IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

United States of America, *et al.*, Plaintiffs, *ex rel.* Scarlett Lutz, *et al.*, Plaintiffs-Relators, v. Berkeley Heartlab, Inc., *et al.*, Defendants.	Civil Action No. 9:14-cv-00230-RMG (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2458-RMG) **ORDER and OPINION**

This matter is before the Court on the United States' motion to exclude the opinions in Sections II and VI of Jessica Schmor's expert report proffered by BlueWave Healthcare Consultants, Inc., Floyd Calhoun Dent, III, and Robert Bradford Johnson (collectively, "the BlueWave Defendants"). (Dkt. Nos. 441, 441-1.) For the reasons set forth below, the motion to exclude is granted.

I. Background

The Government has filed a complaint in intervention against the BlueWave Defendants and Latonya Mallory alleging violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the False Claims Act ("FCA"), 42 U.S.C. § 3729(a). (Dkt. No. 75.) The alleged FCA violations arise from BlueWave's marketing of laboratory tests for two laboratory companies, Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"), between 2010 and 2014. The Government has alleged that Defendants violated the FCA when they engaged in multiple kickback schemes to induce physicians to refer blood samples to HDL and Singulex for large panels of blood tests, many of which were medically unnecessary. For

example, the Government alleges that Defendants offered and facilitated the payment of processing and handling ("P&H") fees to physicians to induce referrals, in violation of the AKS and FCA.

II. Legal Standard - *Daubert*

Under Rules 104(a) and 702, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). The trial court must ensure that (1) "the testimony is the product of reliable principles and methods," (2) "the expert has reliably applied the principles and methods to the facts of the case," and (3) the "testimony is based on sufficient facts or data." Fed. R. Evid. 702(b), (c), (d). "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid," *Daubert*, 509 U.S. at 592-93, and whether the expert has "faithfully appl[ied] the methodology to facts." *Roche v. Lincoln Prop. Co.*, 175 F. App'x 597, 602 (4th Cir. 2006). To make this determination, Courts consider several factors, including "whether a theory or technique . . . can be (and has been) tested," "whether the theory or technique has been subjected to peer review and publication," the "known or potential rate of error," the "existence and maintenance of standards controlling the technique's operation," and whether the theory or technique has garnered "general acceptance." *Daubert*, 509 U.S. at 593-94; *accord United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014). However, these factors are neither definitive nor exhaustive, *United States v. Fultz*, 591 F. App'x 226, 227 (4th Cir. 2015), and "merely illustrate[] the types of factors that will bear on the inquiry." *Hassan*, 742 F.3d at 130.

Courts have also considered whether the "expert developed his opinions expressly for the purposes of testifying," *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998), or through "research they have conducted independent of the litigation," *Daubert v. Merrell Dow*

Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand), and whether experts have "failed to meaningfully account for . . . literature at odds with their testimony." *McEwen v. Balt. Wash. Med. Ctr. Inc.*, 404 F. App'x 789, 791 (4th Cir. 2010).

Rule 702 also requires courts "to verify that expert testimony is 'based on sufficient facts or data.'" *EEOC v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015) (quoting Fed. R. Evid. 702(b)). Thus, "trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." *Id.* The court may exclude an opinion if "there is simply too great an analytical gap between the data and the opinion offered." *Id.* (internal citations and quotations omitted). "The proponent of the [expert] testimony must establish its admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The Court is mindful that the *Daubert* inquiry involves "two guiding, and sometimes competing, principles." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). "On the one hand, . . . Rule 702 was intended to liberalize the introduction of relevant expert evidence," *id.*, and "the trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. Stanley*, 533 F. App'x 325, 327 (4th Cir. 2013) *cert. denied*, 134 S. Ct. 1002 (2014). On the other hand, "[b]ecause expert witnesses have the potential to be both powerful and quite misleading,' it is crucial that the district court conduct a careful analysis into the reliability of the expert's proposed opinion." *United States v. Fultz*, 591 F. App'x 226, 227 (4th Cir. 2015).

III. Discussion

The United States has disclosed expert reports from Kathy McNamara, opining on the commercial reasonableness of Defendants' offering P&H fees to physicians and the fair market value of P&H fees, and Eric Hines, calculating the damages to the United States resulting from

the alleged false claims. The BlueWave Defendants have proffered Jessica Schmor, a nurse and professional coder, to "examine [Hines's and McNamara's] implicit and explicit coding opinions." (Dkt. No. 473 at 1.) Schmor states that her expert opinion is limited to "coding, billing and reimbursement of the [Current Procedural Terminology] Code 99000 - handling and/or conveyance of specimen for transfer from the office to a laboratory." (Dkt. No. 441 at 3.) Specifically, she intends to testify as to the following four opinions:

(1) The non-payment of Code 99000 is a payment policy, and the costs are not included in the evaluation and management fee setting.

(2) Physicians are ultimately responsible for their claims submitted.

(3) Code 99000 billed by physicians should not have resulted in financial damages.

(4) The plaintiff may have inflated damages due to improper inclusion of claims.

(Dkt. No. 441-1 at 3.) Before the Court is the Government's motion to exclude Schmor's testimony. (Dkt. No. 441.) The BlueWave Defendants have filed a motion in opposition, and the Government has filed a reply. (Dkt. Nos. 473, 485.)

a. CPT Code 99000

Medicare applies the Medicare Physician Fee Schedule ("MPFS") to determine reimbursement for physicians' services. The MPFS uses a standardized coding system called the Current Procedural Terminology ("CPT") that identifies each service and the appropriate reimbursement for that service. The CPT codes are published annually by the American Medical Association.

CPT Code 99000 is the code used by physicians to capture the processing and handling services completed by the physician's office to prepare a specimen for transport to a laboratory (i.e., centrifuging, separating serum, labeling specimens, packing specimens, or filling out forms). Code 99000 is an adjunct code, meaning that it cannot be reported independently but

must be reported in conjunction with a code for one of the basic services rendered to the patient. During the relevant period, 2009 through 2014, Code 99000 was "bundled" with the code for physician reimbursement for Evaluation and Management ("E&M") services. The E&M code covers the costs associated with a patient's visit to an office and evaluation by a physician.

For example, during an office visit with a patient, a physician may identify the need for a blood panel, collect a blood sample from the patient, and prepare that sample for transport to a laboratory. That physician would bill Medicare for reimbursement using the E&M code for an office visit. Although the physician would also record Code 99000 to account for the preparation of the blood sample, Medicare would not separately reimburse him for those P&H services because it considers the P&H costs to be "subsumed by the payment for the services to which they are incident,"[1] in this case, the office visit during which the need for the blood panel was identified.

b. Schmor's Challenge to Kathy McNamara's Expert Opinion

According to McNamara, the bundling of Code 99000 with the code for E&M services means that the "expenses (including practice overhead expenses) needed to provide P&H services are included within the MPFS calculation to determine payment for E/M services." (Dkt. No. 441-3 at 18.) In other words, because reimbursement for E&M services *includes* reimbursement for P&H services, it was not commercially reasonable for physicians involved with the defendants to get paid twice for the same P&H services: once as a bundled payment from Medicare or TRICARE under the E&M code and a second time as a P&H fee from HDL or Singulex.

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[1] CMS Fee Schedule Administration and Coding Requirements available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf.

In contrast[2], the BlueWave Defendants seek to offer Schmor's opinion that "The non-payment of 99000 is a payment policy and the costs are not included in the evaluation and management fee setting." (Dkt. No. 441-1 at 3.) Schmor's point is simple: although Medicare has decided to bundle P&H services with E&M services, it is not necessarily true that a physician is "reimbursed" for the costs of P&H services under the E&M code because the E&M code does not necessarily cover the costs a physician incurs to provide P&H services. She explains:

> The [Medicare] fee schedule is arrived at by using all physicians' charges and costs . . . . [T]o the extent that some physicians' offices are performing blood drawing and processing services, it would be included in their data to Medicare and used for evaluation of the calculation of the Medicare physician fee schedules. Given that not all physician practices perform these services, it is not reasonable to assume that the average costs of an evaluation and management code will cover additional incidental services performed by some practices.

(Dkt. No. 441-1 at 8-9.) The BlueWave Defendants therefore proffer Schmor's opinion that "a medical provider is not reimbursed twice for the same services when the provider accepts a process and handling fee from a third-party laboratory and a reimbursement from Medicare for E/M services." (Dkt. No. 473 at 3.)

The Government argues that Schmor's opinion about CPT Code 99000 should be excluded because it is not based on sufficient facts or data, is not based on a reliable methodology, and it would mislead a jury. (Dkt. No. 473 at 5.) The Government takes issue in particular with Schmor's description of how the MPFS is formulated. While Schmor represents the MPFS as the product of a simple calculus using physicians' charges and costs, McNamara

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[2] McNamara and Schmor do not dispute that Medicare has made the decision not to separately reimburse P&H services covered by Code 99000 because, at least in part, the costs of performing these services is not significant when compared to the overall cost of the services covered by the E&M office visit code. They also do not dispute that Medicare considers "multiple" factors to determine what constitutes fair and equitable reimbursement for each service defined by a CPT code. (Dkt. No. 441-2 at 33.)

explains in her rebuttal that the MPFS is actually determined using many pieces of information from a variety of sources, including surveys and expert panels. (Dkt. No. 448-5 at 2-3.) Schmor conceded in her deposition that she had oversimplified the process for developing the MPFS and acknowledged that many factors are considered. (Dkt. No. 441-2 at 33.) Nonetheless, she confirmed her belief that "Medicare has developed what it believes to be a fair and equitable reimbursement for the bundled service of E&M visit and processing and handling blood specimens" and stated that she had "no reason to doubt" that the reimbursements were indeed fair and equitable. (Dkt. No. 441-2 at 33-34.)

Schmor's opinion that "a medical provider is not reimbursed twice for the same services when the provider accepts a process and handling fee from a third-party laboratory and a reimbursement from Medicare for E/M services" is inadmissible because it is not based on sufficient facts or data, and because her own expert report directly contradicts this point. (Dkt. No. 473 at 3.) Schmor stated in her expert report that the MPFS "represents a packaged rate which should cover the cost of that particular service" and that although "some care provided will cost more and some will cost less . . . on average, the total cost of care to patients[] should be covered by the reimbursement received." (Dkt. No. 444-1 at 8.) In short, the MPFS does not correlate directly to a physician's costs. To the extent a physician's P&H costs may not adequately reimbursed under the MPFS, this is true for the cost of *any* physician service. This is the nature of a standardized reimbursement schedule.

Schmor has admitted that she is "not particularly clear" on how the responsible committee determines the fair and equitable reimbursement amount attached to each CPT code (e.g., what the committee might do to control for outliers). (Dkt. No. 441-2 at 33.) She does not know what steps that committee may or may not take to ensure that the reimbursement schedule

is fair and equitable. She could not analyze whether reimbursement under the E&M code in this case may have covered physicians' actual P&H costs because she did not analyze the physicians' actual P&H costs. Finally, in her deposition, she stated that she had no reason to doubt that the MPFS reimbursements are actually fair and equitable. For these reasons, Schmor's opinion that medical providers are not paid twice for the same services when they receive a fee from a third-party laboratory and Medicare reimbursement for E&M services is not based on sufficient facts or data.

c. Schmor's Challenge to Eric Hines's Expert Opinion

The BlueWave defendants also seek to offer Schmor's expert opinion on Eric Hines' damages calculation, specifically that, if his calculations included double counting of reimbursement for P&H fees then

(1) CPT Code 99000 billed by physicians should not have resulted in financial damages

(2) The plaintiff may have inflated damages due to improper inclusion of claims

(Dkt. No. 441-1 at 3.) These opinions are based on Schmor's determination, discussed above, that physicians are not reimbursed for P&H costs when they are reimbursed under the MPFS code for E&M services. The Government seeks to exclude Schmor's testimony based on Federal Rules of Evidence 104(a), 401, 402, 403, 702, and 703, arguing that she is not qualified to opine on damages resulting from false claims or kickbacks (Dkt. No. 441 at 2-6) and that her opinion is speculative because she failed to review the hundreds of documents the Government's forensic accounting expert considered as basic evidence of damages (e.g., claims data, spreadsheets of fee payments, financial statements, and bank records. (Dkt. No. 44 at 6-7).

In her deposition, Schmor stated that if Mr. Hines' damages calculations did not include CPT Code 99000, then she would not have an opinion on the accuracy of his damages calculation. (Dkt. No 441-2 at 27.) In his rebuttal report, Hines explained that CPT Code 99000

was not present in any of HDL or Singulex's Medicare or Tricare claims so did not feature in his damages calculations. (Dkt. No. 445-4 at 12.) Schmor's opinion about the impact of Code 99000 on Hines's damages calculations is therefore irrelevant and would not be helpful to the jury. For these reasons, this testimony is not admissible.

IV. Physician Responsibility for Claims Submitted

The BlueWave Defendants also seek to present Schmor's opinion that "Physicians are ultimately responsible for their claims" submitted to Medicare. (Dkt. No. 441-1 at 3.) In her export report, Schmor explains that on the standard form physicians use to submit claims to Medicare and Tricare, they must certify that they are not submitting any false claims. She explains:

> As of the drafting of this report, I have not been provided with any of the claims data which was available to Eric Hines. I cannot validate if the physicians were billing Medicare for the process and handling fees in addition to being reimbursed by HDL and Singulex. However even if the physicians did[] bill Medicare and Tricare for the process and handling fee (99000), the physician, not BlueWave, is responsible for the provider's improper actions resulting in damages to the government.

(Dkt. No. 441-1 at 10.) Schmor's opinion appears to target the Government's damages calculations to the extent CPT Code 99000 was included in those calculations. Eric Hines has explained that his damages calculations did not include reimbursements under CPT Code 99000. For this reason, Schmor's opinion about physician responsibility for claims is irrelevant.

V. Conclusion

For the reasons set forth above, the Government's motion to exclude the expert testimony of Jessica Schmor (Dkt. No. 441) is GRANTED.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

June 29, 2017
Charleston, South Carolina