Office of the Inspector General Issues Advisory Opinions:

- **Performance-Based Compensation from Hospital to Cardiology Group for Cost Containment Measures Permissible**
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**OIG Issues Advisory Opinion: Performance-Based Compensation from Hospital to Cardiology Group for Cost Containment Measures Permissible**

The Office of the Inspector General (OIG) recently issued Advisory Opinion 12-22 (Advisory Opinion) regarding a clinical co-management agreement between a rural acute care hospital (the Hospital) and a cardiology group (the Group) involving the payment of performance-based compensation based on the attainment of certain metrics, including cost savings benchmarks (the Arrangement). The OIG ultimately concluded that, while the Arrangement has the potential to generate prohibited improper payments or remuneration under (i) the civil monetary penalty provision (CMP) prohibiting payments intended to induce a provider to reduce or limit services to Medicare or Medicaid beneficiaries and (ii) the Anti-Kickback Statute (AKS), sufficient safeguards were in place so that the OIG would not impose administrative sanctions.

**The Arrangement**

The Hospital operates four cardiac catheterization laboratories (the Labs) on its campus, the only such labs within a 50-mile radius of the campus. The Group is made up of 18 physicians, six of whom perform professional clinical services for the Labs (the Physicians). The Group is the only cardiology group on the Hospital's medical staff and the only cardiology group in the Hospital's town.

Under the Arrangement, the Group provides certain management and medical direction services for the Labs, including, but not limited to: providing strategic planning and medical direction services; developing the Hospital's cardiology program; and recommending Lab
equipment, medical devices and supplies (the Management Services). In exchange for the Management Services, the Hospital pays to the Group both a fixed payment (the Fixed Fee) and a potential annual performance-based payment (the Performance Fee), which is capped at a maximum amount each year. The Arrangement has a three-year term.

The Performance Fee consists of the following components: the Hospital's employee satisfaction; patient satisfaction with the Labs; improved quality of care within the Labs; and implementation of certain cost-saving measures (the Cost Savings Component). For each component, specific measurable metrics must be attained or surpassed to receive that portion of the Performance Fee. Most of these metrics incorporate three possible levels of achievement, or benchmarks, that trigger payment to the Group. If the Group does not achieve the baseline benchmark for a certain metric, it does not receive a corresponding portion of the Performance Fee.

The Hospital made a number of certifications to the OIG regarding the Arrangement:

- all purchasing decisions are based on the best interests of patients, and the Hospital utilizes products that are clinically safe and effective;
- the Hospital has reduced costs by (i) contracting with a single vendor for supplies; (ii) managing the use of devices, items and supplies, and (iii) product standardization, though the Physicians are able to request the most clinically appropriate device or supply for a patient;
- the Hospital and the Group protect against inappropriate reductions in services by (i) basing the cost savings measures on clinical outcomes and (ii) setting the Fixed Fee and the Performance Fee at fair market value;
- the Hospital engages an independent utilization review firm to determine if activities under the Arrangement have adversely affected patient care provided by the Labs based on a review of (i) data related to the components of the Performance Fee and (ii) the clinical appropriateness of procedures performed at the Labs.

**OIG Findings**

**The Civil Monetary Penalty**

The CMP prohibits a hospital from making payments to induce a physician or physician group to reduce or limit services provided to Medicare and Medicaid beneficiaries. The OIG determined that the Cost Saving Component of the Arrangement, which requires standardization of devices and supplies and limits the use of certain devices, might induce the Physicians to alter their practices and to reduce or limit services provided to patients of the Labs. The OIG concluded, however, that it would not seek sanctions against the Hospital under the CMP because the Arrangement contains the following safeguards against inappropriate reduction or limitation of services:

- the Hospital certified that the Hospital's Board of Directors, internal auditing staff, Hospital committees, and third-party firms engage in regular monitoring of the Group's performance to protect against inappropriate reductions or limitations of services;
- the risk is low that the Arrangement will lead the Group to apply a specific cost savings measure in medically inappropriate situations. The OIG noted that the Arrangement is structured to allow the Physicians to use the most cost-effective clinically appropriate items and that nonstandard items are readily available to physicians upon request;
- the term of the Arrangement is limited in duration and the amount of the potential
Performance Fee is capped each year;

- Group's receipt of the Performance Fee is conditioned upon the Group not: (1) limiting the provision of necessary medical services to the Hospital's patients; (2) increasing referrals to the Hospital; (3) cherry-picking healthy patients or those with desirable insurance for treatment in the Labs; or (4) accelerating patient discharges. If the Group engages in these prohibited activities, the Hospital does not pay any earned Performance Fee to the Group.

The Anti-Kickback Statute

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of services reimbursable by a federal health care program. The OIG determined that the personal services and management contracts safe harbor to the AKS does not apply to the Arrangement because the aggregate compensation paid to the Group is not set in advance. Nonetheless, the OIG concluded that it will not impose sanctions on the Hospital or the Group as a result of certain safeguards in the Arrangement.

The OIG found that the risk that compensation paid by the Hospital to the Group is payment for referrals is low based upon (i) the amount of services the Group actually performs for the Hospital pursuant to the Arrangement, (ii) the Hospital's certification that the compensation is consistent with fair market value for such services, and (iii) the fact that the compensation paid does not vary with the number of patients treated at the Labs. In addition, because there are no competing cardiac catheterization labs within a 50-mile radius of the Hospital, and because the Group does not provide cardiac catheterization services at any other location, it is unlikely that the compensation is incentive for the Group's physicians to refer business to the Labs. Furthermore, the specific measures within the Arrangement help ensure that the purpose is to improve the quality of Lab services rendered rather than to reward referrals by the Group. Finally, the OIG noted that the Arrangement is set forth in a written agreement between the Hospital and the Group, with a limited term.

The Advisory Opinion is limited to the Hospital and the specific Arrangement and certifications contained therein. Nonetheless, the Advisory Opinion provides guidance to other hospitals entering into clinical co-management agreements with private physician groups. Such hospitals may be well served to consider putting in place similar safeguards to those cited by the OIG and described above to prevent allegations of prohibited conduct under the CMP or the AKS.

OIG ISSUES ADVISORY OPINION: HEALTH CENTER’S PROPOSAL TO OFFER GROCERY GIFT CARDS TO CERTAIN ENROLLEES NOT SUBJECT TO SANCTIONS

The U.S. Department of Health & Human Services Office of Inspector General (OIG) recently issued Advisory Opinion 12-21, related to a proposal by a federally qualified health center (Health Center) to offer grocery gift cards redeemable for $20 in groceries to certain patients in capitated managed care plans (the Proposed Arrangement). The OIG ultimately concluded that the Proposed Arrangement does not violate the civil monetary penalties law (CMP) related to beneficiary inducements, and that, while the Proposed Arrangement has the potential for generating prohibited remuneration under the Anti-kickback Statute (AKS), the Proposed Arrangement had sufficient safeguards to prevent a violation of AKS from occurring.
The Arrangement

The Health Center, a 501(c)(3) nonprofit organization, has been engaged by managed care plans that contract with the state to serve as a contracted provider for the managed care plans' Medicaid enrollees on a capitated basis. The managed care plans assign enrollees to specific contracted providers (such as the Health Center) based on such considerations as the enrollees' geographic location, family ties, and the contracted provider's available capacity. Under the Proposed Arrangement, the Health Center would send letters to newly assigned enrollees and previously assigned enrollees not seen in the previous 12 months, and offer a $20 grocery gift card in exchange for a visit to the Health Center for a screening or any other clinical service performed on behalf of the enrollee. The gift card would not be redeemable for cash or items or services from the Health Center and enrollees would be limited to one gift card in any given 12-month period. The Proposed Arrangement would not be advertised or marketed other than in the letters described above.

OIG Findings

The OIG analyzed the Proposed Arrangement under both the CMP and AKS. The CMP imposes civil monetary penalties against any person who offers or transfers remuneration to any individual eligible for benefits under a Medicare or state health care program that the benefactor knows or should know is likely to influence the beneficiary's choice of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program. "Remuneration" is defined to include "transfers of items or services for free or for other than fair market value."

With respect to the CMP, the OIG determined that, while the gift card would constitute remuneration to federal health program beneficiaries and would be of more than nominal value, it is unlikely to influence beneficiaries to select the Health Center as their contracted provider because of the following factors:

- the enrollees are assigned to a contracted provider by their managed care plan and would have to affirmatively elect reassignment in order to select the Health Center as their contracted provider;
- the gift card would be of relatively modest value and would not be redeemable for cash, items or services provided by the Health Center; and
- the offer of the gift card would not be advertised or marketed, except to certain groups of beneficiaries already assigned to the Health Center.

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services paid by a federal health care program. Under the AKS, remuneration can include the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Since the AKS is so broad, the OIG has issued regulatory safe harbors, which define certain practices not subject to the AKS (and therefore in a safe harbor), because it is believed that such practices are unlikely to result in fraud or abuse. The failure to satisfy the requirements of a safe harbor does not mean that a particular arrangement or practice constitutes a violation of the AKS; it simply means that the arrangement will not receive safe harbor protection and may be subject to scrutiny.

With respect to the AKS, the OIG concluded that the Proposed Arrangement poses a minimal risk of fraud and abuse. The OIG based this conclusion on the following factors (in
combination with the factors set forth above):

- the Health Center would offer the gift card only to beneficiaries enrolled in Medicaid managed care programs that are reimbursed on a capitated basis, and therefore, the Proposed Arrangement would not result in increased costs to the federal health care programs or provide the Health Center with an incentive to provide unnecessary care or services;
- the Proposed Arrangement would limit the annual amount of incentives offered to such beneficiaries to one gift card of relatively modest value;
- the offer of a $20 gift card to certain beneficiaries is unlikely to harm the Health Center’s competitors;
- the Proposed Arrangement would provide a benefit to members of the largely poor and underserved community the Health Center serves; and
- the Proposed Arrangement would engage beneficiaries and educate them about the Health Center and its potential role in the delivery of their health care, both to improve health outcomes and to make the best use of resources in connection with capitated managed care plans.

Although the OIG stressed that this Advisory Opinion is limited to the Health Center, it provides guidance to other health care providers contemplating or already using gift cards or similar incentives. Please contact any member of Robinson & Cole’s Health Law Group with respect to any potential incentive arrangements or similar matters.

If you have any questions regarding these advisory opinions, please contact a member of Robinson & Cole’s Health Law Group.

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