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MONDAY
APRIL 23, 2001

Scrutinize sampling to challenge overpayment demands

Key areas to challenge include sample size, randomness, stratification, and relative error

Even as overpayment assessments continue to surge, many health care providers have yet to learn how to respond effectively to the Health Care Financing Administration's (HCFA) aggressive audit and post-payment reviews of provider claims, according to several health care attorneys.

"We are definitely seeing more effort by HCFA to influence administrative law judges (ALJs) with regard to this issue, and many of those efforts are probably improper," says **Lester Perling**, a health care attorney with Broad & Cassel in Fort Lauderdale. He says that is because recent efforts to clarify sampling requirements actually have made matters worse.

Worse yet, "a lot of providers tend to roll over and pay it and don't do anything about it," says health care attorney **Kathy Fritz**, of Davis Wright in Seattle.

That approach can carry a heavy price tag, warns Fritz. Some hospitals have even suspended practitioners simply because they were under investigation, even though they weren't even close to being excluded from the program, she notes.

Fritz says the good news is that HCFA's overpayment demands often can be successfully

*See **Sampling errors**, page 2*

Industry downplays GAO report on False Claims Act

The General Accounting Office (GAO) recently concluded that the U.S. Department of Justice (DOJ) now is utilizing the False Claims Act (FCA) more appropriately. But several veteran health care attorneys say the report mainly takes a look back at two initiatives that have largely run their course — prospective payment system transfer and pneumonia upcoding. "I am not sure that it matters," asserts former DOJ attorney **Stuart Gerson**. "Those programs are not affecting all that many people at this point."

According to Gerson, an attorney with Epstein Becker in Washington, DC, the greater area of

*See **GAO report**, page 4*

Ten steps to limit your *qui tam* exposure

The False Claims Act (FCA) continues to drive the federal government's efforts against fraud and abuse efforts in the health care industry. *Qui tam* recoveries have increased dramatically since the FCA statute was amended in 1986, with more than $3 billion now in the pockets of the government and whistle-blowers.

Worse yet, that number doesn't even begin to take into account the millions of dollars spent by providers defending themselves in those cases. **Lynn Snyder**, a health care attorney with Epstein Becker in Washington, DC, argues that while there is no way to completely eliminate this threat, there are steps providers can take to help limit their risk.

Here are 10 steps Snyder says providers can take to reduce their *qui tam* exposure.

1. **Beware of the knock.** Snyder says providers must educate all current employees as to what constitutes a "knock at the door" by the federal or

*See **Qui tam exposure**, page 3*

Sampling errors

Continued from page 1

challenged, and the place to start is by demanding the government's documentation. In fact, Fritz says the adequacy of the sample often becomes a moot point because the government fails the documentation test.

"A major point that seems to have escaped most carriers is that they have an absolute obligation under law to provide the provider with all of their information regarding the extrapolation and stratification of sample size and how they conducted their audit," she asserts.

"I have yet to get that information," she reports. "When that happens at a carrier hearing, I win slam-dunk because their extrapolation gets thrown out."

Beyond that, Perling says failure by the government or a contractor to perform the sample study correctly is one of the most effective ways to challenge an overpayment determination. "This can have a very significant impact on the amount due, often reducing the overpayment by a very significant percentage," he says.

Nobody argues the need for scientific statistical sampling and extrapolation in cases of overpayment determination. "It would be impossible or prohibitively expensive to audit all claims in the overall population using a census covering 100% of these claims," explains **Michael Intriligator**, statistics professor at the University of California at Los Angeles.

On the other hand, the government often falls short in making its case, says Intriligator, who has testified as an expert witness in numerous appeals before ALJs and the Departmental Appeals Board. In fact, he says there are several areas where carriers and intermediaries often go wrong when it comes to sampling and extrapolation.

Here are four key areas to challenge carriers and intermediaries:

- **Sample size.** Frequently, Intriligator says the sample size of the claims selected is too small and inconsistent not only with generally accepted statistical principles, but with HCFA's own guidelines for a "basic sample size." In some instances, the number of claims actually selected can be less than a tenth of the number required, he says.
- **Randomness of the sample.** To be statistically valid, the sample must be selected at random, with no biases or other distortions that could make it not "representative," according to Intriligator. Sampling that specifically omits low-charge claims, for example, would not yield a reasonable sample, he says.

He points out that the HHS Office of the Inspector General's software package RAT-STATS has an associated manual that describes how to use it, but no documentation to confirm that it is providing valid results other than its random number generator. As a result, Intriligator says, except for the random number generator, none of its components have been audited and verified independently to determine whether they perform properly.

- **Stratification of the sample.** A third area of possible error is improper stratification. That process divides the population into different subpopulations that are relatively homogeneous, even when the overall population is heterogeneous. But Intriligator says that must be based on some "real differences" that caused the need for stratification in the first place.

For example, hospital services might be stratified into inpatient/outpatient or other categories, while physician services might be stratified by diagnostic categories, he explains.

- **Relative error.** A fourth area Intriligator points to is estimated relative error, which he says is the

(Continued on page 3)

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single-best measure of the variability in the estimate. "If it exceeds the HCFA tolerance levels, then the whole study is questionable as exhibiting too much variability," he explains. "We have had some cases dismissed simply on the basis of an unacceptably high estimated relative error."

"Any one of these issue areas or some combination of them could represent a basis for challenging the sampling/extrapolation," he says. It is also possible to challenge the qualifications and capabilities of those performing the study.

Perling and Intriligator currently are working on an upcoming report on this subject for the American Health Lawyers Association. ■

Experts: HCFA sampling memo muddies the waters

Earlier this year, the Health Care Financing Administration issued a program memorandum (PM) to help clarify the requirements carriers must follow when using statistical sampling in overpayment determinations. But experts say the PM significantly reduces the requirements that carriers must follow and gives them even more latitude in conducting their audits.

"What they have done is a huge step backwards because it gives the carriers no guidance in how they should be conducting these surveys," asserts **Michael Intriligator**, statistics professor at the University of California at Los Angeles. "They essentially threw out all the guidelines they had and gave carriers or intermediaries virtual carte blanche to do whatever they want."

Intriligator says the PM omits the previous basic sample size requirements as well as other requirements previously in place. It also reduces the amount of documentation required, he adds.

Health care attorney **Lester Perling** of Broad & Cassel in Fort Lauderdale, takes a similar view. "The vagueness of the guidelines are likely to lead to more litigation," he predicts.

He notes that the PM also states that if a sampling study has certain characteristics, then assertions that the sample and its resulting estimates are not "statistically valid" cannot legitimately be made. "In other words, the PM takes the position that a probability sample and its results are always 'valid,'" says Perling.

"The memorandum does state that the sample design must be 'properly executed,'" Perling adds. But exactly what that means will have to be addressed in future litigation, he contends. ■

Qui tam exposure

Continued from page 1

state government so they are prepared to contact counsel when that occurs. "Consider using wallet cards," she says. With whistle-blower lawsuits, the company may not be served with a complaint for a very long time, and contacts often begin with former employees who may share the contact information with current employees, she adds.

II. **Chasing down the alumni club.** "Be proactive," says Snyder. If the whistle-blower is a former employee, be sure to contact other former employees who may have interacted with the whistle-blower to let them know that they may be contacted and to find out what they may know about potential allegations. Anything human resource offices can do to maintain the names, addresses, and phone numbers of former employees can prove very valuable, but all too often that information is maintained only for a short time for tax purposes, she adds.

III. **Don't forget human resources.** Snyder says providers must train their human resources staff to conduct thorough investigations of potential employees during the hiring process and then help identify disgruntled former employees who may have a "compliance" ax to grind at the time of termination.

She warns that human resource staff may ignore claims about improper billing and simply file them away. "You must connect the dots between human resources and compliance and reach out to those people to find out if those claims are true," she advises. "Be sensitive to 'righteous indignation' resignation letters."

IV. **Don't guess; confirm and formalize your confirmation.** Regulatory ambiguities must be clarified, and regulatory advice must be formalized, recorded, and made part of an organization's institutional memory, according to Snyder. Be sure that billing personnel maintain a government contact's "chronology," which records all contacts with the fiscal intermediary, carrier, or

(Continued on page 4)

Medicaid agency, whether oral or in writing, to help "institutionalize" informal billing advice, which may become the subject of the whistle-blower's allegations, she adds.

V. **Focus on the allegations, not just on the whistle-blower.** "Once you are aware of a *qui tam* suit, focus on educating the government so it opts not to intervene in the case," Snyder advises. Too often, providers become fixated on discovering who the whistle-blower is. "That becomes their mission in life," she says. Once that happens, attempts are made to discredit the whistle-blower rather than focusing on the allegation, she adds. Snyder's advice: "Avoid personalizing the matter."

VI. **Get everyone on board if there is a settlement.** When trying to settle a whistle-blower allegation, providers should confirm the government has the whistle-blower's agreement throughout the settlement negotiation process. "Remember that the whistle-blower has the right to challenge the reasonableness of the settlement if the whistle-blower does not agree to the settlement terms," she warns. Don't forget the statutory right to attorney's fees and other costs that may need to be negotiated, she adds.

VII. **Use employment agreements.** Snyder says that a written employment agreement in which the employee waives any rights to a financial recovery should be considered for certain potential employees who deal with sensitive company information. But she adds that it is still unclear whether such provisions will be considered enforceable.

VIII. **Train, train, train.** "Companies can never do too much compliance training," Snyder asserts. "Training should be frequent, fun, and informative." Providers must know the "hot topics" in the industry and prioritize their compliance plan accordingly. Training also should include time for informal communications with the trainer. "Often, compliance issues will percolate during these training sessions," she says.

IX. **There is an end.** According to Snyder, providers should read an entire set of settlement documents to become better acquainted with what a possible settlement could look like in order to understand their options. "Start with a settlement and work backward," she says. "Try to determine what the company could have done differently to avoid or at least to minimize its health care fraud exposure."

X. **Don't be myopic.** "Every health care fraud settlement could affect your business because these settlements are like 'case law' precedent," warns Snyder. Providers should follow settlements in their segment of the health care industry to identify areas where they may become a target. "Apply compliance program resources accordingly," she concludes. ■

GAO report

Continued from page 1

interest and possible reform is with the Health and Human Services Inspector General rather than DOJ. "The greater focus of concern on the part of people who are negotiating with the government is with the increasing demand from corporate integrity agreements," he explains.

The GAO says the DOJ now is implementing the pneumonia upcoding and prospective payment transfer system initiatives, both of which prompted industry concern, in a way that's consistent with an internal DOJ guidance designed to reign in overzealous prosecutors.

That guidance, commonly referred to as the "Holder Memo," was issued nearly three years ago by Deputy Attorney General Eric Holder in part to avert legislation from Congress that would have reigned in use of the FCA. The guidance instructs DOJ attorneys and U.S. Attorneys to establish that claimants knowingly submitted false claims before they allege violations of the act.

The GAO says that DOJ's review of each U.S. Attorney's Office's compliance with the guidance now appears to be "an integral part" of the periodic evaluations of all those offices.

DOJ's annual requirement that all offices involved in civil health care fraud control certify their compliance with the guidance has promoted conformity, and its periodic evaluations of U.S. Attorney's Offices now incorporate "a more substantive examination of compliance with the guidance," the GAO adds.

This is GAO's fourth assessment of DOJ's compliance with that guidance. Each report has been progressively more favorable in assessing the department's compliance. ■