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OIG advisory opinions
Two hospital gainsharing arrangements approved

Using reimbursement incentives to promote quality of care

How does your physician rate?
Large health plans implement physician ranking

Keep the FTC out of your hospital merger

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OIG advisory opinions

Two hospital gainsharing arrangements approved

Late last year, the Office of Inspector General (OIG) issued two advisory opinions approving two different hospital gainsharing arrangements. In the arrangements, physician groups shared a percentage of a hospital's cost savings arising from the groups' use of specific cost-saving measures in certain procedures.

THE OIG'S POSITION

The Social Security Act's civil monetary penalty (CMP) prohibits hospitals from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries. In the past, the OIG has stated that gainsharing arrangements are the kind of physician incentive programs that Congress prohibited when it enacted the CMP. The 2007 advisory opinions don't substantially change the OIG's previous determination that such arrangements are prohibited by the CMP.

The OIG found that both arrangements could constitute improper payments under the CMP and implicate the antikickback statute. But it concluded that it wouldn't impose CMPs or administrative sanctions because the arrangements contained sufficient safeguards. Let's take a closer look at the facts giving rise to the OIG's most recent advisory opinions.

THE ARRANGEMENTS

The facts of the two different cases are quite similar. Advisory opinion 07-21 addressed the hospital's arrangement with a group of cardiac surgeons, who were the only group of cardiac surgeons at the hospital and who performed 100% of the hospital's cardiac surgery. Advisory opinion 07-22 covered a similar arrangement between the hospital and a group of anesthesiologists who were the only group that administered cardiac anesthesia at the hospital.

Under the arrangements, the hospital hired a third-party administrator to manage the arrangements. After studying hospital practices, the administrator identified 25 cost-saving opportunities for the surgeons grouped into four categories:

1. Use-as-needed supplies,
2. Product substitutions,
3. Product standardization, and
4. Disposable cell saver components.

The administrator identified five cost-saving opportunities for the anesthesiologists that fell into the first three categories.

THE SAVINGS

The administrator calculated the actual cost of each item or service identified as a cost-saving opportunity in the 12 months preceding the start of the arrangements (base year). Then, the administrator calculated the actual costs for the same items and services used during the one-year contract year (contract year) and calculated the savings achieved by the hospital by subtracting the contract-year costs from the base-year costs. Under the arrangements, the hospital pays 50% of the savings to the respective physician group.

These payments are subject to several limitations, including:

Excess procedures. If the physician group's number of procedures payable by a federal health care program in the contract year exceeds the number of similar procedures in the base year, the arrangements exclude the sharing of cost savings attributable to the excess procedures.

Referral patterns. If changes from historical measures of case severity, patient age and payors indicate that a physician altered his or her referral patterns to maximize cost savings, the administrator will terminate the physician's participation.

Aggregate payments. The hospital's aggregate payments can't exceed 50% of the cost savings projected by the administrator before the start of the contract year.

The arrangements contain other safeguards designed to protect against inappropriate reductions in services. For example, the arrangements use objective, historical and clinical data to establish "floors" for certain cost-saving opportunities. The physician groups cannot share in savings attributable to reductions in items or services below the floor number.

The administrator also tracks the procedures covered by the arrangements against quality indicators established by the Society of Thoracic Surgeons (STS). Physicians can't share in any savings attributable to procedures involving reductions in historical STS quality indicators. Finally, the individual physicians make patient-by-patient determinations regarding the most appropriate device or supplies to use, and the same selection of supplies is available to the physicians during the contract year as was previously available.

THE CMP PROVISIONS

The OIG found that the arrangements likely implicated the CMP, but it wouldn't seek sanctions because they contained sufficient safeguards. These safeguards included:

- The specific cost-saving opportunities were clearly and separately identified and the savings determinations were transparent,
- Credible evidence showed that the arrangements didn't adversely affect patient care,
- The cost savings were calculated based on all surgeries regardless of the patients' insurance coverage, subject to a cap on federal health care program procedures,
- The arrangements prevented physicians from sharing in cost savings attributable to a reduction in supplies or services below a pre-established threshold or STS quality indicators,
- The physicians still had the same selection of devices and supplies available under the arrangements as they did previously, and
- The hospital and physicians provided written disclosures of the arrangements to patients whose care might have been affected by the cost-saving measures.

The OIG also noted that the financial incentives to the physician groups were reasonably limited in duration and amount. And finally, any incentive for a physician to generate disproportionate cost savings was mitigated by requiring the physician groups to distribute the profits to its members on a *per capita* basis.

THE ANTIKICKBACK STATUTE

The OIG also found the arrangements could result in illegal payment under the antikickback law if intent to induce referrals was present. But it didn't impose sanctions because several characteristics of the arrangements reduced the likelihood that the arrangements could be used to attract referring physicians or to increase referrals from existing physicians.

For example, participation was limited to physicians already on the medical staff, and patient admissions were monitored for changes in case severity, age or payor status to ensure that the arrangements didn't result in physicians inappropriately changing referral patterns. Further, the OIG noted that cost-saving opportunities represented changes in operating room practice carrying some increased liability risks for the physicians, for which compensation was reasonable.

> *The OIG had stated that gainsharing arrangements are the kind of physician incentive programs that Congress prohibited when it enacted the CMP.*

THE OPINIONS' EFFECT

Does this most recent approval of a gainsharing arrangement signal a change in the OIG's position? To date, the OIG hasn't officially withdrawn its position against them, so don't interpret these favorable advisory opinions as a general approval of gainsharing arrangements. As with all advisory opinions, they're limited to the specific facts and circumstances surrounding these particular arrangements. Improperly designed or implemented arrangements risk adversely affecting patient care and may be viewed as a means to disguise payments for referrals or a CMP violation. Any hospital considering such arrangements should seek advice from legal counsel before proceeding.

Using reimbursement incentives to promote quality of care

Using reimbursement incentives to promote improved quality of care and reduce program costs isn't new to the Centers for Medicare and Medicaid Services (CMS). During the past several years, CMS has implemented a variety of pay-for-performance programs that it hopes will improve quality by financially rewarding providers who meet certain performance expectations.

These programs generally distribute bonus payments or differential updates to providers who either achieve specific quality benchmarks or demonstrate improvements from year to year. Embracing the belief that financial rewards — and sometimes penalties — are among the most powerful tools for bringing about behavior changes, CMS has announced plans to implement two new programs starting in October 2008.

POSITIVE INCENTIVE PROGRAM

CMS is authorized to develop a value-based purchasing (VBP) plan starting in October for Medicare services provided by hospitals paid under the inpatient prospective payment system (IPPS). By law, the plan must include the development and selection of measures of quality and efficiency in inpatient settings; the reporting, collection and validation of quality data; the structure, size and source of value-based payment adjustments; and the disclosure of information on hospital performance.

Late last year, CMS published a report discussing its plan to implement a Medicare hospital VBP program. CMS suggested building on an existing Medicare program that provides differential payments to hospitals that meet certain requirements, such as publicly reporting performance on a defined set of inpatient care performance measures. CMS will phase out the existing program and replace it with a new program that will make a portion of hospital payment contingent on actual performance-specified quality measures.

CMS recommended the VBP plan include these basic components:

- A performance assessment model that scores a hospital's performance on a specified set of measures, generating a total performance score for each hospital,
- Translation of the VBP total performance score into an incentive payment,
- A measure development process, including selection criteria for choosing performance measures for the financial incentive, and candidate measures for the VBP program start,
- A phased transition from the existing program to the new VBP,
- Redesigned data submission and validation infrastructure to support the VBP program requirements,

- Enhancements to the existing Web site to support expanded public comments, and
- An approach to monitoring VBP effects, including potential outcomes on health disparities.

Even though the specific details of the VBP program haven't been formally adopted yet, it seems clear that CMS intends to incorporate VBP initiatives into the IPPS in the near future.

NO PAYMENT FOR "NEVER EVENTS"

Under the second program, beginning Oct. 1, 2008, Medicare will no longer reimburse hospitals for eight conditions that are acquired by patients while in the hospital and, in CMS's opinion, could have been prevented. These types of conditions are often referred to as "never events" based on the theory that these events should never occur because they can be prevented with implementation of certain measures by providers.

By law, CMS was required to designate at least two hospital-acquired conditions that will prevent assignment of a hospital stay to a higher paying diagnosis-related group (DRG) unless the hospital can document that the condition was present at the time of admission. To be designated as such, the hospital-acquired conditions must:

- Be associated with high cost or high volume or both,
- Result in the assignment of a case to a DRG that has higher payment when present as a secondary diagnosis, and
- Have been reasonably preventable through the application of evidence-based guidelines.

Applying these criteria, CMS, in the 2008 IPPS, set forth the following eight hospital-acquired conditions that it will not reimburse if the condition was not present at admission:

1. Serious preventable event — object left in surgery,
2. Serious preventable event — air embolism,
3. Serious preventable event — blood incompatibility,
4. Catheter-associated urinary tract infections,
5. Pressure ulcers,
6. Vascular catheter-associated infections,
7. Surgical site infections — mediastinitis after coronary artery bypass graft surgery, and
8. Hospital-acquired injuries — fractures, dislocations, intracranial injury, crushing injury, burn, and other unspecified effects of external causes.

CMS also announced it intends to include three additional hospital-acquired conditions in the 2009 IPPS: ventilator associated pneumonia, staphylococcus aureus septicemia and deep-vein thrombosis/pulmonary embolism.

What the opponents say

The effectiveness of pay-for-performance programs is still largely untested. Some providers are skeptical about the structure and motives behind the programs. They believe that incentives shouldn't be necessary when doctors are trained to provide the highest level of care possible. Further, opponents fear that payors are simply shifting existing payments among providers — not creating new sources of revenue.

Some providers claim such rationing is solely about maximizing payor profits and ignores differences in patient populations when scoring and comparing providers. Providers who attract disproportionate shares of clinically complicated cases may find it difficult to score well on quality measures based on patient outcomes.

Similarly, many opponents point out that hospitals and other providers are already trying to improve patient safety as part of their mission to provide quality care and reduce suffering. They question whether making providers pay for mistakes will lead to quality improvements or, instead, pressure providers to hide certain errors or provide care that, while avoiding errors on the no-pay list, may lead to increases in other types of complications.

Because reimbursement will hinge on whether such conditions were documented at the time of admission, screening procedures on admission will be critical to accurately identifying, diagnosing and documenting all of the then-present conditions.

> *Beginning Oct. 1, 2008, Medicare will no longer reimburse hospitals for eight conditions that are acquired by patients while in the hospital and could have been prevented.*

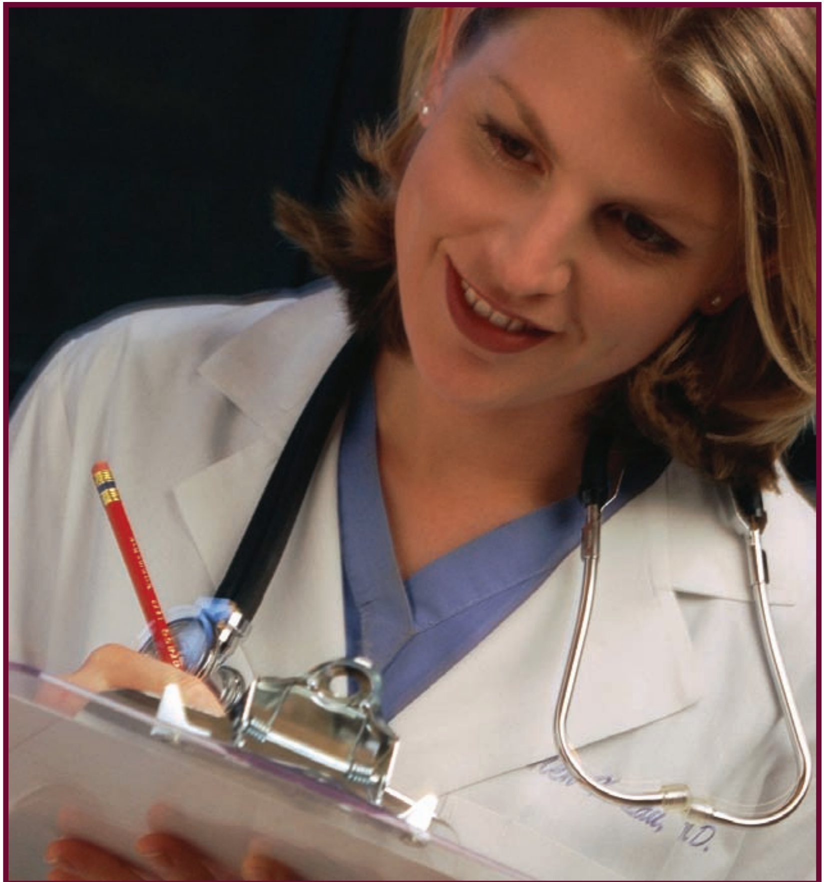
ARE YOU PREPARED?

This October will be a busy month for the CMS as the VBP program takes shape and the "never event" program begins. Hospitals may wish to implement screening procedures to rule out on admissions the conditions that are flagged by CMS as preventable hospital-acquired conditions.

How does your physician rate?

Large health plans implement physician ranking

It's no secret that the quality and cost-efficiency of health care vary. To help consumers make informed choices of where and from whom to seek care, some industry leaders are looking for ways to measure and report the comparative quality of physician practices.



In fact, a growing number of health plans rate physicians on certain quality and efficiency measures. The plans classify physicians in tiers and give plan beneficiaries incentives to select certain high-performing physicians. Such programs have become a significant component of a broader movement to use public reporting and consumer choice to drive improvements in the quality and value of health care.

RANKING CRITICISM

Recent efforts by health plans to implement physician-ranking programs have drawn criticism. Some say they may confuse or deceive consumers with the lack of transparency regarding how they make their rankings. Physician groups have claimed that such programs are driven by the health plan's financial motives and are designed to steer patients to the cheapest — but not necessarily the best — doctors.

Physician groups in Washington state and Connecticut have argued in lawsuits that the health plans rely on too little (often inaccurate) data to assign physicians to tiers, thus producing erroneous results. And physicians have objected to being shut off from the ranking process and unable to appeal the results.

Last fall, the New York State Attorney General (OAG) announced settlement agreements with all health plans that were operating, or had plans to implement, physician-ranking programs in the state. The health plans committed to complying with the OAG's physician-ranking program model. Four of the nation's largest health plans — WellPoint, CIGNA, Aetna and United Healthcare — agreed to use the model's principles on a nationwide basis.

RANKING MODEL

The OAG's model was created in consultation with the American Medical Association and the Medical Society of the State of New York, as well as numerous consumer advocacy groups. It focuses on accuracy and transparency of information, accountability, oversight of the process and fairness in physician comparisons.

Under the model, health plans will have to:

Disclose how cost affects ranking. Health plans must ensure that physician rankings aren't based solely on cost and clearly identify the degree to which any ranking is based on cost. Health plans must calculate and disclose cost-efficiency and quality of performance separately. If they're combined for a total ranking, the plan must disclose the proportion of each measure.

Use established national standards to measure quality and cost-efficiency. The measurements must be evidence-based or consensus-based clinical recommendations or

guidelines, including measures endorsed by the National Quality Forum and other generally accepted national standards. In evaluating physician quality and cost-efficiency, health plans should seek to achieve the goals of safe, timely, effective, efficient, equitable and patient-centered care.

Use several measures to provide accurate physician comparisons. These include valid sampling and risk adjustment to account for the characteristics of the physician's patient population, including case mix, severity of the patient's condition, comorbidities, outlier episodes and other factors.

Disclose program design and how it ranked physicians to consumers. If the health plan presents a total score, it should disclose the specific measures used for quality and cost-efficiency and each measure's relative weight in determining the total score.

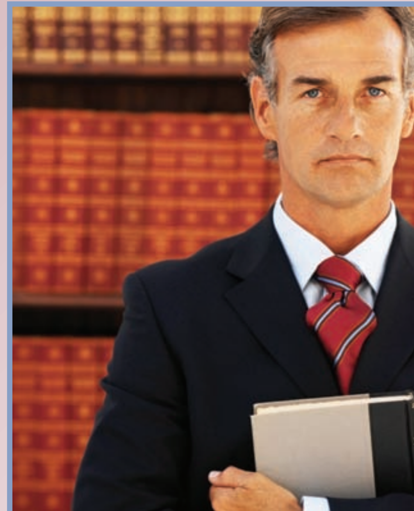
Disclose program design to physicians. Plans must tell physicians how they designed the program and provide a process to appeal disputed rankings and inclusion or exclusion in certain networks.

Oversee compliance with the model. Health plans must nominate and pay a ratings examiner to oversee compliance with the new ranking model and report to the OAG on a regular basis. This entity must be an independent, nonprofit, national standard-setting organization.

RANKING THE FUTURE

As health plans begin to revise existing — and introduce new — physician ranking programs, physicians and other health care providers should pay close attention to the methods used to calculate the rankings. How a physician is ranked or tiered within the health plan likely will affect the physician's overall satisfaction with his or her agreement with the health plan.

KEEP THE FTC OUT OF YOUR HOSPITAL MERGER



Last year, the Federal Trade Commission (FTC) ruled that the 2000 merger between Evanston Northwestern Healthcare (ENH) and Highland Park Hospital was an anticompetitive acquisition in violation of the Clayton Act. The act prohibits transactions that may substantially lessen competition.

ENH had appealed the FTC's 2005 order that ENH divest of Highland Park Hospital because of Clayton Act violations. In response, the FTC still found that the merger violated aspects of the act, but permitted the merger to remain intact and withdrew its divestiture order. In its place, it ordered ENH to negotiate separately with managed care companies on behalf of its member hospitals.

By challenging the merger retrospectively, the FTC had the benefit of postmerger evidence. This evidence showed that ENH had exercised its postmerger increased market power to obtain significant price increases that were substantially larger than price increases obtained by comparable hospitals.

So what should you do if a merger is in your future? First, mergers and acquisitions raise numerous complex antitrust issues. Consult your health care attorney to make sure you understand all of the complexities. Your attorney will help you address potential antitrust issues early in the premerger planning process and anticipate potential government action. Focus on how the proposed transaction will specifically and uniquely achieve quality and efficiency improvements, provide new services, and expand geographic reach, resulting in benefits to consumers.

Your conduct after the merger is complete is open to scrutiny as well. Both the FTC and the U.S. Department of Justice can bring an antitrust enforcement action against the parties at any time.

If the government challenges a hospital merger retrospectively, the antitrust analysis most likely will focus on evidence demonstrating the transaction's *actual* anticompetitive effects. The timing and size of the price increases implemented by ENH shortly after the transaction provided compelling evidence that the merger was anticompetitive. The advice in this short article can't cover all of the antitrust issues surrounding mergers and acquisitions. A knowledgeable attorney can help steer you through the maze.

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