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Congress closes in on Stark law reform

Competing bills vie to simplify or eliminate Stark's confusing compensation provisions

If Rep. Bill Thomas (R-CA) has his way, hospitals will see a rollback of a major portion of the self-referral laws passed by Congress in 1993. Last week, the House Ways and Means Health Subcommittee Chairman unveiled legislation that would strip the compensation portion of the self-referral laws otherwise known as Stark I and Stark II.

Notably, Thomas opted to introduce this measure as a freestanding bill and not part of a larger Medicare reform package he is known to be working on. Aides say that's because Thomas is intent on passing Stark reform measure and fears tying it to the fate of a more complex Medicare bill. "We are not going to rule out the prospect that this bill could be attached to something but right now it is independent," says a Ways and Means aide. "We won't really know anything else until we get back from recess after Labor Day."

Repeal of the compensation provision in Stark would have a major impact on the ability of hospitals to enter a variety of arrangements with physicians and other providers. "That's really 90% of the law," adds the aide. "This bill will clarify the law so that doctors can be reimbursed by hospitals even if they have been given a parking space at the hospital."

"This would solve a huge number of problems," agrees **Bob Homchick** of the Seattle-based Davis Wright Tremain. "A lot of the problems with Stark revolve around the incredibly broad defini-

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Supreme Court to hear case challenging FCA suits

The U.S. Supreme has agreed to hear Vermont's challenge to False Claims Act (FCA) suits against sovereign state entities. Court watchers say the fate of the federal government's aggressive FCA enforcement efforts under the PATH (Physicians at Teaching Hospitals) initiative will be hanging in the balance of that decision.

"Any state-affiliated health care provider, including teaching hospitals, would be affected," says **Rick Robinson**, an attorney with Fulbright & Jaworski in Washington, DC. But it all depends on

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JCAHO scraps advance notice of random surveys

The Joint Commission on the Accreditation of Healthcare Organizations' (JCAHO) is wasting no time responding to the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) July report that sharply criticized its oversight of hospitals. Hospitals can say goodbye to 24-hour advance notice and to notice of which standards will be reviewed, the Commission announced Aug. 4.

As of Jan. 1, 2000, hospitals will receive no advance warning about random unannounced surveys. In addition, the window of time during which they may be conducted will be nine to 30 months after the full survey conducted every three years.

JCAHO spokeswoman **Donna Larkin** says the next set of changes will be announced in November, but gives no specifics on what those changes might include. Meanwhile, a Health Care Financing Administration official reports that the

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tion of 'financial relationship' and 'direct' or 'indirect' compensation arrangements," he says. "HCFA has clearly struggled with this law from Day One."

"But there are still some very difficult issues quite frankly," he adds. Homchick says he still has questions about how this revision would affect the group practice exception and the in-office ancillary services exception as well as other areas.

Thomas signaled he would try to reign in current self-referral laws at a May 13 Health Subcommittee hearing.

He argues that while the ownership portion of Stark II is workable, the compensation portion is not. "We have a statute on the books that is unenforceable," he said at a press conference on Capitol Hill July 29. "The whole intent was to draw bright lines to allow people to have guidelines about what was and what was not permissible," he asserted. "The problem is that since 1993 HCFA has not been able to write the regulations dealing with that compensation portion."

Thomas admitted that increased flexibility will lead to increased services and said the Congressional Budget Office estimates his bill will cost Medicare $100 million to $200 million over five years. "Cost is not necessarily an evil," he argued, "but rather an indication government is not allowing creativity."

Rep. Pete Stark (D-CA), the main sponsor of the original laws, wasted no time blasting Thomas' bill and introducing his own. "Total repeal of the compensation provisions is a loophole you can drive an armored division through," argues Stark. He says his measure would simplify and streamline the law by creating a "fair market value exception" or "safe harbor" for providers who have compensation relationships with entities to which they refer Medicare and Medicaid beneficiaries for health services.

Under the fair market value test, an agreement must be in writing for a definite period of time and not be dependent on the volume or value of referrals and the compensation in the contract must be a reasonable fair market rate.

Stark's proposal simplifies some of the issues but probably does not go far enough, says Homchick. "Combining all of the compensation exceptions into the fair market value exception makes things somewhat easier but the statute still presents very thorny issues."

Support for Thomas' bill is tough to gauge since he sought no co-sponsors. "The smart money right now is on the Thomas bill," says one Ways and Means aide. "It helps to be in the majority." ■

OIG targets 35 hospitals for stroke upcoding

In a study released last week, the Health and Human Services Office of Inspector General (OIG) determined that 35 of the nation's 4,883 prospective payment hospitals had "atypically high" billing patterns for DRG 014 — "specific cerebrovascular disorders except transient ischemic attacks."

Despite the small percentage of hospitals thought to be guilty of upcoding DRG 014 between 1993 and 1996, OIG is recommending that the Health Care Financing Administration (HCFA) considering adding it to its list of "monitored" DRGs. Medicare reimbursed hospitals almost $1.9 billion for DRG 014 in 1996. HCFA estimates that the total Medicare overpayment due to DRG 014 upcoding that year was $11.9 million.

All 35 hospitals suspected of upcoding DRG 014 have been referred to the OIG's Office of Investigations. ■

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agency's "detailed" Hospital Oversight Plan is probably at least two weeks away from being released. That plan will expand on the version HCFA included in the OIG's report last month.

Other immediate changes under way at JCAHO include the development of "a pre-survey information packet" that will give surveyors specific information about the hospital's performance and allow more thorough investigation. In addition, the Joint Commission will begin pilot testing of "off-hour evaluations" during evening and weekend hours later this year.

Finally, JCAHO is working on guidelines that will permit closer scrutiny of peer review and credentialing processes, including the hospital's definition of circumstances that prompt peer review, the participants included in that process, and the timeframes in which the review must be conducted and results reported. ■

FCA case

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whether it's a public university or a private university, he adds. Federal investigators could still continue a PATH investigation and even private schools would be responsible to return refund overpayments, he explains. "The distinction is that investigators could not use the False Claims Act in PATH cases involving PATH entities."

"Supreme Court review is relatively rare in civil False Claims Act jurisprudence," says **John Boese**, an attorney who specializes in FCA cases. There have been only two FCA decisions in the last twelve years and both were decided in favor of the defendants. In this case, the Court will determine whether states are "persons" subject to liability under the FCA, and whether the Eleventh Amendment precludes a private relator from prosecuting a FCA suit against an unconsenting state, according to Boese, of Fried, Frank, Harris, Shriver & Jacobsen in Washington, DC.

The Supreme Court's review was anticipated, says Boese, in light of the significant split among the Circuit Courts of Appeal following the Fifth Circuit's ruling in *United States ex rel. Foulds v. Texas Tech University,* and the D.C. Circuit's rulings in *United States ex rel. Long v. SCS Business & Technical Institute*. **(See "FCA decisions may lead to Supreme Court showdown," *Compliance Hotline,* April 19, 1999, p. 1.)**

"In *Foulds,* the court held that that the government has not 'commenced or prosecuted' an action within the meaning of the Eleventh Amendment," Boese explains. "In Long, the D.C. Circuit held that states are not 'persons' subject to suit under the FCA." But contrary results were reached in the Fourth, Eighth, and Ninth Circuits.

Boese says state entities will have a major victory if the Court agrees with the results in the Long and Foulds decisions but adds that Court's review is likely to have almost no impact on non-state entities. That's because immunity might not extend to suits prosecuted against a municipal corporation or other government entity which is not an arm of the state, he says. "Cities and states are treated differently under some of these decisions," explains Robinson. "Typically, cities are not considered to be arms of the state; if a city had a health care clinic that might not be protected by this decision."

Nobody knows where the Court will come out when it decides the case later this year, but both Boese and Robinson note that in the last two terms, the Supreme Court has been very supportive of states rights. That bodes well for providers looking for relief from the FCA. ■

OIG lays out 'seven pillars of advisory opinion wisdom'

The Health and Human Services (HHS) Office of Inspector General (OIG) has released a "preliminary checklist for advisory opinion requests" that outlines what must be included in advisory opinion requests.

But to fully understand the real costs and benefits of getting an advisory opinion, it's important to look beyond the guidelines to understand how the OIG itself views the advisory opinion process.

Here is an exclusive look at "the seven pillars of advisory opinion wisdom," according to OIG Senior Counsel **Vicki Robinson:**

I. **Almost everything implicates the anti-kickback statute.** "Simply put," says Robinson, "the anti-kickback statute is broad

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enough to encompass almost any arrangement between parties that do business together and get federal health care program reimbursement." She warns that if such an arrangement exists, her office will likely construe that it implicates the statute. "But that does not mean you will get an unfavorable opinion," she adds.

Many opinions, including the recent opinion on St. Jude's Children's Hospital, have concluded that while there was a potential violation, if there were adequate safeguards and benefits OIG would not impose sanctions. "That determination is binding on the parties that requested the opinion," she adds, "unless there was a failure to disclose material information in which case all bets are off.

II. **If it increases costs, forget about it.** According to Robinson, there are at least four evils addressed by the anti-kickback statute — increased program costs, increased utilization, improper steering of patients, and unfair competition. "If an arrangement increases costs either through increased charges or increased utilization, the probability that we are going to issue a favorable opinion is low," she warns. However, if the arrangement will implicate the statue without increasing costs, the OIG will be more amenable to looking at its potential benefits. According to Robinson, the best example of this is Opinion 98-3, which involves the donation of an ambulance to a municipality.

III. **Don't blow smoke.** "If the arrangement has safeguards against increased costs and utilization or provides offsetting benefits," says Robinson, "then show us." She urges providers to be specific and be detailed. "Conclusory statements [about] your arrangement will result in better quality of care, or that the parties have good intent carry very little weight because everybody tells us they have good intent," she says. "We can hypothesize about risks and kick-backs but when it comes to benefits we want proof."

IV. **Sometimes, you have to wait until the fat lady sings.** The ultimate determination to the potential for fraud and abuse will turn on what happens after the arrangement is implemented, Robinson warns, no matter how much information the OIG receives beforehand about a proposed arrangement. In other words, she says, don't expect the OIG's opinion to immunize you from sanction. For example, a joint venture that doesn't meet the small entity joint venture safe harbor may have safeguards that appear to provide equivalent protection, but final determination will turn largely on whether the referral source investors actually contribute to operation of the success of the joint venture or simply make referrals and cash their dividend checks. "Sometimes you simply cannot predict how an arrangement will work in practice even if the contract and documents look very good," she warns.

V. **A negative can be a positive.** "There can be a lot of very good guidance in a negative opinion," says Robinson. "It is generally easier for us to generalize if we are saying what we don't like." By contrast, she adds, when the OIG approves an arrangement, it is very careful to do so narrowly that the opinion can not be misconstrued or misapplied.

VI. **Beware of the dog that doesn't bark.** Robinson warns providers to be very cautious in comparing arrangements they may be working on with the arrangements in published opinions.

"You may think your arrangement is very close to what is in the published opinion; but remember that you have not seen the things that have not been approved, and you certainly have not seen our view about the hundreds and thousands of arrangements that we are not asked about," she says. "Differences in the facts of similar arrangements will often lead to a different result. You must be very careful not to generalize too much from the advisory opinion."

VII. **Remember, you have been warned.** The final tenet, according to Robinson, is that the OIG believes that in many substantive areas advisory opinions are filling gaps in guidance and setting up benchmarks. "To the extent that advisory opinions address an area or practice that subsequently becomes the subject of an investigation, we will expect providers to have read the opinion and have taken it to heart," she concludes.

[Editor's note: An upcoming issue of Compliance Hotline *will outline the dangers that Robinson says are associated with the advisory opinion process and how to minimize those risks.]* ■