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Gainsharing deals could violate proposed Stark changes

Be wary of gainsharing agreements, especially in light of looming Stark changes. The OIG is keeping an eye on these arrangements. That's the message the agency sent in Advisory Opinions 07-21 and 07-22, issued Dec. 28.

The arrangements in question follow suit with agreements featured in a series of gainsharing opinions issued since 2001: a hospital will share 50% of the money it saves with a physician group if it implements cost-effective changes, such as using cloth rather than disposable blankets.

The specific arrangements mentioned in the most recent opinions get an "all clear" from the OIG because each agreement is highly detailed. But that doesn't mean *all* gainsharing agreements pass muster.

"'Gainsharing' plans can present substantial risks for both patient and program abuse," including threats to quality of care and the possibility of physician kickbacks, the OIG writes in the opinions.

"If you have a high level of detail as to what specific [high cost] products and behaviors you're looking at, and you've got good baseline data and you put in safeguards like [the hospital] did, then gainsharing is fine," says Bill Horton, an attorney with Haskell Slaughter Young in Birmingham, Ala.

Less detailed arrangements could violate the anti-kickback statute and Civil Monetary Penalties Law, he adds.

The gainsharing agreements could also implicate Stark in the near future. CMS specifically mentioned the arrangements in the proposed 2008 Medicare Physician

Fee Schedule, under possible changes to percentage-based compensation agreements.

"We are proposing to clarify that [percentage-based] compensation arrangements…must be based on the revenues directly resulting from the physician services *rather than based on some other factor such as a percentage of the savings by a hospital department*," CMS wrote in the proposed rule [italics added].

Coming soon: More guidance on gainsharing

CMS chose not to address percentage-based compensation in the final PFS, but warned that it will be taking up the issue soon.

If CMS chooses to define percentage-based arrangements based on physician services only, "you could end up with a situation where an arrangement that's been blessed by an advisory opinion doesn't fit under Stark" anymore, Horton speculates.

If the proposed rule goes into effect as is, "gainsharing could put doctors outside of the Stark law, with no exception," concurs Dan Mulholland, a senior partner with Horty Springer in Pittsburgh. "We advise our clients to proceed with caution. I think it's likely [CMS] will implement the rule," he adds.

All this comes in light of the fact that CMS is still toying with two gainsharing demonstration projects. Each project is slated to study gainsharing at hospitals nationwide for three years, says David Harlow, a health care attorney and consultant with The Harlow Group, LLC in Boston. There's no word yet on when the projects could start, but you could possibly see them in 2008, Harlow says.

Looking ahead: Tips for cost-saving deals

If you plan to move forward with a gainsharing agreement, keep in mind these factors the OIG praised in both featured arrangements:

Historical clinical measures: The hospitals undertook a study of costs in certain departments. These costs, and subsequent cost-saving measures, were built on baselines from the study.

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Cost-saving changes were based on fiscal need: Medical necessity was taken into account. The hospitals never reduced costs by restricting devices or supplies that were critical to patient care.

Transparency: Patients in departments subject to the arrangements are able to review the cost-saving program before admission to the hospital. "While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust," the OIG writes.

Specifics: Both arrangements set out detailed actions that can save costs, and ties physician payments to actual costs saved.

The arrangements are good for only one year: This limits the potential for the program to attract additional physicians. "We caution that payments of 50% cost savings in other arrangements, including multi-year arrangements with generalized cost savings formulae, could well lead to a different result," the OIG warns.

You can read the advisory opinions, including those on gainsharing dating back to 2001, at oig.hhs.gov/fraud/advisoryopinions/opinions.html ◘

Despite delay, anti-markup rule could affect you right now

Your practice could be subject to the anti-markup rule despite a one-year delay CMS announced Dec. 28 (*MCA* 01/14/08).

Based on the wording of the announcement, the rule could apply to you right now, even if your practice doesn't rely on pathology services performed by so-called "pod labs," experts believe. CMS officials did not respond to requests for clarification.

The rule targets practices that do business with pod labs, usually by paying them to analyze biopsies, says Matt Schulze, senior manager for federal and state affairs with the American Society for Clinical Pathology in Washington. CMS wants to stop practices from billing Medicare marked-up prices for pathology services that pod labs perform for much less.

But the wording of the delay announcement means many practices that aren't abusing Medicare will also be prohibited from marking up in-office pathology services, says Julie Kass, principal with Ober Kaler in Baltimore.

"CMS has a concern for the amount of testing that is being done in-office," she says. "Their concern is that when it's brought into a physician office, physicians are more likely to perform the test rather than if they sent it out [to a reference lab]."

CMS's standard for applying the anti-markup rule is confusing, but it seems to boil down to one key question: **Is the lab located in the same building in which physicians from the practice see patients?**

If the lab performing the pathology services is in "a place where you as a [practice] maintain an office and see patients … then this anti-markup provision *doesn't* apply," says Peter Kazon, an attorney who specializes in clinical lab issues with Alston & Bird in Washington.

Note: It doesn't matter if your practice owns the lab or even if your full-time employees run it; the above question is key, Kass says.

"The way they have crafted the delay, it encompasses more than pod labs," she says. "It encompasses *any* centralized lab that does anatomic pathology," she says.

If your practice **doesn't satisfy the key location condition**, you're left with two options, Kazon says. "Either you have to let that outside laboratory bill for those services, or if you want

to bill, you'll have to calculate and bill the net charges, on a per-slide basis."

You can bill the pod lab, but not mark up the service, or you can use larger, less specialized labs, Schulze says.

"[The practice] may send it to another reference lab that has a full menu of tests, that doesn't engage in these kinds of discounting practices to exclusively allow the billing practice to mark up the tests," he says.

CMS may try to limit the scope of the services physicians can provide in their office under the Stark in-office ancillary exception even further in the future, Kass says. ◘ –S*pecial contribution by* Grant Huang*, associate editor,* Part B News

Emergency response: Specialty hospitals face more scrutiny

The OIG has a message for doctors who own specialty hospitals: Take a close look at your facility's ability to respond when a patient has a medical emergency.

The OIG inspection report: **"Physician-owned specialty hospitals' ability to manage medical emergencies,"** released this month, uncovered compliance problems that include failures to have appropriate medical staff on duty; the use of 9-1-1 to stabilize patients; and incomplete medical emergency management policies. The OIG also noted CMS does not identify or track physician-owned specialty hospitals, which made it difficult to find hospitals to review [OIG Inspection Report OEI-02-06-00310].

In its response to the report, CMS says it will rectify the flaw by

- **Revising its enrollment forms and PECOS system** to capture information on specialty hospitals. CMS states it is already in the process of making these changes so watch for new 855 forms.
- **Taking steps to ensure hospitals follow the correct protocol for medical emergencies** and **have appropriate staff on duty** at all times, through inspections and responses to complaints.
- **Considering regulatory changes** that would create more specific policy, staff and equipment requirements.

Note: Facilities that are inspected by The Joint Commission or the American Osteopathic Association, rather than CMS, can also expect closer scrutiny. CMS will pass along OIG's report to these accreditation organizations. ◘ –S*pecial contribution by* Julia Kyles*, editor,* The Fraud and Abuse Answer Book

Stay in touch with carriers, CMS to avoid identity theft

Keep CMS informed that you're moving practices to avoid missed payments and protect yourself from fraud and abuse.

Physician reassignment of benefits is a hot topic on the OIG 2008 Work Plan (*MCA* 10/15/07) after recent cases of provider number fraud in south Florida, where companies were fraudulently billing Medicare using the provider identity numbers of physicians who weren't in the practice.

"It's virtually like identity theft," says Bill Maruca, a partner with Fox Rothschild in Pittsburgh. If the wrong people get a hold of a physician's number and bill Medicare with it, he or she could be at risk for submitting false claims.

Avoid provider identity theft by alerting CMS when you change practices. Only you can assign your benefits to a billing entity by submitting an 855-R enrollment form to the agency.

When you move, send another 855-R to request termination of your relationship with your current group; if you'd like to reassign your benefits to the group that you're relocating to, fill out section 3 of the form, says Nicci Warner, a content specialist with First Coast Service Option, a subsidiary of Blue Cross and Blue Shield in Florida.

Note: Your new group will not be able to bill for your services until your relationship with the first group is terminated, which means you

won't get paid until you fill out the proper paperwork, Warner says.

TIP: Call your carrier and request a list of all your current practice locations if you suspect your number is being used fraudulently, suggests Billy Quarles, a spokesperson for Blue Cross and Blue Shield of South Carolina. Check the list to ensure your number hasn't been picked up by a group you don't know.

You can also request to see your utilization for a specific time period, says David Sokolow, a partner with Fox Rothschild in Philadelphia. If you're a neurologist, and you see there are orthopedic procedures billed under your number, that should obviously raise a red flag, he says.

Follow these additional tips from Quarles to avoid provider identity theft:

- **Conduct your own background check.** Before you enter into a contract with a billing company or physician group, check the OIG's list of sanctioned and excluded providers (at *oig.hhs.gov/fraud/exclusions.html)*, Quarles suggests. You might also want to call the Better Business Bureau for references on a group's reputation. Working with a company that has a history of poor business practices can put you at risk.

- **Don't let others complete contracts or agreements for you.** CMS can't terminate a relationship with your previous group, or reassign your benefits to another group without your signature.

- **Keep your records** of referred services and orders for items or equipment. This way, if your number is used fraudulently, you can keep a tally of legitimate claims.

Note: If your provider number is inactive for four quarters, CMS will deactivate it, so keep your information up to date, Warner adds.◘

OIG approves free post-op preparation videos

Providing pre- and post-operative educational videos for patients could prove an inexpensive and OIG-friendly alternative to in-home safety checks.

The OIG takes up the free videos in Advisory Opinion 07-16, issued Dec. 5. The arrangement in question involves a home health agency (HHA) that gives videos to potential hip- and knee-replacement patients who've been referred to the HHA.

The video prepares patients and families for post-operative, home-based recovery by advising patients on furniture placement, sleeping and bathing arrangements and proper clothing, according the opinion. No medical advice is offered in the video, and the HHA is only men-

tioned as the video's producer.

The arrangement passes the OIG's standards because the videos have little monetary value, are offered to all prospective patients, and are unlikely to influence patient choice when choosing an HHA. The OIG previously slammed a similar arrangement in Advisory Opinion 06-20.

That opinion involved an HHA that provided free in-home oximetry tests. The OIG ruled against the visits. The "…Requestor has an opportunity to initiate a personal relationship with the beneficiary, and it is reasonable and probable that the beneficiary would select a supplier…with whom the beneficiary is already familiar," the OIG said in the opinion.

"I think because it's so hard to supervise and prove what goes on in peoples' homes, [home visits] tend to draw a lot of attention from the government," says Bill Maruca, a partner with Fox Rothschild in Pittsburgh.

Physical therapists who visit potential patients in the home could try to convince patients to use a particular home health agency, even though the HHA discourages it, Maruca says. "The OIG considers these videos less of a hard-sell component, plus, you can police it and know what's in it," he adds.

You can read both opinions at oig.hhs.gov/fraud/advisoryopinions/opinions.html. ◘

More states roll out False Claims Acts

If you work with vendors in multiple states, the Deficit Reduction Act requires that you educate all employees and vendors on the federal and individual state False Claims Acts. New Jersey has joined the ranks of states with individual FCAs. That brings the total to 20 states, along with the District of Columbia, New York City and Chicago. Check out which states make the list:

States with False Claims Acts

California	Montana
Delaware	New Hampshire
Florida	New Jersey
Georgia	New Mexico
Hawaii	New York
Illinois	Nevada
Indiana	Oklahoma
Louisiana*	Tennessee*
Massachusetts	Texas*
Michigan	Virginia

*Medicaid FCAs only

Watch Pennsylvania and Ohio. They could be the next states to adopt individual FCAs, says Patrick Burns, communications director for Taxpayers Against Fraud, a group that tracks false claims policy and whistleblower lawsuits.

TIP: Ensure compliance with the DRA by directing employees to your organization's internal web site, recommends Matt Torney, vice president of compliance, internal audit and security for Health Management Associates. There, you can keep information on the federal FCA, as well as each state's FCA, without mailing stacks of paper to employees and vendors, he says. ◘