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**From:** Cassidy, Mike  
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**From:** Advisory Opinions Task Force [mailto:MemberUpdate@healthlawyers.org]  
**Sent:** Wednesday, January 16, 2008 4:34 PM  
**To:** Cassidy, Mike  
**Subject:** Summary of OIG Advisory Opinions 07-21 and 07-22



## PRACTICE GROUPS

*advisory opinion*

Date: January 16, 2008

**Summary of OIG Advisory Opinions 07-21 and 07-22**  
*Issued December 28, 2007, and Posted January 14, 2008*  
Written by Joseph Kahn, Reviewed by Claire Turcotte\*

On December 28, 2007, the Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinions 07-21 and 07-22, in which the OIG reiterated its position regarding gainsharing arrangements. After reviewing the arrangements established by the requestors, involving cardiac surgeons and anesthesiologists respectively, the OIG found that the arrangements implicated the anti-kickback statute and civil monetary penalty (CMP) provisions of the Social Security Act, 42 U.S.C. 1320a-7b and 1320a-7a, respectively, but concluded that it would not impose civil monetary penalties or administrative sanctions.

Although the OIG redacts identifying information in the published opinions, the facts described the opinions are similar enough that, for purposes of this summary, the hospitals involved in the arrangements covered by the opinions will be collectively referred to herein as "Hospital". Opinion 07-21 addresses the Hospital's arrangement with a group of cardiac surgeons (Surgeons), in which the Hospital proposes to share a portion of the cost savings achieved by the gainsharing arrangement entered into between the parties. Opinion 07-22 addresses a similar arrangement between the Hospital and a group of anesthesiologists (Anesthesiologists). The Hospital, Surgeons, and Anesthesiologists have already implemented the cost saving measures in conjunction with their respective arrangements, but the Hospital has withheld payment under the arrangements until it received a positive opinion from the OIG.

*Summary of Surgeon Arrangement*

The Surgeons are the only group of cardiac surgeons at the Hospital and perform 100% of the Hospital's cardiac surgery. Under the arrangement, the Hospital agreed to share a portion of the cost savings directly attributable to specific changes in the Surgeons' operating room practices. The Hospital engaged a third-party program administrator (Administrator) to collect and analyze data related to the proposed cost saving practices, and to manage the arrangement. The Administrator was paid a fixed, fair market value fee for its services. After conducting a study of historic practices at the Hospital, the Administrator identified 25 specific cost-savings opportunities for the Surgeons that can be grouped into the following four categories: (1) Disposable Cell Saver Components (Surgeons to refrain from opening until need established); (2) Use As Needed Supplies (Surgeons to make patient-by-patient determinations); (3) Product Substitutions; and (4) Product Standardization (review vendors and products).

*Summary of Anesthesiologist Arrangement*

Under a similar arrangement between the Hospital and Anesthesiologists, the Administrator identified 5 specific cost-savings opportunities that can be grouped into the following three categories: (1) Use As Needed Items; (2) Product Substitution; and (3) Product Standardization.

Each of the arrangements contained several safeguards to protect against inappropriate reductions in services, including: (a) the Administrator used objective historical data and clinical measures; (b) where appropriate, the Administrator established "floors" below which no savings would accrue to the physicians; (c) the Administrator tracked the quality of performance of the procedures covered by the arrangements against indicators established by the Society of Thoracic Surgeons (STS), and the physician groups would not share in any savings attributable to procedures involving reductions in historical STS quality indicators; and (d) the physicians made case-by-case determinations as to the most appropriate devices, items or supplies to be used, and the Hospital ensured that the same selection of supplies was available for the physicians during the arrangements as were available before the arrangements.

For each arrangement, the Administrator calculated the actual cost of the items and services covered by the arrangements in the 12 months preceding each arrangement (Base Year). After the one-year contract year (Contract Year), the Administrator calculated the actual costs for the same items and services used during the Contract Year, adjusting for inappropriate reductions based on the "floors" or STS indicators. The Administrator then calculated the savings (Savings) achieved by subtracting the Contract Year costs from the Base Year costs. Subject to the limitations set forth below, the Hospital will pay the Surgeons and Anesthesiologists an aggregate payment equal to 50% of their respective Savings. The Hospital's payments are subject to the following limitations: (a) if the respective physician group's volume of procedures payable by a Federal program in the Contract Year exceeded the volume of similar procedures in the Base Year, the group would not share in the cost-savings attributable to the additional procedures; (b) if any physician

materially altered his/her historical referral pattern during the Contract Year (e.g., by steering patients by case severity, age or payor), the physician would be subject to termination from the arrangement; and (c) the Hospital's payments would not exceed 50% of the projected cost-savings. Additionally, the physician groups provided written disclosures of the arrangements to affected patients.

The OIG noted its overall concerns related to gainsharing arrangements, including the potential the arrangements could encourage: (i) stinting on patient care; (ii) "cherry picking" healthy patients; (iii) payments in exchange for referrals; and (iv) unfair competition. The OIG then turned its attention to analyzing the arrangements under the CMP statutes. The OIG found that the arrangements likely implicated the CMP; however, the OIG determined the safeguards built into the arrangements would preclude the OIG from seeking sanctions for the following reasons:

- The specific cost-saving actions were clearly and separately identified, and the savings determinations were transparent.
- There was credible support that the arrangements did not adversely affect patient care.
- The arrangements applied to all covered procedures, regardless of insurance coverage.
- By utilizing objective historical and clinical measures to establish baselines, the arrangements protected against inappropriate reductions in services.
- The physicians had the same supplies available to them under the arrangements as they had before the arrangements.
- The Hospital and physicians provided written disclosures of the arrangements to patients.
- The arrangements limited the duration and scope of the financial incentives.
- Each group distributes the Hospital's payment among its members on a per capita basis.

The OIG then turned its analysis to the anti-kickback law, and determined that the personal services safe harbor would not afford protection to the arrangements because the aggregate compensation was not set forth in advance. Although the OIG found that the arrangements could result in illegal remuneration under the anti-kickback law if the requisite intent was present, the OIG determined that it would not impose sanctions under the anti-kickback law for the following reasons:

- The arrangements were unlikely to increase referrals because: (i) the arrangements were limited to physicians already on staff, thus reducing the likelihood that the arrangements would attract other physicians to the Hospital; (ii) the savings attributable to Federal program beneficiaries was capped; and (ii) the term of the arrangements were limited in duration to one year.
- Each group was the sole participant of their respective arrangement, and each group is composed entirely of their respective specialty. In addition, the groups distributed their payment on a per capita basis.
- The activities required of the groups under the arrangements

carried some increased liability risks for the physicians, for which compensation was reasonable. In addition, the compensation was reasonably limited in duration, amount, and scope.

Although the OIG applied the same analysis set forth above for the Anesthesiologists, the OIG did note that it was less likely that the Anesthesiologists would make referrals to the Hospital in violation of the anti-kickback law.

The OIG reiterated its emphasis on the transparency of these gainsharing arrangements, and cautioned against similar arrangements, including multi-year arrangements or those based on generalized, less specific cost-savings formulae. The OIG's findings and position in these Opinions are similar to those found in previous guidance and opinions addressing gainsharing arrangements. (See OIG Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999); OIG Advisory Opinions 01-01, 05-01, 05-02, 05-03, 05-04, 05-05, and 05-06).

To access a copy of OIG Advisory Opinion 07-21, [click here](#).

To access a copy of OIG Advisory Opinion 07-22, [click here](#).

*\*The Fraud and Abuse, Self-Referrals, and False Claims Practice Group Leadership would like to thank Advisory Opinions Task Force members Joseph Kahn (Nexsen Pruet PLLC, Greensboro, NC) and Claire Turcotte (Bricker & Eckler LLP, Cincinnati-Dayton, OH) for drafting and reviewing, respectively, this summary.*

For summaries of other OIG Advisory Opinions, please visit your Practice Group's website and click on the Advisory Opinions link on the left hand navigation menu. Courtesy of the Fraud and Abuse, Self-Referrals, and False Claims Practice Group.

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