IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA, ex rel. GERALD POLUKOFF, M.D., Plaintiff/Relator, v. ST. MARK'S HOSPITAL; INTERMOUNTAIN HEALTHCARE, INC.; INTERMOUNTAIN MEDICAL CENTER; SHERMAN SORENSEN, M.D.; and SORENSEN CARDIOVASCULAR GROUP, Defendants.	MEMORANDUM DECISION AND ORDER DENYING RELATOR'S AMENDED MOTION FOR PARTIAL SUMMARY JUDGMENT AND DENYING AS MOOT RELATOR'S MOTION TO TAKE JUDICIAL NOTICE OF CERTAIN ADJUDICATIVE FACTS AND MATERIALS Case No. 2:16-CV-304 TS District Judge Ted Stewart

This matter is before the Court on Plaintiff/Relator Gerald Polukoff, M.D.'s ("Relator") Amended Motion for Partial Summary Judgment.[1] For the reasons discussed below, the Court will deny the Motion. The Court will also deny as moot Relator's Motion for the Court to Take Judicial Notice of Certain Adjudicative Facts and Materials.[2]

I. SUMMARY JUDGMENT STANDARD

Summary judgment is proper if the moving party can demonstrate that there is no genuine issue of material fact and it is entitled to judgment as a matter of law.[3] In considering whether a genuine dispute of material fact exists, the Court determines whether a reasonable jury could return a verdict for the nonmoving party in the face of all the evidence presented.[4] "An issue of

[1] Docket Nos. 382, 384. While Docket No. 384 is the operative amended Motion, the relevant exhibits are attached to Docket No. 382.

[2] Docket No. 381.

[3] FED. R. CIV. P. 56(a).

[4] *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986); *Clifton v. Craig*, 924 F.2d 182, 183 (10th Cir. 1991).

fact is 'material' if under the substantive law it is essential to the proper disposition of the claim."[5] The Court is required to construe all facts and reasonable inferences in the light most favorable to the nonmoving party.[6]

"The movant bears the initial burden of making a prima facie demonstration of the absence of a genuine issue of material fact."[7] "Such a movant may make its prima facie demonstration simply by pointing out to the court a lack of evidence for the nonmovant on an essential element of the nonmovant's claim."[8] Once a movant has carried its initial burden, "the burden shifts to the nonmovant to go beyond the pleadings and 'set forth specific facts' that would be admissible in evidence in the event of trial from which a rational trier of fact could find for the nonmovant."[9]

II. DISCUSSION

Relator's Motion provides 74 statements of allegedly undisputed material facts.[10] Dr. Sorensen and Sorensen Cardiovascular Group (collectively, "Defendants") contest eight of these and offer 44 additional material facts.[11] Relator makes evidentiary objections to seven document exhibits Defendants submitted in opposition to the Motion and contests 22 of Defendants'

[5] *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 670 (10th Cir. 1998).

[6] *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Wright v. Southwestern Bell Tel. Co.*, 925 F.2d 1288, 1292 (10th Cir. 1991).

[7] *Adler*, 144 F.3d at 670–71.

[8] *Id.* at 671; *accord Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

[9] *Adler*, 144 F.3d at 671 (quoting FED. R. CIV. P. 56(e)).

[10] *See* Docket No. 384 ¶¶ 1–74.

[11] *See* Docket No. 414, at 6–23.

additional material facts.[12] As none of these objections affects the Court's analysis, they need not be addressed here.

This case is about whether Sherman Sorensen, M.D. ("Dr. Sorensen") violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–32, by submitting legally false claims for reimbursement under the Medicare Act from 2002 to 2011.[13] Dr. Sorensen is a board-certified cardiologist experienced in a medical procedure called Patent Foramen Ovale ("PFO") closure.[14] A PFO is a "tunnel-like opening between the two upper chambers of the heart" that usually closes naturally after birth.[15] It is not uncommon, however, for it to remain open to a degree, and for some, it may be medically advisable to eliminate the opening through a transcatheter PFO closure.[16]

The Medicare Act provides that items or services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" may not be reimbursed.[17] To define "reasonable and necessary," the Medicare Program Integrity Manual ("Medicare Manual") provides that:

> Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary if the contractor determines that the service is:
> - Safe and effective;
> - Not experimental or investigational . . . ; and

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[12] *See* Docket No. 424, at 2–8.

[13] *See* Docket No. 289 ¶¶ 171–86; *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018) ("'[F]alse or fraudulent' includes both factually false and legally false requests for payment. . . . [Relator] claims the PFO closures do not comply with Medicare's 'reasonable and necessary' requirement, meaning Dr. Sorensen submitted *legally* false requests for payment.").

[14] *See* Docket No. 414, at 9.

[15] Docket No. 384 ¶¶ 27–28 (internal quotation marks and citations omitted).

[16] *Id.* at ¶ 31; Docket No. 414, at 7–8.

[17] 42 U.S.C. § 1395y(a)(1)(A)*; see also* Docket No. 384 ¶ 2.

- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.[18]

The Tenth Circuit has held "that a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of that phrase [provided above]."[19]

Relator seeks summary judgment on two issues. He claims there is no genuine issue of material fact to challenge (1) that "PFO closures from 2002–2011 were not reasonable and medically necessary as a matter of law,"[20] and (2) what constituted the "standard of care/medical necessity of PFO/ASD closure in the medical community" during that timeframe.[21] Regarding each issue and its subparts, either Relator fails to make a "prima facie demonstration of the absence of a genuine issue of material fact,"[22] or Defendants successfully go beyond the pleadings to set forth facts admissible at trial "from which a rational trier of fact could find for [Defendants]."[23]

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[18] Center for Medicare and Medicaid Services, *Medicare Program Integrity Manual* § 13.5.4 (Rev. 863, 02-12-19).

[19] *Polukoff*, 895 F.3d at 743.

[20] Docket No. 384, at 34.

[21] *Id.* at 42.

[22] *Adler*, 144 F.3d at 670.

[23] *Id.* at 671 (quoting FED. R. CIV. P. 56(e)).

1. PFO Closures Not Reasonable and Necessary

Relator argues universally that PFO closures from 2002–2011 were not medically reasonable and necessary because they were: (a) investigational and experimental, (b) not demonstrated as safe and effective, (c) not demonstrated as having benefit over other forms of therapy, and (d) not a generally accepted medical practice.[24] Regarding (a) and (b), Defendants' evidence shows a question of material fact exists.[25] Regarding (c), the relevant standard from the Medicare Manual states that a reasonable and necessary service must be "[a]t least as beneficial as an existing and available medically appropriate alternative."[26] Relator argues that randomized clinical trials did not establish the benefit of PFO closure until 2013, but he fails to show such trials are the only way to establish that benefit.[27] Finally, regarding (d), Relator fails to show that this language—from the 2014 Medicare Manual and applicable to contractors making Local Coverage Determinations[28]—applies to Dr. Sorensen.[29]

2. Standard of Care/Medical Necessity of PFO/ASD Closures in Medical Community

Relator asserts that his evidence regarding the standard of care and medical necessity of PFO/ASD closures in the medically community during the relevant period has not been "meaningfully challenged."[30] He argues: (a) transcatheter PFO closures are appropriate only in patients with at least one cryptogenic stroke, (b) the diagnosis of cryptogenic stroke must be

[24] Docket No. 384, at 34–35.

[25] *See e.g.*, Docket No. 414-3, at 290; Docket No. 382-1, at 179.

[26] CMS, *Medicare Program Integrity Manual* § 13.5.4 (Rev. 863, 02-12-19).

[27] Docket No. 384, at 42; *see* Docket No. 382-1, at 188, 194–95.

[28] *See* Docket No. 382-2, at 22; Docket No. 384, at 40.

[29] *See* CMS, *Medicare Program Integrity Manual*, Exhibits (Rev. 943, 02-21-20) (providing definition for "contractor").

[30] Docket No. 384, at 42.

made by a neurologist and cardiologist, and (c) this diagnosis requires comprehensive evaluation to rule out other potential causes of stroke.[31] Defendants counter that PFO closure is warranted in a broader range of patients,[32] and diagnosis by a neurologist is not always necessary.[33] This is a material issue of fact that is "essential to the proper disposition of the claim,"[34] as it partially determines whether Dr. Sorensen's procedures met the appropriate standard of care. Both parties provide support for their contradictory assertions, and partial summary judgment must be denied.

III. CONCLUSION

It is therefore

ORDERED that Relator's Amended Motion for Partial Summary Judgment (Docket No. 384) is DENIED. It is further

ORDERED that Relator's Motion for the Court to Take Judicial Notice of Certain Adjudicative Facts and Materials (Docket No. 381) is DENIED as moot.

DATED this 19th day of August 2020.

BY THE COURT:

Ted Stewart
United States District Judge

[31] *Id.* at 43; *see, e.g.*, Docket No. 382-1, at 375, 426–27.
[32] Docket No. 414, at 7–8; *see e.g.*, Docket No. 414-2, at 20, 23–27.
[33] *See, e.g.*, Docket No. 414-2, at 306, 567.
[34] *Adler*, 144 F.3d at 670.