The Use of Expert Witnesses in Medical Necessity Cases

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Allegations regarding the provision of medically unnecessary health care services are becoming increasingly common. These types of allegations against health care providers arise in the context of administrative matters, False Claims Act (FCA) cases, and even in criminal fraud prosecutions. Proving and defending these allegations will almost certainly involve the testimony of multiple expert witnesses.

Most commonly, a plaintiff in a medical necessity case will offer testimony from at least three types of experts: medical experts who offer opinions regarding the medical necessity and appropriateness of the medical services provided; repricing experts, who will offer testimony about the financial impact of the allegedly unnecessary services that were provided; and perhaps statistical experts who will offer testimony regarding sampling procedures and extrapolation of damages. Defendants may choose to offer their own experts to refute each of these experts or instead simply challenge the admissibility of the proffered opinions. This article provides a primer on the key issues in identifying, engaging, and working with experts in medical necessity cases.

Medical Experts

Both sides in any medical necessity case will likely offer testimony of a medical expert to establish or refute the essential allegation that medically unnecessary or inappropriate services were provided. A medical expert witness must be able to examine the material facts of the case, including medical records and billing records. The opinions of a medical expert may be based on personal experience as well as academic studies and relevant regulatory guidance.[1] The expert should be able to break down the technical language and terminology so that someone without any experience in the field can understand the key issues of a case.

Finding a medical expert with the right set of qualifications can be a challenge particularly where the subject matter relates to specific areas of patient care or provider types. Any expert's experience and qualifications should match precisely the issue to be opined on.[2] For example, retaining a neurosurgeon to review nursing home cases when the neurosurgeon has never cared for a nursing home patient might be a bad choice. On the other hand, ignoring the need for testimony from a physician entirely may be a mistake.[3]

There are three important characteristics of effective medical experts: independence and objectivity, proper demeanor, and relevant experience.

A medical expert should be independent of the parties to any matter and provide objective opinions regarding the subject matter. While it may be tempting for the government to offer testimony from an employee of a Medicare contractor, or for a defendant company to use an employee with a medical background as an expert, these types of employment direct connections provide easy targets for the opposing side to challenge the independence and objectivity of the expert's opinions.[4]

Most health care cases involve patient conditions or social situations that can be heart wrenching. The alleged behavior or practices of the provider can often be presented in a manner that provokes an emotional, or even angry, response. Effective experts are able to read through the noise to identify the key relevant issues, contributing factors, and relationship to applicable regulatory guidance. Their demeanor shows a healthy tempering of emotions, a balance between the extremes of "the sky is falling" and overproviding benefit of the doubt.

Perhaps the most important characteristic of an effective witness is having relevant clinical experience.[5] The medical expert should be able to explain highly technical facts and interpret complex medical issues in a manner that can be understood by others who do not have extensive provider or medical experience. This type of experience can include one or more of the following characteristics:

» Industry/subject matter experience and expertise

» Providing care to patients in a specific health care setting relevant to the case

» Managing patient care and staff with the type of provider in the case

» Experience conducting regulatory reviews relevant to the case

» Prior testimony experience

The need for the medical expert to possess the relevant expertise to testify about medical necessity is central to the case because exclusion of the medical expert may cascade down through the litigation resulting in exclusion of other experts like the repricing expert and the statistician.[6]

One area often overlooked, perhaps intentionally, is the maintenance of work product relating to expert documentation. In some cases, an expert will produce spreadsheets or datasets that are devoid of any information that would allow a reader to know what the data represents, where it came from, and how it is used.[7] In other cases, a link between voluminous source data and a conclusion is not explained well or at all.[8] But any expert should be able to produce work product with a clear delineation of the source of the data and how it supports any conclusions or opinions.

Using appropriate review protocols from the start is closely related to employing good practices regarding work product documentation. Frequently, experts are required to develop or review sample-based reviews of voluminous data and medical information. For these types of analyses, the expert should be able to:

» Discern sampling patterns and bias;

» Objectively and consistently apply relevant standards and guidance;[9]

» Quantify the impact of results; and

» Discern the difference between technical documentation deficiencies and standard of care/medical necessity deficiencies.

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It is possible that the Electronic Medical Record (EMR) has been one of the greatest tools in advancing medicine and patient care.[10] However, EMRs have frequently created additional challenges to medical experts. While EMRs have significantly improved the ability of clinicians to capture objective data about patients and their treatments and largely eliminated issues of legibility and poor handwriting, they have created a whole new set of challenges.

One new challenge is the pure functional ability to retrieve medical records. Printing a record to paper can significantly increase the size of the records. What was once two or three pages in a paper record is now ten pages because of the way information is managed in the EMR. Information is sometimes difficult to find and may also not be in one logical location. Information may be duplicated in many areas of the patient chart, which also contributes to the increase in the size of a printed record.

Further, information may be housed in more than one system. It is not unusual for clinical information to be in one system and financial information to be in another. Contracted providers may maintain documentation in yet another system. The medical expert should be prepared and able to marry all the information from many sources of information into a cohesive set of information and data.

Perhaps the biggest challenge of the EMR for the medical expert is the information in the record itself. EMRs typically allow the use of check boxes and intelligent text to create information on the patient's conditions. The challenge is that clinicians may choose a check box or intelligent text that is a

"good fit" or generally describes the observation as opposed to an exact description in their own words. This challenge is compounded when an EMR system limits the ability to provide free text or edit intelligent text. Unfortunately, intelligent text is not always intelligent, and it does not always make sense. For example, we have seen EMR systems using check boxes and intelligent text to create a summary patient assessment with 150 or so words, 35 commas, and one period. The resulting text actually ends up saying nothing useful.

While some clinicians have become more reliant on check boxes and moved away from thoughtful assessments of clinical conditions, a distinct lack of documented professional assessments in the EMR often results in widely disparate opinions on what a patient needs and whether the services provided were reasonable. As a result, medical experts frequently must provide their own interpretations based on their read of objective data in the EMR. The medical expert should be prepared to address the services of a variety of disciplines affecting the patient's care, such as physicians, nurses, and therapists. This may require a variety of medical experts depending on the nature of the case.

Reimbursement (Repricing) Experts

Once medical experts form an opinion on the medical necessity, appropriate level, or setting of services, the reimbursement impact of those findings must be determined. In some instances, the medical expert may calculate the reimbursement impact. This will happen if the impact is straightforward to determine, for example, if the entire service is either accepted or denied, or if the clinician has the necessary billing background. In many cases, however, the reimbursement impact may be more complicated and often clinicians lack billing knowledge because they rarely deal with the back-office functions in their day-to-day work. This necessitates engaging the reimbursement (or repricing) expert who understands and can apply complex reimbursement rules relevant to the case. The repricing expert is an intermediary between the medical expert and the statistical expert as she takes findings from the medical expert, calculates the dollar impact of those findings, and in turn supplies the inputs necessary for the statistician to extrapolate from the sample to the universe and determine damages.[11]

The repricing expert develops models that replicate the original payments for services and applies changing inputs to calculate the resulting differences in payment between the original payment and the "should have been" payment.[12] These differences may be a result of the clinical findings, coding changes, changes in rates or reimbursement methodology, or differences due to coverage changes. Those factors frequently change, so the repricing expert should not only be familiar with the current reimbursement practices but also with the historical developments in the specific area of health care and be able to apply the retroactive rules.

The repricing expert should possess appropriate qualifications to evaluate the financial impact, including:

>> Experience related to type of claims subject to review

>> Technical expertise in developing models

>> Technical ability to handle large data files efficiently

>> Testimony experience (or guidance from experienced practitioner) in explaining such models, inputs, assumptions used, and resulting outcomes

Reimbursement rules vary greatly across health care disciplines, such that even someone deeply familiar with physician fee schedules or inpatient diagnosis-related groups may find himself hopelessly out of his depth when it comes to pricing skilled nursing facility (SNF), long-term acute care, inpatient rehabilitation facility, or other post-acute services. The government may rely on program integrity contractors as a source of the pricing experts it employs.[13] Consulting firms that employ former health care practitioners with expertise in data handling and manipulation are a good source of repricing experts.

The models used in determining reimbursement may be publicly available from the Centers for Medicare & Medicaid Services (CMS) website,[14] may be available for purchase from a third-party vendor,[15] or may need to be constructed from scratch by the repricing expert. In any case, the repricing expert ought to be well familiar with the intricacies of the model used to price claims.

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The repricing process should commence with verifying the provided data to ensure its completeness and relevance. Most repricing experts will replicate the original payment and the work of the opposing party, allowing an understanding of any built-in assumptions and identification of any errors in the reimbursement methodology applied by the opposing party. Such miscalculations may be a result of data errors or omissions, or incorrect or inconsistent inputs used in the model perhaps by multiple people working on pricing claims, or an incorrect or inconsistent interpretation of the clinician's findings.[16] Working through the detailed pricing also will reveal any unclear clinical findings subject to multiple interpretations.

Replication of the opposing party's work allows pressure testing the methodology to understand the key drivers of any reimbursement differences. Once the differences in methodology, incorrect built-in assumptions, and any other errors are addressed, the model built by the repricing expert could be used for calculating alternative damages that reflects the scenarios and revisions in assumptions requested by counsel. How and when these alternative calculations are prepared is a matter of case strategy because materials from testifying experts may need to be disclosed. Counsel should consider whether it is more desirable to hire a repricing expert to testify to the alternate calculations or a consulting expert who can assist counsel about challenging and attempting to impeach the opposing side's repricing expert.

Similar to the medical expert, the repricing expert should maintain a verifiable work product that supports the conclusions reached, identifies all assumptions made, and identifies the sources of data relied upon. For example, repricing experts should avoid producing files with defunct macros and non-working formulas that show only the final pricing outcome without revealing the calculations and assumptions that went into its derivation. As the model is developed and goes through multiple iterations, version control can be a frequent source of errors, such as when a figure from one schedule is incorrectly carried over to a subsequent schedule or appears to be left over from a prior version. Such errors can be easily identified through the replication of the other side's model and serve to undermine expert witness credibility. Because the repricing expert's conclusion is frequently subject to extrapolation, any errors may be multiplied.

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Statistical Experts

Identifying a Qualified Statistical Expert Witness

There are two major areas to consider when identifying and selecting a statistical expert witness. First, experience in statistical sampling in the health care field should be a priority.[17] Second, consider an expert in health care economics who can combine health care policy with statistical methods.[18]

Unlike certain highly specialized medical experts, statisticians with the appropriate qualifications for these types of cases tend to be easier to locate, and experienced litigators may be familiar with at least one statistical expert. Unlike the medical and repricing experts, statisticians are sometimes judged less harshly for spending most or all of their professional careers working as expert witnesses. Consulting firms often have statisticians with health care experience either on staff or within their consulting networks. Such firms also have expertise and sufficient resources to deal with increasingly large data sets that accompany health care fraud cases and are the basis of the statistical work. However, one issue to watch for when considering retention of a consulting firm is whether your statistical expert witness and any supporting staff will need to be walled off from other employees or associates of the consulting firm due to conflicting engagements. This is most likely to be an issue when your client is one of many plaintiffs or defendants involved in a large-scale litigation.[19] Usually consulting firms have manageable procedures in place to handle such conflicts. If a conflict exists that precludes the retention of a consulting firm, an alternative may be to engage an academic.

Not only does the statistical expert need to have high proficiency in applied statistical analyses and sampling, but she also must have a deep understanding of the health care services involved and prior familiarity with the issues and regulations in the case. All statistical experts must understand the source, the meaning, and any issues with the health care claims data they are working with, as it is expected that they will have a full understanding of the factual basis of their opinion.[20] It is also important for the statistical expert to be able to clearly explain statistical results and applied methodology in plain language because those tend to be complicated and full of specialized terminology.

The ability to challenge statistical sampling depends primarily on the employed methodology, processes, and analyses used to determine this methodology.[21] Detailed attention to the documentation and methods employed by the opposing party's statistical expert may result in identification of vulnerabilities in the sampling approach and resulting extrapolation of damages.

When it comes to challenging an opposing party's statistical expert, the largest vulnerability lies in the statistical expert's methodology. While Medicare contractors have the benefit of procedures and requirements for statistical sampling set forth in various government manuals, the FCA is silent as to the statistical methodology that should be applied so it is necessary to have an experienced statistical expert who can reliably apply principles and methods to the facts of the case.[22]

The procedures most frequently challenged are: (1) sample size; (2) sampling method, and specifically the need for stratification; (3) margin of error (or precision); and (4) documentation. Below is a brief discussion of each of these potential challenges. A thorough summary of statistical sampling and suggested methods for challenging its use can be found in the article, *Statistical Sampling in the Medicare Program: How to Use It and How to Challenge It.*[23]

Sample Size

A sample must be a probability (random) sample to help ensure representativeness and allow for potential extrapolation.[24] The nature of data, variables of interest, objectives of the study, resources available, and tolerance for error (precision) influence the sampling approach and sample size.[25] A good sample will be representative, that is, a characteristic of interest can be estimated from a sample with a known degree of accuracy. Not all samples may be representative of the data universe. First, samples may be too small to accurately reflect a universe. Second, there is always a chance that a sample will consist of non-typical observations. Third, samples may also have a selection bias, which occurs when units with particular characteristics are selected. Examples of selection bias are convenience or judgmental samples, such as when only longer stays or only claims with higher payment amounts are selected.[26]

One of the most frequent challenges to sampling methodology is that the sample size is too small.[27] Computer programs, such as RAT-STATS, may be used to determine an appropriate sample size, if one knows the expected error rate and variance.[28] The software recommendations need to be balanced against the effort required to complete the review of the sampled observations. Sometimes practitioners elect to review a smaller sample size than suggested by the software. That happened in a Minnesota administrative appeal, *In the Matter of the SIRS Appeals of the Lazarus Project*.[29] In that case, the Minnesota Department of Human Services used RAT-STATS to select a random sample of Medicaid claims, and the computer program produced 206 claims from the universe of 13,531.[30] Instead of reviewing all 206 claims, the department "weighed the time and expense required to review additional claims" and chose to limit the review to 150 claims.[31] The administrative law judge found this methodology to be deficient and lacking evidence of the statistical validity necessary to satisfy the legal requirements under Minnesota law.[32]

Sampling Method and Potential for Stratification

Other areas of opportunity for challenging the opposing statistical expert's sampling methodology are whether the universe should have been stratified and what variables are the most appropriate to use for the stratification.[33] Stratification is the process whereby a sample is divided into groups in which the members are similar to each other when the universe is heterogeneous in containing dissimilar elements.[34] Each stratum is separately sampled and an error rate is derived for each stratum.[35] The error rate for each sampled stratum is then applied to the universe of that stratum and added across strata to obtain an estimate for the entire universe.[36]

Stratification is not appropriate in every case. For example, if a universe is homogenous, such as one type of service provided in the same location, there is no need to stratify.[37] Payment amount is the stratification methodology used most often because that variable often works as a proxy for overpayments.[38] Other variables, such as site of service or payer,

also may be used to stratify.[39] A statistical expert who has deep understanding of statistical principles and health care data is valuable to advise on appropriate sampling methods and stratification variables.

Margin of Error

When a universe is sampled, typically an average (or point estimate) is computed by dividing the number of observations with a desired characteristic by the number of sampled observations. However, an indication of the accuracy of the estimate (precision) is also needed. An accuracy estimate refers to the confidence interval, which consists of a point estimate +/- margin of error at a specified probability level expressed through a T-statistic.[40] A larger sample size produces a smaller margin of error, all else remaining equal. Thus, a large margin of error (or poor precision) provides ripe grounds for challenging the statistical expert's sampling methodology.[41]

Documentation

Just like other experts, the statistician is expected to maintain documentation of the sampling methodology and provide sufficient information to allow for the replication of the universe and the sample.[42] Lack of documentation regarding the methodology applied and inability to reproduce the other side's methodology can be further grounds for challenging the opposing expert's method. For example, in *In re American Health Services*, the Department of Health and Human Services Office of Inspector General failed to properly document and preserve its sampling methodology such that it could be replicated so a $1,248,747 overpayment determination was overturned.[43]

Responding to novel or unexpected expert testimony can be difficult if the timeline is short and there is not advanced warning of the novel nature of the expert's proffered opinions.

Other Experts

Recent medical necessity cases reveal attempts by parties to present testimony from a variety of expert witnesses not specifically addressed above. Because they are not the typical fare, such expert reports may take litigants by surprise and create difficulties in responding to them.

In a recent relator-led FCA action involving allegations of medically unnecessary therapy services provided in a SNF setting, the relator offered testimony by an expert in economics and data analysis who performed a multi-factor regression analysis of data obtained from the defendants and CMS in an attempt to show that defendants provided more therapy during assessment periods than non-assessment periods.[44] The expert then extrapolated the data to provide an estimate of alleged damages in the form of Medicare overpayments.[45] Upon challenge by the defendants, the court concluded that the estimate of damages was not reliable, and therefore not admissible, because it was not based on information regarding any patient's actual medical needs.[46]

Similarly, in a recent FCA case involving allegations of billing Medicare for unnecessary therapy services, the Department of Justice (DOJ) offered testimony from Dr. John N. Morris and Dr. Brant E. Fries, two scholars who were involved in the development of the Minimum Data Set, the clinical assessment tool that SNFs use to collect specific information regarding a patient's medical conditions and treatments at specific points in time.[47] Drs. Morris and Fries purport to have created a damages model using logistic regression analysis to determine the amount by which SNF providers allegedly over-billed Medicare. This model has not yet been tested in court and it is unclear whether the DOJ has engaged other experts to develop similar damages models that do not rely directly upon the testimony of a medical expert.

Responding to novel or unexpected expert testimony can be difficult if the timeline is short and there is not advanced warning of the novel nature of the expert's proffered opinions. On the other hand, it may not make sense to directly rebut these types of opinions. The time and expense to develop a contrasting model to disprove a correlation that the proffered expert has identified just may not be worth it. Instead, the responding party may choose to focus resources on attacking the reliability of the proffered testimony in hopes of having it excluded.

Conclusion

Cases involving the medical necessity of services provided to patients and the appropriateness of billing for those services arise in a variety of contexts and settings. While the use of expert witnesses is likely inevitable in these cases, there are a variety of ways that these experts can be engaged and relied upon to prove or disprove the allegations. **C**

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Endnotes

1   FED. R. EVID. 702 (An expert may be qualified by "knowledge, skill, experience, training, or education"); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) ("It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.").

2   *See, e.g., Pyramid Techs., Inc. v. Hartford Cas. Ins. Co.*, 752 F.3d 807, 813 (9th Cir. 2014) ("Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline.).

3   *See, e.g., United States ex rel. Ribik v. HCR ManorCare*, 1:09-cv-13-CMH-TCB (E.D. Va.) (excluding testimony of physical therapist in an FCA case alleging unnecessary therapy services because the expert was not a medical doctor, occupational therapist, or speech language pathologist but offered testimony about the necessity of occupational therapy and speech language pathology services); *Poust v. Huntleigh Healthcare*, 998 F. Supp. 478, 492-493 (D.N.J. 1998) (Expert, who held engineering and law degrees, was not qualified to offer his conclusion in product liability action as to specific, medical cause of plaintiff's injury allegedly from pneumatic compression device, as expert was not medical doctor and had no experience, education, or training that would qualify him to render medical causation opinion).

4   *Orthoflex, Inc. v. ThermoTek, Inc*., 986 F. Supp. 2d 776, 798 (N.D. Tex. 2013) ("Although in forming an independent opinion an expert can rely on information provided by a party's attorney, an expert cannot forgo his own independent analysis and rely exclusively on what an interested party tells him.").

5   FED. R. EVID. 702.

6   *See United States ex rel. Ribik*, *supra* note 3, at *1 (granting motion to exclude testimony of extrapolation witnesses since their reports and testimony were based on evidence from a clinical witness, who was not a medical doctor, and was determined to be unqualified to testify); *see also United States v. Long Grove Manor, Inc.*, 315 F. Supp. 3d 1107, 1114-19 (N.D. Ill. 2018) (granting motion to exclude testimony of two of relator's proposed experts when both experts offered opinions about whether care was fraudulent without reviewing or analyzing whether the care provided to the patients in question was medically necessary).

7   *See United States ex rel. Barron v. Deloitte & Touche, LLP,* No. CIV SA-99-CA-1093-FB, 2008 WL 7136869, at *4 (W.D. Tex. 2008) (granting motion to exclude expert testimony, finding "the data upon which [the expert] relied in forming an opinion as to damages is so unreliable and lacking in probative force that no reasonable expert could base an opinion upon them").

8   *See Long Grove Manor, Inc.*, *supra* note 6, at 1113-14, 1118 (granting motion to exclude testimony of two of relator's proposed experts when one expert's assumption found "no basis in the facts [the expert] considered" and the other expert's opinion was "disassociated from any of the CMS-prescribed methodologies he discusses in his report and testimony").

9   The use of guidance in investigations is an evolving area with the issuance of the Department of Justice's (DOJ's) January 25, 2018 Memorandum on "Limiting the Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases," issued by Associate Attorney General Rachel Brand (the "Brand Memo") stating that DOJ "may not use its enforcement authority to effectively convert agency guidance documents into binding rules" and instructing that DOJ attorneys "may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE [affirmative civil enforcement] cases." In addition, the Brand memo says that DOJ "should not treat a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation."

10 A significant increase in the availability and use of EMRs resulted from the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. *See* Stephen T. Mennemeyer, Nir Menachemi, Saurabh Rahurkar, Eric W. Ford, *Impact of the HITECH Act on physicians' adoption of electronic health records*, 23 J. AM. MED. INFORMATICS ASS'N 375–379 (Mar. 1, 2016), *available at* https://doi.org/10.1093/jamia/ocv103.

11 In certain cases an expert may serve the role of both the repricing expert and statistician to opine on ultimate damages. *See, e.g. United States ex rel. Brown v. Celgene Corp.,* No. CV 10-3165 GHK (SS), 2016 WL 6562065 (C.D. Cal. Aug. 23, 2016) (where plaintiff's "damages expert" analyzed both the repricing changes in the disputed claims and proposed ultimate damages).

12 The repricing expert may use different types of reimbursement analytics to evaluate what the payment should have been. *See* David C. Lewis & Charlie Mills, PROVIDER REIMBURSEMENT ANALYTICS (Milliman White Paper, 2016) (discussing provider reimbursement analytic approaches).

13 Program integrity contractors include program safeguard contractors (PSCs), zone program integrity contractors (ZPICs), and Audit Medicaid Integrity Contractors (Audit MICs) that contract with CMS or state Medicaid programs to identify and stop potential fraud. Their primary tasks include identifying cases of suspected fraud, developing them thoroughly and in a timely manner, and taking immediate action to ensure that payments are not inappropriately made and that any mistaken payments are identified. *See generally* CMS, Medicare Program Integrity Manual (MPIM) § Section 1.7, Medicare Improper Payments: Measuring, Correcting, and Preventing Overpayments and Underpayments, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c01.pdf.

14 For example, the Medicare Physician Fee Schedule is available from the CMS website *at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSLookup/index.html. The Medicare Prospective Payment System PC pricers can be found *at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PC-Pricer/index.html and include, among others, inpatient pricer and Skilled Nursing Facility pricer.

15 *See, e.g., A better bottom line starts with coding accuracy,* 3M Science (2018), *available at* https://www.3m.com/3M/en_US/health-information-systems-us/providers/coding-and-reimbursement/.

16 Deborah R. Farringer, *The Computer Made Me Do It: Is there a Future for False Claims Act Liability Against Electronic Health Record Vendors,* 18 Nev. L.J. 735, 747 (2018).

17 Duane L. Steffey, Stephen E. Fienberg, and Robert H. Sturgess, *Statistical Assessment of Damages in Breach of Contract Litigation*, 46 Jurimetrics J. 129-138 (2006).

18 *See In re Neurontin Mktg. & Sales Practices Litig*., 712 F.3d 21, 29-30 (1st Cir. 2013).

19 *See* Mark R. Patterson, *Conflicts of Interest in Scientific Expert Testimony*, 40 Wm. & Mary L. Rev. 1313 (1999).

20 *See* Fed. R. Evid. 702 (Expert testimony may be admissible under Rule 702 if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case); *see also United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998) (court rejected use of audits as statistical data for extrapolation because the data was "tainted").

21 *See, e.g.*, *United States ex rel. Loughren v. UnumProvident Corp*., 604 F. Supp. 2d 259, 269 (D. Mass. 2009) (in granting motion to exclude expert's testimony, court found the statistical sampling and expert testimony was unreliable because expert's methodology had not gained acceptance within the relevant discipline and was susceptible to manipulation and significant error); *United States ex rel. Wall v. Vista Hospice Care*, No. 3:07-cv-00604-M, 2016 WL 3449833, at *14 (N.D. Tex. June 20, 2016) (expert's "errors in selecting the sample are fatal to his conclusions," and a court cannot determine whether an expert's opinions are reliable when he fails to provide details regarding methodology or merely assures the court he has utilized generally accepted scientific methodology).

22 31 U.S.C. §§ 3729-3733; *see also United States v. Life Care Ctrs. of Am., Inc*., 114 F. Supp. 3d 549 (E.D. Tenn. 2014) (relying on the FCA's silence as to the use of statistical sampling generally, held that statistical sampling could be used by a plaintiff to attempt to prove liability in FCA litigation).

23 *See* Lester J. Perling and Jamie B. Gelfman, *Statistical Sampling in the Medicare Program: How to Use It and How to Challenge It*, 2018 Health L. Handbook 14 (2018).

24 *See generally* Medicare Program Integrity Manual (MPIM) § 8.4.2 Probability Sampling; *see also Vista Hospice Care*, *supra* note 21, at *13.

25 MPIM at § 8.4.4.3 (Determining Sample Size); Perling & Gelfman*, supra* note 23, at 11; *see also Vista Hospice Care*, *supra* note 21, at *13-*14 (expert's extrapolation was unreliable given the nature of the underlying data, expert's failure to select a random sample, and expert's failure to account for relevant variables).

26 *Pruchniewski v. Leavitt*, No. 8:04-CV-2200-T-23TBM, 2006 WL 2331071, at *7, *11 (M.D. Fla. Aug. 10, 2006) (unpublished opinion) (in a Medicare overpayment case, expert testified that sample was not representative because the average payment in the sample was 70% higher than the payment in the universe) *cited in* Perling & Gelfman, *supra* note 23, at 12, n. 144 (because federal courts have been reluctant to invalidate statistical sampling and extrapolations based on sample size, "[p]roviders attempting to challenge statistical sampling based on sample size should also be prepared to argue that the sample size resulted in an imprecise, unreliable conclusion.").

27 Perling & Gelfman*, supra* note 23, at 11.

28 RAT-STATS *User Guide* and *Companion Manual, available at* https://oig.hhs.gov/compliance/rat-stats/index.asp.

29 *In the Matter of the SIRS Appeals of the Lazarus Project*, OAH-68-1800-33278, St. of Minn. Off. of Admin. Hearings for the Dep't of Hum. Serv. (July 24, 2017), *available at* https://mn.gov/oah/assets/1800-33278-lazarus-project-dhs-sirs-report_tcm19-283675.pdf.

30 *See id.* at ¶ 46.

31 *Id.* at ¶¶ 51-53.

32 *Id.* at Conclusion of Law ¶¶ 20-23.

33 *See* MPIM § Section 8.4.4.1.3, Administrative Actions and Statistical Sampling for Overpayment Estimates; *cf. Pruchniewski v. Leavitt*, No. 8:04-CV-2200-T-23TBM, 2006 WL 2331071, at *12–13 (M.D. Fla. Aug. 10, 2006) (finding that plaintiff did not demonstrate that a different stratification would have made a significant difference in the overpayment estimation); *Puerto Rico Dep't of Health*, No. A-11-54, 2011 WL 3251316, DAB Decision No. 2385 (Jun. 9, 2011) (finding that appellant failed to identify which of the overlapping variables should have been used to stratify the sample, and failed to explain how stratification by any particular variable would be relevant to the purpose of the audit).

34 *See* Perling & Intriligator*, supra* note 23.

35 MPIM § 8.4.4.1.3.

36 MPIM § 8.4.5.1, The Point Estimate.

37 Because one generally defines strata to make them as internally homogeneous as possible with respect to overpayment amounts, a stratified sample from an already-homogenous set would not yield significantly more precise estimates than a simple random sample of the same size without stratifying. *See* MPIM § 8.4.11.1, Stratified Sampling.

38 *Id.*

39 *Id*.

40 "Confidence interval" measures the probability that a population parameter will fall between two sets of values, or the probability that a value will fall between an upper and lower bound of a probability distribution. *See also* "Confidence Interval," Investopedia, *available at* https://www.investopedia.com/terms/c/confidenceinterval.asp.

41 *United States v. Robinson,* 2015 WL 1479396, at *10 (E.D. Ky. Mar. 31, 2015) (admitting sampling evidence and collecting cases supporting the finding that "statistical sampling methods and extrapolation have been accepted in the Sixth Circuit and in other jurisdictions as reliable and acceptable evidence in determining facts related to [False Claims Act] claims as well as other adjudicative facts" (internal citations omitted)).

42 MPIM § 8.4.4.4, Documentation of Sampling Methodology.

43 *In re American Health Services*, HICN 103-01-0077 A (2000).

44 *See Long Grove Manor, Inc.*, *supra* note 6.

45 *Id.* at 5.

46 *Id.*

47 *See United States ex rel. Ribik*, *supra* note 3.