OIG Proposes New Safe Harbors to the Anti-Kickback Statute and New Exceptions to the Two Civil Monetary Penalty Provisions

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On October 3, 2014, the Department of Health and Human Services’ Office of Inspector General (“OIG”) published a proposed rule (“Proposed Rule”) to add new safe harbors to the federal health care program anti-kickback statute (“Anti-Kickback Statute” or “AKS”) as well as new exceptions to the civil monetary penalty (“CMP”) for inducements being offered to federal health care program beneficiaries and to the CMP related to a hospital paying a physician for reducing or limiting the provision of items or services (referred to generally as the “Gainsharing CMP”).

From the outset, the OIG should be commended for issuing the Proposed Rule. It is the first time in seven years that the OIG has either issued any significant changes to or proposed any new safe harbors under the Anti-Kickback Statute. It has been nearly 20 years since the OIG first tried to promulgate regulations addressing the Gainsharing CMP. The issues addressed in the Proposed Rule are significant in that they wrestle with ever-changing health care industry. To that end, the Proposed Rule sets forth a number of provisions that codify into the regulations certain exceptions and modifications to the laws that Congress has adopted over the last decade. In addition, the Proposed Rule attempts to address the changes in how health care is being paid for and how to align the financial incentives among health providers. The Proposed Rule also attempts to further assist patients in being able to access health care in situations in which these laws have impeded health care providers and suppliers from offering services free of charge or at reduced amounts.

1 Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59,717 (proposed Oct. 3, 2014) (to be codified at 42 C.F.R. 1001, 1003), available at http://r20.rs6.net/tn.jsp?e=001vYPaV8Swt-4OJYyg5JiVrlLqz5Q99Q3Xw4rV7lXqzLxim84dRRQhBo8LvoHVBGlH0jhT4Em1EEdc3Ge2X7pPQNYaUPMfALr1K_vkCzx18UcfQ2tZXHU9RHEYNNydnebnf3G_U6FjZWXSYCEGnDjEpP6bTZwU37u2TFS0_Mxw=. 
While the Proposed Rule addresses a number of important topics, we believe that the Proposed Rule falls short of providing full flexibility to health care organizations to accomplish the access and cost-efficiency goals that the Affordable Care Act ("ACA") amendments were designed to address, and is otherwise unnecessarily narrow. For example, the OIG has proposed a safe harbor for waivers of cost-sharing amounts offered by a governmental entity furnishing emergency transportation services in an ambulance but neither extends safe harbor protection to non-governmental entities providing ambulance services nor offers to protect the waiver of such co-insurance amounts for non-emergency transportation. Other examples include the OIG’s proposed safe harbor for local transportation. While the concept of a transportation safe harbor is welcomed, the OIG’s proposal is too narrow and contemplates excluding transportation services (1) by certain industry segments and (2) to certain providers.

Importantly, what was published in the October 3rd Federal Register was a proposed rule; the public has the opportunity to submit comments to the OIG up until 5 p.m. (EST) on December 2, 2014. We strongly encourage members of the health industry to take advantage of this comment period and offer the OIG suggestions on ways in which the Proposed Rule, and the issues contained therein, should be expanded to address a broader array of financial arrangements needing protection from these laws.

ANTI-KICKBACK STATUTE AND SAFE HARBORS

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals or services reimbursable by the federal or state health care programs (e.g., Medicare, Medicaid). Each offense under the Anti-Kickback Statute is punishable by a fine of up to $25,000 and imprisonment for up to five years. Violators of the AKS also are subject to exclusion from federal health care programs and may be subject to CMPs: (1) up to $50,000, and (2) three times the amount of the remuneration in question.

In light of the breadth of the Anti-Kickback Statute, Congress adopted several statutory exceptions. Additionally, Congress provided the Secretary of the Department of Health and Human Services with the authority, which has been delegated to the OIG, to promulgate safe harbor regulations that protect certain conduct from AKS liability. While compliance with the criteria of a safe harbor offers absolute protection against liability under the Anti-Kickback Statute, the preamble to the initial final safe harbor regulations clearly states that the failure to fall squarely within the terms of a safe harbor does not necessarily mean that the arrangement is illegal or that it will be investigated or prosecuted. Over the years, the OIG has issued a number of safe harbor regulations that address an array of topics. Some of these safe harbors either mirror an already existing statutory exception or also provide further “clarification” on the OIG’s views on the purview of these statutory exceptions.

As such, over the last several years, the Anti-Kickback Statute has undergone a number of changes and been amended with the addition of some statutory exceptions. For example, as part of the Medicare Modernization Act of 2003 ("MMA"), Congress established the Part D prescription drug benefit and amended the Anti-Kickback Statute
to permit pharmacies to waive or reduce cost sharing under Part D, as long as certain criteria are met. Therefore, the Proposed Rule includes a new safe harbor addressing these types of waivers and reductions in cost-sharing requirements. In addition, for many years, the OIG has also contemplated the issue of free or discounted transportation services in the context of Section 1128A(a)(5), which precludes the offering or transferring of remuneration to an individual that is likely to influence the individual to order or receive from a particular provider or supplier any item or service. In response, the OIG has proposed a new safe harbor to protect free or discounted services for local transportation.

The various proposed new safe harbors and clarification of one already existing safe harbor (for referral services) that are included in the Proposed Rule are each separately described below.

**Part D Cost-Sharing Waivers by Pharmacies**

As stated above, when Congress adopted the MMA and the Part D program, Congress amended the Anti-Kickback Statute to permit pharmacies to waive or reduce cost sharing under Part D for financially needy Medicare beneficiaries, as long as certain criteria are met. In the proposed regulation, OIG has set out a new safe harbor that tracks the statutory exception and states the criteria that must be met:

1. The waiver or reduction is not advertised or part of a solicitation;
2. The pharmacy does not routinely waive the cost sharing; and
3. Before waiving the cost sharing, the pharmacy either determines that the beneficiary has a financial need or fails to collect the cost-sharing amount after making a reasonable effort.

If, however, the waiver is made on behalf of a “subsidy eligible” individual (which is defined as a Part D enrollee who has income below 150 percent of the poverty line and meets certain other statutory requirements set out in 42 U.S.C. 1395w-114), then only the first condition must be met.

Unfortunately, the safe harbor does not provide any further protection than the existing statutory exception. Dual eligibles—that is, those individuals enrolled in both Medicare and Medicaid—would not be covered automatically as “subsidy eligible” under this safe harbor. The word “routinely” in the second criteria remains ambiguous and may prevent a pharmacy from establishing a protocol for waiving the cost-sharing amount. Moreover, additional clarity is necessary to aid pharmacies in determining “financial need” and also in determining when a “reasonable effort” has been made to collect the cost-sharing amount.

**Cost-Sharing Waivers for Emergency Ambulance Services**

Over the years, the OIG has issued numerous Advisory Opinions on the issue of the reduction or waiver of coinsurance or deductible amounts owed for emergency
ambulance services. Because the Advisory Opinions are only binding on the parties that have requested them, and the OIG continues to receive similar Advisory Opinion requests, the OIG proposes to establish a new safe harbor for cost-sharing waivers as long as the following conditions are met:

1. The ambulance provider or supplier must be owned and operated by a state, a political subdivision of a state, or a federally recognized Indian tribe;
2. The ambulance provider or supplier is the Medicare Part B provider or supplier of the ambulance services;
3. The reduction or waiver of coinsurance or deductible amounts is not considered to be the furnishing of free services paid for directly or indirectly by a government entity;
4. The reduction or waiver is offered on a uniform basis, without regard to patient-specific factors; and
5. The ambulance provider or supplier must not later claim the amount reduced or waived as a bad debt.

Unfortunately, the proposed new safe harbor is limited to only those circumstances in which the ambulance provider or supplier is owned and operated by a governmental entity. However, the safe harbor does not address either for-profit or nonprofit (but not government operated) ambulance providers offering such waivers, even if the other above-referenced conditions were satisfied, and even if they are operated pursuant to a federal, state, or municipal contract. This is an issue for which non-government ambulance providers should consider submitting comments. The OIG has recognized that emergency ambulance services have inherent safeguards that warrant special treatment in a number of Advisory Opinions, and these safeguards exist irrespective of whether the ambulance supplier is operated by a governmental authority.

In addition, the OIG states in the preamble that it intends only to address in the safe harbor “emergency ambulance services” and would not include non-emergency transport services. As such, the OIG asks for public comment on whether the terms “emergency ambulance services” and “ambulance provider or supplier” need to be expressly defined in the safe harbor, as well as public comment on the applicability of the waiver to Medicare or other federal health care programs.

**FQHCs and Medicare Advantage Organizations**

As part of the MMA, Congress addressed the ability of a Medicare Advantage enrollee being able to obtain services from a Federal Qualified Health Center (“FQHC”) and that the Medicare Advantage organization must pay the FQHC no less than the level and amount of payment that the Medicare Advantage plan would pay to another type of entity furnishing such services. The OIG has simply mirrored the statutory exception by proposing a safe harbor that would protect any remuneration between a FQHC and a
Medicare Advantage organization pursuant to a written agreement that meets certain requirements in the Social Security Act.

**Medicare Coverage Gap Discount Program**

The Medicare Coverage Gap Discount Program, established by the ACA, allows prescription drug manufacturers to enter into an agreement with the Secretary of Health and Human Services to provide discounts at point of sale to certain beneficiaries. The ACA included an exception to the Anti-Kickback Statute to protect these discounts in the price of an “applicable drug” being furnished to an “applicable beneficiary.”

The Proposed Rule codifies not only this exception but also the definitions included in the statute of the terms “applicable beneficiary” and “applicable drug” under the program. Specifically, “applicable beneficiary” is defined as:

- an individual who, on the date of dispensing a covered Part D drug—
  - A. is enrolled in a prescription drug plan or [a Medicare Advantage Prescription Drug (MA-PD)] plan;
  - B. is not enrolled in a qualified retiree prescription drug plan;
  - C. is not entitled to an income-related subsidy under section 1860D-14(a); and
  - D. who—(i) has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) during the year; and (ii) has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B).

“Applicable drug” is defined as follows:

- with respect to an applicable beneficiary, a covered Part D drug—
  - A. approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and
  - B. (i) if the sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; (ii) if the [prescription drug plan (PDP)] sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or (iii) is provided through an exception or appeal.
Local Transportation

The OIG proposes a new safe harbor to protect free or discounted local transportation services (collectively “transportation services”) provided to federal health care program beneficiaries who are *established patients* (and, if needed, a person to assist the patient) to obtain medically necessary items or services. The OIG suggests that *established patients* are patients whom the provider offering the free or discounted transportation has previously serviced. However, to prevent impermissible arrangements, the OIG has imposed a number of requirements on the transportation services.

First, the transportation services, whether free or discounted, must be available only to established patients and be determined in a manner unrelated to the past or anticipated volume or value of federal health care program business. Within this condition, the OIG proposes a number of safeguards and limitations, including, but not limited to:

1. Limiting the transportation services to only be offered by an “Eligible Entity,” which would exclude individuals and/or entities acting on their behalf that primarily supply health care items (including, but not limited to, durable medical equipment (“DME”) suppliers or pharmaceutical companies).

2. Limiting whether certain types of health care providers or suppliers of services should not receive protection when they provide transportation services to other health care providers or suppliers that refer to them; specifically, transportation services provided by home health care providers to physician offices that are actual or potential referral sources. The OIG is proposing that the safe harbor would not protect transportation services that an Eligible Entity makes available only to patients who were referred by a particular health care provider or supplier. Similarly, the OIG is proposing that the safe harbor would not protect transportation services that are contingent on a patient seeing a particular provider or supplier that may be a referral source for the Eligible Entity.

Second, the transportation safe harbor restricts the form of transportation to not include air, luxury (e.g., limousine), and ambulance-level transportation.

Third, the OIG proposes to exclude the following from safe harbor protection: (1) transportation services that are publicly advertised or marketed to patients or to potential referral sources; (2) Eligible Entities paying drivers or others involved in arranging the transportation on a per-beneficiary transported basis; and (3) the marketing of health care items and services during the course of the transportation.

Fourth, the OIG proposes limiting the safe harbor to only local transportation (anything within 25 miles). The OIG is specifically soliciting comments on determining what “local” means, the approach and method to determine the service area, whether to permit free or discounted local transportation to the nearest facility capable of providing medically necessary items and services, and whether the Stark Law’s prohibition related to
compensation arrangements regarding “geographic area served by the hospital” would be useful.

Finally, the OIG is proposing to require the Eligible Entity to bear the cost of the transportation services and not shift the burden of the costs onto Medicare, a state health care program, other payers, or individuals.

Unfortunately, the proposed safe harbor is unduly narrow in that the OIG proposes to exclude transportation by certain entities (e.g., suppliers or pharmaceutical manufacturers) to certain providers (e.g., referral sources of the transportation provide) and to new, as opposed to existing, patients. If the concept of a transportation safe harbor is, as the OIG states, to promote “legitimate financial and patient care interests in the provision of local transportation to patients,” the safe harbor should not universally exclude from protection a whole segment of the industry that may be legitimately offering transportation services. There are many legitimate reasons why these entities may provide transportation services. For example, a pharmaceutical manufacturer may want to transport a patient to a clinical trial site. Likewise, the OIG’s proposal to potentially exclude transportation services to referral sources unnecessarily limits the potential applicability of the safe harbor, and its beneficial effect on patient access, since health care organizations and professionals are typically part of a community of intertwined referral networks. Additionally, limiting the transportation safe harbor to existing patients means that those who have had no means of transportation to establish a relationship with a health care provider will never be able to obtain the necessary transportation to do so.

EXCEPTIONS RELATED TO OIG’S CMP AUTHORITY

The OIG proposes to codify the various statutory exceptions to the OIG’s CMP authority that were included in the ACA, and also proposes an exception to the so-called “gainsharing” prohibition.

Specifically, the Social Security Act provides the OIG with the authority to impose CMPs on those health care entities that engage in certain behaviors. The Proposed Rule addresses two specific CMP provisions: (1) inducements being offered to beneficiaries and (2) hospitals making payments to physicians to reduce or limit services.

Beneficiary Inducements

The CMP Statute addressing inducements to beneficiaries prohibits a person from:

Offer[ing] to or transfer[ing] remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].

2 Social Security Act § 1128A(a)(5); 42 U.S.C. § 1320a-7a(a)(5).
The CMP Statute defines “remuneration” as including the waiver of coinsurance and deductibles and the transfer of items or services for free or for other than fair market value.

**Remuneration That Promotes Access/Low Risk of Harm**

The OIG proposes to codify the ACA exception to the definition of “remuneration” that protects “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.” For purposes of this exception, the OIG is proposing that the phrase “promotes access to care” means that the “remuneration provided improves a particular beneficiary’s ability to obtain medically necessary health care items and services.” This is a very narrow definition that could preclude many of the recent advancements in patient care that combine “medically necessary” services with alternative treatments. The OIG apparently recognizes this and is seeking comments as to whether this phrase should be interpreted more broadly, especially in light of the movement towards coordinated or integrated care arrangements that depend, in part, on patient interaction. The OIG is specifically asking for examples of remuneration that would promote access to care under a broader definition. Also, the OIG acknowledges that some of these programs might encourage patients to “engage in arrangements that lower health care costs” or that promote wellness and health care and is seeking comments on whether otherwise prohibited incentives for compliance with treatment regimens should be permitted, and, if so, what limitations or safeguards should be required.

The OIG is proposing 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.

In addition, the OIG is considering whether to make a special provision in the rule for incentives offered by participants to beneficiaries covered by these programs and seeking proposals for regulatory text language, including “specific examples of the types of remuneration to beneficiaries” that would implement the principles described herein.

**Remuneration Offered Through a Retailer Rewards Program**

The OIG proposes to codify the retailer rewards exception from the ACA in the Social Security Act by protecting the offer or transfer of items or services for free or less than fair market value by a person 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, in whole or in part, under Medicare or a state health care program.

The OIG’s interpretation in the proposed regulation is largely consistent with its interpretation of the exception in its various Advisory Opinions. Moreover, the OIG proposes to interpret the various terms used in the exception, including the term “coupon,” which is broadly defined as “something authorizing a discount,” so it need not be an actual coupon; “rebates,” which is interpreted as “a return on part of a payment”; “other rewards,” which is interpreted as free items or services such as store merchandise, gasoline, or frequent flyer miles; and “retailer,” which is interpreted as “having its usual meaning” as “an entity that sells items directly to consumers.”

In light of the increasing “retailization” of health care services, restricting the definition of “remuneration” to the sale of items is unnecessarily narrow, not taking into account that services that traditionally have been furnished in professional offices are increasingly moving out of professional offices and into shopping malls. The OIG is soliciting comments on whether entities that primarily sell items that require a prescription should be considered retailers.

The requirement for offering or transferring items on equal terms available to the general public, regardless of health insurance status, is interpreted as consistent with the OIG’s longstanding concern about discrimination against or in favor of certain patients (i.e., lemon dropping and cherry picking). Therefore, rewards offered only to Medicare patients would not qualify under the exception. However, a dollar amount off any purchase in the store, including prescriptions, would qualify if offered to everyone in a zip code without regard to health insurance status.

The OIG is unnecessarily restrictive in its interpretation of the third criterion prohibiting “tying.” The language of the tying prohibition provides that the offer or transfer of items not be tied to the provision of other federal or state health care program items or services. The OIG interprets this as requiring a complete attenuation of any connection between federally payable items and services and a loyalty program’s rewards to include the manner in which a reward is both “earned” and “redeemed.” At the “earning” end, the OIG states that the reward should not be conditioned on the purchase of goods or services reimbursed by a federal health care program, and should not treat federally reimbursable items and services in a manner that is different from non-reimbursable items. To the OIG, this means that a coupon for all customers, including Medicare beneficiaries, who transfer prescriptions, would not meet the exception because it would be tied to getting the customer’s Medicare Part D business.

At the “redeeming” end, the OIG states that programs in which the rewards themselves are federally reimbursed items or services do not qualify for the exemption. This would mean, for example, that reward programs that award points only for cost-sharing amounts on DME, prescription drugs, or other federally payable items or services would not meet the criterion for exemption. However, if the points or other rewards applied to
anything purchased in the store, including cost-sharing amounts, then the exception could be met.

This non-attenuation at both the “earning” and “redeeming” ends, which also has been adopted in the OIG’s Advisory Opinions, warrants public comment. The plain language of the statute only restricts tying to “other” items or services, not to the initial item for which the remuneration is offered. This interpretation would protect gift cards for prescription transfers for federal health care program beneficiaries, which was commonly understood to be the conduct that was sought to be protected by the ACA language.

Financial-Need-Based Exception

Section 1128A(i)(6) of the Social Security Act defines “remuneration” to transfers of items or services for free or which are not fair market value. However, an exception at 1128(A)(i)(6)(h) exists for such transfers provided that:

1. the items or services are not offered as part of any advertisement or solicitation;
2. the items or services are not tied to the provision of other services reimbursed by certain federal and state programs;
3. there is 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 remains consistent with its position on prior issuances regarding the transfer of cash or cash equivalent items to beneficiaries. The OIG restates that such cash or equivalents (which can be converted to cash) are not protected as items or services under the exemption. However, the OIG does not take the opportunity to further clarify or modify what it considers impermissible cash equivalent instruments.

The OIG restates that protected items or services may not be offered as part of any advertisement or solicitation without further clarification on what conduct is considered an advertisement or solicitation.

Moreover, the OIG reaffirms the position that it took in the retailers reward section above, namely that “we do not interpret the prohibition on tying the free or below-market items and services to services reimbursable by Medicare or Medicaid as requiring a complete severance of the offer from the medical care of the individual,” but it is soliciting comments for this provision.

The OIG states its belief that this exception was enacted to assist financially needy individuals access items or services related to their medical care, and was not intended
to cause a patient to seek additional care. The term “medical care” was defined broadly in the issuance as “treatment and management of illness or injury and the preservation of health through services offered by the medical, dental, pharmacy, nursing, and allied health professions.” According to the OIG, what constitutes a “reasonable connection” between the remuneration and the patient’s medical care requires consideration of two factors; first, whether a reasonable connection exists from a medical perspective, and second, whether a reasonable connection exists from a financial perspective.

Additionally, the OIG suggests that 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. The OIG provides limited examples of items and services that under certain circumstances might qualify as medical care. However, the Proposed Rule suggests that all of the examples could run afoul of the exemption if, for example, they were provided but were not medically indicated. The OIG solicits comments on what should be considered medically indicated. The OIG is also considering whether it should identify the specific conditions under which remuneration would be “reasonably connected” to medical care.

The OIG also suggests that financial need would not be limited to “indigence” and “could include any reasonable measure of financial hardship.” The Proposed Rule states that a good faith determination of financial need may vary depending on a particular patient’s circumstances and that the offeror of the items or services has some degree of flexibility to consider “relevant variables.” Though the OIG has not previously taken the position that the financial need determination was required to be memorialized, it is considering whether it can necessitate the creation of such documentation. The OIG also suggests that, even if it does not ultimately decide to require a memorial, it would nonetheless be “prudent for those seeking protection under the proposed exception to maintain accurate and contemporaneous documentation of the need assessment and the criteria applied.”

Finally, the OIG remains consistent with its prior views on routine copayment waivers and states that it proposes to interpret this provision as requiring a good faith individualized assessment of the patient’s financial need on a case-by-case basis. The rule states that such an assessment should use an objective, uniform, and reasonable set of income guidelines that takes into account locality.

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

The OIG is also proposing to finalize the exemption to the definition of remuneration found in Section 1128A(i)(6)(I). This exception permits Prescription Drug Plan (“PDP”) sponsors of Part D plans or Medicare Advantage plans to waive enrollee copayments for the first fill of a covered generic drug. The OIG acknowledged that such a waiver could minimize drug costs by encouraging the use of lower-cost generic drugs. The Proposed Rule suggests that sponsors who offer these waivers will be required to disclose the waiver to the Centers for Medicare & Medicaid Services (“CMS”) in their benefit plan package. Since CMS already permits these waivers as part of Part D and Medicare Advantage plan benefit designs, the OIG clarified that it will not exercise its
enforcement authority against plans complying with CMS requirements for these waivers prior to the finalization of the exception.

**Gainsharing**

The Proposed Rule also contains some long overdue discussion regarding the Gainsharing CMP. Beginning in the early 1980s, Medicare payments to hospitals were based on a prospective payment system ("PPS"), reimbursing the hospitals according to the classification of the patient admission by the hospital into the appropriate Diagnosis Related Group ("DRG"), regardless of the patient’s length of stay. As a result of the implementation of PPS, certain hospitals adopted physician incentive plans that gave physicians financial incentives to control the length of stay of their patients (a practice commonly referred to as “gainsharing” or “shared savings”). In reaction to these physician incentive plans, Congress, in 1986, provided the Secretary of Health and Human Services with authority to impose CMPs on hospitals that “knowingly make[ ] a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals” who are entitled to Medicare or Medicaid benefits, and who are under the direct care of the physician.

In December 1994, the OIG issued a proposed rule to implement this authority, but this rule was never finalized. In the meantime, as health care costs grew, there was a proliferation of physician incentive programs designed to control the problem of medically unnecessary services. These arrangements were typically called "gainsharing" arrangements, and they gave physicians a financial reward based on cost savings achieved from various practice efficiencies. In response to these arrangements, in 1999, the OIG issued a Special Advisory Bulletin regarding hospital gainsharing, stating that such arrangements violated the CMP.

Nevertheless, over the course of the past 15 years, the OIG has issued numerous Advisory Opinions addressing hospitals' proposed cost-savings programs, determining many arrangements permissible under the CMP.

The October 3, 2014, *Federal Register* Notice is the first time since 1994 that the OIG has addressed the adoption of a regulation to further define and describe the scope of the Gainsharing CMP through the regulatory process under the Administrative Procedures Act.

The OIG acknowledges that one of the challenges with the gainsharing statute is that it is not limited to incentive plans that reduce or limit "medically necessary" services but, instead, simply those that reduce "services." The OIG states in the preamble to the proposed regulation that "given the changes in the practice of medicine over the years, including collaborative efforts among providers and practitioners and the rise of widely accepted clinical metrics, we are considering a narrower interpretation of the term ‘reduce or limit services’ than [the OIG has] previously held.”
In the Proposed Rule, the OIG proposes language that mirrors the statute and the following additional criteria to assess the magnitude of damages in reduction of services enforcement actions:

- nature of payment,
- extent to which the payment encouraged limiting medical care or premature discharge,
- actual or potential beneficiary harm, and
- financial condition of the hospital or physician.

Nevertheless, the OIG has asked the public to provide comment on a number of significant issues, including the following:

1. Should the OIG develop a definition of the phrase “reduce or limit services” and, if so, what should it consist of? Should the regulation include a requirement that the hospital and/or physician participating in a gainsharing program notify potentially affected patients about the program?

2. The OIG states in the preamble that it has interpreted the prohibition on payments to reduce or limit services as including payments to limit items used in providing services. Is this interpretation appropriate or necessary?

3. Should a hospital’s decision to standardize certain items (e.g., surgical instruments, medical devices) be deemed to constitute “reducing or limiting care”? Would the answer be different if the physician were simply encouraged to choose from the standardized items but could still use other items if the physician so chose?

4. Should a hospital’s decision to rely on protocols based on objective quality metrics for certain procedures be deemed to constitute “reducing or limiting care”? Should hospitals deciding to compensate physicians in connection with the use of such protocols be required to maintain quality monitoring procedures to ensure that these protocols do not, even inadvertently, involve reductions in care? What types of monitoring and documentation should be kept?

5. Should a hospital’s decision to standardize items or processes be required to establish certain thresholds based on historical experience or clinical protocols beyond which participating physicians could not share in cost savings?

This is an important step in the development of a workable gainsharing solution. Now, parties must go through a lengthy Advisory Opinion process to obtain full protection for their gainsharing activities.
CONCLUSION

The OIG will be accepting comments on the proposal until 5 p.m. (EST) on December 2, 2014. We encourage all stakeholders to provide public comment to the OIG regarding these proposals. Comments should address considerations in this proposal, discuss significant challenges related to implementation, and provide detailed suggestions based on experience with similar requirements.

Epstein Becker Green is available to assist with drafting and submitting comments to the Proposed Rule. If stakeholders need assistance, please contact one of the authors of this Client Alert or the Epstein Becker Green attorney who regularly handles your legal matters.

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