

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

**UNITED STATES OF AMERICA,
ex rel. THOMAS SCHROEDER,**

Plaintiff,

v.

**MEDTRONIC, INC., COVIDIEN, L.P.,
HUTCHINSON REGIONAL
MEDICAL CENTER, and WICHITA
RADIOLOGICAL GROUP, P.A.,**

Defendants.

Case No. 17-2060-DDC-BGS

MEMORANDUM AND ORDER

Before the court is defendants Medtronic, Inc., Covidien, L.P., and Hutchinson Regional Medical Center's Rule 56(d) Motion to Defer Deadline to Respond to Relator's Motion for Partial Summary Judgment (Doc. 402). Plaintiff Schroeder filed a Motion for Partial Summary Judgment (Doc. 397) months ahead of the dispositive motion deadline set forth in the court's Second Revised Scheduling Order (Doc. 361). In his motion, plaintiff asks the court to decide whether defendants Medtronic and Covidien's alleged provision of no-charge devices to defendant HRMC constitutes illegal remuneration under the Anti-Kickback Statute (AKS) or whether—as defendants contend—those devices qualify for the AKS's safe harbor provision. Doc. 397 at 2. Defendants argue that they need completed expert reports to respond adequately to plaintiff's motion. And, because defendants' deadline for producing an expert report "has not yet arrived," the Relator's motion is "premature." Doc. 402 at 2. So, defendants ask the court to defer consideration of plaintiff's motion to allow time for "focused expert discovery." *Id.* at 1. Defendants also propose an expedited discovery schedule on the narrow issue of the AKS's safe

harbor provision, 42 U.S.C. § 1320a-7b(b). *Id.* at 2. In response, plaintiff argues defendants don't need experts to respond to his motion. Plaintiff asserts that the safe harbor issue "is a straightforward legal determination that can only be made by this Court based on facts—not any expert witness' statements or opinions." Doc. 406 at 1.

The court grants defendants' request to defer consideration of plaintiff's motion and adopts defendants' proposed schedule expediting discovery on the narrow issue of the AKS's safe harbor provision. The court holds that defendants' Motion to Defer Deadline to Respond (Doc. 402) satisfies the requirements for a Rule 56(d) motion under the Federal Rules of Civil Procedure and Tenth Circuit precedent. The court also recognizes that defendants' experts—at least potentially—may help the court understand the statutory and regulatory context of the AKS and federal health care payment systems. The adopted schedule supplements, but doesn't otherwise alter, the court's Second Revised Scheduling Order (Doc. 361).

The court begins, in Part I, with a brief overview of the relevant deadlines at issue. The court then evaluates defendants' Motion to Defer Deadline to Respond (Doc. 402) under the legal standard for a Rule 56(d) motion in Part II. Next, in Part III, the court addresses plaintiff's argument that expert opinion on the safe harbor issue is unnecessary and inappropriate. Finally, the court recites its conclusions.

I. Deadlines Overview

The parties concluded factual discovery on April 30, 2023. Doc. 406 at 2. The court's Second Revised Scheduling Order requires plaintiff to disclose experts by December 1, 2023, and defendants to disclose experts by February 2, 2024, with a dispositive motions' deadline of June 7, 2024. Doc. 361 at 2. Plaintiff filed his Motion for Partial Summary Judgment (Doc. 397) on September 28, 2023. Defendants' Rule 56(d) motion asks the court, given the February

2, 2024 expert disclosure deadline, to defer the response deadline to plaintiff's motion to allow for "focused expert discovery." Doc. 402 at 1.

Plaintiff argues that the already-completed factual discovery reveals all the "uncontroverted facts" necessary to decide the safe harbor issue. Doc. 406 at 3. Also, plaintiff asserts that the court set the expert discovery deadlines "far from the conclusion of the fact discovery deadlines" solely to facilitate parties' ability to get medical records, which "has nothing to do with the pending Motion." *Id.* at 6. Defendants contend that, because the court's deadlines to finalize expert discovery haven't passed, the court should allow them time to finish "procuring and producing" relevant evidence "before the Court considers the safe harbor issue." Doc. 402 at 5. In determining whether to grant defendants the requested time, the court first must evaluate defendants' motion under Rule 56(d). The court thus recites the legal standard for a Rule 56(d) motion, below.

II. Rule 56(d)

In response to a summary judgment motion, if "a nonmovant shows by affidavit or declaration"—and cites "specified reasons"—why it "cannot present facts essential to justify its opposition," then the court may "allow time to . . . take discovery[.]" Fed. R. Civ. P. 56(d). According to Tenth Circuit precedent, the nonmovant's affidavit must specify "(1) the probable facts not available, (2) why those facts cannot be presented currently, (3) what steps have been taken to obtain these facts, and (4) how additional time will enable the party to obtain those facts and rebut the motion for summary judgment." *Adams v. C3 Pipeline Constr. Inc.*, 30 F.4th 943, 968 (10th Cir. 2021) (quoting *Gutierrez v. Cobos*, 841 F.3d 895, 908 (10th Cir. 2016)). The Tenth Circuit also has clarified that the court should treat a Rule 56(d) motion "liberally," so long as it isn't "dilatory or lacking in merit." *Jensen v. Redevelopment Agency of Sandy City*,

998 F.2d 1550, 1554 (10th Cir. 1993) (citation and internal quotation marks omitted) (discussing Rule 56(f), the previous version of Rule 56(d)); *see also Aragon v. Collings*, No. 2:18-CV-00620, 2022 WL 1693785, at *2 (D. Utah Apr. 25, 2022) (“Although relief is not automatic, Rule 56(d) motions ‘should ordinarily be treated liberally.’”) (quoting *Nat’l Union Fire Ins. Co. of Pittsburgh v. Dish Network, LLC*, 17 F.4th 22, 34 (10th Cir. 2021)).

Here, defendants have provided declarations that explain their experts’ putative role on the safe harbor issue. These declarations meet all four Tenth Circuit Rule 56(d) requirements: *First*, defendants contend, facts about the AKS discount exclusions context remain unavailable without these expert reports, including, for example, the Centers for Medicare and Medicaid (CMS)’s specific reimbursement methodologies, CMS’s billing and claims submission requirements, and the separate cost-reporting system for certain healthcare entities. Doc. 402-1 at 3; Doc. 402-2 at 2. *Second*, defendants assert, they cannot present these facts currently because the complexity of “health care administrative procedures, [and] Medicare practices” leave an “untrained layperson” in need of expert help to “navigat[e] the complex systems and requirements.” Doc. 402 at 4. *Third*, defendants allege that they have taken steps to secure these facts by retaining “experts with significant experience with federal health care payment systems and the discount safe harbor provisions,” *Id.* at 5, one of whom “previously served as deputy chief of the Administrative and Civil Remedies Branch of the US Department of Health and Human Services (HHS) Office of Inspector General (OIG),” Doc. 402-1 at 2. And, *last*, defendants report that their experts can complete the reports within a reasonable time, even offering to accelerate the court-imposed schedule as applied to the safe harbor issue. Doc. 402 at 2.

Not only do defendants' declarations meet the four Tenth Circuit requirements, but our Circuit also counsels liberality when deciding Rule 56(d) motions. The court concludes, therefore, that defendants meet the basic legal standard for a successful Rule 56(d) motion. The only remaining question asks whether the motion is dilatory or meritless. As noted above, the court previously granted defendants a much longer timeframe for expert discovery. So, while deferring consideration of plaintiff's Motion for Partial Summary Judgment (Doc. 397) will delay the court's ruling on the safe harbor issue, that delay is slight in the larger context of this case. And it won't hinder the pace of the larger case's disposition. Thus, the motion isn't dilatory. Neither does the motion lack merit. The experts may help the court understand the safe harbor issue, one that is, as explained below, reasonably complex.

The court thus grants defendants' Rule 56(d) motion. The court also adopts defendants' proposed schedule expediting their safe harbor discovery, which the court specifies in Part IV below. The court now turns to plaintiff's argument that expert input isn't appropriate at all.

III. Expert Opinion and Statutory or Regulatory Schemes

Plaintiff's response to defendants' Rule 56(d) motion (Doc. 402) contends that the court should deny defendants' motion because expert opinion is both unnecessary and inappropriate for the court's safe harbor analysis. He asserts that the "completed fact discovery" is determinative on the safe harbor issue because it already "addressed what reporting and documentation was done by HRMC and Medtronic regarding the no-charge devices." Doc. 406 at 4–5. And so, plaintiff argues, all that remains is a legal question—whether defendants' "actions met the regulatory requirements"—and that question is in "the province of this Court to decide, not the Parties' experts." *Id.* at 5. "Expert witnesses are not permitted to testify," plaintiff contends, about "how statutes and regulations should be interpreted" or "whether their

client’s conduct met statutory or regulatory requirements.” *Id.* at 2. The court evaluates plaintiff’s argument in light of relevant case law, below.

“Expert witnesses may testify about ultimate issues of fact, but an expert may not state legal conclusions drawn by applying the law to the facts.” *United States v. Dental Dreams, LLC*, 307 F. Supp. 3d 1224, 1260–61 (D.N.M. 2018) (citing *United States v. Richter*, 796 F.3d 1173, 1195 (10th Cir. 2015)). Examples abound in case law, however, where district courts allowed experts to explain “a complex statutory and regulatory scheme.” *United States v. Blair*, No. CR ELH-19-00410, 2021 WL 5040334, at *12 (D. Md. Oct. 29, 2021) (collecting cases); *see also*, e.g., *United States v. Wade*, 203 F. App’x 920, 930 (10th Cir. 2006) (affirming admission of IRS agent expert testimony that “necessarily will include the agent’s understanding of the applicable law as a backdrop”); *United States v. Strange*, 23 F. App’x 715, 717 (9th Cir. 2001) (affirming admission of expert testimony “regarding Medicare regulations and reimbursement procedures”); *United States v. Onyenso*, 615 F. App’x 734, 738 (3d Cir. 2015) (affirming admission of “expert testimony regarding the purposes of the Anti-Kickback Statute” and that “Medicare does not allow the payment of claims tainted by kickbacks”); *United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011) (noting that “courts and commentators have consistently concluded that expert testimony that ordinarily might be excluded on the ground that it gives legal conclusions may nonetheless be admitted in cases that involve highly technical legal issues”).

Even a case plaintiff cites as support for the proposition that the “experts’ testimony would invade the province of the court,” indicates an expert’s role isn’t as clear-cut as plaintiff suggests. Doc. 406 at 10 (citing *Klaczak v. Consolidated Medical Transport*, 458 F. Supp. 2d 622 (N.D. Ill. 2006)). As plaintiff notes, “the court ‘barred Relators’ purported experts from offering opinion testimony as to the ultimate issues of law in the case, including whether

Defendants violated the AKS or the FCA.” *Id.* at 10 (quoting *Klaczak*, 458 F. Supp. 2d at 663). But plaintiff neglects to mention that *Klaczak* “did not entirely exclude Relators’ experts’ reports at that time.” *Klaczak*, 458 F. Supp. 2d at 663. Instead, in *Klaczak*, the court reserved judgment about some parts of the expert reports because of the possibility that the “proposed testimony providing background information about the Medicare system, provider reimbursement, and hospital cost reports at least could potentially be helpful to the trier of fact.” *Id.* at 663–64. And, though the court in *Klaczak* later excluded the experts’ testimony on other grounds—a lack of expert qualifications—it was *not* because the testimony provided information about the Medicare system, reimbursements, and cost reports. *Id.* at 664.

Here, defendants’ experts purportedly will offer insight about “the reimbursement methodologies used in peripheral vascular procedures, the requirements of cost reporting, and what constitutes an appropriate charge disclosure, among other things.” Doc. 402 at 5. Such insight aligns with the types of expert testimony—the backdrop of applicable law, Medicare regulations and reimbursement procedures, and the purposes of the AKS—affirmed by the various courts noted above. Potentially, such insight also could help the court understand a highly technical legal issue. So, the court concludes that the types of expert reports forecast by defendants could comply with relevant case law. The court thus deems it appropriate to allow defendants sufficient time to develop that expert testimony and make appropriate expert disclosures.

IV. Conclusion

The court grants defendants’ Rule 56(d) Motion to Defer Deadline to Respond (Doc. 402). Defendants’ motion meets Rule 56(d)’s requirements. The court also recognizes the expert reports—at least potentially—could assist the court’s effort to understand the relevant

regulatory context. Finally, the court also adopts defendants’ proposed schedule expediting expert discovery solely on the safe harbor issue, as specified in the table below. The adopted schedule supplements the Second Revised Scheduling Order entered on June 27, 2023 (Doc. 361), but does not disturb it otherwise.¹

SUPPLEMENT TO SUMMARY OF DEADLINES AND SETTINGS (DOC. 361) SOLELY ON SAFE HARBOR ISSUE	
Event	Deadline/Setting
Defendants’ expert reports on safe harbor issue	November 3, 2023
Plaintiff’s rebuttal report, if any	November 20, 2023
Depositions of safe harbor experts, if any	November 27, 2023 – December 8, 2023
Defendants’ opposition and cross motions	December 29, 2023, or 28 days from completion of expert discovery, whichever is earlier
Plaintiff’s reply and opposition	28 days from defendants’ filings
Defendants’ replies	14 days from plaintiff’s reply brief

IT IS THEREFORE ORDERED BY THE COURT THAT defendants’ Rule 56(d) Motion to Defer Deadline to Respond to Relator’s Motion for Partial Summary Judgment to Allow for Focused Expert Discovery (Doc. 402) is granted. Defendants’ proposed schedule solely on the AKS safe harbor issue is adopted, as outlined in the table above, to supplement the Second Revised Scheduling Order (Doc. 361).

¹ Defendants ask the court for “explicit and advance permission” to present a cross-motion on the safe harbor issue “without prejudice to Defendants ability to seek summary judgment on any and all remaining claims in accordance with the Second Revised Scheduling Order.” Doc. 402 at 13. Because the supplemental schedule outlined here doesn’t alter the Second Revised Scheduling Order, defendants don’t need the requested explicit and advance permission. Any summary judgment motions addressing issues other than the safe harbor issue will remain due according to Doc. 361, which sets June 7, 2024, as the deadline for other potentially dispositive motions.

IT IS SO ORDERED.

Dated this 16th day of October, 2023, at Kansas City, Kansas.

s/ Daniel D. Crabtree
Daniel D. Crabtree
United States District Judge