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4th Circ. Suggests FCA Extrapolation Is Evidentiary Issue

Law360, New York (November 4, 2016, 11:05 AM EDT) -- In September 2015, both the False Claims Act defense bar and the relators bar took note when the Fourth Circuit agreed to hear an interlocutory appeal in United States ex rel. Michaels et al. v. Agape Senior Community Inc. et al. on the question of whether statistical sampling is an appropriate methodology for establishing liability and damages in FCA cases.

Gail D. Zirkelbach

Statistical sampling involves the collection and analysis of data from a subset of the population of interest and then projecting those results (i.e., extrapolation) across the population. This methodology is routinely used in other areas of litigation and is regularly used by administrative agencies when estimating overpayment amounts. It has also been used to establish damages in FCA cases once liability has been established. However, in a new trend, FCA plaintiffs have begun to rely on sampling to prove liability. Specifically, FCA plaintiffs are identifying a subset of a type of claim, reviewing all of the claims within that subset, proving that a percentage of those claims were false and then extrapolating that percentage across the universe of claims, without reviewing (or proving false) any additional claims.

Jason M. Crawford

By agreeing to hear the appeal in Agape, the Fourth Circuit appeared poised to be the first appellate court to rule on the question of whether this type of sampling could be used to establish liability in FCA cases. However, if the comments from the Fourth Circuit panel during the Oct. 26, 2016, oral argument are any indication, it seems unlikely that the court will weigh in on the substantive question of whether sampling can be used to prove liability and damages. Indeed, the Agape panel seemed to second guess whether the question was appropriate for interlocutory appeal. That said, the panel's view that statistical sampling is an evidentiary issue, rather than a pure issue of law, is itself instructive.

Mary Kate Healy

Statistical Sampling in FCA Cases

Statistical sampling has been used to determine damages in FCA cases only where the defendant did not challenge liability[1] or where the defendant agreed to the sampling methodology.[2] This usage was expanded in 2014, with the United States ex rel. Martin v. Life Care Centers case.[3] In Life

Care, the government alleged that a nursing home charged CMS for services that were not medically necessary. In similar cases, an expert was usually required to review each claim file to determine if a course of treatment was necessary.

However, in Life Care the U.S. Department of Justice argued that the case involved too many claims to litigate on a claim-by-claim basis. Instead, the DOJ's expert proposed relying upon a random sample of 400 patient admissions from a total universe of more than 50,000 admissions to show liability. Life Care moved for partial summary judgment as to the claims outside the sample arguing that the use of extrapolation violated Life Care's due process rights because Life Care could not make a claim-by-claim defense.

In his opinion, Judge Harry Mattice acknowledged that the DOJ was proposing to use sampling in a manner that was different from how it had been used in the past as the DOJ was proposing to use it to prove liability rather than damages. After surveying the case law and reviewing the legislative history, the court decided that there was nothing that prohibited the use of statistical sampling to prove FCA liability.

The judge wrote "[i]f Congress intended to preclude statistical sampling from being used in this context, it has had ample opportunity to have that intention reflected in the language of the FCA." Judge Mattice reasoned that Life Care's due process rights were protected because Life Care had a right to challenge the government's sampling methods and experts. He explained that his ruling was based in part on public policy considerations because the court was concerned that requiring individualized review in all cases could diminish the FCA's deterrent effect because relators or the DOJ might not bring a large case if it would be too expensive to litigate.

The Agape Case

In Agape, relators allege that a chain of South Carolina nursing homes submitted fraudulent claims to Medicare and Medicaid for hospice reimbursement. According to the relators, Agape admitted patients to hospice even though the patients did not have a terminal illness with a prognosis of six months or less. During the relevant time period, the hospital chain submitted over 50,000 claims. While the case was still in discovery, relators proposed that their experts review a small percentage of the claims to determine what percentage of those claims were not medically necessary. The relators proposed then to extrapolate that percentage across the population of submitted claims to determine the number of false claims. The relators informed the court that the sampling method was necessary because its experts would cost between $1,600 and $3,600 to review the claims of a single patient, resulting in up to $36 million of costs to review all relevant claims. The relators argued that it would simply take too much time and money to review such a large volume of data.

Although the district court was sympathetic to the time and expense it would take to litigate the case on a claim-by-claim basis, the court rejected the use of statistical sampling, emphasizing the fact-intensive inquiry that an expert has to make when making a medical necessity determination. The court recognized that there could be significant variability among the claims at issue as the claims involved the care of individual patients with different medical conditions.

In short, although the court recognized the efficiencies of using sampling, it decided that the practical considerations were outweighed by the need for the individualized review of evidence related to each alleged false claim. The court acknowledged that sampling might be proper in select circumstances such as cases in which direct proof of damages is impossible because the evidence no longer exists.

Recognizing that the sampling issue would have a profound impact on the management of the case, the court certified its ruling for interlocutory appeal to the Fourth Circuit pursuant to 28 U.S.C. § 1292(b) on the grounds that the statistical sampling issue involved a controlling question of law.

During oral argument, the Fourth Circuit appeared to disagree with the lower court that the statistical sampling question involved a controlling question of law. Judge Robert B. King suggested that the interlocutory appeal should not have been granted because — rather than a pure legal issue — the statistical sampling order involved an "evidentiary ruling that's committed to the discretion of the district judge." Reading the tea leaves, it seems likely that the issue will be sent back to the lower court so that there can be a more fully developed record. If this occurs, it will reinforce the argument increasingly made by the relators and the DOJ that the use of sampling is an evidentiary issue and there is nothing unique about the FCA that prohibits plaintiffs — as a matter of law — from using sampling to prove liability.

Practical Effect of Agape on the Litigation of Cases with Sampling

Defendants have challenged the use of extrapolation at the summary judgment stage on the grounds that it is impermissible as a matter of law because sampling sidesteps the individualized claim-by-claim proof required under the FCA. Because FCA liability is based on individual claims, some in the defense bar argue that statistical sampling is an end-run around a plaintiff's burden of proof.

In fact, in March, the American Health Care Association filed an amicus brief in Agape and categorized the use of sampling as a "novel shortcut" with no textual basis in the statute. The ACHA also described statistical sampling as a "giant sledgehammer" that could be used by plaintiffs to create pressure on defendants to settle cases for fear that plaintiffs will have an easier time proving that a large number of claims were false at trial. Indeed, on Oct. 24, 2016, the DOJ announced that Life Care Centers had agreed to pay $145 million to settle the case.

In future cases, lower courts may well agree with the Fourth Circuit's reasoning that the use of sampling is an evidentiary issue rather than a pure legal issue. If courts find that there is nothing about the FCA that precludes the use of sampling as a matter of law, plaintiffs and defendants will continue to fight over the use of sampling but rather than resolving the issue at the summary judgment stage it will likely be resolved on Daubert motions or at trial in a battle of experts.

If statistical sampling in FCA cases is viewed as a purely evidentiary issue, defendants will want to use Daubert motions to identify defects in an expert's methodology in an effort to keep an expert's testimony from a jury. For example, in U.S. ex rel. Ruckh v. Genoa Healthcare LLC et al,[4] the relator moved in limine to admit expert testimony on statistical sampling, prior to any expert performing any sampling. The court denied the motion as premature, while stating that sampling would not be excluded solely because it sidesteps the need to put on individualized proof for every claim. The court highlighted the importance of Daubert motions to challenge an expert's sample, noting that defects in methodology or other evidentiary defects could result in exclusion of an expert's sampling analysis. Such an evidentiary attack was successful in United States ex. rel. Loughren v. Unum Provident Corp. where the defendant excluded a statistician's expert testimony.[5]

In sum, to the extent sampling is permitted to prove FCA liability, defendants will want to challenge the plaintiff's sampling plan — i.e., is the sample random and representative of the larger population. If defendants are unsuccessful at the pretrial stage, defendants will want to challenge the plaintiff's expert through rigorous cross-examination and by introducing their own expert testimony at trial.

What Comes Next

Thus far, plaintiffs have been attempting to use statistical sampling to establish liability in FCA cases alleging a lack of medical necessity. However, the sampling method would be equally applicable in any FCA case where a plaintiff could argue that an examination of individual claims would be expensive and time consuming. For instance, a plaintiff might use statistical sampling in a case where it was alleged that a government contractor provides goods some subset of which contained defective parts. Rather than examining each individual part, a plaintiff could attempt to use an analysis of a representative sample to make assumptions about the extent of the problem in the larger population of parts.

For now, it seems unlikely that the Fourth Circuit will discredit the use of sampling to prove FCA liability. Instead, the panel's comments during argument seem to signal that the future battles over sampling will be fought in pretrial evidentiary motions in which defendants will attempt to restrict the use of sampling or at trial where defendants will put on competing expert testimony to undermine the weight afforded to evidence derived from sampling by the jury.

In complex cases involving a large number of claims, both plaintiffs and defendants will want to have statisticians as part of the trial team. Plaintiffs will need such experts to craft sampling plans and defendants will want their own experts to refute the plaintiff's sampling methodology. In short, although Agape may not be the win that some in the defense bar hoped for, it will likely be a welcome development for expert statisticians.

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[1] U.S. v. Cabrera-Diaz, 106 F. Supp. 2d 234, 240 (D.P.R. 2000)

[2] U.S. v. Krizek, 859 F. Supp. 5, 7 (D.D.C. 1994), aff'd in part and remanded,

11 F.3d 934 (D.C. Cir. 1997).

[3] U.S. ex rel. Martin v. Life Care Ctrs., 2014 WL 10937088 (E.D. Tenn. Sept. 29, 2014).

[4] U.S. ex rel. Ruckh v. Genoa Healthcare LLC et al., 2015 WL 1926417 (M.D. Fla. April 28, 2015).

[5] United States ex. rel. Loughren v. Unum Provident Corp., 604 F.Supp.2d 259, 263 (D. Mass. 2009).