meets *both* of these standards. In this regard, the OIG distinguishes potentially beneficial practices (e.g., certain hospitals offering lodging assistance that is necessary to obtaining treatment, and providing patients with items to record health data such as blood pressure cuffs) from potentially abusive ones (e.g., offering beneficiaries valuable gifts in connection with direct or indirect marketing activities). The OIG seeks comments on whether otherwise-prohibited incentives for compliance with treatment regiments should be permitted.

The OIG interprets "promotes access to care" as remuneration that improves a particular beneficiary's ability to obtain medically necessary health care items and services. The OIG solicits comments on whether this phrase should be interpreted more broadly in light of coordinated or integrated care arrangements that depend, in part, on patient engagement. For example, the OIG asks whether the term should include encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient. Likewise, the OIG seeks comments on whether the term should include promoting access to care for a defined beneficiary population, such as a network or those treated under a designated care protocol. Finally, the OIG asks whether "access to care" should include care that is non-clinical but reasonably related to the patient's medical care, such as social services.

With respect to the phrase "low risk of harm" to Medicare and Medicaid beneficiaries and programs, the OIG interprets this to mean (i) unlikely to interfere with, or skew, clinical decision-making; (ii) unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient-safety or quality-of-care concerns.

Finally, the OIG seeks comments on whether to make a special provision for incentives offered by participants in CMS-sponsored initiatives and demonstrations for beneficiaries covered by these programs, such as the Bundled

Payment of Care Initiative. The OIG reasons that many of these programs have safeguards built into their structures, and include CMS review and monitoring to assess the overall impact and cost and quality of care. This CMS oversight could mitigate against fraud and abuse risks.

Retailer Rewards Programs

The ACA excludes from the definition of remuneration the offer or transfer of items for free, such as coupons, rebates or rewards, for less than fair market value from a retailer to the general public regardless of payor status, as long as the remuneration is not tied to items and services reimbursable by federal health care programs. In the preamble, the OIG reviews the current limitations on providing items to beneficiaries under its 2002 Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, noting the permissibility of providing inexpensive gifts or services that have a retail value of no more than $10 individually and no more than $50 in the aggregate. The OIG acknowledges that many retailers have excluded federal health care program beneficiaries from their programs in light of these limitations. The OIG states that this new exception "should increase retailers' willingness to include Federal health care program beneficiaries in their reward programs in appropriate circumstances."

To implement the ACA provision, the Proposed Rule would exclude from the definition of "remuneration" the offer or transfer of items or services for free or less than fair market value that meet the following three criteria:

(i) *The items or services consist of coupons, rebates, or other rewards from a retailer.* The OIG proposes to define "coupon" as something authorizing a discount on merchandise or services, including a "buy one get one free" reward. A "rebate" would be a return on part of a payment, such as a store credit on previously purchased store items. A rebate could not exceed what the customer spent at the store. The term "other rewards" would be interpreted "primarily as describing free items or services, such as store merchandise, gasoline, frequent flyer miles, etc." Finally, "retailer" would have its usual meaning, *i.e.,* an entity that sells items directly to consumers. The OIG would not include "individuals or entities that primarily provide services (*e.g.,* hospitals or physicians)" as "retailers." The OIG expressly solicits comments on whether entities that primarily sell items that require a prescription (*e.g.,* medical equipment stores) should be considered "retailers." The OIG does not discuss mail order or internet sales, but does not exclude them from the definition of "retailers."

(ii) The items or services *are offered or transferred on equal terms available to the general public*, regardless of health insurance status. For example, a retailer could not offer its reward program only to Medicare beneficiaries, whereas a $10 off coupon for everyone within a given zip code could permissibly include prescription drugs.[8]

[8] The OIG cites its longstanding concern with providers and suppliers creating programs that "lemon drop" (discriminate against) and "cherry pick" (benefit) certain patients based on their health insurance status.

(iii) The offer or transfer of the items or services *is not tied to the provision of other items or services reimbursed in whole or in part by any federal health care program.* The OIG stresses that connections between the reward program and federal programs must be "attenuated," both at the front end and on redemption. For example, a pharmacy could not offer a $20 coupon to all customers, including Medicare beneficiaries, who transferred their prescriptions, since there would be a tie-in to obtaining Part D business, but a $20 coupon with every $1,000 spent out of pocket could include co-pays for prescription drugs, and the $20 coupon could be redeemed on co-pays for federally reimbursed items.

Financial-Need Based Exception

The ACA added an exclusion from prohibited remuneration for the offer of transfer or items or services for free or for less than fair market value to financially needy individuals. Specifically, under the ACA, giving such items does not implicate the ACA if they are not part of any advertisement or solicitation; it they are not tied to the provision of other services reimbursable by federal health care programs; if there is a reasonable connection between the items or services and the medical care of the individual; and if the person or entity providing the items or services does so after determining in good faith that the individual is in financial need. The OIG proposes to codify this requirement and spells out the four statutory criteria.

To qualify for this exclusion, the items or services provided to financially needy individuals could *not* be:

- cash or cash equivalents;
- part of an advertisement or solicitation; or
- conditioned on other reimbursable items or services.

In addition, there must be a "reasonable connection" between the items or services and the individual's medical care. This would be determined on a case-by-case basis with a two-part test. First, is there a "reasonable connection" in terms of identifiable medical care or treatment for the individual patient (i.e., is the item or service "medically indicated")? Examples of items and services that, in context, might qualify as reasonably connected to medical care could include: protective helmets and safety gear provided to hemophiliac children (note the existence of an unfavorable OIG Advisory Opinion 02-14 (2002) on this issue); nutritional supplements to malnourished patients with end stage renal disease; and air conditioners to asthmatic patients. Second, the value of the items and services could not be disproportionately large compared with the medical benefits. For example, a complimentary download to a diabetic patient's smart phone of a monitoring "app" for blood sugar would be valued proportionate, but transferring a smart phone with the app could not. The OIG also solicits comments on whether to identify specific conditions that would be deemed "reasonably connected" to the patient's medical care (e.g., physician or other health care professional's determination, lack of access to care, etc.).

Finally, the items or services could only be provided after a good faith individualized assessment of the patient's financial need on a case-by-case basis. The OIG observes that "financial need" would not be limited to "indigence" but could include any reasonable measure of financial hardship. The OIG seeks comments on

whether documentation of the financial need assessment should be required, but in any event states that it would be prudent for providers seeking protection under this exception to document contemporaneously the needs assessment and the criteria applied (for example, a reasonable set of income guidelines uniformly applied). This is similar to documentation many providers maintain for waiving applicable copayments based upon indigence, for example.

Waivers of Part D Cost-Sharing for First Fill of a Generic Drug

The ACA included a statutory exclusion from the definition of "remuneration" for waivers, by Part D plan sponsors, of a Part D enrollee's copayment for the first fill of a generic drug. The OIG has proposed to codify this exception in its CMP regulations. The OIG has proposed adding a requirement that "such waivers be included in the benefit design submitted to CMS," a requirement that does not appear in the statute. The OIG states that it is proposing to interpret the statutory provision consistent with current CMS guidance, noting that CMS already permits such waivers as part of Part D plan benefit designs.

Beneficiary Inducements - Hospital Outpatient Department Services

In addition to the ACA amendments to the beneficiary inducement CMPs, the OIG proposes to amend the beneficiary inducements CMP regulations to add a self-implementing exception that was enacted in Balanced Budget Act of 1997 (BBA) but was never codified. Specifically, the BBA required the Secretary to establish a procedure to permit hospitals to elect to reduce copayment amounts for some or all covered hospital outpatient department (OPD) services to no less than 20 percent of the Medicare OPD fee schedule amount.[9] The BBA likewise excluded from the definition of remuneration such a reduction in copayment amount for a covered OPD service. The OIG proposes to codify the statutory reduction in copayment at proposed 42 CFR § 1003.110, with an update to the statutory citation to reflect subsequent redesignation of statutory references. The OIG states its belief that the proposed change is consistent with congressional intent and "merely addresses an inadvertent oversight." The OIG solicits comments on this proposal.

Gainsharing CMP

The OIG has long struggled with gainsharing arrangements and how to promote their benefits within the statutory restrictions of Section 1128A(b)(1) of the Social Security Act, which expressly prohibits hospitals from knowingly paying a physician to reduce or limit services provided to Medicare or Medicaid beneficiaries. The gainsharing CMP is intended to address the conflict between the Medicare payment system for hospitals, which is based on a predetermined, fixed amount based on a patient's diagnosis, and the Medicare payment system for physicians, which is based on the number of procedures and services a physician provides to a patient. To critics of the gainsharing CMP, the broad language of the statute prohibits hospitals from offering appropriate incentives to

[9] The Secretary established these procedures at 42 CFR 419.42.

physicians to control the cost of care and the items and services they order in the hospital setting. Since the time Congress imposed this limitation, the OIG has emphasized in a series of advisory opinions and a Special Advisory Bulletin entitled "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries"[10] that the agency has no authority to create an exception to this broad prohibition. Here again in the Proposed Rule, the OIG repeats its previous interpretation that the statute not only prohibits payments to reduce "medically necessary" services, but services more generally as well.

Under this interpretation, and in the absence of new authorizing legislation, the OIG believes it lacks authority to apply a medically necessary standard to the prohibition, which, if permitted, would expand the incentives hospitals could employ to reduce cost. Given this restriction, the OIG is left debating in this latest Proposed Rule whether a narrow interpretation of the term "reduce or limit services" would allow hospitals greater flexibility in developing incentive programs that reduce costs without directly impacting the "services" offered to Medicare beneficiaries. For example, in the preamble to the Proposed Rule, the OIG asks whether hospitals should be permitted to offer incentives that reduce or limit "items" used in providing services. Most of the 16 gainsharing arrangements the OIG has approved through its advisory opinion process have involved standardization of surgical instruments, medical devices, drugs, or drug protocols. If the OIG were to limit its interpretation of the statutory restriction to *services*, such as medical procedures, providers would have greater flexibility in adopting standardization programs without the time and expense of seeking an advisory opinion or the risks that accompany a decision to forego the advisory opinion process.

As proposed, the regulation would simply codify the statutory language, the amount of penalties imposed for violating the prohibition, and the factors the OIG would consider in applying any penalty. However, in the preamble to the Proposed Rule, the OIG seeks comments on its interpretation of what constitutes reducing and limiting services, and also on what safeguards should be put in place to protect patients and the Medicare program from abuse. The types of safeguards the OIG suggests are consistent with the safeguards found in most of the gainsharing programs it has previously approved, such as notifying patients of the program, requiring quality monitoring procedures, and establishing thresholds in any incentive program that are based on historical experience prior to initiation of a gainsharing program. Any new interpretation the OIG adopts in connection with codifying the restrictions of Section 1128A(b)(1) is likely to offer providers greater comfort in implementing gainsharing arrangements. The question is whether the regulations or any accompanying interpretation will provide sufficient clarity and flexibility necessary for providers to continue providing quality health care while at the same time adopting arrangements that meaningfully reduce costs on a wider scale.

[10] https://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.

Conclusion

The Proposed Rule represents a thoughtful approach by the OIG to address in a realistic fashion a rapidly changing health care delivery system. While admittedly required by Congress to develop regulations in some of these areas, the OIG is clearly interested in and fundamentally open to industry comment. The OIG provides multiple examples of factual circumstances that it recognizes cause none of the evils the OIG has long guarded against – particularly overutilization and misutilization of items and services – even though those circumstances, service incentives, and the like may include federal health care beneficiaries along with commercial and private pay patients (i.e., in some cases, the OIG makes no distinction based upon payor source). The OIG also recognizes new delivery models, including formal ones (ACOs and bundled payment arrangements) and other evolving ones, in which the benefits to patients of access to care -- especially for preventative or chronic care -- appear to outweigh potential fraud and abuse risks. It appears that the more tied such benefits are to patient health and access, the more likely the OIG is to accept them. In the controversial area of gainsharing, where there is a concern that financial incentives instead could lead to *disincentives* to provide medically-necessary care, the rulemaking offers a real opportunity for greater clarity on the types of gainsharing programs that the OIG views as permissible, but without the cost and time of the advisory opinion process. Overall, to its credit, the OIG seems to recognize that new health care delivery mechanisms demand a more flexible approach to fraud and abuse enforcement than has been the case in the past.

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