IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

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

Relator,

v.

HUTCHINSON REGIONAL MEDICAL CENTER, MEDTRONIC, INC., COVIDIEN, LP and WICHITA RADIOLOGICAL GROUP, PA,

Defendants.

Case No. 17-2060-DDC-BGS

MEMORANDUM AND ORDER

This is a case about doing enough. Specifically, it asks the court to decide whether defendants Medtronic, Inc., Covidien, LP (together "Medtronic"), and Hutchinson Regional Medical Center completed enough documenting and reporting to avoid violating the law. Defendants engaged in medical device transactions, with Medtronic supplying—and HRMC purchasing—directional atherectomy devices and drug-coated balloons (DCBs) for the treatment of peripheral artery disease (PAD). Some of those DCB transactions involved bulk sales—where purchasing a given quantity of DCBs decreased the price per unit because of the number purchased. It's a familiar arrangement for anyone who has frequented a wholesale club. And some of the DCB transactions involved bundled sales—where Medtronic provided directional atherectomy devices, and additional DCBs, for no extra charge alongside a bulk DCB purchase. Again, not an unusual scheme, as any late-night infomercial watcher can attest. Neither of these transaction types appear problematic on its face. But here's the kicker: HRMC reports its costs

to Federal health care programs, like Medicare. And so, the bulk and bundled sales transactions pass muster solely when the Federal health care programs also benefit from the deal. Otherwise, such bulk and bundled transactions violate the Anti-Kickback Statute (AKS), a law designed to address fraud and other abusive practices involving Federal health care programs.

Relator contends defendants didn't do enough with the bundled transactions—not enough documenting and not enough reporting. And so, he argues, the no-charge[1] devices Medtronic supplied to HRMC from April 2015 to July 2019 qualify for the AKS's illegal remuneration category. Illegal remuneration violates the AKS and taints HRMC's Federal health care program claims—ultimately making them false claims. And so, on behalf of the government, Relator brings this action under the False Claims Act (FCA). The FCA provides civil liability for violating the AKS's criminal provisions.

But defendants cry foul. They contend that their transactions are protected under the law, asserting a safe harbor affirmative defense. Defendants invoke both the AKS's statutory discount exception (and the corresponding regulatory safe harbor provisions) to absolve their exchange of no-charge medical devices in the bundled transactions.

Relator moves for partial summary judgment against defendants' safe harbor affirmative defense. Doc. 397. He argues that the documents defendants produced in discovery speak for themselves—defendants didn't do enough to qualify for the statutory exception and the regulatory safe harbor. Defendants Medtronic and HRMC each filed cross summary judgment

[1] The parties quibble over semantics, with Relator preferring the term "free devices," *e.g.*, Doc. 398 at 2–4, and defendants insisting on the term "no-charge devices," Doc. 430 at 26–27; Doc. 435 at 2. The court employs the phrase "no-charge" devices because it more closely tracks the regulatory language that describes the transactions at issue here. *See* 42 C.F.R. § 1001.952(h)(5)(ii) ("The term discount does not include . . . [s]upplying one good or service *without charge* or at a reduced charge[.]" (emphasis added)). What's more, Medtronic provided no-charge devices to HRMC solely alongside bulk orders—never, strictly speaking, for free (*i.e.*, without any purchase at all). And so, the term "no-charge" more accurately describes the nature of the transactions at issue here.

motions. Doc. 429; Doc. 434. Their motions ask the court to hold that the statutory exception and the regulatory safe harbor protect their bundled transactions.

But before the court can rule on these cross summary judgment motions, it must address a preliminary issue. It asks whether the court should limit or exclude Medtronic's expert report when evaluating these cross motions. Relator argues that Medtronic's expert (Tony Maida) inappropriately draws legal conclusions and purports to speak on behalf of the government—all without authorization from his former employer, the Department of Health and Human Services (HHS). The court grants in part and denies in part Relator's Motion to Limit or Exclude Expert Testimony and Report (Doc. 465). The court limits expert Maida's testimony and report to exclude legal conclusions but finds his expert opinions otherwise admissible.

Then the court evaluates the parties' cross partial summary judgment motions together to answer this question: did defendants, as a matter of law, satisfy—or fail to satisfy—the regulatory safe harbor provisions or the statutory discount exception? To answer these questions, the court engages in regulatory and statutory interpretation, applying both the regulatory safe harbor provisions and the statutory discount exception to the undisputed facts. The court provides an overview of the rulings to come, below.

On both Relator's motion and Medtronic's cross motion, the court holds that no reasonable jury could find from the summary judgment facts that defendant Medtronic failed to satisfy the regulatory safe harbor provisions. And so, the court grants summary judgment in Medtronic's favor on its safe harbor affirmative defense. When considering Relator's motion and HRMC's cross motion, no reasonable jury could find that HRMC failed to satisfy the statutory discount exception. The court thus grants summary judgment in HRMC's favor on its safe harbor affirmative defense.

And the court denies Relator's partial summary judgment motion. The court explains the reasons for all its decisions and how they interact in more detail, below.

I. Background

The following facts are uncontroverted for purposes of the parties' summary judgment motions, unless otherwise noted. The court first introduces the parties to the transactions at issue and then explains the devices sold. Next, the court outlines the bulk and bundle devices sales—and their accompanying documents—all before explaining how HRMC reported those transactions to the Federal health care program. Each description is relevant to the statutory and regulatory analysis that follows.

Parties to the Device Transactions

HRMC is a not-for-profit hospital in Hutchinson, Kansas. Doc. 233 at 5 (Fifth Am. Compl. ¶ 7). It's organized under the laws of the state of Kansas. *Id.* Medtronic is a medical device company. Doc. 384 at 2. Medtronic, Plc. acquired Covidien, Plc. in 2015 and both Medtronic, Inc. and Covidien, LP are wholly owned subsidiaries of Medtronic, Plc. *Id.* Over time, by and through its employees, Medtronic began making, using, selling and/or importing medical devices formerly sold by Covidien. *Id.*

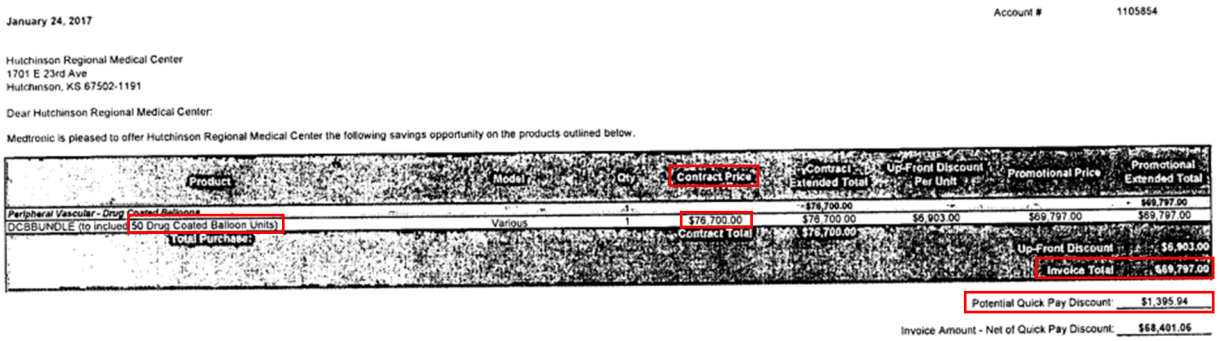
The Devices Sold

In the transactions at issue in these motions, Medtronic supplied two types of devices to HRMC: directional atherectomy devices and drug-coated balloons. *See, e.g.*, Doc. 432-11 at 3 (HRMC Ex. C-1); Doc. 432-16 at 2 (HRMC Ex. D-3); Doc. 432-26 at 2 (HRMC Ex. H-3). These devices treat peripheral artery disease in the legs, a progressive disorder that causes vessels that carry blood from the heart to the legs to narrow or close. *Peripheral Vascular Disease*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/conditions-and-diseases/peripheral-vascular-disease (last visited Sept. 19, 2024). Three directional atherectomy

devices are involved in the bundled transactions—the HawkOne, the TurboHawk, and the SilverHawk. *See, e.g.*, Doc. 432-11 at 3 (HRMC Ex. C-1); Doc. 432-16 at 2 (HRMC Ex. D-3); Doc. 432-26 at 2 (HRMC Ex. H-3). These devices allow physicians to excise plaque from the peripheral vascular system to restore blocked flow. *Directional Atherectomy Systems*, Medtronic, https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/directional-atherectomy-systems.html (last visited Sept. 14, 2024). The drug-coated balloons, for their part, function to transfer a drug—paclitaxel—to the artery walls to prevent an opened artery from becoming narrow again (re-stenosis). Doc. 430-3 at 37–38, 39–40 (Huyser Decl. Ex. 2, Oster Dep. 89:20–90:9; 91:20–92:8). Some combination of directional atherectomy devices and DCBs made up all the transactions relevant here.

Documents Associated with the Device Sales

During the 2015 to 2019 time period, Medtronic occasionally offered HRMC bulk deals on DCBs at the end of a quarter. Doc. 398-2 at 81 (Winger Dep. 315:19–25). These bulk deals gave HRMC a volume-based discount. Doc. 430-15 at 3–4 (Winger Decl. ¶ 9). Medtronic provided invoices corresponding to these bulk deal offers. *See, e.g.*, Doc. 432-6 at 2 (HRMC Ex. A2); Doc. 432-9 at 2 (HRMC Ex. B-2). For example, here's an invoice from a 50 DCBs bulk deal—dated January 24, 2017—with an invoice total of $69,797, before any potential quick pay discount.



January 24, 2017

Account # 1105854

Hutchinson Regional Medical Center
1701 E 23rd Ave
Hutchinson, KS 67502-1191

Dear Hutchinson Regional Medical Center:

Medtronic is pleased to offer Hutchinson Regional Medical Center the following savings opportunity on the products outlined below.

Product	Model	Qty	Contract Price	Contract Extended Total	Up-Front Discount Per Unit	Promotional Price	Promotional Extended Total
				$76,700.00	-	-	$69,797.00
Peripheral Vascular - Drug Coated Balloons							
DCBBUNDLE (to include 50 Drug Coated Balloon Units)	Various	1	$76,700.00	$76,700.00	$6,903.00	$69,797.00	$69,797.00
Total Purchases			Contract Total	$76,700.00		Up-Front Discount	$6,903.00
						Invoice Total	$69,797.00

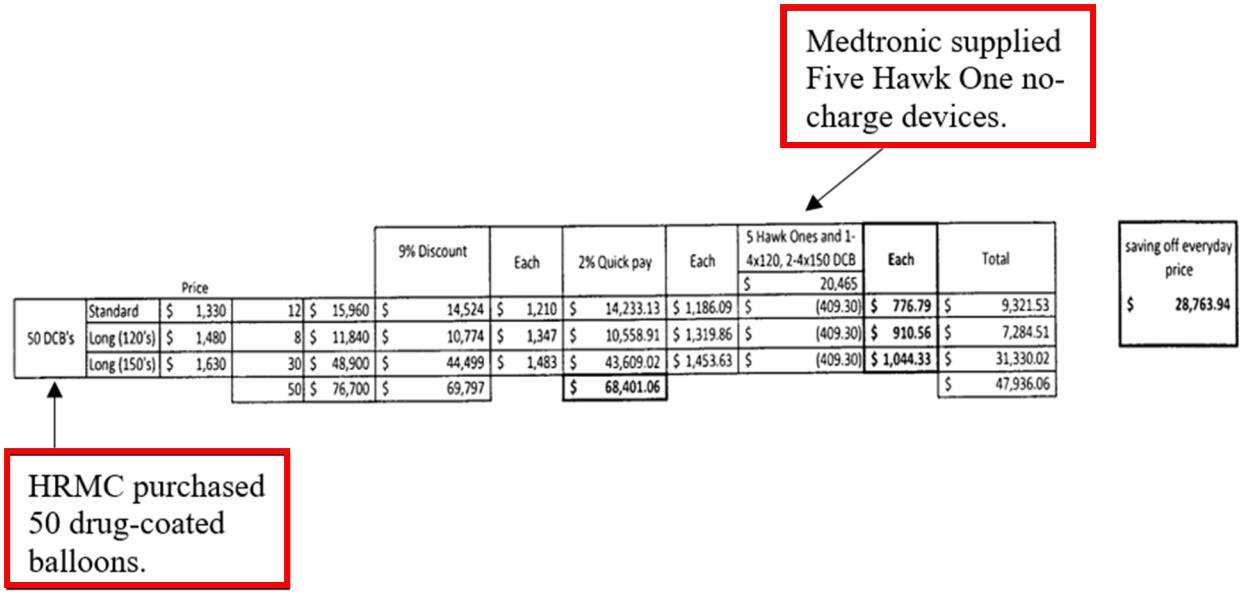
Potential Quick Pay Discount: $1,395.94

Invoice Amount - Net of Quick Pay Discount: $68,401.06

Doc. 430 at 10; Doc. 432-15 at 2 (HRMC Ex. D-2). The bulk invoice identifies the number of devices in the bulk offer (*i.e.*, 50 DCBs), the contract price ("$76,700"), the invoice total ("$69,797"), and the potential quick pay discount ("$1,395.94"), among other things. *Id.* (red outline added by the court). It doesn't list any no-charge devices. *Id.* All of Medtronic's bulk invoices also provided notice informing the buyer of its discount reporting obligations under the AKS. *See, e.g.*, Doc. 432-6 at 2 (HRMC Ex. A2); Doc. 432-9 at 2 (HRMC Ex. B-2).

Sometimes, Medtronic also included no-charge devices as part of these bulk sale purchases, including them as a package deal. Doc. 435-3 at 3 (Davisson Dep. 268:10–13). When offering these no-charge device bundles, the Medtronic salesperson would create a table on a separate piece of paper to reflect the no-charge devices. *See, e.g.*, Doc. 432-7 at 2 (HRMC Ex. A-3); Doc. 432-10 at 2 (HRMC Ex. B-3); Doc. 432-11 at 3 (HRMC Ex. C-1); Doc. 432-16 at 2 (HRMC Ex. D-3).

As an example, the following table corresponds to the January 24, 2017 bulk invoice (shown above). This table indicates a bulk purchase of 50 DCBs and also lists no-charge devices, including five Hawk One atherectomy devices. Doc. 430 at 12; Doc. 432-16 at 2 (HRMC Ex. D-3). In the separate box on the right of the table bundle sheet, it identifies the value of the no-charge devices. Doc. 430 at 12; Doc. 432-16 at 2 (HRMC Ex. D-3).



		Price			9% Discount	Each	2% Quick pay	Each	5 Hawk Ones and 1-4x120, 2-4x150 DCB	Each	Total	saving off everyday price
									$ 20,465			
50 DCB's	Standard	$ 1,330	12	$ 15,960	$ 14,524	$ 1,210	$ 14,233.13	$ 1,186.09	$ (409.30)	$ 776.79	$ 9,321.53	$ 28,763.94
	Long (120's)	$ 1,480	8	$ 11,840	$ 10,774	$ 1,347	$ 10,558.91	$ 1,319.86	$ (409.30)	$ 910.56	$ 7,284.51	
	Long (150's)	$ 1,630	30	$ 48,900	$ 44,499	$ 1,483	$ 43,609.02	$ 1,453.63	$ (409.30)	$ 1,044.33	$ 31,330.02	
			50	$ 76,700	$ 69,797		$ 68,401.06				$ 47,936.06	

Doc. 430 at 12; Doc. 432-16 at 2 (HRMC Ex. D-3) (explanation in red text boxes added by the court). The total payment price for this bundle is reflected in the final row of the 9% discount column—$69,797. Doc. 430 at 12; Doc. 432-16 at 2 (HRMC Ex. D-3). Neither the associated invoice (shown above), Doc. 430 at 10; Doc. 432-15 at 2 (HRMC Ex. D-2), nor the purchase order generated by HRMC's purchasing department (not shown here) included these no-charge devices, Doc. 432-14 at 2 (HRMC Ex. D-1). But the total payment price of $69,797 remained constant over all three documents—the invoice, the purchase order, and the bundle table sheet. Doc. 432-15 at 2 (HRMC Ex. D-2); Doc. 432-14 at 2 (HRMC Ex. D-1); Doc. 432-16 at 2 (HRMC Ex. D-3).

To make a device offer to HRMC, the Medtronic sales representative would deliver the bundle table sheet to HRMC. Doc. 398-2 at 79 (Winger Dep. 307:10–308:2). HRMC's purchasing director then would forward the bulk invoice and the bundle table sheet to the purchasing department. Doc. 398-5 at 11–12 (Atkins-Ray Dep. 32:17–33:3).[2] After receiving

[2] The deposition testimony cited here referenced "Exhibit 1" and "Exhibit 3." Earlier in the same deposition, the questioning attorney identified these exhibits by Bates number. Doc. 398-5 at 11 (Atkins-

these two documents, the purchasing department input the total purchase price into HRMC's software system, producing a purchase order. *Id.* at 12 (Atkins-Ray Dep. 34:4–11).[3]

HRMC's Report of Expenses

Because HRMC is a cost-reporting entity, it owes an obligation to submit an annual Cost Reports to HHS. Doc. 435-12 at 20 (Russo Expert Report). The purchases entered into HRMC's software enabled a third-party accountant to compile the data from HRMC's general ledger to prepare this HHS-required Cost Report. Doc. 398-6 at 14 (Baldetti Dep. 41:18–43:3).

The process moving the purchase price from HRMC's software system to the Cost Report occurred like this: For each purchase entered into HRMC's software system, HRMC staff assigned that total purchase price a "spend category." *Id.* at 10 (Baldetti Dep. 27:3–10). The "spend category" identified which "cost center" received the allocation for that purchase—such as the cath lab, the operating room, or the laboratory. *Id.* at 10 (Baldetti Dep. 27:11–17). HRMC's "cost center" for medical devices billed to Medicare and other payors was designated as revenue code 272. Doc. 435-12 at 20 (Russo Expert Report). Once HRMC paid for the devices, the software system automatically reflected the expense as part of the relevant cost center on the hospital's general medical supplies ledger line. *Id.* at 8–9 (Russo Expert Report). HRMC's accounting firm then used its general ledger to catalogue the costs it must include in its

Ray Dep. 31:13–16). The attorney identified Exhibit 1 as marked with HRMC Bates number 3853. *Id.* It thus corresponds to Doc. 399-1 at 75 and is a bundle table sheet. Similarly, the attorney identified Exhibit 3 as marked with HRMC Bates number 3852. Doc. 398-5 at 11 (Atkins-Ray Dep. 31:13–16). It thus corresponds to Doc. 399-1 at 78 and is a bulk invoice.

[3] Relator disputes this fact, contending—because HRMC's purchasing department didn't include any of the no-charge device data in HRMC's software system—that the purchasing department didn't enter the data accurately. Doc. 445 at 34. And so, the background facts state solely that the purchasing department entered the total purchase price—which didn't change regardless of whether the purchasing department represented the no-charge devices in its system. To be sure, the price per unit would change with those no-charge devices added in. But the relevant figure for the court's analysis here is the total purchase price, not any itemized, price-per-unit amount. *See* § IV.B.1.b.

Cost Report. Doc. 398-6 at 26 (Baldetti Dep. 91:12–21). To say it another way, the purchase invoice "rolls up" to the department cost center, then it "rolls up" to medical supplies as the sub-general ledger line, and then it "rolls up" to HRMC's trial balance (or general ledger), from which HRMC compiled its Cost Report. *Id.*

Before applying the relevant statutory and regulatory language to the undisputed facts recited above, the court addresses a threshold issue—one presented by Relator's Motion to Limit or Exclude Expert Testimony and Report (Doc. 465). The outcome of this motion affects the content of the summary judgment record the court considers when deciding the cross summary judgment motions. So, the court deems it prudent to begin with this later-filed motion.

II. Motion to Limit or Exclude Expert Testimony and Report (Doc. 465)

After the parties had completed the summary judgment briefing on the safe harbor issue, Relator moved to limit or strike the testimony and report of Medtronic's designated expert, Tony Maida. Relator's motion relied on *Daubert* and Federal Rules of Evidence 403 and 702. Doc. 465. The court construes these arguments as ones asserting objections under Rule 56(c)(2).[4]

[4] Medtronic argues that Relator's motion is procedurally improper, and the court thus should deny it. Doc. 479 at 8–10. Medtronic is correct. Following amendments to Rule 56 in 2010, a party may not properly move to strike an opposing party's evidence at summary judgment. Instead, the challenging party should object in its summary judgment briefing, as provided under Rule 56(c)(2). *See* Fed. R. Civ. P. 56 advisory committee's note to 2010 amendment ("There is no need to make a separate motion to strike."). What's more, courts have expressed concern about parties using motions to strike to manipulate page limits. *See TDY Indus., LLC v. BTA Oil Producers, LLC*, No. 18-CV-0296-SWS/MLC, 2019 WL 12661227, at *1 (D.N.M. June 5, 2019) ("The Court is wary of Defendant's attempt to evade the page limitations and get further briefing on why it believes the Court should not consider Plaintiff's evidence."); *Mobile Shelter Sys. USA, Inc. v. Grate Pallet Sols., LLC*, 845 F. Supp. 2d 1241, 1253 (M.D. Fla. 2012) (denying a motion to strike evidence submitted with a summary judgment motion and concluding such a motion may function "as a procedural device by which a party may try to exceed the page limits imposed by the Local Rules and the orders of the Court").

Nonetheless, when confronted with improper motions like this one, district courts have taken one prevailing approach: to construe the arguments as objections and consider them at summary judgment. *See Lee v. Burwell*, No. CV-16-366-SCY/KK, 2018 WL 4964547, at *1 n.1 (D.N.M. Oct. 15, 2018) ("[F]or the sake of judicial efficiency, the Court will construe Plaintiff's motion as making objections to the defense exhibits. . . . If the Court determines that Plaintiff's objection to a defense exhibit is valid, the

The court must decide this Rule 56(c)(2) issue first. That's so because its outcome will define, in part, the summary judgment facts that apply on summary judgment.

Federal Rule of Civil Procedure 56(c)(2) provides that a "party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence." The objection "functions much as an objection at trial, adjusted for the pretrial setting." Fed. R. Civ. P. 56(c)(2) advisory committee's note to 2010 amendment. "The burden is on the proponent to show that the material is admissible as presented or to explain the admissible form that is anticipated." *Id.*

Relator here asserts three grounds for his objections. *First*, Relator argues that the court should limit Maida's opinions because he draws legal conclusions which "are improper, inadmissible, and should be excluded from consideration at summary judgment." Doc. 465 at 3. Specifically, Relator takes issue with Maida's "conclusion that Medtronic's (and even HRMC's) actions complied with the requirements of the safe harbor defense." *Id.* *Second*, Relator argues that Maida improperly offered opinions on behalf of the government. *Id.* at 9–10. *Third*, Relator contends that the court should strike Maida as an expert because he didn't secure agency authorization before rendering his opinions—as mandated by the *Touhy* regulations of the United States Department of Health and Human Services (HHS), his former employer. *Id.* at 3–4. Relator asserts that Maida's failing to secure authorization precludes him from serving as an

Court will disregard the exhibit as inadmissible evidence rather than strike it from the summary judgment record."); *TDY Indus., LLC*, 2019 WL 12661227, at *2 ("[T]he Court will construe Defendant's motion to strike as objections under Rule 56(c) and consider them when resolving the summary judgment motions."); *Douglass v. Garden City Cmty. Coll.*, No. CV-20-2076-KHV, 2023 WL 137501, at *1 (D. Kan. Jan. 9, 2023) (denying motion to strike but clarifying that the "Court is aware of its duty to consider only evidence which would be admissible at trial and will consider defendants' evidentiary arguments in its forthcoming order on defendant's motion for summary judgment"). Here, the court follows suit and construes Relator's motion as one presenting objections.

expert here because Maida's expert opinion flows from the knowledge and experience he secured while working at HHS. *Id.* at 11.

The court addresses each of Relator's arguments, in turn. But first, the court recites the legal standard governing admission of expert testimony.

A. Expert Testimony Admissibility under *Daubert* and Fed. R. Evid. 702 & 704

The court bears a "gatekeeping obligation" to determine whether expert testimony is admissible. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). This duty applies at the summary judgment stage, just as it does at trial. *See Johnson v. Weld Cnty.*, 594 F.3d 1202, 1209 (10th Cir. 2010) (clarifying that it is "well settled in this circuit" that courts can consider only admissible evidence at summary judgment (citation omitted)); *see also* Fed. R. Civ. P. 56(c)(2) ("A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence."). When performing this gatekeeping role, the court has broad discretion. *Kieffer v. Weston Land, Inc.*, 90 F.3d 1496, 1499 (10th Cir. 1996) (citation omitted). Courts exercise this discretion under the standard adopted in Fed. R. Evid. 702. It provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (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's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Our Circuit has directed trial judges to apply a two-part test when determining admissibility of expert testimony under *Daubert* and Rule 702. *Conroy v. Vilsack*, 707 F.3d 1163, 1168 (10th Cir. 2013). *First*, the court must determine "whether the expert is qualified 'by knowledge, skill, experience, training, or education' to render an opinion." *United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009) (en banc) (quoting Fed. R. Evid. 702). *Second*, the court "'must satisfy itself that the proposed expert testimony is both reliable and relevant, in that it will assist the trier of fact, before permitting a jury to assess such testimony.'" *Id.* (quoting *United States v. Rodriguez-Felix*, 450 F.3d 1117, 1122 (10th Cir. 2006)). On this second prong, "the touchstone of admissibility is helpfulness to the trier of fact." *Werth v. Makita Elec. Works, Ltd.*, 950 F.2d 643, 648 (10th Cir. 1991) (quotation cleaned up). "The proponent of expert testimony bears the burden of showing that the testimony is admissible." *Conroy*, 707 F.3d at 1168 (citing *Nacchio*, 555 F.3d at 1241). "[R]ejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702 advisory committee's note to 2000 amendments.

1. Expert Qualifications

Here, the court concludes, Medtronic has carried its burden to show that Maida is qualified by knowledge, experience, training, and education to render an opinion. Even Relator agrees. He doesn't challenge Maida's qualifications. Doc. 465 at 6. Nor could he plausibly do so. Maida worked from 2005 to 2014 as an attorney in the Administrative & Civil Remedies Branch (ACRB) of the Office of Counsel to the Inspector General of the Department of Health and Human Services. Doc. 435-10 at 7–8. ACRB partners with the Department of Justice "on investigating and resolving False Claims Act cases involving HHS programs, including Medicare." *Id.* at 8. And Maida served during that time "as the internal subject matter expert on the Anti-Kickback Statute[.]" *Id.* at 7. After his time at ACRB, Maida became a partner at an

international law firm where he serves as co-leader of the Healthcare Regulatory & Compliance practice. *Id.* So, for nearly two decades, Maida has worked intimately on matters that involve the regulations and statute at issue here. The court concludes this work history demonstrates that Maida possesses knowledge, experience, and training—coupled with his legal education—sufficient to satisfy the first part of our Circuit's test for admissible expert testimony. Now, the court takes up the second part of the test: admissible expert testimony must consist of reliable, relevant testimony that is helpful to the trier of fact.

2. Reliable, Relevant Testimony Helpful to the Trier of Fact

"An opinion is reliable if the reasoning or methodology of the expert is valid and 'can be applied to the facts in issue.'" *Lua v. QBE Ins. Corp.*, No. 18-CV-01233-KLM, 2019 WL 5104477, at *2 (D. Colo. Oct. 11, 2019) (quoting *Daubert*, 509 U.S. at 592). "An opinion is relevant if it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.'" *Id.* (quoting *Daubert*, 509 U.S. at 592).

Here, Relator doesn't attack Maida's reliability. *See generally* Doc. 465. Instead, Relator challenges whether Maida's testimony is relevant to help the trier of fact. Relator concedes that Maida provides some information about the AKS's history and background, as well as statutory/regulatory context that may help the trier of fact. Doc. 465 at 2; Doc. 482 at 4–5. But Relator seeks to limit what he calls Maida's "legal conclusions" because Maida allegedly "renders opinions on ultimate issues of law." Doc. 465 at 6. Given the type of relevance challenge Relator levels at Maida's report, the court concludes Relator's argument more appropriately falls under the line of cases analyzing *both* Fed. R. Evid. 702 and Fed. R. Evid. 704, together.

Rule 704 allows an expert witness to testify about an ultimate question of fact. But our Circuit limits the scope of Rule 704 testimony, holding it permissible "as long as the expert's

testimony assists, rather than supplants, the jury's judgment." *United States v. Dazey*, 403 F.3d 1147, 1172 (10th Cir. 2005). That is, to "ensure testimony is helpful, an expert may not state legal conclusions drawn by applying the law to the facts, but an expert may refer to the law in expressing his or her opinion." *United States v. Richter*, 796 F.3d 1173, 1195 (10th Cir. 2015) (quotation cleaned up). And so, expert testimony crosses the line between helpful and impermissible when it either "'usurps the function of the jury in deciding facts'" or "'interferes with the function of the judge in instructing the jury on the law.'" *Id.* at 1196 (quoting *Dazey*, 403 F.3d at 1171).

To avoid crossing into impermissible territory "an expert may not simply tell the jury what result it should reach without providing any explanation of the criteria on which that opinion is based or any means by which the jury can exercise independent judgment." *Id.* at 1195–96 (quotation cleaned up). Instead, our Circuit permits witnesses "to testify about how the law applies to a certain set of facts, so long as they provide adequate explanations for their conclusions." *Id.* at 1196. And so, "[p]ermissible testimony provides the jury with the tools to evaluate an expert's ultimate conclusion and focuses on questions of fact that are amenable to the scientific, technical, or other specialized knowledge within the expert's field." *Id.* at 1195.

Of course, the "'line between a permissible opinion on an ultimate issue and an impermissible legal conclusion is not always easy to discern.'" *Id.* (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)). Offering some assistance is another regulation-centric case: *Adams v. New England Scaffolding, Inc.*, No. 13-12629-FDS, 2015 WL 9412518 (D. Mass. Dec. 22, 2015). The court finds the analysis in *Adams* both persuasive and instructive. There, the United States Occupational Safety and Health Administration (OSHA) had issued a regulation concerning scaffolds. *Id.* at *1. Plaintiff had fallen from a scaffold, incurring a

workplace injury that instigated his negligence action. *Id.* Defendant moved the court to exclude an expert report opining about the OSHA scaffold regulations. *Id.* at *4. Defendant asserted that the report "constitute[d] improper expert testimony as to a legal issue, which is properly reserved to the Court." *Id.* The report opined at issue, in part:

> A review of OSHA standards indicates several safety standards were not being followed by [defendant]. . . . These unsafe conditions were created by [defendant] and were in violation of OSHA standards. . . . [Defendant] had a duty under OSHA standards and contractually to provide[] a minimum level of safety protection. They failed to do so.

Id. at *2–*3. The court admitted one portion of this expert's opinion—the portion asserting that defendant had violated OSHA regulations. *Id.* at *9. It reasoned that defendant's violating the OSHA regulations wasn't dispositive of the negligence issue but functioned, instead, as evidence of negligence potentially helpful to the jury. *Id.* But the court also limited the expert's opinion to the extent it "effectively [told] the jury how to decide the ultimate legal issue of negligence." *Id.* Here, the court concludes it must split the same hair.

Start with Maida's report. Relator identifies two specific opinions in the report that Relator contends are impermissible legal conclusion:

- "'[T]he discounts [given by Medtronic to HRMC] are each protected by the Statutory Discount Exception.'" Doc. 465 at 7 (quoting Doc. 435-10 at 28 (Maida Expert Report)).
- "'This [transaction] information satisfies Medtronic's obligations as a seller to claim protection under the Discount Safe Harbor.'" *Id.* (quoting Doc. 435-10 at 38 (Maida Expert Report)).

Relator argues these statements in the report, and others of a similar tenor, "are all simply legal conclusions that Medtronic's and HRMC's conduct complied with the requirements of the safe

harbor affirmative defense, and thus, they did not violate the AKS." *Id.* The court agrees—but only to a point.

On one hand, this court concludes that a significant portion of Maida's expert report is admissible. Maida didn't offer his allegedly offending opinions in isolation. If he had, these statements would qualify as "bare legal conclusion"—without accompanying explanation—that our Circuit has found impermissible. *Richter*, 796 F.3d at 1196. But Maida explained, instead, how he reached these opinions. For example, he helpfully explained that the Statutory Discount Exception merely requires that a provider properly disclose and appropriately reflect a discount in its costs claimed but needn't disclose the *value* of the discount in terms of the percentage off the original price. Doc. 435-10 at 26–27. This opinion helps the trier of fact to understand a complex regulatory framework. *See Antrim Pharms. LLC v. Bio-Pharm, Inc.*, 950 F.3d 423, 430–31 (7th Cir. 2020) ("[C]ourts have permitted regulatory experts to testify on complex statutory or regulatory frameworks when that testimony assists the jury in understanding a party's actions within that broader framework.").

On the other hand, Maida also included several conclusory statements—often asserted in a final concluding sentence at the end of an explanatory paragraph. These concluding statements invade the province of the trier of fact. They thus are inadmissible—not because they are "bare"—but because they decide defendants' affirmative defense. The opinions about the safe harbor defense typify this problem.

Defendants contend their discounts fall under AKS's safe harbor provision. When Maida concludes, for example, that the discounts at issue "are each protected by the Statutory Discount Exception[,]" he effectively decided the ultimate affirmative defense issue, thus supplanting—rather than assisting—the trier of fact. Doc. 435-10 at 28 (Maida Expert Report); *Dazey*, 403

F.3d at 1172. In sum, the court will consider those significant portions of Maida's report that assist the trier of fact. But it will disregard as inadmissible Maida's concluding statements that overwhelm the court's exercise of independent judgment. *See Moses v. Halstead*, 477 F. Supp. 2d 1119, 1124 (D. Kan. 2007) ("To the extent that [the expert's] opinions include legal conclusions, the Court . . . is capable of screening factual statements from legal conclusions.").

Relator also argues that the tables Maida formulated—Exhibits B and C—include inappropriate legal conclusion. *See* Doc. 435-10 at 62–70 (Def. Ex. B), 71–73 (Def. Ex. C). The opinion statements in Exhibit B read like this:

- A given purchase order "meets the requirements of the Discount Safe Harbor and Statutory Discount Exception; it fully and accurately reports the discount submitted to the buyer." Doc. 435-10 at 62–70 (Def. Ex. B).

These tables present a heightened risk of "bare legal conclusion" because—when cited in isolation from Maida's report—the table format offers little opportunity to "provide adequate explanations for their conclusions." *Richter*, 796 F.3d at 1196. Indeed, every opinion statement in Exhibit B proffers a legal conclusion because it asserts a given order "meets the requirements of the Discount Safe Harbor and Statutory Discount Exception." Doc. 435-10 at 62–70. Those statements are inadmissible both because they invade the province of the trier of fact—like the concluding sentences in Maida's report, above—and also because they don't offer adequate explanation. The accompanying statement—that "it fully and accurately reports the discount submitted to the buyer"—insufficiently explains how Maida reached his conclusion. *See id.* And so, the court sustains Relator's objection to Maida's opinion in Exhibit B and thus won't consider the "Opinion" column when deciding the summary judgment motions.

Finally, Relator also challenges the admissibility of statements in Exhibit C. Here's a list of the challenged statements from that table:

- "This order contains a single bulk product type and provides a bulk discount." *Id.* at 71 (Def. Ex. C).
- "Bulk discounts are calculated separately for each product. Documentation shows that the balloons included at no additional charge are applied only to the purchase of the balloons." *Id.*
- "Bulk discounts are calculated separately for each product." *Id.*
- "Purchase occurred after Add-On Payment Period ended." *Id.* at 72.
- "DCB were eligible for Add-On Payments." *Id.* at 73

These statements less obviously assert legal conclusions. They don't assert directly that defendants' actions fall under the AKS's safe harbor provisions. And so, the court consults a different test—the "inadequately explored legal criteria" test—to determine their admissibility.

The court begins by explaining the test. Rule 704's advisory committee notes from 1972 clarify that the court should exclude opinions involving "inadequately explored legal criteria." For instance, the advisory committee notes contrast a question about one's "capacity to make a will"—inadequately explored and excludable—with a question about one's "sufficient mental capacity to know the nature and extent of his property and the natural objects of his bounty and to formulate a rational scheme of distribution"—adequately explored and allowed. Fed. R. Evid. 704 advisory committee's note to 1972 proposed rule. Notice that both questions ask for the responsive answer content, and both utilize the word "capacity." But the second question "adds a description that explains how the legal test for capacity relates to the facts. [Thus] a jury will be better able to understand the answer . . . and employ that answer in resolving the factual issues

in the case." Charles A. Wright, Arthur R. Miller, & Victor J. Gold, *Federal Practice & Procedure* § 6284 (2d ed. 2024). At bottom, then, "the admissibility of opinion testimony that may involve legal conclusions ultimately rests upon whether that testimony helps the jury resolve the fact issues in the case." *Id.* And so, the court should exclude testimony "when an expert uses a specialized legal term and usurps the jury's function." *United States v. Schneider*, 704 F.3d 1287, 1294 (10th Cir. 2013).

Here, Maida's vocabulary in Exhibit C is largely pedestrian. Words like "bulk discounts" and "no additional charge" don't qualify as specialized legal terms—any consumer is familiar with this kind of arrangement. Nor do words like balloons or DCBs, though a jury might not know their meaning in this case until it has heard some of the evidence. But "Add-On Payment Period" and "Add-On Payments"—by their capitalization alone—appear to qualify as specialized legal terms. And Maida's report supports that conclusion. *See* Doc. 435-10 at 33 (explaining that Medicare alone provides certain Add-On Payments under specific plans). While Maida's report explores the legal criteria of this term, Exhibit C—when cited in isolation—offers no such explanation. And so, the court determines that the Add-On statements in the Analysis column of Exhibit C are inadmissible as well. The court thus will disregard those statements in its summary judgment ruling.

In sum, the court limits the portions of Maida's expert report and tables it will consider, as set forth above, to avoid inadmissible legal conclusion. The court addresses next the second objection embodied in Relator's motion: the purported inadmissibility of Maida's opinions on behalf of the government under Fed. R. Evid. 403.

B. Admissibility of Maida's opinions under Fed. R. Evid. 403

Relator next argues that some of Maida's opinions are improper because they purport to explain how the government would view Medtronic's conduct pertinent to this matter. Doc. 465 at 9. And, Relator contends, these opinions could mislead or create confusion for the trier of fact and so the court should exclude them under Fed. R. Evid. 403. Rule 403 provides that the court may exclude relevant evidence "if its probative value is substantially outweighed by a danger of . . . confusing the issues [or] misleading the jury[.]" However, our Circuit has instructed district courts to remain mindful that "exclusion of evidence under Rule 403 that is otherwise admissible under the other rules is an extraordinary remedy and should be used sparingly." *United States v. Smalls*, 605 F.3d 765, 787 (10th Cir. 2010) (quotation cleaned up).

Here, Relator contends that Maida speaks as if he knows the government's views. Relator neglects to specify where in the record Maida allegedly speaks on the government's behalf. But he twice directs the court to this purportedly offending sentence: "there is no reason that the government would be concerned about the discounts that Medtronic provided." Doc. 465 at 9–10. The court reviewed Maida's report and discovered that this offending sentence—in one variation or another—appeared in the following contexts:

- "Additionally, there is no reason that the government would be concerned about the discounts that Medtronic provided, including the bundled discounts, because: . . . The government has provided favorable advisory opinions approving arrangements that involve bundled discounts[.]" Doc. 435-10 at 9.
- "Further, based on its favorable guidance regarding non-safe harbored arrangements, including bundled discounts, the government would not likely have concerns about the discounts in Exhibit B because they are unlikely to result in harms to federal healthcare programs or beneficiaries[.]" *Id.* at 24.

- "Furthermore, these bundled discounts are otherwise unlikely to harm federal healthcare programs and beneficiaries and therefore, the government would not be concerned about any of these discounts. Specifically, there are several mitigating facts and circumstances, including: The government has provided favorable advisory approving arrangements[.]" *Id.* at 42–43.
- "The government would not be concerned about the bundled discounts, which are unlikely to result in harms to federal healthcare programs and beneficiaries for a variety of reasons, including that the costs are reported together under a common methodology and the availability of the discount[.]" *Id.* at 44.

Relator doesn't persuade the court that these assertions could suggest that Maida spoke on behalf of the government. In context, all but the last statement couches the government's absence of concern in terms of the government's own guidance and advisory opinions, not Maida's experience. He doesn't identify himself as someone who speaks for the government but, instead, refers to government-produced sources.

To be sure, excerpts from Maida's deposition testimony suggest that he may have viewed his opinion as synonymous with the opinion of HHS. Consider, for example, the following exchange:

> Q. Is your testimony based in any way on the fact that you believe that HHS would basically be rendering the same opinion as you have in your report?
> . . .
> A. I mean, as my -- you know, as somebody who was an attorney there for almost 10 years, I think that that's how people in the agency would -- you know, I think how I approach and think about the situation is similar to how people in the agency would.

Doc. 465-1 at 6 (Maida Dep. 178:20–179:6). But, in fairness, Maida clarifies shortly thereafter that the opinions are his alone: "You know, I can't speak for the agency. I'm speaking for myself

based on my experience and my career, and looking at the guidance, you know. My report is essentially based on the publicly available guidance that OIG has issued over the years." *Id.* (Maida Dep. 180:21–181:2). And so—considering the whole of this exchange—Maida didn't consider his opinions as synonymous with those of HHS. What's more, his role with HHS ended about a decade ago—a timeline clearly communicated in his expert qualifications. So, the trier of fact isn't likely to confuse his opinions with his employer of ten years ago. Nonetheless, out of an abundance of caution, the court offers Relator this reassurance: To the extent the court might confuse Maida with a government spokesperson based on the phrasing of his opinions at summary judgment, it will disregard them under Rule 403.

This holding means that the designated portion of the expert's opinions qualify as facts properly considered at the summary judgment stage.

C. Touhy Regulations

Finally, Relator argues that the court should strike Maida as an expert because Maida failed to secure HHS's authorization to function as an expert under HHS's *Touhy* regulations. Doc. 465 at 11. Relator cites two cases for the proposition that an expert must request and secure this kind of authorization. *Id.* at 13 (first citing *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 246 F.R.D. 322, 324 (D.D.C. 2007) (noting that HHS *Touhy* regulations require agency approval before securing the testimony of a former agency employee and finding HHS had approved the testimony) then citing *In re Scully*, No. Civ. A. 06-0077(GK), 2006 WL 1523231, at *1 (D.D.C. April 11, 2006) (holding motion to compel testimony of a former HHS administrator premature because party seeking to compel had failed to exhaust administrative remedies)). To be sure, these cases suggest that HHS *Touhy* regulations may apply here.

But Relator has cited no authority—nor has the court found any—that the court's proper response to Maida's absence of HHS authorization is striking Maida as an expert. Indeed, the weight of authority—in similar contexts—suggests the opposite conclusion. *See Roy v. County of Los Angeles*, No. CV 12-09012-AB (FFMx), 2018 WL 914773, at *11 (C.D. Cal. Feb. 7, 2018) ("DHS is attempting to use noncompliance with its *Touhy* regulation as a basis for striking the expert witness declarations. This is inappropriate . . . . [B]ecause a *Touhy* regulation does not provide an independent ground of privilege, this Court cannot strike the expert witness declarations on that basis alone[.]"); *Gordon v. United States*, No. C20-0980-JCC, 2021 WL 3472376, at *2 (W.D. Wash. Aug. 6, 2021) (holding that VA's *Touhy* regulation doesn't govern admissibility of expert testimony and so isn't a sufficient basis to exclude expert testimony); *Spears v. United States*, No. 13-CV-47-DAE, 2014 WL 258766, at *4 (W.D. Tex. Jan. 23, 2014) (denying motion to strike plaintiff's expert under Army *Touhy* regulations and collecting cases holding "that a court's power to govern the admissibility of expert witnesses cannot be circumscribed by regulation"). What's more, Relator never explains how he has standing to act on HHS's behalf and enforce its regulations. And so, even if HHS's *Touhy* regulations apply to this case, it doesn't follow that the court should strike Maida as an expert or should enforce—at Relator's behest—HHS's regulations. The court overrules this objection.

With the scope of Maida's admissible opinions thus defined, the court attends next to the parties' cross partial summary judgment motions. The court begins by reciting the legal standard for partial summary judgment motions, specifically partial motions premised on an affirmative defense.

III. Partial Summary Judgment Legal Standard

Fed. R. Civ. P. 56(a) explicitly contemplates partial summary judgment motions and permits a movant to train such motions on an affirmative defense: "A party may move for

summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought." Fed. R. Civ. P. 56(a). The same rule clarifies the standard a court employs in evaluating such motions: "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Id.* A plaintiff may move for summary judgment "to test a defense's sufficiency." 10B Charles A. Wright, Arthur R. Miller, & Adam N. Steinman, *Federal Practice & Procedure* § 2734 (4th ed. 2024). Likewise, a "defendant may use a motion for summary judgment to test an affirmative defense which entitles that party to a judgment as a matter of law." *Hutchinson v. Pfeil*, 105 F.3d 562, 564 (10th Cir. 1997). For a defendant to succeed on such a motion, he "must demonstrate that no disputed material fact exists regarding the affirmative defense asserted." *Id.* (citation omitted). To defeat the motion, a plaintiff thus "need only identify a disputed material fact relative to the affirmative defense." *Hamric v. Wilderness Expeditions, Inc.*, 6 F.4th 1108, 1122 (10th Cir. 2021) (quotation cleaned up).

"An issue of fact is 'genuine' 'if the evidence is such that a reasonable jury could return a verdict for the non-moving party' on the issue." *Nahno-Lopez v. Houser*, 625 F.3d 1279, 1283 (10th Cir. 2010) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "An issue of fact is 'material' 'if under the substantive law it is essential to the proper disposition of the claim' or defense." *Id.* (quoting *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 670 (10th Cir. 1998)). Those "facts must be identified by reference to affidavits, deposition transcripts, or specific exhibits incorporated therein." *Adler*, 144 F.3d at 671. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248. The court views the evidence and draws inferences in the light most favorable to the non-moving party. *Nahno-Lopez*, 625 F.3d at 1283.

When deciding whether the parties have shouldered their summary judgment burdens, "the judge's function is not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249.

The federal courts don't view summary judgment as a "disfavored procedural shortcut." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). To the contrary, it's an important procedure "designed 'to secure the just, speedy[,] and inexpensive determination of every action.'" *Id.* (quoting Fed. R. Civ. P. 1).

While a court can treat cross motions for summary judgment separately, and "the denial of one does not require the grant of another[,]" *Buell Cabinet Co., Inc. v. Sudduth*, 608 F.2d 431, 433 (10th Cir. 1979), it properly may address the legal arguments together, *Berges v. Standard Ins.*, 704 F. Supp. 2d 1149, 1155 (D. Kan. 2010). Here, the three motions, and their legal arguments, overlap substantially. Indeed, the parties' papers invoke and incorporate briefing filed to respond or reply to another one of the motions.[5] The court thus exercises its discretion and addresses together the legal arguments made by the three dueling motions.

IV. The Safe Harbor Affirmative Defense

Relator moves the court to grant partial summary judgment against defendants' safe harbor affirmative defense. Doc. 397 at 2. Medtronic and HRMC have asserted the safe harbor

[5] All three parties to these cross summary judgment motions identify the interrelated nature of their motions by referencing and incorporating briefing. For instance, HRMC "incorporate[d] by reference Medtronic's statement of undisputed facts in its Motion for Partial Summary Judgment[.]" Doc. 435 at 11. Similarly, Medtronic repeatedly cited Relator's Response to HRMC's Partial Summary Judgment Motion in its Reply in support of its own motion. Doc. 464 at 19, 21, 22. And Relator—in his response/reply to HRMC's cross motion—refers the court "to the response/reply to Medtronic's brief for additional analysis" on more than one occasion. Doc. 450 at 29, 32 n.6. All parties thus have acknowledged the interrelatedness of their motions, which explains the court's decision to address the arguments together.

defense to excuse Medtronic providing no charge medical devices to HRMC in conjunction with bulk medical device purchases. Doc. 379 at 25; Doc. 384 at 24. Defendants bear the burden of establishing this affirmative defense. *See In re EpiPen Direct Purchaser Litig.*, No. 20-CV-0827 (ECT/TNL), 2021 WL 147166, at *15 (D. Minn. Jan. 15, 2021) ("Courts generally treat the AKS's safe-harbor provisions as affirmative defenses. . . . Defendants have the burden to plead and prove affirmative defenses[.]").

Relator asks the court to conclude on summary judgment that the safe harbor defense isn't available to defendants. He contends that defendants' "testimonial admissions and documentation" preclude any possibility that defendants could prevail under "the AKS's 'safe harbor' affirmative defense." Doc. 398 at 58–59. Medtronic and HRMC, in their cross partial summary judgment motions, ask the court to conclude (again, at the summary judgment stage) just the opposite: that defendants' "conduct falls within the applicable statutory and regulatory 'safe harbor' to the Federal Anti-Kickback Statute." Doc. 429 at 1; Doc. 434 at 1 ("Based on the arguments and evidence submitted with this Motion, [HRMC] is entitled to judgment as a matter of law on Relator's [claims] because the medical device purchases are protected by exceptions and safe harbors to the Anti-Kickback Statute."). Summary judgment is an "'appropriate procedural device'" to address the relevant safe-harbor provisions. *In re EpiPen*, 2021 WL 147166, at *15 (quoting 5B Arthur R. Miller, Mary K. Kane, & A. Benjamin Spencer, *Federal Practice and Procedure* § 1357 (3d ed. Oct. 2020 Update)); *see also, e.g.*, *United States v. Aids Healthcare Found., Inc.*, 262 F. Supp. 3d 1353, 1362 (S.D. Fla. 2017) (granting summary judgment to defendants because bonus payments met both elements required by AKS's employee safe harbor provision), *aff'd sub nom. Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267 (11th Cir. 2018).

The court addresses these overlapping cross summary judgment motions, first, by outlining the statutory and regulatory scheme under which the safe harbor affirmative defense arises. Then, the court explains the specific regulatory requirements for a given transaction to qualify for the safe harbor provisions. Next, the court evaluates the at-issue transactions in light of those specific requirements. This analysis begins with the regulatory definition of a discount and then addresses the requisite standards for a seller and a buyer to qualify under the safe harbor. Because the court concludes that the safe harbor regulations protect Medtronic, the court addresses the statutory discount exception solely as it applies HRMC. In the end, the court grants Medtronic and HRMC's partial summary judgment motions and denies Relator's partial summary judgment motion.

A. Statutory and Regulatory Scheme

The pertinent statutory and regulatory scheme involves three tiers. The top tier is the FCA. The middle tier is the AKS. And the bottom tier includes both the statutory exception and the safe harbor regulations. The court explains each tier, beginning at the top.

Relator alleges defendants violated the FCA. The FCA imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim [to the government] for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The FCA also contains a *qui tam* provision that allows a private party—a relator—"'to bring an FCA action on behalf of the Government.'" *U.S. ex rel. Louderback v. Sunovion Pharms., Inc.*, 703 F. Supp. 3d 961, 969 (D. Minn. 2023) (quoting *State Farm Fire & Cas. Co. v. U.S. ex rel. Rigsby*, 580 U.S. 26, 29 (2016)). This *qui tam* provision "'encourage[s] insiders to disclose fraud and thereby bolster[s] enforcement" of the FCA. *U.S. ex rel. Everest Principals, LLC v. Abbott Lab'ys, Inc.*, 622 F. Supp. 3d 920, 930 (S.D. Cal. 2022) (quoting *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 995 (9th Cir. 2010)).

Relator here premises his FCA claims on defendants violating the AKS. *See* 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the [FCA]."); *see also U.S. ex. rel. Gaskill v. Nw. Cmty. Action Program of Wyo., Inc*., No. 16-CV-00201-ABJ, 2019 WL 13226259, at *2 (D. Wyo. July 3, 2019) ("[I]f [defendant] violated the AKS and a Medicaid claim resulted from [defendant's] violation, then [defendant] is deemed to have also violated the FCA."). That is, the "AKS and FCA work in conjunction to create a private right of action for violation of the federal criminal anti-kickback statute." *U.S. ex rel. Hart v. McKesson Corp.*, 602 F. Supp. 3d 575, 584 (S.D.N.Y. 2022). And Relator here invokes that private right of action. Under this approach, to prove defendants violated the FCA, Relator first must prove that defendants violated the AKS. *See U.S. ex rel. Brown v. Celgene Corp.*, No. CV-10-3165-GHK (SSX), 2014 WL 3605896, at *8 (C.D. Cal. July 10, 2014) ("Because the government would not knowingly reimburse kickback-tainted claims, any claims resulting from [defendants'] alleged kickbacks constitute false claims.").

Congress intended for the AKS to "to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96 (3d Cir. 2018) (quotation cleaned up). To accomplish this end, the AKS sweepingly prohibits illegal remuneration when "payment may be made in whole or in part under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(1)–(2). Courts and the HHS Office of the Inspector General (HHS OIG) have interpreted remuneration under the AKS broadly, including "virtually anything of value including goods, meals, and gifts" or, put another way, "anything of value in any form whatsoever." *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015)

(quotation cleaned up) (collecting cases and HHS OIG authority "affirm[ing] this expansive understanding of remuneration"). But—or, more precisely, because of this broad definition—Congress has implemented an exception to the AKS under 42 U.S.C. § 1320a-7b(b)(3)(A).

This statutory exception to the AKS provides that discounts and price reductions—if properly disclosed and appropriately reflected—don't constitute illegal renumeration. *Id.* That is, the penalties the AKS outlines for illegal renumeration don't apply to:

> a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is ***properly disclosed*** and ***appropriately reflected*** in the ***costs claimed or charges made*** by the provider or entity under a Federal health care program[.]

Id. (emphasis added). In 1987, Congress amended the statute by excluding from illegal remuneration "any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w–104(e)(6) [1] of this title[.]" 42 U.S.C. § 1320a-7b(b)(3)(E). These regulations are commonly referred to as "safe harbors." *United States v. Shaw*, 106 F. Supp. 2d 103, 112 (D. Mass. 2000). The safe harbor provisions protect specified pricing arrangements which may reduce costs to Federal health care programs, a desired result. *See, e.g.*, OIG Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999) (to be codified at 42 C.F.R. § 1001.952) ("[W]e are persuaded that in certain circumstances, discounts . . . may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale.").

The court's analysis thus narrows to these two questions: *First*, do the transactions between Medtronic and HRMC qualify for regulatory safe harbor protection as a matter of law?

And, *second*, if they don't, do these transactions qualify for protection under the statutory discount exception? The court analyzes the regulatory safe harbor issue first.

B. Regulatory Safe Harbor Provisions

The regulatory safe harbor provisions clarify that illegal remuneration doesn't include discounts, provided that certain specifications are met. 42 C.F.R. § 1001.952(h) (2023). Section 1001.952(h)(5) identifies what the term discount includes and, just as importantly, what it doesn't. The regulations also identify standards that apply to a seller—here Medtronic—and those that apply to a buyer—here HRMC. *Id.* Applying these regulations to the summary judgment facts, the court first evaluates whether a reasonable trier of fact could find that the transactions at issue qualify as discounts. Concluding a reasonable jury only could find that the transactions at issue qualify as discounts, the court then asks whether a reasonable jury only could conclude on the summary judgment facts that Medtronic necessarily satisfies the seller applicable standards and HRMC necessarily satisfies the buyer applicable standards. To begin, the court recites, in brief, the regulations at issue, emphasizing in bold the regulatory terms on which these summary judgment motions turn.

First, the Code of Federal Regulations clarifies when the term discount applies and when it doesn't. Here's how the relevant portion of the regulation defines the term:

> For purposes of this paragraph, the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term ***discount does not include***—
> . . .
> (ii) Supplying one good or service ***without charge*** or at a reduced charge to induce the purchase of ***a different good*** or service, unless the goods and services are reimbursed by the same Federal health care program using ***the same methodology*** and the reduced charge is ***fully disclosed*** to the Federal health care program and ***accurately reflected*** where appropriate, and as appropriate, to the reimbursement methodology;

> (iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;[6]
> . . .

Id. § 1001.952(h)(5) (emphasis added). The court added emphasis to the terms "same methodology," "fully disclosed," and "accurately reflected" because the parties here explicitly dispute whether HRMC satisfied these requirements in reporting the no-charge goods. The court also added emphasis to the words "different good" and "without charge" because, though the parties don't argue about these terms[7] in the definition of discount, they resurface later in the standards applied to the buyer analysis.

Second, the regulations outline the standards for a seller. Medtronic—as the seller—must comply with these regulatory standards for the safe harbor to apply and thus exclude a discount from the remuneration category. The standards applicable to Medtronic read like this:

> If the buyer is an entity that reports its costs on a cost report required by the Department [HHS] or a State agency, the seller must comply with either of the following two standards—
> (A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, ***the seller must fully and accurately report such discount on the invoice***, coupon or statement submitted to the buyer;

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[6] Relator argues that subsection (iii) also applies to the factual scenario here, Doc. 398 at 63–64, explaining that "[t]he 'one payer' here is HRMC[,]" Doc. 445 at 51. But, as defendants rightly point out, HRMC is a buyer or provider under this regulatory scheme, not a payer. Doc. 463 at 26; Doc. 464 at 18; *see also United States v. UnitedHealth Grp. Inc.*, 630 F. Supp. 3d 118, 123 (D.D.C. 2022) ("At a high level, payments for services in the American healthcare system proceed through a simple process: Health insurers, also known as 'payers,' pay medical claims submitted by caregivers, also known as 'providers.'"); *Id.* at 123 n.1 ("Providers include physicians, hospitals, clinics, and other caregivers."). Relator never contends that a separate payer—that is, another insurer—received through the transactions at issue a price reduction that a Federal health care program didn't receive. And so, the court doesn't address subsection (iii) further.

[7] The parties don't dispute whether Medtronic supplied "a different good," when it supplied "without charge" devices to HRMC. Medtronic directly acknowledges the different goods. Doc. 430 at 46. And while HRMC doesn't address it directly, it implicitly concedes that the bundled deals included different goods. *See* Doc. 435 at 32 ("[T]he discounts were either earned based on the purchase of the same good (Bulk Deals) or as part of bundled deals including devices reimbursed under the same methodology (the Bundle Deals)."). Nonetheless, the court highlights these terms because the issue of the no-charge devices constituting different goods is relevant to HRMC's arguments about the buyer applicable standards.

> ***inform the buyer*** in a manner that is ***reasonably calculated to give notice to the buyer of its obligations to report*** such discount and to provide information upon request under paragraph (h)(1) of this section;[8] and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph;[9] or
> . . .

Id. § 1001.952(h)(2)(ii) (emphasis added). The emphasized words again highlight the parties' arguments: Did Medtronic "fully and accurately" report the discounts on the invoices to HRMC? And did Medtronic "inform" HRMC of its obligation to report the discounts in a manner "reasonably calculated to give notice"?

Finally, to exclude a discount from qualifying as illegal remuneration, HRMC must comply with the standards applicable to a buyer. The regulation identifies three different standards for three different types of buyers—health maintenance organizations and competitive medical plans, cost-reporting entities, and individuals or entities in whose name claims were submitted. *Id.* § 1001.952(h)(1). HRMC is a cost-reporting entity who submits a cost report to its Medicare Administrative Contractor every year. Doc. 435-12 at 20 (Russo Expert Report). The regulation explains the standards that apply to a cost-reporting entity:

> If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

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[8] Relator argues that Medtronic would've come up short if it were required to provide the requested information. Doc. 445 at 56. Medtronic would provide to the Secretary the same documentation it provided in discovery which, Relator argues, would miss the mark. *Id.* But this argument simply repeats Relator's no full and accurate reporting argument that the court addresses separately. What's more, the regulation merely requires the seller to provide such information "on request." 42 C.F.R. § 1001.952(h)(2)(ii)(A). And Relator concedes that no one has made that request. Doc. 445 at 56. So, the court declines to address this repetitive and speculative argument.

[9] Relator never argues that Medtronic impeded HRMC from reporting the discount. *See generally* Doc. 398; Doc. 445. And Medtronic affirmatively asserts it didn't impede HRMC. Doc. 464 at 23. What's more, Medtronic argues that HRMC accurately reported the actual prices of the bundled transactions, fulfilling its disclosure obligations and thus demonstrating that it didn't impede HRMC from said disclosure. *See id.* And so, the court doesn't address this portion of the seller standard in its safe harbor analysis.

> (A) The discount must be earned based on purchases of that ***same good*** or service bought within a single fiscal year of the buyer;
> (B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year; [10]
> (C) The buyer must ***fully and accurately report*** the discount in the applicable cost report; and
> (D) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

42 C.F.R. § 1001.952(h)(1)(ii) (emphasis added). As indicated by the emphasized language, these motions argue about whether HRMC satisfies the buyer standard, particularly under the regulatory requirements to purchase the "same good" and to report "fully and accurately" the discount.

In sum, the court resolves these partial summary judgment motions by applying the regulatory terms "discount," "different good," "fully disclosed," "accurately reflected," "fully and accurately report," "inform the buyer," and "same good," 42 C.F.R. § 1001.952(h)(1)–(5), and the statutory terms "properly disclosed," "appropriately reflected," and "costs claimed or charges made," to the undisputed facts, 42 U.S.C. § 1320a-7b(b)(3)(A). The court's task requires it to interpret documents[11] utilized in the at-issue transactions between Medtronic and

[10] Relator also argues that HRMC hasn't met part B of the buyer applicable standards. But Relator doesn't take issue with the year of the discount—the emphasis of this subsection. Instead, Relator argues that HRMC never reported the discount at all (and hence didn't report it in the proper fiscal year). Doc. 398 at 66. The court concludes this part B argument overlaps sufficiently with Relator's part C argument—that HRMC didn't report the discount fully and accurately—that the court doesn't address part B here.

[11] Some of the documents Relator presents to the court for consideration aren't material to a safe harbor defense analysis. *See, e.g.*, Doc. 398 at 26 (presenting Medtronic's master sales data excel sheet and Medtronic's delivery note). For example, Medtronic produced master sales data Excel sheets for sales to HRMC. But these were internal documents, not documents exchanged between the buyer and the seller. Doc. 430-9 at 90 (Huyser Decl. Ex. 8, Maida Dep. 234:7–24). Relator concedes as much. *See* Doc. 398 at 68 ("Medtronic's Excel data for all sales to HRMC are not 'documents' *per se* provided to HRMC[.]"). And so, under the regulatory framework described above, such internal documents aren't material to whether Medtronic and HRMC fulfilled the safe harbor requirements. Similarly, delivery

HRMC. The court thus evaluates these documents—and HRMC's cost-reporting pursuant to these documents—to answer the motions' dispositive question: As a matter of law, could a reasonable jury only conclude that defendants satisfied the regulatory safe harbor provisions for the medical device transactions at issue? Or, instead, could a reasonable jury conclude that defendants failed to satisfy that safe harbor provision? Here's how the parties see these questions.

1. Parties' Arguments about the Safe Harbor Regulations

Relator argues defendants fail to establish, at least at summary judgment, that the safe harbor provisions must apply. He contends that the no-charge goods Medtronic provided to HRMC were different, not the same. And so, he argues, those no-charge goods qualify as a discount if reimbursed with the same methodology, fully disclosed, and accurately reflected under 42 C.F.R. § 1001.952(h)(5)(ii). Doc. 398 at 62–64. And, Relator contends, they weren't, so the no-charge devices didn't qualify as discounts. *Id.* And even if they were discounts, Relator alternatively argues, the safe harbor affirmative defense still fails under the regulations because Medtronic didn't meet its seller applicable standards and HRMC didn't meet its buyer applicable standards under 42 C.F.R § 1001.952(h)(1) and (2), respectively. *Id.* at 64–70.

Not so, defendants say. HRMC asserts that the no-charge devices qualify as discounts because the Federal health care program reimbursed the no-charge devices and the paid-for devices under the same methodology. Doc. 435 at 29. And HRMC contends that it disclosed those discounts by reporting its actual device costs in the Cost Report it submitted to its Medicare Administrative Contractor. *Id.* at 25. What's more, HRMC argues, that reporting fulfills their disclosure requirement, HRMC argues, because there is no method to report or

notes that accompanied shipment of the medical devices functioned as packing slips, not documentation relevant to the safe harbor analysis. Doc. 398-5 at 13 (Atkins-Ray Dep. 37:7–11).

itemize the cost of individual medical devices. *Id.* Finally, HRMC asserts, it satisfies all the requisite standards applicable to a buyer. *Id.* at 31–33.

Medtronic, for its part, concedes that the bundled transactions involved different goods but argues that the no-charge goods still qualify as discounts because the goods are reimbursed with the same methodology. Doc. 430 at 48–49. Medtronic then asserts that it satisfied the standards applied to the seller. It contends that it properly disclosed the transactions to HRMC and provided HRMC with sufficient information—the identity of the devices purchased, the total price paid, and the value of the discounts—so that HRMC could report its costs accurately. *Id.* at 43–44. And, finally, Medtronic asserts that it informed HRMC of the obligation to report these discounts.

The court evaluates the parties' arguments in this sequence: First, the court addresses whether the no-charge goods at issue qualify as discounts under 42 C.F.R. § 1001.952(h)(5)(ii). Then the court evaluates whether Medtronic, as the seller, and HRMC, as the buyer, met the requisite buyer and seller standards so that a reasonable jury only could conclude that they satisfied the respective safe harbor provisions. But the court's analysis must follow a few preliminary clarifications.

The court offers a prefatory note on the buyer and seller standards: HHS OIG's 1999 preamble to its final rule about the safe harbor provisions clarified that the safe harbor protects a buyer and seller independently. 64 Fed. Reg. 63518, 63527 ("[I]f the seller, in good faith, meets its obligations under the safe harbor and the buyer does not meet its obligations due to no fault of the seller, the seller would receive safe harbor protection."). This independent treatment informs the court's approach here: the court will evaluate whether Medtronic satisfied the standards applied to sellers independently of whether HRMC satisfied the standards applied to buyers.

Also, the court conducts its analysis keeping in mind that—in general—the HHS OIG looks on discounts in this context with favor. *Id.* at 63,526 ("As a general rule, discounts for health care items and services are encouraged under the Federal health care programs so long as the Federal health care programs share in the discount where appropriate, and as appropriate, to the reimbursement methodology.").

2. Legal Standard for Interpreting Regulations

The parties' arguments require the court to interpret certain regulations. And so, the court recites the legal standard that governs this task and thus controls the rest of this Order. When interpreting a regulation, our Circuit applies the same rules it uses to interpret statutes. *Canyon Fuel Co. v. Sec'y of Lab.*, 894 F.3d 1279, 1287 (10th Cir. 2018) (quotation cleaned up). That is, a court should "examine the plain language of the regulation and give each word its ordinary and customary meaning." *Id.* (citation omitted). And courts "often begin an ordinary meaning analysis by consulting contemporary dictionary definitions." *Nat'l Credit Union Admin. Bd. v. Nomura Home Equity Loan, Inc.*, 764 F.3d 1199, 1227 (10th Cir. 2014). "If, after engaging in this textual analysis, the meaning of the regulations is clear, our analysis is at an end, and we must enforce the regulations in accordance with their plain meaning." *Mitchell v. Comm'r*, 775 F.3d 1243, 1249 (10th Cir. 2015). But "[w]hen an agency reasonably interprets a genuinely ambiguous regulation that it has promulgated, federal courts generally defer to that interpretation." *Suncor Energy (U.S.A.), Inc. v. U.S. Env't Prot. Agency*, 50 F.4th 1339, 1353 (10th Cir. 2022) (quoting *Kisor v. Wilkie*, 588 U.S. 558, 563).[12] When deciding whether

[12] In the rest of this Order, the court frequently cites comment responses and preamble statements provided by the HHS OIG. The court acknowledges that these responses and statements aren't binding. *See Jones-McNamara*, 630 F. App'x at 400 (explaining that the HHS OIG's guidance about the meaning of renumeration is "not binding"). And it understands that recent Supreme Court jurisprudence counsels against deference to agency interpretations, though that ruling occurred in a different context altogether—that of *Chevron* deference when deciding whether an agency had acted within its statutory authority.

regulatory language is ambiguous, courts "look to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *In re Taylor*, 899 F.3d 1126, 1129 (10th Cir. 2018) (quotation cleaned up). Ambiguity inheres when a regulation "is capable of being understood by reasonably well-informed persons in two or more different senses." *Id.* (quotation cleaned up).

3. Discounts as Defined by the Regulatory Safe Harbor

a. Different Goods and Bundled Transactions

The bundled transactions at issue here involved different goods. For example, in one bundled transaction, Medtronic supplied five Hawk Ones (and additional drug coated balloons) to induce HRMC's purchase of 50 drug-coated balloons. Doc. 432-16 at 2 (Medtronic Ex. D-3). Recall that the Hawk One is an atherectomy device allowing physicians to excise plaque from the peripheral vascular system to restore blocked flow. *Directional Atherectomy Systems*, Medtronic, https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/directional-atherectomy-systems.html (last visited Sept. 14, 2024). The drug-coated balloons, however, function to transfer a drug to the artery walls to prevent an opened artery from becoming narrow again (re-stenosis). Doc. 430-3 at 37–38, 39–40 (Huyser Decl. Ex. 2, Oster Dep. 89:20–90:9; 91:20–92:8). All that's to say, the two are different devices.

Also recall that a "discount" doesn't include supplying one no-charge good to induce the purchase of a different good under the regulatory safe harbor. 42 C.F.R. § 1001.952(h)(5)(ii).

Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244, 2273 (2024) ("But courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous."). The court understands *Auer* deference—when agencies interpret their own regulations—to survive *Loper Bright*. *See Friends of the Floridas v. Bureau of Land Mgmt*., No. CIV-20-0924 JB/GBW, 2024 WL 3952037, at *60 (D.N.M. Aug. 27, 2024) (explaining post-*Loper Bright* that "courts accord agencies what is known as *Auer* deference" "despite the demise of *Chevron*").

But the pertinent regulations also include a caveat: a discount doesn't include this arrangement *unless* four requirements are met, two applying to reimbursement and two applying to disclosure. *Id.* The first two require that the same Federal health care program must reimburse the goods involved and must use the same reimbursement methodology to do so. *Id.* The last two require that the buyer fully disclose the reduced charge to the health care program and accurately reflect it where appropriate to the reimbursement methodology. *Id.* The court starts with the same reimbursement methodology requirements, below.

b. "Same Methodology" Requirements

The regulation's "same methodology" requirements don't lend themselves to plain language interpretation. While one may define easily enough the words "same" and "methodology," combining those words doesn't provide a clear understanding of what the regulation requires. The specific context of the regulation means that the court must ascertain the methodologies by which an entity seeks reimbursement from a Federal health care program. And so, the court consults the HHS OIG's interpretation for aid.

The HHS OIG's 1999 preamble to the final rule amending the safe harbor regulatory provisions proves helpful. There, the HHS OIG addressed a scenario that illuminates when the safe harbor protects a bundled arrangement—that is, an arrangement where the seller provides one good at no charge (or a reduced charge) to induce the purchase of a different good. Commenters—concerned that the AKS prohibited bundled purchases—argued their case with this example: "[S]afe harbor protection should be available for a discount to a hospital for sterile gauze pads in exchange for the purchase of surgical tape, both of which are included in the hospital's [Diagnostic Related Group] payment and recorded on the hospital's cost report as routine costs not separately reimbursable." 64 Fed. Reg. 63518, 63530. The HHS OIG agreed. Its preamble explained that "where the goods and services are reimbursed by the same Federal

health care program in the same manner" these discounts "may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale." *Id.* And the HHS OIG also clarified the type of bundled arrangements that caused it concern: when bundled arrangements induce purchases of products for which the Federal health care programs pay full price, then the programs don't benefit from the discount. Put another way, discounts shifting costs among different reimbursement systems are problematic. *Id.* The HHS OIG provides an example of problematic cost shifting: "For example, the safe harbor was not intended to protect a discount on hospital supplies covered by a Diagnostic Related Group (DRG) payment in exchange for the purchase at the full price of capital equipment separately reimbursed by Medicare on a reasonable cost basis in accordance with a hospital's cost report." *Id.* In short, vendors properly can't combine hospital supplies and capital equipment to form an acceptable bundled discount because they are reimbursed separately. On the other hand, a bundled transaction of sterile gauze pads and surgical tape is just fine—better than fine, actually, because it stands to lower costs that may benefit the Federal health care programs. It thus qualifies as a discount—meriting safe harbor protection—even though surgical tape and gauze pads are different goods.

Here, then, the question is whether the no-charge atherectomy devices HRMC received with its DCB bulk purchase resemble the impermissible combination of hospital supplies and capital equipment or, instead, resemble the permissible combination of gauze and tape. Recall the hospital supplies and capital equipment were different goods reimbursed differently, under different methodologies. Whereas the gauze and tape were different goods reimbursed under the same methodology. On the undisputed facts governing HRMC's motion, no reasonable jury

could find that the atherectomy and DCBs resembled the impermissibly combined hospital supplies and capital equipment.

HRMC's expert explained that Medicare reimbursed all the at-issue devices under the same methodology. Highly simplified, here's how: In most cases, Medicare reimburses a fixed fee for patients who stay in the hospital—determined prospectively according to a patient's given Diagnostic Related Group—to capture the average resource use of the inpatient stay. Doc. 435-12 at 22 (Russo Expert Report). This fixed fee reimbursement doesn't change with any "individual line-item charges billed, including those for medical devices." *Id.* at 21 (Russo Expert Report). And for outpatients, Medicare reimburses using a "packaging" approach—a pre-determined fixed fee for a patient's primary Ambulatory Payment Classification (APC) wipes out most separate payments otherwise required for medical devices. *Id.* at 12 (Russo Expert Report). HRMC's expert reviewed the outpatient transactions at issue and reached this conclusion: "[W]hen PAD devices were billed by Hutchinson [HRMC] to the Medicare program with any of these codes during the time period at issue, payment for them was packaged into the APC payment made for the procedure(s) in which they were used, and they were not separately reimbursed." *Id.* at 28 (Russo Expert Report). In other words, the Federal health care program reimbursed these devices according to a fixed fee methodology.[13]

[13] HRMC's expert also identified two situations when a fixed-fee reimbursement methodology doesn't apply: with outlier patients and with a New Technology Add-On Payment (NTAP). Doc. 435-12 at 22–25 (Russo Expert Report). But, he also explained that the use of the no-charge devices still wouldn't have affected the Medicare payment HRMC received. Here's why, again highly simplified: Medicare uses the hospital's cost-to-charge ratio (CCR) to determine both the outlier payment and the NTAP reimbursement. *Id.* at 24–25 (Russo Expert Report). And Medicare calculates that CCR using specified lines from HRMC's Cost Report. *Id.* at 24 (Russo Expert Report). None of those specified lines included costs attributable to the devices. *Id.* (Russo Expert Report) (explaining that "charges and costs attributable to devices billed with revenue code 272 were reported *only* on line 71 of the Cost Report" (emphasis in original) and Medicare just used lines 30–46, not line 71, to calculate the CCR).

In response to the HRMC expert's analysis, Relator "agrees these types of deals are permitted *where they are properly documented*." Doc. 450 at 35 (emphasis in original). And in his response to Medtronic's motion, Relator doesn't address the reimbursement methodology requirement at all. *See* Doc. 445 at 50–51. That is, Relator's silence concedes that the no-charge devices satisfy the same-reimbursement requirements. And Relator focuses, instead, on the disclosure requirements. So, this evidence about the fixed fee reimbursement method—unchallenged by any conflicting evidence—precludes a reasonable jury from finding that the devices at issue were like the hospital supplies and the capital equipment—that is to say, separately reimbursable. Instead, in light of this unchallenged expert testimony, a reasonable jury only could find that the devices at issue were like the gauze and tape—not separately reimbursable and thus not problematic. The court thus moves on to these disclosure requirements, next.

c. Fully Disclosed and Accurately Reflected

It's been a while. And so, the court reiterates the relevant regulatory language specifying how a bundled arrangement can qualify as a discount, even when it involves different goods. In addition to the same methodology requirements discussed in the previous section, the regulation also imposes two disclosure requirements: a bundled transaction qualifies as a discount when "the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology[.]" 42 C.F.R. § 1001.952(h)(5)(ii). And so, the no-charge devices at issue here fall into the "discount" definition only if "fully disclosed" and "accurately reflected."

Keep in mind that a court often conducts an "ordinary meaning analysis by consulting contemporary dictionary definitions." *Nat'l Credit Union*, 764 F.3d at 1227. The HHS OIG amended the pertinent regulatory requirements in November 1999. *See* 64 Fed. Reg. 63518,

63527 (adopting clarifications to the discount safe harbor). So, the court looks to a 1999 contemporary dictionary for aid in interpreting the two adjective phrases—"fully disclosed" and "accurately reflected." The 1999 Black's Law Dictionary defines "full disclosure" as a "complete revelation of all material facts." *Full Disclosure*, Black's Law Dictionary (7th ed. 1999). This definition serves only to beg the question: What facts are material in this regulatory safe harbor context? The HHS OIG has answered that question like this:

> [F]or purposes of submitting a claim or request for payment . . . what is necessary is that the value of the discount be accurately reflected *in the actual purchase price*. It is *not necessary to distinguish* whether this price is the result of a discount or to state "net discount." Consequently, parties who were uncertain *about how or where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact*, as long as the actual purchase price accurately reflects the discount.

64 Fed. Reg. 63518, 63527 (emphasis added). The HHS OIG thus clarifies that accurately reporting the actual purchase price—even apart from any designation that such purchase price was due to a discount—suffices for a party to reflect the value of the discount accurately.

Here, Relator contends that HRMC didn't reflect accurately these bundled discounts because HRMC didn't identify anywhere in its reporting to the Federal health care program that it received no-charge devices. He cites how the HRMC purchasing department neglected to enter the no-charge devices when it created purchase orders for these transactions. Doc. 398-5 at 12–13 (Atkins-Ray Dep. 35:25–37:6) (agreeing that the no-charge devices weren't included on the invoice, purchase order, or delivery note). And Relator's expert walks through how this failure to reduce each unit price to account for the no-charge devices resulted in inflated unit prices later charged to Medicare. She explains:

> When [HRMC's buyer] failed to reduce the unit price to include the free devices, the system captured a cost for each unit that was too high and did not include the discount associated with the free devices. . . . When the claims for the free devices were submitted to the government for payment *with inflated charges*, the

> government assumed these devices had a cost and added an additional payment based upon the pass-through methodology to defray HRMC's costs for the device.

Doc. 451 at 80 (Schmor Rebuttal Report) (emphasis in original).

Relator's argument has some logical appeal. But here's the problem. Relator never cites any authority hinting even that Medicare requires reporting these sorts of unit-based price reductions to qualify for fully disclosing and accurately reflecting a discount. And the court has found none. The sole authority Relator invokes are two HHS OIG Advisory Opinions. *See* Doc. 450 at 31, 36–37. And neither of those opinions says what Relator wants it to say. But first, before supporting that conclusion, the court considers the appropriate weight of advisory opinions.

"Congress created a process by which parties may seek advisory opinions from HHS OIG as to whether a proposed course of action would violate the AKS." *Pfizer, Inc v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 72 (2d Cir. 2022). But advisory opinions are, by their own terms, not authoritative. *See* HHS OIG Advisory Op. No. 99-03 (Dep't of Health & Human Servs. March 23, 1999) ("This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope."); *see also Mills v. Natchitoches Nursing & Rehab. Ctr., LLC*, No. 21-CV-00336, 2021 WL 6129102, at *3 (W.D. La. Apr. 30, 2021) ("The advisory opinions do not create binding legal norms, are not meant to bind the public in any way, do not have the force and effect of law, and are not final agency action." (quotation cleaned up)). And so, the court treads lightly when reviewing them, understanding that the HHS OIG never intended them to bear much weight, particularly not authoritative weight. Instead, "interpretations contained in formats such as opinion letters are entitled to respect . . . but only to the extent that those

interpretations have the power to persuade." *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (quotation cleaned up).

The first advisory opinion Relator invokes addresses an arrangement between a distributor of therapeutic mattresses and Medicare-certified skilled nursing facilities (SNFs). HHS OIG Advisory Op. No. 99-03 (Dep't of Health & Human Servs. March 23, 1999). The mattress distributor sought to bundle powered and non-powered support surface mattresses, thus providing them at a discount to SNFs. *Id.* And the distributor described its plan to document the discounted price: it would "apportion the discount between the two products in proportion to their fair market value." *Id.* The HHS OIG concluded that it wouldn't subject the distributor to sanctions under the anti-kickback statute. *Id.* In reaching its conclusion, the HHS OIG took into account—among other considerations—the discount apportioning approach, explaining that it would "assure that the price reported . . . will fairly reflect the value of the discount." *Id.* But this conclusion suggests, at most, one possible means to structure a bundled transaction—not a singular acceptable approach. And this opinion issued *before* the discount safe harbor regulation under which this case arises.[14] So, any guidance it may provide didn't purport to interpret the "fully disclosed" or "accurately reflected" language of Section (h)(5)(ii).

The Relator's cited second advisory opinion provides even less insight for how a discount is "fully disclosed" or "accurately reflected." In it, a seller of products used to treat ophthalmologic disorders inquired whether a tiered rebate program would qualify for protection under the discount safe harbor. HHS OIG Advisory Op. No. 13-07 (Dep't of Health & Human

[14] The final rule adding Section (h)(5)(ii)—which permitted bundled arrangements—became effective on November 19, 1999. *See* 64 Fed. Reg. 63518, 63518. The cited advisory opinion issued March 23, 1999. Indeed, that discrepancy in time explains why the HHS OIG concluded that it wouldn't impose sanctions, instead of concluding that the bundled arrangement met the discount safe harbor. *See* HHS OIG Advisory Op. No. 99-03.

Servs. July 1, 2013). A buyer would reach each new tier based on purchase combinations that included both reimbursable and non-reimbursable products. *Id.* at 1. The HHS OIG concluded that, with a percentage rebate program, the customer easily could calculate the net price of each item by applying the rebate percentage to the individual item's original price. *Id.* at 5. The ability to calculate the net price was crucial to this rebate program, where not all products were reimbursable. *Id.* On the other hand, a bundled discount system—such as supplying a free surgical pack if the customer purchased five surgical packs—made such calculations inherently more difficult. *Id.* at 5–6. And so, the safe harbor provision would protect a bundled discount but only when the Federal health care program reimbursed the items under the same methodology. *Id.* at 6.

Relator contends that this second advisory opinion demonstrates an appropriate way—in contrast to HRMC and Medtronic's bundled deals—to structure a safe harbor deal. Doc. 450 at 36–37. Namely, a deal should permit a customer to determine—and write down and report—the effective cost of every device. *Id.* at 36. But this advisory opinion doesn't prescribe line-item pricing for safe harbor deals. Instead, it stands for the proposition that when the discount involves both reimbursable and non-reimbursable products, line-item pricing is important. But if the items all are reimbursed under the same methodology, such line-item pricing isn't crucial. Indeed, the opinion recognizes the difficulty inherent in determining line-item pricing for a bundled deal like HRMC and Medtronic's. But that difficulty doesn't disqualify bundled deals. Instead, the opinion suggests that such an inability to determine an effective cost for each device isn't an issue—so long as the same reimbursement methodology is used. So, this advisory opinion thus *supports* HRMC and Medtronic's bundled deals—without line-item pricing—

because they were reimbursed under the same methodology. And it *undermines* Relator's argument that HRMC should have itemized the bundled deals.

In the end, Relator concedes what he must. There is no requirement to structure a deal in a specific way. Doc. 450 at 36. He then provides carefully crafted suggestions for ways HRMC and Medtronic could have disclosed their discount—such as submitting claims with $0 charges for no-charge devices or lowering line-item invoice pricing. *Id.* These suggestions might work, though the second advisory opinion suggests the line-item pricing may prove difficult. But the regulations don't require it. Nowhere do the relevant regulations discuss unit-based pricing. Nor do they appear concerned with a hospital's charges to its patient for a given device. The court understands how "fully disclose" and "accurately reflect" could include unit-based pricing and patient device charges. But these are simply options, not requirements. Thus, they provide no basis for a reasonable jury to find that HRMC failed to disclose fully or reflect accurately the no-charge device discounts.

In general, deferral district courts shouldn't pretend they're well-versed in the intricate inner-workings of Medicare payment systems. This means they must lean into the legal sources available to interpret the regulations at hand. And those legal sources suggest reporting costs is what counts—and nothing else. *See* 64 Fed. Reg. 63518, 63527 ("[P]arties who were uncertain about how or where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact, as long as the actual purchase price accurately reflects the discount."). What's more, other language in the same regulatory subsection reinforces this understanding. The buyer applicable standards clarify that for a buyer like HRMC to qualify for this discount safe harbor, it must "fully and accurately report the discount *in the applicable cost report*." 42 C.F.R. § 1001.952(h)(1)(ii)(C) (emphasis added). This

standard explicitly links full and accurate reporting with the entity's cost report. The court doesn't opine whether the regulation's sole focus on the cost report adequately serves its purposes. Instead, the court simply concludes that, according to the legal authorities identified by the parties—as supplemented by the court's research—the cost report is what counts. So, as long as the applicable cost report includes the actual purchase price, HRMC fully has disclosed the discount and accurately reflected it. And Relator has conceded that "HRMC properly reported the bulk and quick pay discounts in its cost reports." Doc. 450 at 19.

Undeterred, Relator offers another argument. He contends that HRMC didn't report accurately because it solely reported the price it paid to Medtronic on each purchase, not the *value* of the devices received. *Id.* at 23. But HRMC doesn't have to report the value of the devices received, as long as it reports the total purchase price. The total purchase price—with the bulk and quick pay discounts included—reflected the reportable actual purchase prices because the addition of the no-charge devices didn't increase the price totals. That's what "no-charge" means, after all. What's more, this actual purchase price requirement makes sense. Fraud or abuse would arise when an entity reported a cost *higher* than—not equal to—the price they actually paid, as Medtronic's expert explained.

> [I]f there had actually been an invoice that said or purported to say, you know, [HRMC] you're supposed to pay $105,000 but they really only paid, you know, some lesser amount, you know, that could create some risk because they might then report—they might have an invoice that said you're going to pay 105,000 but really reported—you know, but really paid less, and then somehow an inflated cost is reported.

Doc. 445-2 at 60 (Maida Dep. 232:6–15). No such risk of inflated costs presents itself here.

Piling on, HRMC also has adduced evidence that its cost report included the purchase price HRMC actually paid to Medtronic for the bundled deals. HRMC Corporate Representative Nick Baldetti explained how HRMC tracks costs and discounts to ensure total purchase prices

get reported to Federal health care programs. An order for devices—like those at issue here—would produce a purchasing invoice, which would "roll up" to the general ledger. Doc. 435-7 at 4 (Baldetti Dep. 90:21–91:16). That is, these devices' costs would "roll up" from their purchase invoice to the Cath Lab cost center, to the medical supplies sub-general ledger line, to the trial balance, which feeds into the cost report generated by HRMC's accounting firm. *Id.* (Baldetti Dep. 91:12–21).

HRMC's expert also explained how these costs interacted with other device costs in HRMC's cost report: all the devices at issue here were billed to Medicare under revenue code 272. Doc. 435-12 at 20 (Russo Expert Report). The "[c]osts and charges associated with this revenue code were reported on line 71 of Hutchinson's Cost Report . . . That line aggregated costs for cardiovascular devices. Hutchinson was not required to, and in fact could not, break out the costs of individual devices used in its Cost Report." *Id.* at 20–21 (Russo Expert Report). In light of the guidance from HHS OIG and HRMC's evidence of cost reporting, no reasonable jury could find that HRMC failed to disclose fully and report accurately—as defined by the available legal authority—the discount it received from Medtronic.

The court thus concludes that no reasonable jury would find that HRMC and Medtronic's no-charge devices fail to qualify as discounts under 42 C.F.R. § 1001.952(h)(5)(ii). With that conclusion in mind, the court moves on to the next requirement under the regulatory safe harbor: the applicable standards for buyers and sellers. The court begins this standards analysis with Medtronic—the seller.

4. Medtronic as Seller

For ease of reference, the court recites again the contested standards for a seller under the discount safe harbor. Then, with these standards identified, the court evaluates whether a reasonable jury could find that Medtronic failed to meet the seller applicable standards. Recall

the overarching regulation: A seller "must fully and accurately report" the discount "on the invoice, coupon or statement submitted to the buyer." 42 C.F.R. § 1001.952(h)(2)(ii)(A). So, that's the first standard the court addresses. Also the seller must "inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount[.]" *Id.* The court addresses this "inform the buyer" standard second.

a. Fully and Accurately Reported

Relator argues that Medtronic didn't satisfy the regulatory seller standards because Medtronic didn't report fully and accurately the discounts it provided to HRMC. *First*, Relator takes issue with Medtronic's documentation of the discounts it gave HRMC. Doc. 398 at 63. Medtronic's invoices and price proposal agreements didn't include the no-charge devices. *Id.* And those documents stated that HRMC should use the pricing reflected on those documents to report to Federal and State programs. *Id.* But that's not the whole story, Medtronic insists. It's true that the invoices didn't include the no-charge devices. But Medtronic provided separate sheets with tables—dubbed "deal sheets" by Relator and "bundle statements" by Medtronic—that identified the no-charge devices provided in each bundled deal and the value of those no-charge devices. Doc. 430 at 51. Relator contends that the separate nature of these bundle table sheets precluded Medtronic from satisfying the regulation's requirements. Doc. 445 at 53. And, he argues, the bundle table sheets were insufficient because they didn't contain various details—such as serial number and lot numbers—necessary to track the transfer of these devices. *Id.* at 54.

But Relator's argument assumes more stringent reporting requirements than the regulatory text suggests. Recall that when "interpreting the regulation, we apply the same rules we use to interpret statutes." *Canyon Fuel*, 894 F.3d at 1287 (quotation cleaned up). That is, a court should "examine the plain language of the regulation and give each word its ordinary and

customary meaning." *Id.* (citation omitted). And courts "often begin an ordinary meaning analysis by consulting contemporary dictionary definitions." *Nat'l Credit Union*, 764 F.3d at 1227.

Here, the pertinent regulation requires that a seller "fully and accurately report such discount on the invoice, coupon, *or* statement submitted to the buyer[.]" 42 C.F.R. § 1001.952(h)(2)(ii)(A) (emphasis added). Again, the HHS OIG adopted these seller-specific regulatory requirements in November 1999. *See* 64 Fed. Reg. 63518, 63527 (adopting clarifications to discount safe harbor that include "dividing the parties to a discount arrangement into three groups—buyers, sellers, and offerors of discounts—with descriptions of each party's obligations in separate paragraphs"). The 1999 Black's Law Dictionary defines "invoice" as: "An itemized list of goods or services furnished by a seller to a buyer, usu. specifying the price and terms of sale." *Invoice*, Black's Law Dictionary (7th ed. 1999). This definition of invoice—with its itemized list and specified price—aligns with what Relator interprets as full and accurate reporting. So, Relator's right, sort of. If the regulation required the seller to report the discount on the invoice—full stop, end of analysis—then the stringent reporting Relator envisions would follow. But it doesn't.

Instead, the regulation continues, also permitting a seller to report a discount on a statement, or even a coupon. As Medtronic aptly observes, a coupon typically means a document much less formal—and often physically smaller than the stringent requirement Relator envisions. Doc. 464 at 20 (citing *Coupon*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/coupon (defining coupon as "a small piece of paper that allows one to get a service or product for free or at a lower price")). This definition of the word coupon doesn't describe a stringent standard. And it doesn't suggest the need for lot numbers and

transfer tracking. What's more, the regulation appears indifferent to which form, precisely, the reporting takes, giving the reporting party the option to use any of three documents. Finally, separate documentation of various discounts isn't unique or so unusual that it counsels special caution. *See U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 148 (D. Mass. 2000) (noting hospital supply companies' practice of providing invoices to hospitals for x-ray supplies that reflect one 40% discount but don't include the applicable accrual and tiered discounts). Sometimes business gets done informally. And the regulation's plain language invites such flexibility.

In sum, the flexibility inherent in the plain meaning of the regulation means that no reasonable jury could find that the bulk invoices—together with the bundle table sheets—fail to qualify as full and accurate seller reporting. And so, Medtronic satisfies the first contested seller standard.

b. Inform the Buyer

The second contested standard for a seller to qualify for the regulatory safe harbor involves notice to the buyer. Relator argues that Medtronic's notice to HRMC didn't suffice because that notice appeared on the bulk invoices, not the bundle table sheets.

To review, the regulations require that the seller must "inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount[.]" 42 C.F.R. § 1001.952(h)(2)(ii)(A). Black's Law dictionary defines "reasonable notice" as notice "that is fairly to be expected or required under the particular circumstances." *Reasonable Notice*, Black's Law Dictionary (7th ed. 1999). In the due process context, the Supreme Court has defined reasonably calculated notice as that which "apprise[s] interested parties of the pendency of the action and afford them an opportunity to present their objections." *Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 314 (1950). And the Court explained in *Mullane* that

the means to give such notice should align with "one desirous of actually informing" another party. *Id.* at 315. So, the operative question here is whether Medtronic informed HRMC of its obligation to report in a fashion that demonstrates an actual desire to inform HRMC, under the particular circumstances.

Also, the HHS OIG has clarified the particular circumstances for notice here, identifying the flexibility given to defining the requisite notice: "We are not prescribing a specific form of notice. The form of notice appropriate in particular situations may vary. . . . [A] seller will only be protected by the safe harbor if it is not complicit in a buyer's noncompliance[.]" 64 Fed. Reg. 63518, 63529.

Here, Medtronic included a notice statement on its bulk invoices. It announced:

> Treatment and Reporting of Discounts: The parties intend that all discounts and rebates, if any, earned by the Customer under this Agreement shall constitute discounts as that term is defined in the Discount Safe Harbor to the Anti-Kickback Statute, (42 U.S.C. 1320a-7(b)). Customer agrees that it shall have the sole responsibility to properly allocate, disclose, and report all discounts and rebates earned under this Agreement to its respective state and federal payors in accordance with the requirements of all applicable state and federal laws and regulations.

Doc. 432-6 at 2–6 (HRMC Ex. A-2). Relator concedes that this language complies with the regulatory requirement of notice. Doc. 398 at 68. Given the specificity of the notice—which even cites the statute explicitly—no reasonable jury could find that Medtronic failed to apprise HRMC of its obligations. *Mullane*, 339 U.S. at 314–15. And it did so as one desiring to inform would do. *Id.* But, Relator contends, this notice doesn't count because it appeared on the bulk invoices—a separate piece of paper which didn't include the no-charge devices. Doc. 398 at 68.

The court is unpersuaded by this separate-piece-of-paper argument. HHS OIG didn't prescribe a specific form of notice. 64 Fed. Reg. 63518, 63529. And every bundled transaction included an invoice. So, each time Medtronic sold devices to HRMC, Medtronic informed

HRMC of its obligations anew. To be sure, the bundle table sheets didn't include this language. *See, e.g.*, Doc. 432-7 at 2 (HRMC Ex. A-3); Doc. 432-10 at 2 (HRMC Ex. B-3); Doc. 432-11 at 3 (HRMC Ex. C-1); Doc. 432-16 at 2 (HRMC Ex. D-3). But the total purchase price—all that HRMC had to report—didn't change between the invoice (that included the notice) and the bundle table sheet. *See, e.g.*, Doc. 432-15 at 2 (HRMC Ex. D-2); Doc. 432-16 at 2 (HRMC Ex. D-3). What's more, HRMC's purchasing department testified that it received the invoice and the bundle table sheet together at the point when it created a purchase order. Doc. 398-5 at 11–12 (Atkins-Ray Dep. 32:17–33:3; 34:4–11). And, after the purchasing department created the purchase order, the price simply "rolled up" until the accounting firm included it in the Cost Report. Doc. 398-6 at 26 (Baldetti Dep. 91:12–21). So, at the point in the process when accurate cost reporting occurred, *both* sheets were present.

In sum, Relator's notice to the buyer arguments again try to impose more rigid requirements than the regulatory language of the statute or the HHS OIG guidance demands. Presented with these undisputed facts, no reasonable jury could find that Medtronic failed to meet the requirement to inform HRMC in a reasonably calculated manner. And so, Medtronic satisfies both of the contested buyer standards such that no reasonable jury could find that it fails to meet the regulatory safe harbor requirements. The court thus grants summary judgment to Medtronic on its safe harbor affirmative defense.

5. HRMC as Buyer

The safe harbor regulations also provide standards for a buyer who seeks to invoke its shelter. As noted before, HRMC is a cost-reporting entity. And so, it falls into the second buyer category outlined by the regulation, one which requires the buyer to meet four standards. The first standard reads like this: "If the buyer is an entity which reports costs on a cost report . . . it must comply with all of the following four standards . . . The discount must be earned based on

purchases of that same good or service bought within a single fiscal year of the buyer[.]" C.F.R. § 1001.952(h)(1)(ii)(A). The court evaluates whether HRMC satisfies this first standard, next. And, because the court determines that a reasonable jury could find that HRMC fails to satisfy this first standard, it doesn't consider the other three buyer standards.

a. Same good

Relator asserts that HRMC fails to meet this first buyer standard because the no-charge atherectomy devices Medtronic provided—HawkOnes, SilverHawks, TurboHawks—were not the same devices purchased in the bulk transactions—DCBs. Doc. 450 at 40. HRMC responds, arguing that it satisfied the "same good" standard because—for the bulk deals—HRMC purchased the same goods and—for the bundle deals—the Federal health care program reimbursed the purchased and no-charge devices under the same methodology. Doc. 435 at 32. That is, HRMC urges the court to interpret the "same good" standard broadly, importing the bundled discount requirements in subsection (h)(5)(ii) into the buyer standards in subsection (h)(1)(ii)(A). But, as Relator points out, HRMC provides no authority suggesting the court should employ a "same good" means "same reimbursement methodology" approach. Doc. 450 at 41. And the plain language of the regulation counsels against it.

Black's Law Dictionary defines "same" as the "very thing just mentioned or described." *Same*, Black's Law Dictionary (7th ed. 1999). If a bulk transaction describes a drug-coated balloon (as do many of the at-issue transactions here), a no-charge atherectomy device provided in the bundle isn't "the very thing" just described. These two devices serve different purposes, with the atherectomy device scraping plaque out while the drug-coated balloon applies the drug paclitaxel. And it "is a well-established law of statutory construction that, absent ambiguity or irrational result, the literal language of a statute controls." *St. Charles Inv. Co. v. Comm'r*, 232 F.3d 773, 776 (10th Cir. 2000) (quotation cleaned up). It would seem, then, that a reasonable

jury could find that HRMC fails to qualify as a buyer because they didn't earn the discounts at issue "on purchases of that same good or service[.]" 42 C.F.R. § 1001.952(h)(1)(ii)(A).

But there's more to it. Following the regulation's literal language appears—at first blush, at least—to lead to an irrational result. Under this interpretation, the regulation's literal language would *never* provide safe harbor for a cost-reporting buyer who engages in a bundled, different goods transaction. And yet, the same regulation protects that precise bundled, different good transaction. *Id.* at § 1001.952(h)(5)(ii). The literal language of the regulation requiring a buyer to engage in a same good transaction, in effect, nullifies the safe harbor for the different goods discount. And so, the court endeavors to harmonize these subsections in a way that renders neither subsection, nor its attendant words and phrases, meaningless. *See Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 511 (2018) (explaining that rules of statutory interpretation "aim[] for harmony over conflict"); *see also Bridger Coal Co./Pac. Mins., Inc. v. Dir., Off. of Workers' Comp. Programs*, 927 F.2d 1150, 1153 (10th Cir. 1991) (counseling that court should "not construe a statute in a way that renders words or phrases meaningless, redundant, or superfluous").

HRMC would have the court import the different goods conditions into the "same good" language found in the buyer-applicable standards. Doc. 435 at 32. So, as long as HRMC meets the conditions for a bundled transaction to qualify as a discount, it also meets the "same good" buyer standard. But that approach renders the "same good" requirement meaningless. Instead, the regulation identifies three different categories of buyers— (1) health maintenance organizations and competitive medical plans; (2) cost-reporting entities; and (3) individuals or entities in whose name one may submit a claim to a Federal health care program. 42 C.F.R. § 1001.952(h)(1). And just the second category includes this "same good" standard. So, the

regulation avoids irrationality if the two other categories of buyers can utilize—without inter-subsection inconsistency—the different goods bundled discount. When the court harmonizes the regulation this way, it concludes that the "same good" language doesn't produce irrational results for the other two buyers and, thus, determines that the plain language of the statute governs.

Under the plain language of the regulation, HRMC fails the buyer standard in Section h(1)(ii)(A). And the regulation explicitly clarifies that a buyer "must comply with all of the . . . four standards[,]" not just with some of them. 42 C.F.R. § 1001.952(h)(1)(ii). So, one strike means HRMC is out. In sum, no reasonable jury could find that HRMC (as the proponent of an affirmative defense) has carried its burden to establish the regulatory safe harbor shelter.

Nonetheless, HRMC still has a route to safe harbor protection—through the statutory discount exception, which the court addresses, below.

C. Statutory Discount Exception

Before the court can apply the statutory discount exception to the summary judgment facts, it must address a preliminary matter: the relationship between the statutory discount exception and those regulatory safe harbor provisions the court just interpreted.

The parties disagree whether the statutory exception and the regulatory safe harbor provisions form independent bases for protection. Relator says no. He insists that the regulatory safe harbors effectively interpret the statutory exception so that failing to satisfy the safe harbor provisions necessarily results in failing to satisfy the statutory exception. Doc. 445 at 43–47; Doc. 450 at 32 ("There is no way for a hospital to fail the regulation's safe harbor requirements but meet the language of the statute."). Defendants disagree. HRMC asserts that "[p]rotection under the Regulatory Safe Harbor is *in addition* to the Statutory Exception." Doc. 435 at 28 (emphasis added).

The court agrees with defendants. That is, the court is persuaded that one can satisfy the statutory discount exception without meeting a specified safe harbor provision. Here's why. When it permitted the promulgation of safe harbor regulations, Congress explained that any "'practices specified in regulations . . . shall be in addition'" to those exempted under the statutory exception. *U.S. ex rel. Banigan v. Organon USA Inc.*, No. CV 07-12153-RWZ, 2016 WL 10704126, at *3 n.5 (D. Mass. Aug. 23, 2016) (quoting Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (1987)). And the HHS OIG has clarified that the "regulatory discount safe harbor both incorporates *and enlarges upon* the statutory discount exception." *Id.* (brackets omitted and emphasis added) (quoting 64 Fed. Reg. 63518, 63528). In other words, "the regulatory safe harbor expands upon the statutory safe harbor by defining *additional* discounting practices *not included* in the statutory exception[.]" 64 Fed. Reg. 63518, 63528 (emphasis added). And so, a defendant may assert an affirmative safe harbor defense under either the statutory exception, the regulatory provisions, or both. *See Shaw*, 106 F. Supp. 2d at 113 (explaining that the statutory exception and the safe-harbor provisions provide independent bases for exclusion from criminal liability such that a defendant may raise just one, or both).[15]

Anyone who has made it this far may have forgotten the relevant statutory language. So, the court repeats it here. The statutory discount exception to the AKS provides that discounts

[15] Relator spends a chunk of his response/reply brief to Medtronic's motion explaining why it finds *Shaw*'s separate statutory and regulatory holding inapplicable here. Doc. 445 at 43–47. He argues that *Shaw* was a rebate safe harbor case and that the federal safe harbor regulations governing rebates have changed considerably since 1991. *Id.* at 46. He also contends that the bundled discounts at issue here haven't changed over time. But the court doesn't read *Shaw*'s analysis as one premised on changes over time. Instead, *Shaw* uses changes over time to prove that the regulations exist to account for a "broad range of commercial transactions in a changing marketplace[.]" 106 F. Supp. 2d at 117. But the relationship between the regulations and the statutory exception doesn't rest on those changes occurring, such that the rebate regulations have a different relationship to the statutory exception than other discount regulations. In other words, the changes simply explain why both the statutory exception and the regulations are necessary. The changes—or their absence—don't determine how a specified safe harbor regulation relates to the statutory exception. And so, the ways in which *Shaw* is distinguishable from this case don't affect its application here.

and price reductions—if properly disclosed and appropriately reflected—don't qualify as illegal renumeration. 42 U.S.C. § 1320a-7b(b)(3)(A). That is, the penalties the AKS outlines for illegal renumeration don't apply to:

> a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is ***properly disclosed*** and ***appropriately reflected*** in the ***costs claimed or charges made*** by the provider or entity under a Federal health care program[.]

Id. (emphasis added). Both Medtronic and HRMC claim to satisfy the statutory discount exception. Doc. 435 at 24–26; Doc. 464 at 23–25. The court already has concluded that Medtronic has satisfied the regulatory safe harbor provisions, meaning that no reasonable jury could find Medtronic failed to meet those provisions. So, the court needn't include Medtronic in the following statutory discount exception analysis. The court's analysis, below, thus focuses solely on HRMC.

As explained above, the statutory exception provides an independent basis to legitimize otherwise illegal remuneration in the form of discounts. *Shaw*, 106 F. Supp. 2d at 113. It requires that HRMC "properly disclosed and appropriately reflected" the discount. 42 U.S.C. § 1320a-7b(b)(3)(A). And it also requires that HRMC captured such disclosure and reflection in the "costs claimed or charges made[.]" *Id.* In short, "manufacturers are allowed to provide the discount so long as the discount is documented and passed on to the government." *Shoemaker v. Cardiovascular Sys., Inc.*, No. CV-16-568 (DWF/KMM), 2017 WL 1180444, at *10 (D. Minn. Mar. 29, 2017).

1. Properly Disclosed and Appropriately Reflected

Starting as it must with the statute's plain language, the court discerns no basis to interpret this "properly disclosed and appropriately reflected" statutory language, 42 U.S.C. § 1320a-7b(b)(3)(A), differently than it interpreted the "fully disclosed" and "accurately

reflected where appropriate" regulatory language it already analyzed, 42 C.F.R. § 1001.952(h)(5)(ii). *See Shaw*, 106 F. Supp. 2d at 113 ("The independent status of the safe-harbor provisions from the 'discount exception,' however, does not mandate their isolation from each other when one is looking for guidance as to the proper interpretation and application of one of the statutory exceptions to criminal liability."). Indeed, the language itself differs just slightly—"properly" instead of "fully" and "appropriately" instead of "accurately . . . where appropriate." And "it is reasonable that a court charged with the task of interpreting and applying the statutory 'discount exception' would look to the regulatory agency's implementation of its own discount safe-harbor provision as guidance[.]" *Id.* So, the court reiterates (without repeating) what it already concluded about HRMC disclosing and reflecting its costs. The court refers any unsatiated reader to § V.B.1.b., above. There, the court concluded that—given HHS OIG's guidance that actual purchase price constitutes proper disclosure, coupled with HRMC's evidence of cost reporting—no reasonable jury could find that HRMC had failed to disclose properly or reflect appropriately the discount it received from Medtronic.

2. Costs Claimed or Charges Made

The analysis so far leaves the last of the statutory phrases for the court to interpret: "in the costs claimed or charges made by the provider or entity under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(3)(A). This phrase, too, elicits robust debate among the parties. HRMC argues that use of "or" in this phrase indicates that HRMC—as the provider and a cost-reporting entity—solely reports its costs claimed. Its charges are irrelevant. Not so, Relator contends. He argues that such a reading "would allow HRMC to hide the existence and value of the free devices from the government." Doc. 450 at 32.

But the plain language of the statute tilts in HRMC's favor. The disjunctive "or" suggests either that an entity has a choice, or that "costs" applies to one party and "charges"

applies to another. The *Shaw* court analyzed this language in the AKS and explained that it establishes:

> The phrase "costs claimed . . . by the provider" refers to those costs claimed to Medicare or Medicaid by the buyer-provider. The phrase "charges made by the ... entity" refers to those costs charged to the buyer-provider by the seller-supplier. Both phrases are modified by the phrase "properly disclosed and appropriately reflected," which describes the required reporting activities for both the "provider" and the "entity." Thus both parties to the transaction, the seller-supplier and buyer-provider, must properly disclose and appropriately reflect the reductions in price in order to find shelter under the discount exception.

Shaw, 106 F. Supp. 2d at 120 (ellipses in original). The court finds *Shaw*'s interpretation persuasive. A buyer-provider like HRMC need concern itself solely with costs claimed, not charges made. Not only does this interpretation align with the plain language of the statute, which Congress wrote in the disjunctive, but it also lines up with the HHS OIG guidance already cited: "[P]arties who were uncertain about how or where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact, as long as the actual purchase price accurately reflects the discount." 64 Fed. Reg. 63518, 63527. And this emphasis on costs for cost-reporting entities parallels the regulatory requirements, as well, which, again are relevant here insofar as they assist the court's interpretation. *See Shaw*, 106 F. Supp. 2d at 113 (explaining that the regulations can provide guidance even though they are an independent basis for safe harbor). The regulatory safe harbor buyer standards say *nothing* about charges. Instead, they require solely that the "buyer must fully and accurately report the discount in the applicable cost report[.]" 42 C.F.R. § 1001.952(h)(1)(ii)(C). It stands to reason, then, that the "or charges made" language in the statutory discount exception doesn't apply to buyers. At bottom, the statute, regulations, and HHS OIG guidance all indicate that when a cost-reporting entity accurately reflects its costs in its cost report, that's enough. Relator's focus on charges is—in HRMC's language—a red herring. Doc. 463 at 16. Therefore, no reasonable jury could

find that HRMC failed to report its costs. So, HRMC qualifies under the statutory discount exception, and the court thus grants summary judgment in HRMC's favor on its safe harbor affirmative defense.!

V. Conclusion

The court grants in part and denies in part Relator's Motion to Limit or Exclude Expert Testimony and Report (Doc. 465). The court grants the motion to the extent Medtronic's expert announced legal conclusions. The court denies the motion to the extent Medtronic's expert provided context to interpret a complex regulatory scheme.

Defendants Medtronic and HRMC's Motions for Partial Summary Judgment (Doc. 429; Doc. 434) are granted. Defendants' no-charge medical device transactions qualify for safe harbor treatment under either the regulatory safe harbor provisions or the statutory discount exception (or both). Defendants' safe harbor affirmative defense thus precludes the no-charge medical devices from violating the AKS as a form of illegal remuneration. And so, none of the Medtronic devices purchased by HRMC were tainted, and billing them to the Federal health care program didn't give rise to a false claim under the FCA. As such, the court grants summary judgment in defendants' favor on Relator's FCA claims that the no-charge devices violated the AKS.

IT IS THEREFORE ORDERED BY THE COURT THAT United States of America, *ex rel.* Thomas Schroeder Relator's Motion for Partial Summary Judgment (Doc. 397) is denied.

IT IS FURTHER ORDERED THAT defendant Medtronic, Inc. and Covidien LP's Motion for Partial Summary Judgment (Doc. 429) is granted.

IT IS FURTHER ORDERED THAT defendant Hutchinson Regional Medical Center's Motion for Partial Summary Judgment (Doc. 434) is granted.

IT IS FURTHER ORDERED THAT United States of America, *ex rel.* Thomas Schroeder Relator's Motion to Limit or Exclude Expert Testimony and Report (Doc. 465) is granted in part and denied in part. The motion to limit expert Tony Maida's legal conclusions is granted. The motion to limit or exclude expert Tony Maida's legal conclusions otherwise is denied.

IT IS SO ORDERED.

Dated this 26th day of September, 2024, at Kansas City, Kansas.

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