PUBLICATION

Highlights of OIG's Proposal to Amend Safe Harbors to the Antikickback Statute and CMP Rules, and to Add New Safe Harbors [Ober|Kaler]

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On October 3, 2014, the Department of Health and Human Services Office of Inspector General (OIG) issued a proposed rule to establish new safe harbors under the antikickback statute and the civil monetary penalty (CMP) rules, and to make revisions to the safe harbors already in place. The proposed rule was driven by legislative changes put forth in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA); the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA); and the Balanced Budget Act of 1997 (BBA).

The OIG's proposals could impact a variety of business practices in the health care industry. Protection under the antikickback safe harbors would be extended in certain circumstances to cost-sharing waivers by pharmacies and for emergency ambulance services, remuneration between Medicare Advantage Organizations and federally qualified health centers, drug discounts, and complimentary local transportation services. Protection under the civil money penalty safe harbors would be extended by adding additional exceptions to the definition of *remuneration* under the beneficiary inducement CMP. Finally, the OIG seeks to codify regulations to interpret the statutory language of the CMP prohibition against gainsharing. The OIG has solicited comment on a number of important issues that may influence whether or not particular business practices are protected. **Comments are due on December 2, 2014.**

Safe Harbors Under the Antikickback Statute

Technical Correction to Referral Service Safe Harbor

The OIG's proposed rule impacts the second standard in the referral services exception to the anti-kickback statute. Characterizing the change as a technical correction, the OIG proposed to revert back to the language from the 1999 final rule. The current language 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.” The OIG proposes to revise the second standard of the exception to replace “by either party for the referral service” with “by either party for the ***other party***.” The revision is intended to eliminate unintended ambiguity created by the existing language, which could support the interpretation that referral services may adjust their fees on the basis of the volume of referrals made to participants.

Pharmacy Waivers of Cost-Sharing

The OIG noted its long-standing concerns regarding the reduction or waiver of Medicare or other cost-sharing amounts, before proposing to modify 42 C.F.R. § 1001.952(k) by extending the safe harbor's protection to “certain cost-sharing waivers that pose a low risk of harm” and by making associated technical corrections. Under the proposed 42 C.F.R. § 1001.952(k)(3), pharmacy waivers of Part D cost-sharing amounts would be protected so long as the waiver is not routine and is not advertised or part of a solicitation, and the pharmacy determines that the beneficiary has a financial need before making the waiver. The protections would also extend where “the pharmacy fails to collect the cost-sharing amount after making a reasonable effort to do so.”

However, if the waiver or reduction is made on behalf of a subsidy-eligible individual, then it may be routine and the pharmacy need not make a good faith determination of financial need, nor must it make a reasonable effort to collect the cost-sharing amount.

After noting that subparagraph (k) "is limited to reductions or waivers of Medicare and State health care program beneficiary cost-sharing," the OIG requested comments on whether or not to expand the protections to "waivers under all Federal health care programs."

Waivers of Cost-Sharing for Certain Emergency Ambulance Services

Though it has issued a number of favorable advisory opinions regarding "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 a political subdivision of a State," the OIG continues to receive many related requests for advisory opinions. Therefore, the OIG also proposes to extend safe harbor protections to protect qualifying emergency ambulance services. The expanded protection would apply to providers or suppliers of ambulance transport services that furnish emergency ambulance services, but the OIG seeks comment on its interpretation.

Under the proposed language, reductions or waivers must meet five conditions to be protected. First, the provider or supplier must be "owned and operated by a State, a political subdivision of a State, or a federally recognized Indian tribe." The expanded protection would not apply to contracts with non-governmental ambulance providers or suppliers. Second, the provider or supplier must also be a Medicare Part B provider or supplier of emergency ambulance services. Third, the provider's or supplier's reduction or waiver is not construed as the furnishing of free services paid for directly or indirectly by a government entity. Fourth, the provider or supplier must offer the reduction or waiver on a regular basis, without consideration of patient-specific factors. Fifth, the provider or supplier may not claim the reductions and waivers as bad debt for payment purposes, or otherwise shift the burden onto Medicare, State health care programs, other payers, or individuals. The OIG seeks comment on all five proposed conditions, as well as on "whether to include reductions or waivers of cost-sharing amounts owed under other Federal health care programs…."

Protection for Certain Remuneration Between Medicare Advantage Organizations and Federally Qualified Health Centers

The MMA added a new statutory exception to the antikickback statute which would protect remuneration between an MA organization and an FQHC, or an entity controlled by an FQHC, so long as the remuneration is provided pursuant to a written agreement as described in section 1853(a)(4) of the Social Security Act. The OIG is particularly interested in comments on its proposed incorporation of the new exception into the safe harbor regulations.

Protection for Discounts by Manufacturers on Certain Drugs Under the Medicare Coverage Gap Discount Program

Under the Medicare Coverage Gap Discount Program (MCGDP), prescription drug manufacturers may enter into agreements with the Secretary of the Department of Health and Human Services that enable the manufacturers to provide select beneficiaries with access to discounts on drugs at the point of sale. The OIG proposes to extend the reach of the safe harbor regulations by protecting discounts to the price of "applicable drugs" furnished to "applicable beneficiaries" through the MCGDP so long as the manufacturer is in full compliance with the MCGDP requirements.

Protection for Certain Free or Discounted Local Transportation Services

The OIG's proposed regulations address the long-standing issue surrounding the provision of local transportation to federal health care program beneficiaries. The OIG explored Congress's intent to protect the provision of complimentary local transportation of nominal value. In 2000, the OIG published its interpretation

of *nominal value* as “no more than $10 per item or service or $50 in the aggregate over the course of a year.” (65 Fed. Reg. 24,400, 24,411 (April 6, 2000.)) Over time, the OIG became concerned that its interpretation was overly restrictive. In 2002, the OIG solicited public comment on issues regarding the provision of complimentary local transportation, but never finalized a related exception. The OIG's concerns carried through the years, ultimating in the new safe harbor contained in the proposed rule.

The new safe harbor would be added to protect qualifying free or discounted local transportation made available to established patients to obtain medically necessary items and services. Local transportation services that are provided to the patients (and individuals necessary to assist the patient) to enable them to obtain medically necessary items or services in the provider or supplier's local area would be protected under the proposed language. The free or discounted local transportation offered must not be air, luxury, or ambulance-level transportation. To be considered “local,” the transportation distance must not be more than 25 miles. The OIG solicits comments on whether the 25 miles should be a fixed limitation or a distance “deemed” compliant. The OIG also seeks comments on other ways to interpret *local* including: (a) whether the service areas should be more expansive in rural or underserved areas; (b) whether to allow “free or discounted local transportation to the nearest facility capable of providing medically necessary items and services, even if the beneficiary resides farther away than the proposed mileage limits” would permit; (c) whether time is a more appropriate measure than distance; (d) whether to incorporate the “geographic area served by the hospital” from the compensation arrangement exceptions to the self-referral prohibition; and (e) whether taking a general approach, such as “transportation offered to patients within the primary service area of the provider or supplier (or other location) to which the patient would be transported” would be more appropriate.

The OIG identified characteristics of free or discounted local transportation services that, if present, would result in the service not being protected by the safe harbor, including: (a) marketing or advertising the service to potential referral sources; (b) paying drivers or other staff on a per-beneficiary transported basis; (c) marketing health care items and services during the transportation; (d) limiting the offer to patients referred to the offering entity by particular providers or suppliers; (e) making the offer contingent on patients seeing particular providers or suppliers who may be referral sources; and (f) transporting individuals for purposes wholly unrelated to health care. Nonetheless, Eligible Entities could set other limits on the transportation offers that are not related to the volume or value of referrals.

The safe harbor would incorporate a number of additional conditions for transportation services, relating to the proper recipient, eligible provider and suppliers, and the location of the transportation:

Recipient

The free or discounted local transportation is provided only to established patients, and must be determined in a manner unrelated to past or anticipated volume or value of federal health care business. The transportation offer must not be based on the type of treatment received by the patient, but may be restricted to patients whose conditions require frequent or critically timed appointments and who lack reliable transportation. The OIG seeks comments on limiting the protection for free or discounted transportation to be applicable only to established patients.

Eligible Providers and Suppliers

The free or discounted local transportation must be provided by an Eligible Entity, which the OIG defined to exclude laboratories as well as individuals and entities that primarily supply health care items. Eligible Entities may not engage in referral agreements with destination providers or suppliers tied to the transportation of beneficiaries. The Eligible Entity must bear the cost of the transportation offer, and may not shift the burden onto individuals or federal, state, or commercial payors. The OIG is particularly interested in receiving comments from the public that: (a) identify other types of entities that should be excluded, for instance, home

health agencies; (b) address partial limitations on eligibility for providers or suppliers that provide free or discounted local transportation to other health care providers or suppliers who refer to them; (c) address whether additional safeguards are needed depending on type of Eligible Entity; and that (d) address whether to require Eligible Entities to document and keep beneficiary eligibility criteria, given the concern that transportation offers based solely on the number of appointments would relate to the volume of federal health care business.

Location

The free or discounted local transportation may be made to the premises of a health care provider or supplier. The OIG seeks comments on: (a) additional safeguards; (b) whether a provider or supplier should be allowed to provide free or discounted local transportation to the premises of others whatsoever; and (c) the potential impact on health systems, health plans, ACOs, and other integrated provider or supplier networks that would be inclined to develop a free or discounted local transportation program among in-network providers and suppliers, and whether for these entities, the protections should apply only to in-network destinations or conversely whether such entities should be required to provide the transportation to non-network entities.

In addition to the solicitations for comments noted above, the OIG is considering, and seeks comment on, several additional questions, including: (a) whether to limit the safe harbor so that it would protect transportation offers for medical purposes only, as opposed to other purposes that relate to the patient's health care; and (b) whether the safe harbor should protect Eligible Entities' provision of shuttle transportation along regular routes with regular stops, and what additional safeguards might be necessary should such protection be extended.

Civil Monetary Penalty (CMP) Authorities

Revised Definition of Remuneration, Establishing New Exceptions to Beneficiary Inducement CMP

The BBA of 1997 added a section to the Social Security Act that permits hospitals to elect to reduce copayment amounts for some or all covered hospital outpatient department services to no less than 20 percent of the Medicare fee schedule. The OIG proposes to codify this exception to the definition of *remuneration* by using language substantively identical to the statutory language.

The ACA also amended the statutory definition of *remuneration*, adding exceptions protecting certain charitable and other programs. The OIG proposes to incorporate those three additional exceptions in the regulations through an amended definition of *remuneration*, as outlined below.

Remuneration Promoting Access, Posing Low Risk of Harm

While it does not propose regulatory text for such an exception, the OIG is considering various interpretations of the statutory exception to the definition of *remuneration* that permits remuneration that "promotes access to care and poses a low risk of harm to patients and Federal health care programs." The OIG is soliciting comments on what should be included within the meaning of *promotes access to care* and how to interpret *low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs*.

Promotes Access to Care

The OIG proposes that *promotes access to care* be interpreted to mean that the remuneration provided "improves a particular beneficiary's ability to obtain medically necessary health care items and services." However, the OIG seeks comments on whether it should expand that meaning to include "encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient for patients than it would otherwise be." The OIG is also considering whether the test for the exception should be that the remuneration promotes access to care for a *particular* beneficiary or for a defined beneficiary

population. Finally, the OIG is considering whether the term *care* may include nonclinical care such as social services.

Low Risk of Harm to Beneficiaries and Program

The OIG notes that promoting access to care alone is insufficient to obtain protection under this exception and that it is equally important that any remuneration provided must also pose low risk to both beneficiaries and the federal health care programs. The OIG proposes to interpret the phrase *low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs* to mean that the remuneration "(1) is unlikely to interfere with, or skew, clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) does not raise patient-safety or quality-of-care concerns." To illustrate its concerns, the OIG noted that remuneration in the form of rewards may incentivize a beneficiary to seek unnecessary or poor quality care, or cause a provider or supplier to order additional items or services to recoup the costs of offering rewards. Nevertheless, the OIG conceded that the offer of some rewards might in fact encourage beneficiaries to "engage in arrangements that lower health care costs (without compromising quality) or that promote their own wellness and health care…." For this reason, the OIG seeks comments on whether incentives for compliance with treatment regimens should be permitted. The OIG is also considering whether to make a special provision for incentives offered by the participants of programs such as ACOs to their covered beneficiaries.

Protection of Retailer Rewards Programs

The proposed regulatory exception to the definition of *remuneration* would reflect the ACA's revision, permitting the offer or transfer of items or services for free or less than fair market value if (1) the items or services consist of coupons, rebates, or other rewards from a retailer; (2) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (3) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed by the program.

The OIG notes that many retailers currently exclude federal health care program beneficiaries from incentive programs, even where the OIG has indicated its position that gifts worth no more than $10 and no more than $50 in the aggregate annually per patient do not violate the statute. This new exception, according to the OIG, should "increase retailers' willingness to include Federal health care program beneficiaries in their reward programs in appropriate circumstances."

Coupons, Rebates, and Other Rewards from Retailer

The proposed exception would interpret *coupon* as "something authorizing a discount on merchandise or services;" *rebate* as "a return on part of a payment;" and *other rewards* as "free items or services, such as store merchandise, gasoline, frequent flyer miles, etc." *Retailer* would have its "usual meaning, i.e., an entity that sells items directly to consumers" and that individuals and entities that primarily provide *services* would not be considered retailers.

Offered or Transferred Equally to the General Public, Regardless of Insurance Status

Under the proposed language, a retailer must offer the items or services without discriminating or "cherry picking" individuals based on their health insurance status.

Tied to the Provision of Provision of Items or Services Reimbursed by the Program

The OIG does not believe the statutory language of the exception for retailer rewards programs requires that there be no connection whatsoever between the offer and the medical care of the individual; rather, the connection should be "attenuated." That is, the reward cannot be conditioned, on the front end, on the purchase of good or services reimbursed by a federal health care program. A retail pharmacy, for example, cannot offer customers (that would include Program beneficiaries) a coupon for transferring prescriptions to the store. Nor may the reward itself be an item or service that is reimbursed under a federal health care program.

For instance, a customer should be allowed to redeem a coupon for anything purchased in the store rather than being restricted to using the coupon solely on the cost-sharing component of prescription purchases.

Protection of Remuneration Based on Financial Need

The OIG proposes an exception to the definition of *remuneration* to reflect the revision enacted under the ACA permitting the offer or transfer of items or services for free or less than fair market value after a determination that the recipient is in financial need and meets certain other criteria. As an initial matter, the OIG notes that the exception is limited to the offer or transfer of *items* or *services* and does not include cash or instruments convertible to cash. The additional criteria set forth under the statute include: (1) the items or services may not be offered as part of any advertisement or solicitation; (2) the items or services are not tied to the provision of other services reimbursed by the Program; (3) there must be a reasonable connection between the items or services and the medical care of the individual; and (4) the items or services may be provided only after determining in good faith that the individual is in financial need.

The OIG notes that the second and third criteria should be considered together in order to provide any meaningful interpretation, and its discussion regarding these components of the exception is consistent with its interpretation of the exception relating to retail rewards programs. Again, while the free or below fair market value items or services provided may not be *tied* to services reimbursable by Medicare and Medicaid, a "complete severance of the offer from the medical care of the individual" is not necessary. The OIG notes that this exception requires dual consideration:

Whether a reasonable connection exists from a medical perspective and whether a reasonable connection exists from a financial perspective. A reasonable connection exists from a medical perspective when the items or services would benefit or advance identifiable medical care or treatment that the individual patient is receiving. From a financial perspective, remuneration disproportionately large compared with the medical benefits conferred on the individual patient would not have a reasonable connection to the patient's medical care. Such remuneration gives rise to an inference that at least part of the transfer is being provided to induce beneficiaries to obtain additional services….

The fourth requirement, that the items or services be provided only after determining in good faith that the individual is in financial need, would be interpreted to mean that there is an individualized assessment of the patient's financial need on a case-by-case basis that is conducted in good faith. A "good faith" assessment would be one that utilizes a "reasonable" set of income guidelines that are (1) applied uniformly, (2) based on objective criteria, and (3) appropriate for the applicable locality. Further, "financial need" is not limited to indigence. Whether the OIG has the authority to require supporting documentation is under consideration; regardless, for those desiring protection under the exception it would be "prudent" to maintain "accurate and contemporaneous documentation of the need assessment and the criteria applied."

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

The final addition to the statute is intended to "minimize drug costs by encouraging the use of lower cost generic drugs." Under the exception, a PDP sponsor of a Part D plan or MA organization offering MA-PD plans may waive any copayment that would be otherwise owed by their enrollees for the first fill of a covered Part D drug that is a generic drug. Sponsors offering the waivers would be required to disclose the incentive program in their benefit plan package submissions to CMS. The exception would be effective for coverage years beginning after publication of the final rule.

Gainsharing CMP

Generally speaking, gainsharing provides a mechanism for aligning hospitals' economic incentives with physicians' interests and is a well-documented, viable method of facilitating this cooperation, to the benefit not only of hospitals but also of patients and payers. *Gainsharing* is a term that is used to describe arrangements between hospitals and physicians whereby the hospital agrees to share with the physicians any reduction in the hospital's costs for patient care attributable in part to the efforts of the physician.

The OIG's suspicion of gainsharing programs is long-standing. Its guidance on the subject dates back to 1999, with the issuance of a Special Advisory Bulletin outlining the OIG's concerns with generalized gainsharing (payments tied to overall cost savings rather than payments tied to specific, identifiable cost savings). The OIG continues to maintain its position as stated in the 1999 Special Advisory Bulletin: that gainsharing arrangements between hospitals and physicians violate the CMP provision that prohibits a hospital from paying a physician to induce reductions or limitations of patient care services to Medicare or Medicaid beneficiaries under the physician's direct care. Importantly, the OIG's interpretation of the CMP is expansive and is not limited to reductions or limitations of "medically necessary services." The OIG maintains that, absent a change to the statute by Congress, it does not have the authority to read a "medically necessary" requirement into the existing statutory language.

The OIG has acknowledged the benefits of gainsharing through congressional testimony and in the issuance of 16 favorable advisory opinions. The Proposed Rule highlights the OIG testimony and the factors the OIG considered when evaluating the approved gainsharing programs through its advisory opinion process. In addition, the Proposed Rule chronicles the recommendations regarding gainsharing that have come from the Medicare Payment Advisory Commission and the numerous demonstrations and other initiatives involving gainsharing that have been authorized by Congress and approved by the Secretary of Health and Human Services.

Against the historical background of the progression of gainsharing and its role in health care delivery reform, and in recognition of the changing landscape of health care delivery and payment models that shift the focus to efforts to lower costs and improve quality of care, the Proposed Rule appears to be an attempt to address the existing barriers to gainsharing posed by the CMP law. It would provide a codified interpretation of the statutory language of the gainsharing CMP, but would not create a regulatory exception for gainsharing. The regulatory text being proposed largely tracks the CMP statute. The OIG proposes to add a definition of *hospital*, which would refer back to the definitions of *hospitals* and *critical access hospitals* found in the Social Security Act. And most significantly, the OIG is seeking comments on whether to define the term *reduce or limit services*.

Specifically, the OIG seeks comments on how to define *reduce or limit services* in a manner that meets the aim of the CMP statute by providing sufficient safeguards to protect against the potential harms of paying physicians to limit care, discharge patients too soon (quicker and sicker), or inappropriately limit care provided to Medicare beneficiaries.

Finally, the Proposed Rule seeks comments specific to the following areas of concern, many of which are consistent with the aspects of the gainsharing programs reviewed by the OIG through the advisory opinion process:

- Should the OIG's interpretation of the prohibition on the limitation or reduction of services include "items" used in providing those services – consistent with the definition of *services* at 42 C.F.R. § 400.202? Is this appropriate in the context of the gainsharing CMP?

- Should the standardization of certain items (i.e., medical devices, drugs, surgical instruments) constitute the limitation of care? If all items remain available for use as deemed appropriate for a particular patient, would that change or impact the analysis?
- Should the use of clinical protocols based upon objective quality metrics constitute a reduction or limitation of care (i.e., discontinuation of a prophylactic antibiotic after an established period of time)? Should quality monitoring procedures be required to ensure that the protocols do not result in a reduction of care? How should these practices be monitored and documented?
- Should the standardization of items or processes include certain clinical thresholds derived from historical practices and/or clinical protocols that would in essence place limits on the sharing of savings for activities that exceed the clinical thresholds? For example, if blood cross-matching is indicated in approximately 30 percent of a hospital's surgical cases, that hospital would set the clinical threshold for blood cross-matching at 30 percent, rather than performing the procedure on all cases. The hospital would not share cost savings with surgeons for any reduction below the 30 percent threshold.
- Should patient notification of the gainsharing program be required? Would such a requirement assist in ensuring that payments were legitimate and not for reducing or limiting care?

Ober | Kaler Comments

The OIG seeks comment on a number of important questions and on additional safeguards that could limit the risk of fraud and abuse. Providers and suppliers should carefully consider taking the opportunity presented by the OIG to comment on the regulations that could protect their business practices.