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District Court decision on Stark could have broad impact

Federal court opens the door to challenging Medicare regulations, some experts say

A U.S. federal court ruled last month that the Centers for Medicare & Medicaid Services (CMS) exceeded its authority by including lithotripsy services among the designated health services covered by the self-referral prohibition otherwise known as Stark. While the court's decision means that Stark no longer applies to lithotripsy, its broader impact is that parties mounting a pre-emptory challenge to Medicare regulations may be more likely to obtain judicial review without first exhausting their administrative remedies, says **Charles Oppenheim** of the Los Angeles office of Foley & Lardner.

The U.S. District Court for the District of Columbia sided with plaintiffs from two trade associations representing urologists July 16 when it rejected CMS' interpretation that lithotripsy, a noninvasive procedure performed by urologists to remove kidney stones, is covered by Stark. In addition, the court held that the plaintiffs were not required to exhaust their administrative remedies before obtaining judicial review.

In reaching its decision, the court allowed the plaintiffs to appear in federal court without first exhausting their administrative remedies because requiring plaintiffs to go through administrative channels would effectively deny them the opportunity for judicial review, says Oppenheim.

*See **Stark decision**, page 2*

OHRP offers guidance for institutional review boards

The Department of Health and Human Services Office of Human Research Protections (OHRP) last month issued guidance to assist institutional review boards (IRBs) in formulating various procedures set forth in the human research protection regulations.

"Because of the ever-more stringent enforcement environment and the trend toward naming IRBs and their members as defendants in research-related litigation, it is critically important that IRBs review and act on this guidance," warns health care attorney **Bill Sarraille** of Arent Fox, Washington, DC.

*See **IRB guidance**, page 3*

Challenging CMS sampling procedures

Until recently, few attorneys had litigated cases that challenged the sampling procedures used by the Centers for Medicare & Medicaid Services (CMS), says **Lester Perling**, a health care attorney with Broad & Cassel in Tampa, FL. "That has changed now," he says. "It has received a lot of attention inside the government, and a lot more attorneys have raised these issues in overpayment and False Claims cases where it is appropriate."

According to Perling, the courts repeatedly have ruled that sampling itself is not a due-process violation. "The issue is whether it is done correctly or incorrectly." He says the legal argument associated with sampling is very straightforward: If the sampling is not done in accordance with government policy or generally accepted statistical processes, it is a due-process violation.

However, even as overpayment assessments

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Stark decision

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To determine whether plaintiffs were required to first seek an administrative hearing, the court relied on *Shalala v. Illinois Council on Long-Term Care,* notes Oppenheim. In that case, the Supreme Court refused to hear a case involving a challenge to CMS' nursing home regulations because the plaintiff trade association and its member nursing homes had not exhausted administrative remedies.

According to **Krista Callaghan**, also of Foley & Lardner in Los Angeles, the Illinois Council court focused on the severity of the penalty incurred by a violation and the ability of plaintiffs' members to access administrative review. It concluded that the administrative penalties were minor and that the plaintiff or its nursing home members could incur a small penalty and receive an administrative hearing before proceeding to federal court.

In this case, Callaghan says the court held that judicial review was warranted because the penalties for violating Stark II were so severe that the plaintiffs or their members could not risk incurring statutory penalties in order to challenge the regulations. Requiring the plaintiffs to exhaust their administrative remedies would have been tantamount to denying plaintiffs the ability to obtain judicial review, he explains.

Health care attorney **Jeffrey Peters** of Arent Fox in Washington, DC, says it is important to note that while this decision means that physicians may refer personally performed services to lithotripsy centers with which they have a financial interest without violating the Stark law, the referral of other inpatient or outpatient hospital services to hospitals by those physicians still may be prohibited by Stark.

For example, CMS would assert that lithotripsy provided "under arrangements" still will establish a "financial relationship" with the hospital. Peters says that in such instances, a urologist with an ownership interest in the lithotriptor still must meet a Stark exception in order to refer designated health services, (such as inpatient or outpatient l hospital services) to the hospital.

Peters cautions, however, that the Court's decision has no bearing on the applicability of the federal anti-kickback statute to lithotriptor-related ventures. Moreover, the decision also does not alter the status of lithotripsy under many state self-referral laws, says Peters.

"Some state self-referral statutes apply to lithotripsy explicitly, and others may apply more broadly," he explains. "Significantly, many state self-referral prohibitions that could still cover lithotripsy may generally apply regardless of the identity of the payer for the service."

"This holding potentially expands the ability of providers and their trade associations to engage in anticipatory challenges to Medicare regulations that they believe to be invalid, especially if they seek to challenge Stark," says Oppenheim. Assuming the decision is not overturned on appeal, he says it is very helpful to providers who appeared to have little hope after the Illinois Council decision of challenging Medicare regulations in court until they first had exhausted their administrative appeals and incurred administrative penalties. ■

Sampling procedures

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continue to surge, many providers have yet to learn how to respond effectively to CMS' aggressive audit and post-payment reviews of provider claims.

Perling says this issue first will arise when the government audit is initiated and the government

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asks for a sample of a certain number of claims. "That, theoretically, is your first opportunity to intervene in the sampling process before you even get to an appeal," he says.

If the government does not do that job correctly, Perling says there are several opportunities to challenge what it has done. The first is informally negotiating with the carrier, intermediary, or Department of Justice regarding the sampling procedures when the overpayment is received. While Perling says he does this routinely, he adds that most carriers and CMS itself often do not want to hear these arguments.

The first formal opportunity to challenge the sample procedure is at the fair-hearing level if it deals with Part B claims, and the reconsideration level if it deals with Part A claims. However, Perling says his experience is that providers rarely win these arguments at this juncture. The hearing officers are employees or independent contractors of the carriers, he notes. They often say they do not have jurisdiction to hear the case, and if they do hear the case, he says, they typically will rely on what their own in-house statistician tells them.

"That is going to be even more of a waste of time than at the fair-hearing level, because the reconsideration process typically looks at it on a claim-by-claim basis as opposed to an aggregate basis," he explains.

According to Perling, the fair-hearing level can be a steppingstone to a challenge at the administrative law judge (ALJ) level. However, most providers choose to make a summary challenge at the fair-hearing level rather than a full challenge because the chances of success are not that great.

"Where the rubber hits the road in this process is at the ALJ level," Perling asserts. At that stage, providers must determine their strategy on how to proceed, including whether to use an outside expert. "As a practical matter, that is not always necessary," he argues. "We have actually won quite a few cases at the ALJ level submitting only a legal brief on the issue."

Perling says he did that by arguing that the sampling guideline appendix or the program integrity manual required that the fiscal intermediary or carrier did not take all the required steps or cannot document that those steps were taken.

In larger cases, it usually makes sense to hire an expert, says Perling. In those cases, it is more likely that the ALJ will call its own expert. However, he says it is his experience that if providers do no hire an expert, the other side will not call one either. "From a strategy perspective, that is something to think about," he says.

As part of the ALJ process, Perling requests all of the documents the carrier or intermediary should have related to these cases. In several recent cases, the carrier has responded that a critical document could not be provided. Afterward, the extrapolation was withdrawn, and the overpayment demand was reduced.

The ALJ often has had to issue a subpoena to bring that about, he adds. "That certainly advises that in these cases, you always request a subpoena for documentation when you don't get it voluntarily from the carrier," he says.

The next level of appeal after the ALJ is the Medicare Appeals Counsel, which Perling says has been fairly sensitive to the sampling issue. "They will reverse ALJs if they get it wrong," he says. This process, however, take years to complete. ■

IRB guidance

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Given the recent emphasis on the conduct of research on human subjects, publication of the *OHRP Guidance on Written IRB Procedures* provides assistance to IRBs in developing written IRB procedures and policies, says Sarraille.

While the guidance is not all-encompassing, it does provide a basis and partial checklist for IRBs to develop policies and institute changes, if appropriate, regarding these activities, Sarraille notes.

According to the guidance, IRBs must have written procedures for:

- conducting its initial and continuing reviews of research;
- reporting its findings and actions to the institution and investigators;
- determining which projects require more frequent review than once a year and need verification

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from sources other than the investigators that no material changes have occurred since the previous IRB review;

- ensuring prompt reporting to the IRB of proposed changes in a research activity, including provisions that indicate that the IRB must approve any changes in previously approved research (except when necessary to eliminate apparent immediate hazards);
- ensuring prompt reporting to the IRB, appropriate institutional officials, and the appropriate federal department or agency heads of any unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with IRB policy or the requirements or determinations of the IRB, and any suspension or termination of IRB approval.

According to Sarraille, the guidance discusses the required elements in a written IRB policy and mandates that each written policy include a step-by-step description with operational elements for evaluations, reviews, processes, and/or tasks commonly utilized by IRBs. That includes, but is not limited to, the initial research review, review of protocol changes, meeting frequency, communication with investigators regarding IRB determinations, notification of institutional officials, and reporting requirements to the IRB by investigators of various unanticipated events. ■

Court to decide FCA liability for local governments

The Supreme Court may rein in the government's application of the False Claims Act (FCA) when it hears *Cook County, Illinois v. United States ex rel. Chandler* in its next session. The question before the court is whether local governmental entities, which traditionally are considered to be immune from punitive liability, are subject to liability under the civil FCA, says **John Boese** of Fried Frank in Washington, DC.

Boese says private entities will be watching to determine if the court will expand on, or back away from, its watershed holding in *Vermont Agency of Natural Resources v. United States ex rel. Stevens* that the current version of the FCA imposes damages that are "essentially punitive in nature." In that case, the Supreme Court held that State entities are not "persons" subject to *qui tam* liability under the FCA.

While the court's decision will directly affect local government and quasi-government entities, Boese says it also will be closely watched by private entities subject to FCA enforcement, including health care providers.

Because significant amounts of money filter from the federal government through local governments, municipal and other local governmental entities have been the targets of an increasing number of *qui tam* FCA suits," says Boese.

Robert Homchick of Davis Wright Tremaine in Seattle says, "There is a lot of activity going on out there trying to extend *Stevens* in a variety of different ways. There are many issues about when is the state the state," he explains. "To the extent that the Supreme Court draws the distinction between state and other municipal entities, that will provide some guidance on just how broad the *Stevens* exception is going to be drawn."

Many states have public hospital districts or the functional equivalent, where counties can own and run hospitals, notes Homchick. "For example, in Washington state, you form a municipal corporation and public hospital districts have taxing authority and their commissioners are elected," he says. "That sort of governmental entity would not be in the scope of the False Claims Act statute."

The court declined to review a case presenting the same issues earlier this year dealing with local governments. But a growing split among the circuits has developed, demonstrating a more urgent need for Supreme Court review, says Boese.

In *Chandler,* the panel acknowledged that FCA damages now are considered to be punitive, and that municipalities are generally presumed to be immune from punitive damages, Boese says. "Nevertheless, the court concluded that there is no indication that Congress intended to exempt municipalities from liability under the FCA."

"District courts are similarly split on the issue, but a majority of courts have held that local governmental entities are not subject to liability under the False Claims Act, because the act imposes punitive damages," adds Boese. "With much at stake, both economically and politically, the *Chandler* case will be one of the more closely watched cases before the Supreme Court during the next term." ■