APPENDIX

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APPENDIX A

[DO NOT PUBLISH]

In the
United States Court of Appeals
For the Eleventh Circuit

No. 21-10366

[Filed: April 22, 2022]

TROY OLHAUSEN,	)
	)
Plaintiff-Appellant,	)
	)
versus	)
	)
ARRIVA MEDICAL, LLC, ALERE, INC., AMERICAN MEDICAL SUPPLIES, INC., ABBOTT LABORATORIES, INC.,	)
	)
Defendants-Appellees.	)

Appeal from the United States District Court
for the Southern District of Florida
D.C. Docket No. 1:19-cv-20190-RNS

Before WILSON and ROSENBAUM, Circuit Judges, and COVINGTON,* District Judge.

PER CURIAM:

Troy Olhausen appeals from the dismissal of his False Claims Act ("FCA") action against Arriva Medical, LLC ("Arriva"), Alere, Inc. ("Alere"), American Medical Supplies, Inc., and Abbott Laboratories, Inc. ("Abbott") (collectively, "Defendants"). Because dismissal was appropriate, we affirm.

BACKGROUND

Arriva was a Florida provider of mail- order diabetic testing supplies and other medical products. Olhausen was Arriva's Senior Vice President of Business Development and Marketing. In 2011, Alere acquired Arriva. In 2013, the Centers for Medicare and Medicaid Services ("CMS") awarded Arriva a Durable Medical Equipment, Prosthetics/Orthotics and Supplies ("DMEPOS") competitive bidding contract to provide Medicare beneficiaries with mail-order diabetic supplies. In 2017, Abbott acquired Alere, and closed Arriva soon after.

According to Olhausen's second amended complaint, Arriva violated a number of Medicare rules in the course of furnishing supplies to its patients. As relevant here, Olhausen alleged that Arriva provided mail-order diabetic testing supplies without obtaining required Assignment of Benefit forms from patients.

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* The Honorable Virginia Covington, United States District Judge for the Middle District of Florida, sitting by designation.

Olhausen also alleged that Arriva violated Medicare rules and the terms of its competitive-bid contract when it failed to disclose or accredit its Tennessee, Arizona, and Philippines call-center locations. Finally, he alleged that Arriva conspired with its parent companies, Alere and Abbott to submit false Medicare claims based on regulatory violations alleged in the other Counts.

The district court granted the Defendants' motion to dismiss on the grounds that Olhausen failed to sufficiently plead his claims.

STANDARD OF REVIEW

"We review a dismissal with prejudice for failure to state a claim under the False Claims Act de novo." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1050 (11th Cir. 2015) (citing *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1324 (11th Cir.2009)). "In doing so, we accept the allegations in the complaint as true and construe them along with the reasonable inferences therefrom in the relator's favor." *Id.* (citing *McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir.2005)).

DISCUSSION

To prevail on his FCA claims, Olhausen must prove: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. v. Mortg. Inv'rs Corp.*, 987 F.3d 1340, 1346 (11th Cir. 2021), *cert. denied sub nom. Mortg. Inv'rs Corp. v. United States ex rel. Bibby*, 141 S. Ct. 2632 (2021). We assume without deciding that

Olhausen's second amended complaint pled with sufficient particularity that the Defendants submitted false statements to the government. We nonetheless affirm because we hold that Olhausen has failed to allege the element of scienter as a matter of law.[1]

Under the FCA, a person acts with the requisite scienter when she "knowingly" submits a false claim, which the FCA defines as either "actual knowledge," "deliberate ignorance," or "reckless disregard." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017) (citing 31 U.S.C. § 3729(b)). The FCA's scienter requirement is "rigorous." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). It ensures that FCA liability "does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation," nor does it reach "claims made based on reasonable but erroneous interpretations of a defendant's legal obligations." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287–88 (D.C. Cir. 2015) (internal quotation marks omitted). Where "the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007). And the analysis of whether an interpretation of ambiguous law is reasonable is an objective one. *Id.* at 69–70.

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[1] We may affirm on any ground that finds support in the record. *Long v. Comm'r*, 772 F.3d 670, 675 (11th Cir. 2014). Moreover, the parties have fully briefed the scienter issue.

The Medicare rules that Olhausen alleged the Defendants violated are susceptible to multiple reasonable interpretations. As for Olhausen's allegations regarding signatures, because Arriva had a Medicare contract, it was considered a "participating supplier." 42 C.F.R. § 400.202. Generally, "Medicare pays the supplier for covered services if the beneficiary . . . assigns the claim to the supplier and the supplier accepts the assignment." *Id.* § 424.55(a). But "when payment is for services furnished by a *participating physician or supplier*, the beneficiary . . . *is not required* to assign the claim to the supplier in order for an assignment to be effective." *Id.* §424.55(c) (emphases added). And if a supplier "files a claim for services that involved no personal contact between the . . . supplier and the beneficiary . . . a representative of the . . . supplier may sign the claim on the beneficiary's behalf." *Id.* § 424.36(c).

Arriva concludes from these rules that it was not required to obtain beneficiary signatures for every assignment of benefits, including for assignments for products not covered by its DMEPOS contract, such as heating pads, orthotic braces, and vacuum-therapy pumps. Even if Arriva's interpretation is wrong (and it was required to obtain signatures), Olhausen cannot show that Arriva had the requisite scienter because it is an objectively reasonable interpretation of the rules to conclude that the signatures were not required. *See, e.g.*, *U.S. ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010) ("[A] statement that a defendant makes based on a reasonable interpretation of a statute cannot support a claim under the FCA if

there is no authoritative contrary interpretation of that statute.").

The same is true regarding the call-center locations allegations. Medicare regulations require a supplier to "enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities." 42 C.F.R. §424.57(b)(1). The term "furnish" is not defined. It is an objectively reasonable interpretation of the rule that Arriva's call-center locations did not "furnish" DMEPOS, so it was not required to enroll them. Again, even if this interpretation is incorrect, that objectively reasonable conclusion by Arriva negates the scienter element.

And for these same reasons, Olhausen also failed to plead the requisite scienter for Arriva and its parent companies to have conspired to violate the FCA.

AFFIRMED.

APPENDIX B

United States District Court
for the
Southern District of Florida

Civil Action No. 19-20190-Civ-Scola

[Filed: August 27, 2020]

United States of America *ex rel.* Troy Olhausen, Plaintiff,	)
v.	)
Arriva Medical, LLC, and others, Defendants.	)

Order Granting Motion to Dismiss

This matter is before the Court on the Defendants' motion to dismiss the Plaintiff's third amended complaint ("TAC"). (Defs.' Mot., ECF No. 61; TAC, ECF No. 58.) The Plaintiff in this *qui tam* action, Relator Troy Olhausen ("Olhausen"), alleges that Defendants Arriva Medical, LLC ("Arriva"), Alere, Inc. ("Alere"), American Medical Supplies, Inc., and Abbott Laboratories, Inc. ("Abbot"), either submitted or conspired to submit fraudulent Medicare billing for diabetic and other medical supplies in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*. (ECF No. 58 at ¶1.) The Defendants' motion raises statutory,

procedural, and substantive defenses. Having reviewed the record, the parties' exceptional briefs, and the relevant legal authorities, the Court **grants** the motion to dismiss (**ECF No. 61**) for the reasons explained below.

I. Background

In 2011, Alere purchased Arriva, which sells mail-order diabetic testing supplies and other medical products. (ECF No. 58 at ¶¶ 44, 46.) In April 2013, Arriva acquired Olhausen's diabetic supply company, (*id.* ¶¶ 50-51), and Olhausen began to work as a Senior Vice President at Arriva, reporting directly to Arriva's president. (*Id.* ¶ 53.) Arriva also purchased Liberty Medical Supplies' ("Liberty Medical") Medicare business, which was previously owned by Express Scripts, Inc. ("Express Scripts"). (*Id.* ¶¶ 54–55.) In April 2017, Olhausen transferred from Arriva to Alere. (*Id.* ¶ 72.) Later in 2017, Abbott bought Alere and closed Arriva. (*Id.* ¶¶ 77, 79.) During his tenure at Arriva, Olhausen "participated in [Arriva's] weekly meetings" and "Arriva employees . . . report[ed] to him." (*Id.* at ¶73.)

Olhausen alleges that by virtue of his high-level positions with the companies, he learned of Arriva, Alere, and Abbott's allegedly fraudulent scheme, (*id* ¶88), to defraud the Government by: (i) improperly billing Medicare for invalid prescriptions, (*id.* ¶¶ 89–110); (ii) improperly billing Medicare for medical supplies without obtaining the required assignments of benefits from beneficiaries, (*id.* ¶¶ 111–51); (iii) improperly billing Medicare for medically unnecessary medical devices, (*id.* ¶¶ 152–218);

(iv) fraudulently certifying their 2013 and 2016 Durable Medical Equipment, Prosthetic, and Orthotic Supplies ("DMEPOS") Competitive Bidding contracts with the Centers for Medicare and Medicaid Services ("CMS"), (*id.* ¶¶ 219–57); (v) failing to disclose to CMS that they were using unaccredited locations and subcontractors who did not have supplier numbers to furnish DMEPOS related services, (*id.* ¶¶ 258–355); (vi) making unsolicited telephone contacts to beneficiaries whose names they obtained from Liberty after the purchase of Liberty's Medicare assets (patients who were not Liberty patients but whose names Liberty obtained from Express Scripts), with whom they had no prior contact in an attempt to sell diabetic supplies, (*id.* ¶¶ 356–63); and (vii) conspiring to submit false Medicare claims. (*Id.* ¶¶ 439–42.)

II. Legal Standard

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court must accept all of the complaint's allegations as true, construing them in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). Under Federal Rule of Civil Procedure 8, a pleading need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The plaintiff must nevertheless articulate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the

misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Thus, a pleading that offers mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" will not survive dismissal. *Id.*

In applying the Supreme Court's directives in *Twombly* and *Iqbal*, the Eleventh Circuit has provided the following guidance to the district courts:

> In considering a motion to dismiss, a court should 1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, assume their veracity and then determine whether they plausibly give rise to an entitlement to relief. Further, courts may infer from the factual allegations in the complaint obvious alternative explanation[s], which suggest lawful conduct rather than the unlawful conduct the plaintiff would ask the court to infer.

Kivisto v. Miller, Canfield, Paddock & Stone, PLC, 413 F. App'x 136, 138 (11th Cir. 2011) (citations omitted). "This is a stricter standard than the Supreme Court described in *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957), which held that a complaint should not be dismissed for failure to state a claim 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Mukamal v. Bakes*, 378 F. App'x 890, 896 (11th Cir. 2010). These precepts apply to all civil actions,

regardless of the cause of action alleged. *Kivisto*, 413 F. App'x at 138.

Where a cause of action sounds in fraud, however, Federal Rule of Civil Procedure 9(b) must be satisfied in addition to the more relaxed standard of Rule 8. Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake," although "conditions of a person's mind," such as malice, intent, and knowledge, may be alleged generally. Fed. R. Civ. P. 9(b). "The 'particularity' requirement serves an important purpose in fraud actions by alerting defendants to the precise misconduct with which they are charged and protecting defendants against spurious charges of immoral and fraudulent behavior." *W. Coast Roofing & Waterproofing, Inc. v. Johns Manville, Inc.*, 287 F. App'x 81, 86 (11th Cir. 2008) (citations omitted). "When a plaintiff does not specifically plead the minimum elements of their allegation, it enables them to learn the complaint's bare essentials through discovery and may needlessly harm a defendant's goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, [grounded on] baseless allegations used to extract settlements." *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313 n.24 (11th Cir. 2002). Thus, the Rule's "particularity" requirement is not satisfied by "conclusory allegations that certain statements were fraudulent; it requires that a complaint plead facts giving rise to an inference of fraud." *W. Coast Roofing & Waterproofing*, 287 F. App'x at 86. To meet this standard, the complaint needs to identify the precise statements, documents, or misrepresentations made;

the time and place of, and the persons responsible for, the alleged statements; the content and manner in which the statements misled the plaintiff; and what the defendant gained through the alleged fraud. *Id.*

With these standards in mind, the Court turns to the Plaintiffs' complaint to see whether their claims are sufficiently alleged to withstand dismissal.

III. Analysis

The motion to dismiss targets each count of the TAC, which was filed in response to the Defendants' motion to dismiss the second amended complaint and after the Government declined to intervene in this action. The TAC raises six counts arising from Arriva's alleged violations of Medicare rules. Those counts concern:

- **Invalid Prescriptions (Count I).** Arriva provided DTS to patients whose prescriptions on file were allegedly invalid either because they supposedly had lapsed under state law, or because the patients had changed doctors. (*Id.* ¶¶91-99, 102, 104.)
- **Assignments of Benefits (Count II).** Arriva allegedly sent supplies without collecting signed forms from patients that Olhausen says Medicare rules required. (*Id.* ¶¶111-51.)
- **Medically Unnecessary Devices (Count III).** Arriva allegedly shipped DTS and ancillary products without ensuring patients actually needed them or that were unnecessary under Medicare rules. (*Id.* ¶¶152-218.) Relatedly, Olhausen claims Arriva instructed sales representatives to tell

patients they could switch to a new brand of glucose meter despite a rule that forbids suppliers from pressuring patients to change brands. (*Id*. ¶¶219-57.)

- **Undisclosed Locations (Count IV).** When Arriva applied for and executed its 2013 and 2016 Medicare contracts, it allegedly did not disclose locations in Tennessee, Arizona, Kentucky, and the Philippines that supposedly required independent accreditation and supplier numbers. (*Id*. ¶¶258-355.)

- **Unsolicited Contacts (Count V).** After Arriva purchased another mail-order company, it allegedly called its newly acquired patients, with whom it had no prior contacts, to sell them supplies. (*Id*. ¶¶356-63.) Olhausen alleges these calls violated a statute prohibiting calls to Medicare beneficiaries under certain circumstances.

- **Conspiracy (Count VI).** Arriva allegedly conspired with its parent companies, Alere (which acquired Arriva in 2011) and Abbott (which acquired Alere in 2017), to submit false Medicare claims based on the regulatory violations alleged in Counts I-V. (*Id*. ¶440.)

The Defendants move to dismiss Counts I, III, and V based on the statutory first-to-file, government-action and public disclosure rules, and for lack of particularity. The Defendants move to dismiss Counts II and IV for lack of particularity only, as those two counts are not subject to a statutory bar. Finally, the Defendants move to dismiss Count VI, arguing that no

cognizable underlying claim has been made. The Court addresses each argument in turn.

a. First-to-file rule

Although the FCA generally allows actions by private persons, certain restrictions apply. *See, e.g.*, 31 U.S.C. § 3730(b). One such restriction is the "first-to-file" rule, which provides that "[w]hen a person brings an action [alleging a violation of section 3729], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." *Id.* § 3730(b)(5). This means that "once one suit has been filed by a relator or by the government, all other suits against the same defendant based on the same kind of conduct would be barred." *Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 567 (11th Cir. 1994). "A later filed case need not be based on the exact same facts as the earlier one in order to be barred by the first-to-file rule. The question is whether the actions are 'related.'" *U.S. ex rel. Torres v. Kaplan Higher Educ. Corp.*, Case No. 09-21733-CIV, 2011 WL 3704707, at *4 (S.D. Fla. Aug. 23, 2011) (Seitz, J.) (citations omitted). It abates only "pending" related actions "while the earlier suit remains undecided but ceases to bar that suit once it is dismissed." *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S.Ct. 1970, 1978, 191 L.Ed.2d 899 (2015). Accordingly, a dismissal based solely on the first-to-file bar should be without prejudice. *See id.* at 1979; *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 174 (2d Cir. 2018).

However, in this case, Olhausen does not dispute that if the first-to-file bar does apply, then the TAC

must be dismissed with prejudice under the separate "government-action" rule. Under the government-action rule, a putative relator is prohibited from bringing an FCA action "based upon allegations or transactions which are the subject of a civil suit . . . in which the Government is already a party." 31 U.S.C. §3730(e)(3). This case faces the first-to-file bar from the complaint filed *U.S. ex rel. Goodman v. Arriva Medical, LLC*, Case No. 13-CV-00760 (M.D. Tenn. Mar. 12, 2014). The operative complaint in *Goodman* was filed on March 12, 2014, and the Government later intervened in that case. Accordingly, if the first-to-file rule applies from the *Goodman* action, related claims in a related action would be subject to dismissal with prejudice. *See Wood*, 899 F.3d at 174; *Kellogg Brown*, 135 S.Ct. at 1978–79.

Assessing relatedness requires "comparing the complaints side-by-side" to see whether "the claims [in the second action] incorporate 'the same material elements of fraud' as the earlier action, even if the allegations incorporate additional or somewhat different facts or information." *U.S. ex rel. Bernier v. Infilaw Corp.*, 347 F. Supp. 3d 1075, 1083 (M.D. Fla. 2018) (quoting *U.S. ex rel. Heath v. AT&T*, 791 F.3d 112, 121 (D.C. Cir. 2015)). "[T]he whole point of the first-to-file bar is to see 'whether the later [filed] complaint alleges a fraudulent scheme the government already would be equipped to investigate based on [the first] Complaint.'" *Id.* For the reasons set forth below, the Court finds that the earlier-filed *Goodman* action is sufficiently "related" to trigger the first-to-file rule with respect to Counts I, III, and V of the TAC.

i. Count I—Invalid Prescriptions

First, Count I of the TAC alleges that Arriva violated the FCA by "providing supplies to its beneficiaries without obtaining new, valid prescriptions." (ECF No. 58 at ¶89 (emphasis added).) Similarly, the *Goodman* complaint alleged the existence of a "scheme to bill Medicare for diabetic supplies before obtaining the proper prescriptions." (Goodman Compl., ECF No. 61-1 at ¶82 (emphasis added).) These two counts arise from a common scheme to bill Medicare based on invalid or nonexistent prescriptions. In an effort to distinguish his allegations from Goodman's, Olhausen argues that the TAC alleges that Arriva submitted claims for expired prescriptions "across *all* clients" whereas Goodman purportedly described a scheme applicable to only *some* clients (*i.e.*, those new clients Arriva acquired through its purchase of Liberty Medical). (Pl.'s Resp., ECF No. 69 at 3 (emphasis in original).)

However, Goodman's reference to clients acquired from Liberty Medical was only an illustrative example that did not narrow the scope of clients whose supplies were billed to Medicare without proper prescriptions. (ECF No. 71 at 1.) Specifically, the Goodman complaint alleged that a "Conversion Team was *primarily* engaged in converting over former customers of Liberty Medical. However, . . . defendants employed similar conversion campaigns when they acquired *other* mail order diabetes testing suppliers . . . ." (ECF No. 61-1 at ¶71 (emphasis added).) Thus, the Goodman complaint expressly references "other" customers and only refers to Liberty Medical customers as being a "primary" –

not *exclusive* – focus. The use of concrete examples to bolster allegations in a complaint is common practice. Indeed, Olhausen's own complaint specifically refers to five anonymized patients on whose behalf claims were submitted to Medicare without the necessary prescriptions. (ECF No. 58 at ¶¶ 106-110.) Just as Olhausen's reference to five specific patients does not limit the scope of Count I to only five patients, Goodman's reference to Liberty Medical clients does not limit the scope of his action to only Liberty Medical clients.

ii. Count III—Unnecessary Supplies and Anti-Switching Rule Violations

The Court's analysis of whether the first-to-file rule applies to Count III of the TAC proceeds by assessing the three subparts of that count seriatim. Specifically, the parties dispute whether the first-to-file rule applies to the TAC's allegations regarding (1) glucose meters; (2) test strips, lancets, control solution, and batteries; and/or (3) heating pads, orthotics, and vacuum erection devices. For the reasons explained below, the Court finds that the first-to-file rule bars each subpart of Count III and, as a result, the Court need not and does not reach the Defendants' argument that Count III is also barred by the public disclosure rule (ECF No. 61 at 16).

Glucose Meters. The issue with respect to glucose meters is whether the admittedly related factual allegations can be spared from the first-to-file rule because they raise different legal theories. The parties do not dispute that both the *Goodman* complaint and Olhausen's TAC allege that Arriva made claims for

medically unnecessary glucose meters or monitors. (*Compare* ECF No. 61-1 at ¶13 ("[D]efendants have fraudulently billed Medicare for thousands of glucose meters that were not medically necessary") *with* ECF No. 58 at ¶¶162-163 ("Arriva also shipped [glucose monitors] . . . regardless of whether the beneficiary indicated their current device needed replacing . . . .").) To avoid the first-to-file rule, Olhausen argues that "[b]ecause the material elements of [its fraud theories] differ substantially from those described in *Goodman*, the first-to-file rule does not bar Mr. Olhausen's claim." (ECF No. 69 at 4.) As for the "fraud theories," both complaints allege that Arriva violated the anti-switching rule (*compare* ECF No. 61-1 at ¶¶ 210, 263 *with* ECF No. 58 at ¶391), but the TAC also raises "much broader false certification and fraud-in-the-inducement theories." (ECF No. 69 at 4 (footnotes omitted).)

The Court holds that Olhausen's overlapping factual allegations are barred by the first-to-file rule, even though those allegations are used in the TAC to support "much broader" theories of fraud than the theories raised by Goodman. The Court's analysis begins with the applicable statutory text: "When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action *based on the facts* underlying the pending action." 31 U.S.C. § 3730(b)(5) (emphasis added). The statute is plainly concerned with overlapping factual allegations and it is silent as to whether the fraud theories overlap. The Court now turns to the case law, and the Eleventh Circuit has explained, "once one suit has been filed by a relator or

by the government, all other suits against the *same defendant based on the same kind of conduct* would be barred." *Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 567 (11th Cir. 1994) (emphasis added); *see also U.S. ex rel. Torres v. Kaplan Higher Educ. Corp.*, Case No. 09-21733-CIV, 2011 WL 3704707, at *4 (S.D. Fla. Aug. 23, 2011) (Seitz, J.) ("[S]o long as a subsequent complaint raises the same or a related claim based in significant measure on the core fact or general conduct relied upon in the first qui tam action, the § 3730(b)(5)'s first-to-file bar applies.") (citation omitted). The binding case law echoes the statutory text insofar as it reiterates that "relatedness" refers to the underlying facts. Next, the Court considers the purpose of the first-to-file rule, which is to incentivize relators to "promptly alert[] the government to the essential facts of a fraudulent scheme." *U.S. ex rel. Duxbury v. Ortho Biotech Prod., L.P.*, 579 F.3d 13, 24 (1st Cir. 2009) (quoting *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1188 (9th Cir. 2001)). The controlling statute and the Eleventh Circuit, among other circuit courts, make it clear that the first-to-file rule is triggered by duplicative facts. The rule's purpose is to identify and stop fraudulent schemes, not to incentivize factually duplicative lawsuits in order to advance fraud jurisprudence.

The Court is not persuaded by Olhausen's contrary argument, based on three non-binding cases, that a complaint alleging duplicative facts can avoid the first-to-file rule if it asserts different legal theories. Olhausen relies on a line of cases stating that, "[a]ssessing relatedness [under the first-to-file rule]

requires comparing the complaints . . . [to see if they] incorporate the same material elements of fraud." (ECF No. 69 at 4 (citing *U.S. ex rel. Bernier v. Infilaw Corp.*, 347 F. Supp. 3d 1075, 1083 (M.D. Fla. 2018) (internal quotations and citation omitted); *see also U.S. v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 495 (D.S.C. 2016) (describing first-to-file bar as applicable to complaints "based on the same material elements of fraud"); *U.S. ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 2118 (D.C. Cir. 2003) (same)).) As an initial matter, to the extent Olhausen interprets the "same material elements of fraud" language to mean that the first-to-file rule applies to complaints that assert the same legal theories and not the same facts, his interpretation is inconsistent with both the applicable statutory language and the Eleventh Circuit's decision in *Cooper*. However, upon closer review, the language of the cases cited by Olhausen can be reconciled with the first-to-file rule's focus on factual allegations as opposed to legal theories or particular causes of action. The "same material elements of fraud" language used in those cases comes from *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, where the Ninth Circuit reiterated that the objective of the related "facts" standard of the first-to-file rule is to discourage "piggyback claims, which would have no additional benefit for the government, since once the government *knows the essential facts of a fraudulent scheme*, *it has enough information to discover related frauds*." 243 F.3d 1181, 1189 (9th Cir. 2001) (emphasis added). Thus, the "same material elements of fraud" language refers not to the various causes of action that may be supported by a related set of facts, but it instead refers to the factual elements of an underlying

fraudulent scheme. Finally, the Court agrees with the holding of the one case presented in the parties' briefs that actually turned on this issue, which held that "a focus on the theory of fraud is inconsistent with the statutory language . . . which expressly focuses on 'the facts.'" *U.S. v. Unisys Corp.*, 178 F. Supp. 3d 358, 369 (E.D. Va. 2016) (The relator's "argument, which is based on the distinction between the *type of fraud* alleged, is unpersuasive.") (emphasis in original). As the parties do not dispute the material relatedness of the facts alleged in this subpart of Count III, the Court finds that it is barred by the first-to-file rule.

Test strips, lancets, control solution, and batteries. The second subpart of Count III alleges a scheme whereby the Defendants bundled together test strips, lancets, control solution, and batteries, then shipped and billed for them without regard to medical necessity. (ECF No. 58 at ¶¶ 156-61.) The parties do not dispute that Olhausen's allegations are broader than Goodman's allegations. Although both complaints allege that the Defendants shipped unnecessary testing strips (*compare id.* at ¶392 *with* ECF No. 61-1 at ¶237), only Olhausen's complaint alleges that the unnecessary testing strips were bundled with additional unnecessary products (*see, e.g.*, ECF No. 58 at ¶157). Additionally, Goodman alleged that the scheme to ship unnecessary testing strips began in June 2013 (ECF No. 61-1 at ¶237) whereas Olhausen alleged that he became aware of such a scheme "[a]s of April 2013" and that it lasted until 2015 (ECF No. 58 at ¶¶ 152, 160).

Thus, the question is whether Olhausen's allegations concerning the shipment of and billing for

medically unnecessary products may avoid the first-to-file rule where Olhausen's complaint, compared to Goodman's, (1) refers to additional "bundled" products and (2) identifies an earlier start date and precise end date of the scheme. The Court holds that notwithstanding these additional details, Olhausen's allegations concerning the shipment of unnecessary medical products are still barred by the first-to-file rule. As explained above, "once one suit has been filed by a relator or by the government, all other suits against the *same defendant based on the same kind of conduct* would be barred." *Cooper*, 19 F.3d at 567. Further, as a general matter, "[s]imply alleging additional facts as to how the fraud occurred does not avoid the first-to-file bar." *Torres*, 2011 WL 3704707, at *5.

Relying on these fundamental principles of the first-to-file rule, the court in *U.S. ex rel. LaFauci v. AbbVie Inc.*, dismissed a complaint under the first-to-file rule where its allegations regarding billing for additional unnecessary drugs "involve[d] similar wrongdoing [as alleged in the first complaint], just in different business lines." 2019 WL 1450791, at *4 (D.N.J. Apr. 2, 2019). Olhausen attempts to distinguish *LaFauci* on the grounds that it "merely reflects the same fraudulent scheme but involving different brands of medication." (ECF No. 59 at 5.) However, the Court finds *LaFauci* to be analogous and an apposite application of the general principle that a second complaint cannot avoid the first-to-file rule by alleging additional details concerning the same kind of scheme. Turning to the case at bar, the Court finds that the Government, put on notice by Goodman of the

shipment of boxes containing packages of medically unnecessary test strips, would be equipped to investigate whether other medical products within those very same boxes were unnecessary. As such, Olhausen's complaint is related to Goodman's such that it is barred by the first-to-file rule.

The Court also finds that Olhausen's additional allegations regarding the duration of the scheme so closely overlap with Goodman's allegations that these duration allegations also trigger the first-to-file rule. In short, Olhausen alleges that the scheme lasted from April 2013 into the year 2015. By contrast, Goodman alleges that the scheme "began" in June 2013 and does not allege an end date. At bottom, the difference is that Olhausen put the Government on notice that this multi-year scheme began two months earlier than Goodman claims it began. However, Olhausen provides no authority – and the Court doubts any exists – for the proposition that the Government's investigation of Goodman's allegations could only look prospectively from June 2013. On the contrary, it stands to reason that when Goodman apprised the Government of a scheme that began in June 2013, the Government was equipped to investigate the origins of that scheme and uncover that it began, as Olhausen alleges, weeks or months earlier. In sum, the factual and durational details offered by Olhausen do not render the TAC sufficiently distinct from Goodman's complaint.

Heating pads, orthotics, and vacuum erection devices. The last subpart of Count III alleges that Arriva instructed its employees to send heating pads, orthotics, and vacuum erection devices "without

checking with the beneficiary or the beneficiary's doctor as to whether [that group of products] was medically necessary." (ECF No. 58 at ¶166.) Similarly, Goodman alleges that the Defendant attempted to "up-sell" these products to beneficiaries "on every phone call the associates made" and to market these devices "to every patient." (ECF No. 61-1 at ¶¶ 154-155.) Olhausen argues that his allegations of medically unnecessary sales of these products are different from Goodman's allegation that associates would "up-sell" these devices "to every patient" because Goodman never expressly used the phrase "medically unnecessary." (ECF No. 69 at 5.) The Court is not persuaded. In the broader context of Goodman's False Claims Act *qui tam* complaint, it would be clear to the Government, which intervened in that case, that allegations of rampant and aggressive tactics of up-selling medical devices to *every* patient strongly suggested that at least some of those devices were "medically unnecessary," even if Goodman did not always repeat that particular phrase.

i. Count V—Unsolicited Contacts

The last count that the Defendants allege is barred by the first-to-file rule is Count V, which alleges that Arriva improperly contacted Express Scripts patients whose names and contact information Liberty Medical obtained from Express Scripts. (ECF No. 58 at ¶¶ 356-63.) This allegedly violated 42 U.S.C. § 1395m(a)(17), which provides that suppliers may only contact an individual regarding the furnishing of a covered item if that individual has given written permission to the supplier, the supplier has previously furnished a covered item to the individual before and is calling

regarding that item, or if the supplier furnished at least one covered item to the individual during the 15 months preceding the date the supplier makes contact. Olhausen claims that this regulation was "knowingly violated" when Arriva contacted Express Scripts patients who had no prior relationship with Arriva. (ECF No. 58 at ¶¶ 359, 362.) Similarly, Goodman alleged that Arriva "forc[ed] its conversion representatives to cold call patients who had *never* purchased covered items from Arriva," and in doing so "Defendants clearly violated 42 U.S.C. § 1395m(a)(17)." (ECF No. 61-1 at ¶222 (emphasis in original).) Although these allegations are virtually identical, Olhausen argues that, "taken in context," Goodman's complaint only referred to unsolicited contacts with Liberty Medical patients whereas Olhausen's complaint refers to unsolicited contacts with Express Scripts patients. Following the same principles set forth throughout the Court's first-to-file analysis, the Court finds that Goodman's allegations equipped the Government to investigate Arriva's alleged practice of making unsolicited contacts, no matter the source of those contacts.

b. Counts II and IV Lack Particularity

The Defendants argue that Counts II and IV, the only counts that are not subject to a statutory bar, must be dismissed because they lack sufficient particularity. Federal Rule of Civil Procedure 9(b) requires a party "alleging fraud or mistake . . . [to] state with particularity the circumstances constituting fraud or mistake." To satisfy this particularity standard in a *qui tam* action, a relator must allege the

actual "submission of a [false] claim" because "[t]he False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless . . . the provider . . . asks the Government to pay amounts it does not owe." *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002). The complaint also must offer "some indicia of reliability . . . to support the allegation of *an actual false claim* for payment being made to the Government." *Id.* (emphasis in original). It is not enough that a relator "merely . . . describe[s] a private scheme in detail [and] then . . . allege[s] simply and without any stated reason . . . his belief that claims requesting illegal payments must have been submitted, were likely submitted[,] or should have been submitted." *Id.* Nor may he point to "improper practices of the defendant[]" to support "the inference that fraudulent claims were submitted" because "submission . . . [can]not [be] inferred from the circumstances." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1013 (11th Cir. 2005). Indeed, even if the relator is an insider who alleges awareness of general billing practices, an accusation of "[u]nderlying improper practices alone [is] insufficient . . . absent allegations that a specific fraudulent claim was in fact submitted to the government." *Id.* at 1014 (emphasis added). In short, he must "allege the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions." *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1275 (11th Cir. 2018) (citation omitted).

None of Olhausen's claims adequately allege that a fraudulent claim was in fact submitted to the Government. Olhausen concedes that he did not

include "exact billing data or attach a representative sample claim" that was submitted for reimbursement, but he instead points to Eleventh Circuit authority for the proposition that exact billing data or a sample submitted claim is unnecessary where the complaint "establish[es] the necessary indicia of reliability that a false claim was actually submitted." (ECF No. 69 at 6 (quoting *U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 704 (11th Cir. 2014)).) Such "indicia of reliability" may exist where the relator has "direct, first-hand knowledge of the defendants' submission of false claims gained through [his] employment with the defendants . . . ." *Id.* Olhausen also cites to *Hill v. Morehouse Med. Assocs., Inc.*, where the Eleventh Circuit held that since the relator in that case was an employee with firsthand knowledge of the alleged fraudulent submissions, her allegations had the requisite indicia of reliability necessary to allege a fraudulent scheme. No. 02-14429, 2003 WL 22019936, at *5 (11th Cir. Aug. 15, 2003). The Eleventh Circuit has also sustained complaints that did not expressly identify a specific submission of a false claim, but where the relator nevertheless "allege[d] personal knowledge or participation in the fraudulent conduct." *U.S. ex rel. Matheny v. Medco Health Solutions*, Inc., 671 F.3d 1217, 1230 (11th Cir. 2012). Similarly, a complaint that did not identify a fraudulent submission was sustained where the relator was a nurse who personally used incorrect billing codes on a consistent basis and was told by the "office administrator" that the defendant healthcare provider "'never' billed [these fraudulent services] in another manner." *U.S. ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005).

Thus, in the absence of an allegation identifying the submission of a false claim, the question before the Court is whether Olhausen's allegations have nevertheless provided the necessary indicia of reliability to show that a fraudulent scheme took place. To bring the TAC within the realm of complaints that may survive dismissal without expressly identifying a submission of a fraudulent claim, Olhausen argues that he has "direct, first-hand knowledge of Defendants' submission of false claims gained through his employment with Defendants." (ECF No. 69 at 7.) In support of that argument, he claims that he "learned of the practices alleged" in the TAC "[t]hrough his high-level position with the company." (ECF No. 58 at ¶88.) This "high level position" was Olhausen's role "as Arriva's Sr. Vice President of Business Development and Marketing, reporting directly to Arriva's President." (*Id.* at ¶53.) In that position, Olhausen alleges that he "participated in [Arriva's] weekly meetings" and "Arriva employees . . . report[ed] to him." (*Id.* at ¶73.)

Olhausen has not put forth the indicia of reliability that would excuse him from the general rule that a relator must identify a submission of a fraudulent bill. Olhausen's allegations are a far cry from those of the relator in *Mastej* who attended weekly meetings where "every patient was reviewed, including how the services were being billed to each patient"; or the relator in *Hill* who "worked in the very department where . . . the fraudulent billing schemes occurred" and "observed [workers] alter various . . . codes . . . and thus submit false claims"; or the employees in *Matheny* who alleged that they personally participated in a

fraudulent scheme; or the nurse in *Walker* who alleged that she personally entered incorrect billing codes. *U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 704 (11th Cir. 2014); *Hill v. Morehouse Med. Assocs., Inc.*, No. 02-14429, 2003 WL 22019936, at *4 (11th Cir. Aug. 15, 2003); *U.S. ex rel. Matheny v. Medco Health Solutions*, Inc., 671 F.3d 1217, 1230 (11th Cir. 2012); *U.S. ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005). Merely "participat[ing] in . . . weekly meetings," receiving "reports" from employees, and reporting to the President, may establish that Olhausen was an "insider," but it does meaningfully aid the Court in its search for "indicia of reliability . . . to support the allegation of *an actual false claim* for payment being made to the Government." *Clausen*, 290 F.3d at 1311. After all, the act of submitting a fraudulent claim to the government is the "*sine qua non* of a False Claims Act violation." *Id.*

As the TAC fails at the threshold, the Court need not go on to determine whether the unparticularized billing allegations would fail or satisfy the generic fraud elements of falsity, scienter, and materiality. As explained immediately above, Counts II and IV lack particularity with respect to the submission of a fraudulent bill. Earlier, the Court found that Counts I, III, and V are barred by the first-to-file rule and must be dismissed with prejudice under the government-action rule. The only remaining count is Count VI, which the Court turns to next.

c) Count VI—Conspiracy

The parties agree that Count VI, for conspiracy to commit the alleged FCA violations, cannot stand if the Court finds that the TAC fails to adequately allege underlying FCA violations. As the Court has concluded that the TAC fails to adequately allege FCA violations, Count VI must be and is dismissed.

IV. Conclusion

Accordingly, the Court **grants** the Defendants' motion to dismiss (**ECF No. 61**). Counts I, III and V are dismissed **with prejudice** under the first-to-file and government-action rules. Olhausen has not requested leave to amend; nor has he indicated in his response to the motion to dismiss any inclination whatsoever to do so. The Court thus dismisses Counts II, IV, and VI **without prejudice** and **without leave to amend**. *Wagner v. Daewoo Heavy Industries Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) ("A district court is not required to grant a plaintiff leave to amend his complaint sua sponte when the plaintiff, who is represented by counsel, never filed a motion to amend nor requested leave to amend before the district court."); *Avena v. Imperial Salon & Spa, Inc.*, 17-14179, 2018 WL 3239707, at *3 (11th Cir. July 3, 2018) ("[W]e've rejected the idea that a party can await a ruling on a motion to dismiss before filing a motion for leave to amend.").

The Clerk of Court is directed to **close** this case. Any pending motions are **denied as moot**.

Done and ordered in chambers, at Miami, Florida, on August 26, 2020.

/s/ Robert N. Scola
Robert N. Scola, Jr.
United States District Judge

APPENDIX C

United States District Court
for the
Southern District of Florida

Civil Action No. 19-20190-Civ-Scola

[Filed: January 5, 2021]

United States of America *ex rel.* Troy Olhausen, Plaintiff,	)
v.	)
Arriva Medical, LLC, and others, Defendants.	)

Order Denying Motion for Reconsideration and for Leave to Amend

This matter is before the Court upon Plaintiff Troy Olhausen's motion to reconsider denial of leave to amend and motion to amend. (ECF No. 75.) This action arises from Olhausen's allegations that the Defendants either submitted or conspired to submit fraudulent Medicare billing for diabetic and other medical supplies in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*. (ECF No. 58 at ¶1.) After careful review, the Court granted the Defendants' motion to dismiss, dismissing Olhausen's case in its entirety. *See United States ex rel. Olhausen v. Arriva Med.*, LLC, No.

19-20190-CIV, 2020 WL 5077170 (S.D. Fla. Aug. 27, 2020) (Scola, J.). In response, Olhausen now asks the Court to reconsider its order dismissing his complaint and to afford him leave to amend his complaint. (ECF No. 75.) After careful consideration of Olhausen's motion, the record, and the relevant legal authorities, the Court **denies** his request (**ECF No. 75**).

To begin with, "in the interests of finality and conservation of scarce judicial resources, reconsideration of an order is an extraordinary remedy that is employed sparingly." *Gipson v. Mattox*, 511 F. Supp. 2d 1182, 1185 (S.D. Ala. 2007). A motion to reconsider is "appropriate where, for example, the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension." *Z.K. Marine Inc. v. M/V Archigetis*, 808 F. Supp. 1561, 1563 (S.D. Fla. 1992) (Hoeveler, J.) (citation omitted). "Simply put, a party may move for reconsideration only when one of the following has occurred: an intervening change in controlling law, the availability of new evidence, or the need to correct clear error or prevent manifest injustice." *Longcrier v. HL-A Co.*, 595 F. Supp. 2d 1218, 1247 (S.D. Ala. 2008) (quoting *Vidinliev v. Carey Int'l, Inc.*, No. CIV.A. 107CV762-TWT, 2008 WL 5459335, at *1 (N.D. Ga. Dec. 15, 2008)). However, "[s]uch problems rarely arise and the motion to reconsider should be equally rare." *Z.K. Marine Inc.*, 808 F. Supp. at 1563 (citation omitted). Certainly, if any of these situations arise, a court has broad discretion to reconsider a previously issued order. Absent any of these conditions,

however, a motion to reconsider is not ordinarily warranted.

Here, Olhausen does not complain that the Court erred substantively in dismissing his third amended complaint. Instead, he argues that the Court "preemptively den[ied] leave to amend his Complaint." (ECF No. 75 at 1.) The Court disagrees with the Plaintiff's characterization of the dismissal order as a "preemptive" denial of leave to amend. The dismissal order concluded, in relevant part, as follows:

> Olhausen has not requested leave to amend; nor has he indicated in his response to the motion to dismiss any inclination whatsoever to do so. The Court thus dismisses Counts II, IV, and VI **without prejudice** and **without leave to amend**. *Wagner v. Daewoo Heavy Industries Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) ("A district court is not required to grant a plaintiff leave to amend his complaint *sua sponte* when the plaintiff, who is represented by counsel, never filed a motion to amend nor requested leave to amend before the district court."); *Avena v. Imperial Salon & Spa, Inc.*, 740 Fed.Appx. 679, 683 (11th Cir. 2018) ("[W]e've rejected the idea that a party can await a ruling on a motion to dismiss before filing a motion for leave to amend.").

2020 WL 5077170, at *9 (emphasis in original). Accordingly, the Court dismissed the complaint and did not *sua sponte* grant leave to amend (*e.g.*, by *sua sponte* granting Olhausen the option to accept the dismissal or file an amended complaint within a certain timeframe).

Such a procedure is expressly contemplated by *Wagner*. It appears that Olhausen interpreted the Court's dismissal without leave to amend as though it were an order foreclosing the ability to move for leave to amend. That is not the effect of the Court's order. Accordingly, a party may—as Olhausen has—affirmatively seek leave to amend after dismissal. The Court now turns to whether Olhausen has shown good cause supporting leave to amend.

"The only grounds for granting a Rule 59 motion [to amend] are newly-discovered evidence or manifest errors of law or fact." *Arthur v. King*, 500 F.3d 1335, 1343 (11th Cir. 2007). Olhausen does not argue that his new allegations rest on newly discovered evidence and he does not argue that the Court's dismissal of the claims without prejudice was an error at all. The motion thus fails to meet the Rule 59 standard, which is the rule pursuant to which the motion was filed. (ECF No. 75 at 2.) Nevertheless, the Court will proceed to apply Federal Rule of Civil Procedure 16(b)(4). *See Watkins v. Bigwood*, No. 18-cv-63035, 2020 WL 4922359, at *2 (S.D. Fla. Aug. 21, 2020) (Bloom, J.) (citation omitted) (holding, in a case involving a *pro se* plaintiff, "when a motion for leave to amend a pleading is filed after the deadline set in a court's scheduling order, the court employs a two-step analysis" governed by Rule 16(b)(4)). "First, the movant must demonstrate good cause under Rule 16(b) of the Federal Rules of Civil Procedure." *Id.* "If the movant demonstrates good cause, the court proceeds to determine whether an amendment to the pleadings is proper . . . ." *Id.*

The Court finds that Olhausen has not shown good cause for leave to amend after the deadline set in the Court's Scheduling Order. "This good cause standard precludes modification unless the schedule cannot 'be met despite the diligence of the party seeking the extension,'" and trial courts have ample discretion to decide whether a plaintiff has shown good cause to excuse a motion for leave to amend filed after the deadline set forth in a scheduling order. *Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998) (quoting Fed. R. Civ. P. 16 advisory committee's note). The April 20, 2020 Scheduling Order set July 22, 2020 as the deadline to amend pleadings. (ECF No. 69.) Shortly before the scheduling order was entered, the Court granted Olhausen's motion for leave to amend, and he filed his third amended complaint on April 6, 2020. (ECF No. 58.) The Defendants again moved to dismiss and argued that their "last motion to dismiss put Olhausen on notice of this fundamental flaw, yet he has not even tried to address it for most counts—including Counts II and IV, the only theories not subject to statutory bars." (ECF No. 61 at 2.) Thereafter, Olhausen opposed the motion substantively on May 8, 2020. (ECF No. 69.) The Court's July 22, 2020 deadline for amending the pleadings passed and, on August 27, 2020, the Court dismissed the third amended complaint in its entirety.

Four weeks after the dismissal order and two months after the amendment deadline, Olhausen filed the instant motion in which he argues that the case is in a sufficiently early posture such that amendment would not be wasteful, and he further argues that he "reasonably awaited the Court's ruling on Defendants'

Motion to Dismiss before moving to amend now based on that ruling." (ECF No. 75 at 11.) The Defendants' motion to dismiss put Olhausen on notice of his pleading's shortcomings. At that point Olhausen had a choice: stand on his pleading and oppose the motion to dismiss or request leave to amend in order to address his pleading's flaws. As a tactical decision, Olhausen chose to oppose the motion and lost. The Court will not now afford him a fifth bite of the apple where he declined "to follow the well-trodden procedural path toward amendment." *Eiber Radiology, Inc. v. Toshiba Am. Med. Sys., Inc.*, 673 Fed. App'x 925, 930 (11th Cir. 2016) (also noting the propriety of dismissal with prejudice "where a counseled plaintiff has failed to cure a deficient pleading after having been offered ample opportunity to do so"). While it is certainly true that our legal system favors the resolution of cases on their merits, that rule is not without limits. Especially where, as here, the plaintiff's own strategic decisions dictated the course of litigation. Here, Olhausen reviewed the Defendants' motion to dismiss, vigorously opposed it and then sat back and waited to see if the Court would let his pleading stand. And then, four weeks after the Court granted the motion to dismiss, Olhausen suddenly came up with a litany of new facts that he claims fix his pleading's deficiencies. Olhausen had every opportunity to fix the deficiencies the Defendants identified prior to the Court's careful and thorough review. He should have taken his best shot from the get-go; he should not have waited for the Defendants and the Court to have worked through his pleading before bothering to inform all involved that he had a much better pleading in his quiver in case things went badly for him. The Court is not persuaded by

Olhausen's after-the-fact attempt to recast this tactic as a defensible strategy for having the Court provide a party with a roadmap for how to survive dismissal. None of the new allegations are alleged to be tied to new information uncovered in discovery. At bottom, the delay was a tactical choice that does not warrant leave to amend months after the deadline.

Lastly, Olhausen's argument that amendment should be allowed under Rule 15(a)(2) misses the mark. (ECF No. 75 at 13.) While the rule indeed requires "[t]he court [to] freely give leave" to amend "when justice so requires," Olhausen has sought leave to amend long after the deadline to do so has passed. When leave to amend is sought ***after*** the deadline to amend the pleadings has passed, the movant must do more than argue leave is due under Federal Rule of Civil Procedure 15(a). That is, the movant must also show "good cause" under Federal Rule of Civil 16(b)(4) in order to obtain the right to amend. *See Sosa v. Air Print Sys., Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998); Fed. R. Civ. P. 16(b)(4) ("A schedule may be modified only for good cause and with the judge's consent."). The standard set forth in Rule 16(b) "precludes modification [of the scheduling order] unless the schedule cannot 'be met despite the diligence of the party seeking the extension.'" *See Sosa*, 133 F.3d at 1418. Thus, "diligence is the key to satisfying the good cause requirement." *De Varona v. Discount Auto Parts, LLC*, 285 F.R.D. 671, 672–73 (S.D. Fla. 2012) (Ungaro, J.). Only if "good cause" for an untimely amendment is shown under Rule 16(b), does Rule 15(a)'s instruction, that leave should be freely given when justice so requires, come into play. *See* Fed. R. Civ. P. 15(a)(2).

While the standard under Rule 15(a) is lenient, still, "a motion to amend may be denied on numerous grounds such as undue delay, undue prejudice to the [opposing party], and futility of the amendment." *See Maynard v. Bd. of Regents*, 342 F.3d 1281, 1287 (11th Cir. 2003) (citations omitted). As discussed above, Olhausen has failed to satisfy Rule 16(b) as he did not show good cause justifying his untimely proposed amendment. He merely made the strategic choice to await the Court's ruling. "Permitting another round of amendments" at this point, "would . . . unduly protract [these] proceedings . . . and promote[] judicial inefficiency." *Eiber*, 673 Fed. App'x at 930.

For the foregoing reasons, the Court **denies** Olhausen's motion for reconsideration and for leave to amend (**ECF No. 75**).

Done and ordered, in Miami, Florida on January 5, 2021.

/s/ Robert N. Scola
Robert N. Scola, Jr.
United States District Judge

APPENDIX D

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 21-10366-BB

[Filed: July 20, 2022]

TROY OLHAUSEN,	)
	)
Plaintiff - Appellant,	)
	)
versus	)
	)
ARRIVA MEDICAL, LLC, ALERE, INC., AMERICAN MEDICAL SUPPLIES, INC., ABBOTT LABORATORIES, INC.,	)
	)
Defendants - Appellees.	)

Appeal from the United States District Court for the Southern District of Florida

BEFORE: WILSON and ROSENBAUM, Circuit Judges, and COVINGTON,* District Judge.

* The Honorable Virginia Covington, United States District Judge for the Middle District of Florida, sitting by designation.

PER CURIAM:

The Petition for Panel Rehearing filed by Appellant is DENIED.

ORD-41

APPENDIX E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

No. 2019-CV-20190-SCOLA

[Filed: April 6, 2020]

United States of America Ex. Rel. Troy Olhausen,	)
Plaintiff,	)
v.	)
Arriva Medical, LLC; Alere, Inc.; and Abbott Laboratories, Inc.,	)
Defendants.	)

THIRD AMENDED QUI TAM COMPLAINT

JURY TRIAL DEMANDED

COMES NOW, *qui tam* Plaintiff Troy Olhausen, on behalf of the United States and on his own behalf, who states and alleges as follows:

INTRODUCTION

1. This is a *qui tam* action for civil damages and penalties brought pursuant to 31 U.S.C. § 3730(b) for a fraudulent course of conduct connected to Medicare billing in violation of the federal False Claims Act, 31 U.S.C. § 3729, *et seq*. The fraudulent course of conduct alleged herein includes Arriva Medical, LLC and Alere, Inc.'s fraudulent course Medicare billing for diabetic and other medical supplies.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. § 1331. This case is not based upon the prior public disclosures of allegations or transactions as defined by 31 U.S.C. §3730(e)(4)(A). If any such public disclosures have occurred, the *qui tam* Plaintiff qualifies as an "original source" pursuant to 31 U.S.C. § 3730(e)(4)(B).

3. The Court has personal jurisdiction over Defendants because the Defendants transact business in this district and certain acts complained of occurred in this district.

4. Venue is proper in this district under 31 U.S.C. § 3732(a) because certain acts complained of occurred in this district.

PARTIES

5. *Qui Tam* Plaintiff Troy Olhausen is a resident of Arizona and former employee of Arriva Medical, LLC ("Arriva") and Alere, Inc. ("Alere").

6. Defendant Arriva is a limited liability company registered in Florida with its headquarters in Coral Springs, Florida. Arriva was a mail-order supplier of blood glucose monitoring supplies under the Medicare competitive bidding program.

7. Defendant Alere is a Delaware corporation headquartered in Waltham, Massachusetts.

8. Defendant Abbott Laboratories, Inc. ("Abbott") is an Illinois corporation with its headquarters in Lake Bluff, Illinois.

APPLICABLE STATUTES AND REGULATIONS

Federal and State Statutes

9. **The False Claims Act**. The False Claims Act provides, in pertinent part, that any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable to the United States Government. 31 U.S.C. §§ 3729(a)(1)(A)-(B).

10. The terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

11. The term "claim" means:

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
>
> (i) is presented to an officer, employee, or agent of the United States; or
>
> (ii) is made to be a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
>
> (I) provides or has provided any portion of the money or property requested or demanded; or
>
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . ..

31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

12. Regarding establishment of competitive acquisition programs, 42 U.S.C. § 1395w-3(a)(1)(A) provides, in pertinent part:

> The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in

> paragraph (2)) for which payment is made under this part.

13. Items and services are described, pursuant to 42 U.S.C. § 1395w-3(a)(2), as:

> (A) Durable medical equipment and medical supplies
>
> Covered items (as defined in section 1395m(a)(13) of this title) for which payment would otherwise be made under section 1395m(a) of this title, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment . . ..

14. Regarding program requirements, 42 U.S.C. § 1395w-3(b)(1) states that "[i]n general," "[t]he Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services."

15. The conditions for awarding contract, pursuant to 42 U.S.C. §1395w-3(b)(2)(A), include:

> (A) In general
>
> The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1395m(a)(20) of this title.

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(v) The entity meets applicable State licensure requirements.

16. **Competitive acquisition of certain items and services: Contents of contract - Disclosure of subcontractors.** 42 U.S.C. § 1395w-3(b)(3)(C) provides, in pertinent part:

(i) Initial disclosure

Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on--

> (I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and
>
> (II) whether each such subcontractor meets the requirement of section 1395m(a)(20)(F)(i) of this title, if applicable to such subcontractor.
>
> (ii) Subsequent disclosure
>
> Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

17. **Special payment rules for particular items and services: Identification of quality standards – Application of accreditation requirement.** 42 U.S.C. § 1395m(a)(20)(F)(i) provides, in pertinent part:

> In implementing quality standards under this paragraph--
>
> (i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards . . ..

18. **Special payment rules for particular items and services: Identification of quality standards – Prohibition against unsolicited telephone contacts by suppliers.** 42 U.S.C. § 1395m(a)(17) provides, in pertinent part:

> (A) In general
>
> A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:
>
> (i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.
>
> (ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.
>
> (iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.
>
> (B) Prohibiting payment for items furnished subsequent to unsolicited contacts

> If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

19. **Criminal penalties for acts involving Federal health care programs.** 42 U.S.C. § 1320a-7b provides, in pertinent part:

> (b) Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or

> covertly, in cash or in kind to any person to induce such person--
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

Agency Regulations and Guidance

20. **Medicare Program Integrity Manual: Chapter 3 – Verifying Potential Errors and Taking Corrective Actions.** Section 3.2.3 on Requesting Additional Documentation During Prepayment and Postpayment Review provides, in pertinent part:

> In certain circumstances, [Medicare auditors/ reviewers] may not be able to make a determination on a claim they have chosen for review based upon the information on the claim, its attachments, or the billing history found in the claims processing system (if applicable) or the Common Working File (CWF). In those instances, the reviewer shall solicit

> documentation from the provider or supplier by issuing an additional documentation request (ADR). The term ADR refers to all documentation requests associated with prepayment review and postpayment review. [Auditors/reviewers] have the discretion to collect documentation related to the beneficiary's condition before and after a service in order to get a more complete picture of the beneficiary's clinical condition. [Auditors/reviewers] shall not deny other claims submitted before or after the claim in question unless appropriate consideration is given to the actual additional claims and associated documentation. . . .

21. **Medicare Program Integrity Manual: Chapter 5 – Items and Services Having Special DME Review Considerations.** Section 5.2.1 on Physician Orders provides that the "supplier for all Durable Medical Equipment, Prosthetic, and Orthotic Supplies (DMEPOS) is required to keep on file a physician prescription (order). A supplier must have an order from the treating physician before dispensing any DMEPOS item to a beneficiary."

22. **Medicare Program Integrity Manual: Chapter 5 – Items and Services Having Special DME Review Considerations.** Section 5.2.2 on Verbal and Preliminary Written Orders provides that, except as noted, "suppliers may dispense most" DMEPOS items "based on a verbal order or preliminary written order from the treating physician."

23. **Medicare Program Integrity Manual: Chapter 5 – Items and Services Having Special**

DME Review Considerations. Section 5.2.7 on Requirement of New Orders provides, in pertinent part:

> A new order is required in the following situations:
>
> - There is a change in the order for the accessory, supply, drug, etc.;
> - On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;
> - When an item is replaced; and
> - When there is a change in the supplier, if the recipient supplier did not obtain a valid order for the DMEPOS item from the transferring supplier.[1]

24. Conditions of Payment for DMEPOS Suppliers. 42 C.F.R. § 410.38(d) provides, in pertinent part:

> (d) Conditions of Payment. The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.
>
> (1) Written Order/Prescription. All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when

[1] This bullet point was added in 2017.

reviewing for compliance with standardized written order/prescription elements.

25. **Medicare Claims Processing Manual: Chapter 1 – General Billing Requirements.** Section 50.1.2 on Beneficiary Request for Payment on Provider Record provides, in pertinent part:

> A participating provider . . . must use a procedure under which the signature of the patient (or his representative) on its records will serve as a request for payment for services of the provider. To implement this procedure the provider must incorporate language to the following effect in its records:
>
> . . .
>
> I request payment of authorized Medicare benefits to me or on my behalf for any services furnished me by or in (name of provider). I authorize any holder of medical or other information about me to release to Medicare and its agents any information needed to determine these benefits or benefits for related services. . . . For other services the request is effective until revoked. . . .

26. **Medicare Claims Processing Manual: Chapter 1 – General Billing Requirements.** Section 50.1.6 on When Beneficiary Statement is Not Required for Physician/Supplier Claim provides, in pertinent part:

A. Enrollee Signature Requirements

> A request for payment signed by the enrollee must be filed on or with each claim for charge basis reimbursement except as provided below. All rules apply to both assigned and unassigned claims unless otherwise indicated.
>
> 1. When no enrollee signature required:
>
> a. Claim submitted for diagnostic tests or test interpretations performed in a medical facility which has no contact with enrollee.
>
> b. Unassigned claim submitted by a public welfare agency on a bill which is paid.
>
> c. Enrollee deceased, bill unpaid and the physician or supplier agrees to accept Medicare approved amount as the full charge.

27. **Centers for Medicare & Medicaid Services: Local Coverage Determination (LCD) – Glucose Monitors.** LCD L33822 provides, in pertinent part:

> For a beneficiary who is currently being treated with insulin injections, more than 300 test strips and more than 300 lancets every 3 months are covered if criteria (a) – (c) below are met.
>
> a. Basic coverage criteria (1)-(2) listed above for all home glucose monitors and related accessories and supplies are met; and,
>
> b. Within the six (6) months prior to ordering quantities of strips and lancets that exceed the utilization guidelines, the treating practitioner has had an in-person visit with the beneficiary to evaluate their diabetes

control and their need for the specific quantity of supplies that exceeds the usual utilization amounts described above; and,

c. Every six (6) months, for continued dispensing of quantities of testing supplies that exceed the usual utilization amounts, the treating practitioner must verify adherence to the high utilization testing regimen.

If neither basic coverage criterion (1) or (2) is met, all testing supplies will be denied as not reasonable and necessary. If quantities of test strips or lancets that exceed the utilization guidelines are provided and criteria (a) – (c) are not met, the amount in excess will be denied as not reasonable and necessary.

28. **Centers for Medicare & Medicaid Services: Local Coverage Determination (LCD) – Glucose Monitors.** LCD L33822 provides, in pertinent part:

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. . . .

> For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/ designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.
>
> Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted.

29. **Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.** 42 C.F.R § 424.57(c) applies to the Application certification standards. The supplier must meet and certify in its application for billing privileges that it meets and will continue to meet the following standards:

> . . .
>
> (4) Fills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any

> entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity;
>
> . . .
>
> (24) All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if [Centers for Medicare & Medicaid Services ("CMS")] determines that they are not in compliance with the DMEPOS quality standards.

30. **Conditions for Medicare Payment: Subpart P. Requirements for Establishing and Maintaining Medicare Billing Privileges.** 42 C.F.R. § 424.535 on Revocation of enrollment in the Medicare program provides, in pertinent part:

> (a) Reasons for revocation. CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement or supplier agreement for the following reasons:
>
> (1) Noncompliance. The provider or supplier is determined to not be in compliance with the enrollment requirements described in this subpart P or in the enrollment application applicable for its

provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

. . .

(h) Submission of claims for services furnished before revocation.

(1)(i) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

(ii) A revoked HHA must submit all claims for items and services within 60 days after the later of the following:

(A) The effective date of the revocation.

(B) The date that the HHA's last payable episode ends.

(2) Nothing in this paragraph (h) impacts the requirements of § 424.44 regarding the timely filing of claims.

Medicare Part B Program

31. Title XVII of the Social Security Act prescribes coverage requirements under Part B of the Medicare program, which covers durable medical equipment ("DME"). DME is "equipment furnished by a supplier . . . that—(1) [c]an withstand repeated use; (2) [i]s

primarily and customarily used to serve a medical purpose; (3) [g]enerally is not useful to an individual in the absence of an illness or injury; and (4) [i]s appropriate for use in the home." 42 C.F.R. § 414.202.

32. Medicare Part B covers blood sugar self-testing equipment, including blood sugar monitors,[2] blood sugar testing strips, lancet devices, batteries, lancets, and glucose control solutions if the patient meets the following requirements: (1) the patient is under the physician's care for diabetes; (2) the accessories and supplies have been ordered by the patient's treating physician; (3) the patient (or patient's caregiver) has been trained to use the required equipment in an appropriate manner; and (4) the equipment is designed for home rather than clinical use.

33. In general, Medicare will not pay for any expense that is "not reasonab[ly] necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

34. Medicare Part B also limits how often Medicare will pay for DME such as diabetic testing supplies. For glucose monitors, Medicare will only pay for a replacement if the device has continuous use by the beneficiary for the product's reasonable useful lifetime or if the item has been lost, stolen, or irreparably damaged. 42 C.F.R. § 414.210(f). The reasonable useful

---

[2] The devices diabetic beneficiaries use to test their blood sugar are known as both "monitors" and "meters." The two terms are used interchangeably.

lifetime of glucose monitors is recognized by Medicare to be at least five years. 42 C.F.R. § 414.210(f).

35. With respect to testing strips, Medicare Part B covers up to 100 per month for beneficiaries who are insulin dependent and up to 100 per three months for beneficiaries who are not insulin dependent. Suppliers are not permitted to bill for more than three months of supplies at a time.

36. As an additional requirement for diabetic testing strips, the Medicare Program Integrity Manual requires DME suppliers to have a detailed written order from a physician prior to billing Medicare. CMS, Medicare Program Integrity Manual, ch. 5.2.3, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html.

37. If a supplier does not have an order "that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary." *Id.*

38. Any time that a beneficiary switches from one supplier to another, the new supplier is required to obtain a new order prior to billing Medicare. *Id.* at ch. 5.2.4.

39. The Medicare Part B diabetic supplies landscape has recently undergone major reform. The Medicare Modernization Act established requirements for a new competitive bidding program for certain durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). Under the competitive bidding program, DMEPOS suppliers submit competitive bids to furnish

diabetic supplies and CMS awards contracts to enough suppliers to meet beneficiary demand for the bid items. The bids represent the amount a DMEPOS supplier is willing to accept to provide specified items or services to a Medicare beneficiary. All DMEPOS suppliers must comply with Medicare enrollment rules, be licensed and accredited, and meet certain financial standards.

40. On July 1, 2013, this program was expanded to include a national mail order program for diabetic suppliers. As of that date, beneficiaries looking to obtain diabetes testing supplies through the mail were required to get those supplies from an approved contract supplier. 42 C.F.R. § 414.408(e). At the same time, contract suppliers—*i.e.*, those mail order diabetic suppliers that were awarded contracts by CMS—were required to furnish mail order diabetic testing supplies to Medicare beneficiaries in all parts of the United States, including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. The CMS opened the 60-day bid window for the national mail order competition on January 30, 2012, and began the contracting process in late 2012.

41. Additionally, under the terms of their contracts with CMS, all diabetic suppliers were prohibited from "influencing or incentivizing the beneficiary by persuading, pressuring, or advising them to switch from their current brand or for new beneficiaries from their preferred brand of glucose monitor and testing supplies." 42 C.F.R. § 414.422(e)(3). The supplier may not speak to beneficiaries about alternative brands "unless the beneficiary requests such information." *Id.*

42. Contracted mail-order diabetic testing suppliers are obligated to "furnish the brand of diabetic testing supplies that work with the home blood glucose monitor selected by the beneficiary." 42 C.F.R. § 414.422(e)(3).

43. If a contract supplier violates the terms of its agreement with CMS, CMS is expressly authorized to suspend the contract, terminate the contract, and "[a]vail itself of all other remedies allowed by law." 42 C.F.R. § 414.422(g).

FACTUAL BACKGROUND

Defendants' Corporate Structure and Background

44. In 2008, Dave Wallace and Timothy Stocksdale formed Arriva which provided mail-order diabetic testing supplies and other medical products, including, but not limited to, orthotic braces, heating pads, and erectile dysfunction vacuum therapy devices.

45. Arriva was headquartered in Coral Springs, Florida.

46. In 2011, Alere purchased Arriva.

47. Thereafter, Alere purchased National Diabetic Pharmacy ("National Diabetic") which operated a call center and billing operations in the Philippines. Alere moved all National Diabetic's beneficiaries into Arriva and formed a separate company named Arriva Medical Philippines, Inc. ("Arriva Philippines") on September 16, 2011.

48. Arriva Philippines was incorporated as an indirect subsidiary of Alere.

49. Alere purchased National Diabetic and established Arriva Philippines to increase Arriva's beneficiary base and to utilize its existing Philippines workforce to service both Alere's and Arriva's beneficiaries in the U.S., along with Alere Home Monitoring's beneficiaries (a company Arriva did not disclose to Medicare).

50. In April 2013, Arriva acquired Discount Diabetic, LLC ("Discount Diabetic"), which was owned by Mr. Olhausen.

51. In January 2013, prior to the acquisition, Discount Diabetic won a competitive bid contract with Medicare to bill for mail order diabetic supplies. Discount Diabetic was one of the few suppliers to obtain such a contract, and at that time, Arriva had not yet obtained a contract of its own.

52. Three weeks after Arriva executed a binding letter of intent to purchase Discount Diabetic, CMS awarded Arriva the same competitive bid contract as Discount Diabetic.

53. Despite obtaining their own contract, Arriva continued with the purchase of Discount Diabetic, and Mr. Olhausen executed a two-year employment agreement with Arriva. Mr. Olhausen stayed on as Arriva's Sr. Vice President of Business Development and Marketing, reporting directly to Arriva's President, William "Chip" Stocksdale, brother of Arriva's co-founder, Tim Stocksdale.

54. In April 2013, Arriva purchased Liberty Medical Supplies's ("Liberty Medical") Medicare business. In 2014, Arriva acquired Diabetes Care Club/Simplex Medical ("Diabetes Care Club"). These companies had 400,000 and 200,000 Medicare beneficiaries, respectively.

55. Liberty Medical was previously owned by Express Scripts, Inc. ("Express Scripts").

56. On Alere's orders, Arriva Philippines eventually employed more than 800 employees and comprised an estimated 80% of Arriva's workforce providing services to U.S. beneficiaries.

57. Arriva Philippines' employees performed Arriva's material day-to-day operations, handling most initial intake calls, reorders, doctor prescriptions orders, and medical records request and billing for Arriva's U.S. beneficiaries.

58. Arriva Philippines billed claims to CMS as if the services were provided and the claims were processed in Arriva's Florida office.

59. Arriva Philippines billed Arriva at cost plus five percent. There was no contract between these two entities, except for a Business Associate Agreement executed in 2013.

60. Neither Arriva nor Alere ever disclosed Arriva Philippines to CMS.

61. Arriva's U.S. division employed only a small staff in Florida to give the appearance that Arriva's mail-order diabetic supplies business was operated in

the U.S. This practice diverted attention away from the fact that the business was primarily operated outside the U.S. and presented a false front to CMS in anticipation for a probable future audit or investigation. Additionally, Arriva operated call centers in Phoenix, Arizona and Tennessee and shipped items from Hebron, Kentucky. Arriva did not notify Medicare of or obtain accreditation or a Medicare supplier number for these locations.

62. In summer 2013, both of Arriva's co-founders, Dave Wallace and Tim Stocksdale, went part-time and subsequently left at the end of that year. William "Chip" Stocksdale, Tim Stocksdale's brother, took over as Arriva's President.

63. In 2014, the Tennessee Department of Justice began investigating Arriva because a whistleblower lawsuit filed against Arriva. This suit is ongoing, and the investigation continued during Mr. Olhausen's time at Arriva.

64. In 2015, Alere promoted Claudio Araujo to Vice President of Alere Cardiometabolic Services and he became an Alere employee. Chip Stocksdale left Arriva. Mr. Araujo took a more active role in Arriva's management, overseeing Arriva's operations.

65. In 2016, Alere and Abbott entered into a purchase agreement for Abbott to purchase Alere. Shortly after entering this agreement, Alere reported accounting issues and bribery in foreign countries to the SEC.

66. On January 25, 2016, Arriva received a notice of results of prepayment claims review from NHIC, Corp

(a DME Medicare Administrative Contractor) in which NHIC determined that only 1% of Arriva's claims were acceptable as billed, 99% of the claims should have been denied based on medical necessity, and the overall charge denial rate was 96.5%.

67. On November 7, 2016, Arriva received an educational audit from CMS, in which 95% of Arriva's claims were denied for lack of medical necessity.

68. In November 2016, Arriva lost its Medicare billing number because it billed for deceased beneficiaries. Abbott tried to pull out of the purchase agreement and both companies filed suit. As part of its reason for attempting to cancel its purchase of Alere, Abbott cited Arriva's loss of its Medicare billing number.

69. In February 2017, Alere purchased American Medical Supplies, Inc. ("American Medical") which had a valid Medicare billing number and a competitive bid contract.

70. Despite its purchase of American Medical, which had a valid Medicare billing number, Alere did not switch its beneficiaries over to American Medical. Upon information and belief, Alere did this for two reasons: (1) to avoid a Medicare review and, as a result, lose American Medical's billing number; and (2) to avoid losing its appeal to win back Arriva's bidding number as it had obtained a suitable replacement to continue billing Medicare.

71. In April 2017, both Alere and Abbott renegotiated the terms of the purchase and due diligence continued. After Arriva lost its billing number

and before Abbott shut down Arriva to limit its liability, Arriva furnished approximately $70 million in products to its beneficiaries.

72. In April 2017, Mr. Olhausen was transferred from Arriva to Alere and became the General Manager of American Medical. Mr. Olhausen reported to the Global President of Alere Cardiometric Services.

73. Despite his transfer to Alere, Mr. Olhausen continued to work for Arriva, participated in its weekly meetings, and had Arriva employees still reporting to him.

74. Claudio Araujo also reported to Daniella Cramp, the Global President of Alere Cardiometric Services. The companies were kept as separate entities to mask the connection between Arriva and Alere.

75. Ms. Cramp was particularly involved in controlling Arriva's actions, directing Arriva to use the Philippines location and reduce overhead expenses.

76. In addition, Ms. Cramp negotiated contracts on behalf of Arriva with diabetic suppliers.

77. In October 2017, Abbott completed its purchase of Alere.

78. Mr. Olhausen attempted to purchase Arriva and American Medical from Abbott as a stock purchase; however, Abbott declined the deal.

79. Eventually, Abbott decided to control Arriva's shutdown to limit its liability.

80. In November 2016—after Arriva's Medicare billing number was revoked—Abbott instructed Arriva to bill its claims.

81. Many of these claims, as described below, were claims for items that were medically unnecessary.

82. Mr. Olhausen instructed an Abbott executive in charge of the operations of Arriva, Robert "Bob" Kunkler, that many of Arriva's claims were for medically unnecessary items and that Arriva's use of the Philippines was impermissible.

83. Despite Mr. Olhausen's warning, Abbott instructed Arriva to submit these false claims to Medicare beginning in December 2017.

84. Until the revocation of Arriva's Medicare billing number, Arriva's business generated millions of dollars in revenue. Alere took advantage of Arriva's profitability, transferring over $100 million from Arriva to itself. Alere identified these transfers as "loans," but failed, as of the close of its operation, to repay Arriva.

85. Alere controlled Arriva's operations with many executives at Alere also working at Arriva.

86. Additionally, Arriva held $12 million in reserve in preparation for an extrapolation audit by Medicare regarding inappropriate billing of back brace claims from 2014 and a prior Arriva failed audit.

87. Since 2012, Arriva billed Medicare approximately $800 million for its supplies.

88. Through his high-level position with the company, Mr. Olhausen learned of the practices alleged herein.

Defendants' Schemes to Defraud

A. Invalid Prescriptions

89. As of April 2013, when Mr. Olhausen became an employee of Arriva, Mr. Olhausen became aware of Arriva's practice of providing supplies to its beneficiaries without obtaining new, valid prescriptions. These improper practices continued through Mr. Olhausen's departure from Alere.

90. Arriva knowingly provided diabetic supplies to its beneficiaries and billed Medicare without obtaining new, valid prescriptions in violation of CMS's Program Integrity Manual.

91. For instance, Arriva failed to obtain new prescriptions: (1) after one year in those States where a beneficiary must obtain a new doctor's prescription every 12 to 18 months; and (2) when its beneficiaries switched doctors.

92. Specifically, Arriva failed to obtain new prescriptions for its beneficiaries when those prescriptions expired in 29 states that require new prescriptions every 12 months and in one state which requires a new prescription every 18 months. Instead of obtaining new prescriptions, Arriva knowingly continued to place orders using old, invalid prescriptions.

93. Placing orders using old, invalid prescriptions violates 42 C.F.R. § 410.38(d)(1), which requires a written order or prescription for Medicare payment.[3]

94. An email between Mr. Olhausen and Arriva upper management included a list of the 29 states that require new prescriptions every 12 months and the one state that requires a new prescription every 18 months.

95. Pursuant to the following statutes and regulations, the following states prohibit refilling a prescription after 12 months (or 1 year) or after 18 months and require a new prescription for the item: Ariz. Rev. Stat. Ann. § 32-1968; Ind. Code Ann. § 25-26-13-25(h); Iowa Code Ann. § 155A.29(1) (eighteen months); Kan. Stat. Ann. § 65-1637(i); Mont. Code Ann. § 37-7-401; Neb. Rev. Stat. Ann. § 38-2870(1); Nev. Rev. Stat. Ann. § 639.2393; Ohio Rev. Code Ann. § 4729.281; S.C. Code Ann. § 40-43-86 (two years); Utah Code Ann. § 58-17b-609; W. Va. Code Ann. § 30-5-26; *see also* 3 Colo. Code Regs. § 719-1:3.00.00; Fla. Admin. Code Ann. r. 64B16-27.211; Idaho Admin. Code r. 27.01.03.300 (2018) (limiting refills of prescriptions of non-controlled substances to 15 months); 201 Ky. Admin. Regs. 2:185; 46 La. Admin. Code Pt LIII, 2525; Mich. Admin. Code R 338.479b; 30 Code Miss. R. Pt. 3001, Art. XII; Mo. Code Regs. Ann. tit. 20, § 2220-2.110; N.H. Code Admin. R. § 14(a); N.J. Admin. Code § 13:39-7.3(a);

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[3] In addition, Arriva's Competitive Bidding contracts with CMS required Arriva to comply with all state laws. In addition, the Medicare Program Integrity Manual Section 5.2.5-6 requires a new prescription when states require renewals.

Okla. Admin. Code 535:15-3-11; Or. Admin. R. 855-041-1125; 49 Pa. Code § 27.18; 216 R.I. Code R. 40-15-1.4; Tenn. Comp. R. & Regs. 1140-03-.03; 20-4 Vt. Code R. § 1400; Va. Code Ann. § 54.1-3411.

96. In an April 8, 2014, email from Mr. Olhausen to Arriva's legal advisor (who was not yet an attorney), Mr. Olhausen warned that Arriva was not in compliance with the 12- and 18-month prescription rules.

97. A July 24, 2013, email between Arriva upper management shared advice received from a consultant who advised Arriva that many private insurance companies follow the 12-month rule along with State Medicaids.

98. In a series of emails between Mr. Olhausen, Claudio Araujo, and another Arriva employee, Mr. Olhausen warned Arriva against sending supplies when its beneficiaries' prescriptions were over a year old.

99. Arriva implemented for a brief time a procedure requiring the updated prescription before sending supplies--but, when it learned of the impact to its profits, Arriva abandoned the procedure and reverted to improperly sending supplies to beneficiaries with expired prescriptions.

100. Upon information and belief, Arriva improperly submitted these claims to Medicare for payment, did receive payment, and Medicare would not have paid Arriva's claims for DMEPOS items when those prescriptions were invalid.

101. For example, the Medicare Appeals Council determined Medicare overpaid for a power wheelchair when there was no prescription on file. *In the Case of Allied Home Med., Inc. (Appellant) (Beneficiary) Cigna Gov't Servs. (Contractor) Claim for Supplementary Med. Ins. Benefits (Part b) (Hic No.) 1-497717700 (Alj Appeal No.)*, 2010 WL 2831001 (H.H.S. Feb. 8, 2010).

102. Arriva also failed to obtain new prescriptions when its beneficiaries began seeing a new treating physician in violation of 42 C.F.R. § 410.38(d).

103. Despite these warnings and knowledge of the law, Arriva continued to fail to obtain new prescriptions for its beneficiaries when those prescriptions expired and nonetheless knowingly furnished its beneficiaries with supplies without valid prescriptions.

104. In an email to Troy Olhausen, an Arriva manager sent the following message:

> Hi,
> Here's another excerpt from the training manual…
> Physician changes in FLASH Direct are required if:
>
> 1. There is a NEW doctor AND
> 2. There is an *increase* in times testing
>
> Note: If the physician has changed, however, the times testing remains the same, the new physician information is only added to the comments tab.
> They do not confirm the dr unless the pts test time increases. If the pt says the dr changed, but is still testing the same, they do not get a new rx

> from the new dr. They put a note on the acct that there is a new dr and that's it. If they increase testing and have a new dr., they put the new dr on the acct, send the rx, then put the old dr back on the acct so they can continue shipping under the old dr. The LCD says that the RX must be from the treating physician.

105. Arriva conducted internal audits, noting when it did not have the necessary prescriptions for items it submitted to Medicare for payment.

106. For instance, in one of these audits, Arriva identified a claim submitted for patient # 12153242[4] in April 2013, indicating that "MD CIRCLED ALL ITEMS EXCEPT CONTROL SOLUTION, CONTROL SOLUTION WAS SHIPPED AND BILLED."

107. For another patient, Arriva identified a claim submitted for patient # 20393846 in April 2013, indicating that "MISSING ACQ DOF AND ARRIVA DOF."[5]

108. For another patient, Arriva identified a claim submitted for patient # 12170244 in April 2013, indicating that "DOF HAS METER AND BATTERY LINED OUT, SHIPPED AND BILLED FOR METER."

109. For another patient, Arriva identified a claim submitted for patient # 20646383 in May 2013,

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[4] These patient numbers are internal Arriva patient numbers and do not reveal any protected health information.

[5] DOF, or Doctor Order Form, was Arriva's shorthand for a prescription.

indicating that "ACQ DOF 1X TESTING ARRIVA DOF 1X TESTING SUPPLIES SENT FOR 2X TESTING."

110. For another patient, Arriva identified a claim submitted for patient # 21200301 in May 2013, indicating that "ARRIVA DOF MD LINED OUT METER, THIS ITEM WAS BILLED AND PAID FOR BY MEDICARE."

B. No Authorization of Benefits

111. As of April 2013, when Mr. Olhausen became an employee of Arriva, Mr. Olhausen became aware of Arriva's practice of providing medical supplies to beneficiaries without obtaining the required Assignment of Benefits ("AoB"). This improper practice continued through Mr. Olhausen's departure from Alere.

112. Pursuant to 42 C.F.R. § 424.32(a)(3), each claim billed to Medicare must be signed by the beneficiary or on behalf of the beneficiary.

113. Pursuant to 42 C.F.R. § 424.36(a), a beneficiary's signature is required on claims billed to Medicare including the "actual claim form or such form that contains adequate notice to the beneficiary or other authorized individual that for the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary."

114. Pursuant to 42 C.F.R. § 424.55(a), "Medicare pays the supplier for covered services if the beneficiary (or the person authorized to request payment on the

beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment."

115. Pursuant to 42 C.F.R. § 424.55(c):

> when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

116. Pursuant to 42 C.F.R. § 414.404(a), Subpart F related to competitive bidding for certain DMEPOS's "applies to all suppliers that furnish the items defined in § 414.402 to beneficiaries . . .."

117. Pursuant to 42 C.F.R. § 414.402, "item" is defined as:

> a product included in a competitive bidding program that is identified by a HCPCS code, . . . and includes the services directly related to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are:
>
> (1) Durable medical equipment (DME) . . .
>
> (2) Supplies necessary for the effective use of DME other than inhalation and infusion drugs.
>
> (3) Enteral nutrients, equipment, and supplies.

> (4) Off-the-shelf orthotics, which are orthotics . . . that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

118. Pursuant to 42 C.F.R. § 414.408(c), "Payment for an item furnished under [Subpart F. Competitive Bidding for Certain DMEPOS] is made on an assignment-related basis."

119. Per the CMS Medicare Claims Processing Manual, all Medicare billing suppliers are required to obtain AoBs from their beneficiaries before submitting crossover claims to Medicaid/Medigap.

120. Heating pads and vacuum erection devices, while considered Durable Medical Equipment, were not items covered by the DMEPOS competitive bidding program and were not identified by a HCPCS code in either the 2013 or 2016 competitive bidding programs.

121. Back, knee, ankle, and wrist braces were not classified as off-the-shelf orthotics until 2015.

122. As heating pads, vacuum erection devices, back braces, knee braces, ankle braces, and wrist braces were not covered by the DMEPOS competitive bidding program, pursuant to 42 C.F.R. § 424.32(a)(3), 42 C.F.R. § 424.36(a), and 42 C.F.R. § 424.55(a), AoBs were still required for claims for these items to receive payment from Medicare.

123. Arriva knew this was required and had an official policy to obtain AoBs from its beneficiaries through the Customer Account Form; however, in the company's call scripts, it instructed its employees not to ask about the Customer Account Form if the beneficiary had not yet returned it. Instead, Arriva submitted its beneficiaries' claims, falsely indicating it had signatures on file in both the AoBs and Medigap claim lines.

124. Arriva instructed its employees not to discuss the AoBs unless it was brought up by the beneficiary. If a beneficiary asked about the AoB, Arriva's call script instructed employees to tell the beneficiary that mailing the AoB was "unnecessary."

125. Arriva's upper level management were in possession of these call scripts and regularly discussed them in weekly meetings, including revising the scripts.

126. In summer 2013, Mr. Olhausen suggested in an Arriva managers' meeting that Arriva obtain its beneficiaries' AoBs electronically from the beneficiary base.

127. Based on Mr. Olhausen's suggestion, Arriva considered adding a request for the beneficiary to agree to an AoB and several drafts of such a request were circulated throughout Arriva's management throughout fall 2013.

128. Arriva, however, declined to implement the electronic AoB request because Tricia Romero, Arriva's then U.S. Manager of Sales, complained the addition

would make calls lengthier and her sales representatives would lose commission money.

129. In an email to various Arriva managers, on September 24, 2013, Arriva advised that its call center agents no longer asked for the AoBs included in Arriva's Customer Account Form:

- Customer Account Form (CAF):
    - A CAF will continue to be included in the initial shipment to [beneficiaries], however without a pre-paid envelope.
    - If the [beneficiary] returns the CAF to us, it can still be viewed in Document Imaging (no process change).
    - Agents are no longer required to ask about the CAF unless a [beneficiary] asks about it.
    - If the [beneficiary] asks about the CAF, the agents will read the following script: "Mr./Mrs. ([beneficiary] name), to ensure that your testing supplies are delivered promptly and without interruption let me read you this disclosure and it won't be necessary for you to return the form to us. You authorize Arriva Medical to contact you, your physician and your insurance company to discuss your order and to submit claims on your behalf for products authorized and received by you. Do you have any questions?" Respond to any questions as necessary and proceed with

> any other requirements of the call. Insert a standard CAF note in the Comments Tab: PT/CG AGREED TO CAF LANGUAGE.

130. When Arriva submitted its claims to Medicare and Medigap crossover, Arriva told the agencies it had a "signature on file" when, in fact, these signed AoBs did not exist.

131. Arriva failed to seek out AoBs from its beneficiaries but still sent orthotic braces, vacuum erection devices, and heating pads to them. Arriva also submitted claims for diabetic supplies, falsely claiming it had signatures for the Medigap claim line.

132. Arriva knew it did not have signed AoBs for large numbers of beneficiaries yet represented to CMS that it had a signed AoB on file for every claim submitted to CMS.

133. Arriva knew it did not have signed AoBs because it regularly conducted internal audits and hired an outside consulting firm to conduct audits of its claims to CMS.

134. In one of these audits, a consultant found that for new orders in the first quarter of 2013, Arriva only obtained AoBs for sixty percent (60%) of its submitted claims.

135. The consultant found for the second quarter of 2013 that Arriva only obtained AoBs for sixty-five percent (65%) of the claims submitted for new orders and seventy-eight percent (78%) of the claims submitted for its reorders.

136. For the third quarter of 2015, the consultants found that, on average, Arriva had an AoB on file for the beneficiary for only fifty-three percent (53%) of heating pads Arriva shipped to its beneficiaries and billed to Medicare.

137. Despite receiving similar audits and results monthly, Arriva failed to improve its collection of AoBs for claims it billed to Medicare for heating pads, vacuum erection devices, and orthotic braces shipped to its beneficiaries.

138. Instead, Arriva continued to check the "authorization on file" box when it submitted claims to Medicare.

139. If an AoB is not on file for a beneficiary, Medicare will deny the claim if the AoB is not available upon request. *Centers for Medicare & Medicaid Services, Jurisdiction B DME MAC Supplier Manual*, Chapter 12: Claim Submission, at 4 (Dec. 2010).

140. Arriva knew Medicare would deny the claims it submitted for heating pads, vacuum erection devices, and orthotic braces shipped to its beneficiaries for Arriva's failure to obtain an AoB and/or if it didn't check the box indicating it had an AoB on file.

141. Nonetheless, Arriva continued to submit claims to Medicare for these items without having an AoB on file, in violation of the False Claims Act.

142. By virtue of sharing officers and directors with Arriva and communications with Arriva, Alere knew of the audit results.

143. Despite this knowledge, Alere continued to direct Arriva to submit these claims to Medicare.

144. As most claims submitted by Arriva were routed through Arriva Philippines, Alere knew the audits applied to Arriva Philippines.

145. Alere knew of each of the above-described regulations, and, despite this knowledge, directed Alere's subsidiaries, Arriva Philippines and Arriva, to submit claims for heating pads, vacuum erection devices, and orthotic braces to Medicare and check the box in the claim submission form indicating it had AoBs on file, when in fact it did not.

146. Alere knew that without checking the box indicating it had an AoB on file, Medicare would deny Arriva Philippines' and Arriva's claims for these items.

147. Because Alere knew that Arriva Philippines' and Arriva's claims would be denied if it did not indicate it had AoB's on file, Arriva Philippines and Arriva continued to submit claims to Medicare for these items without having an AoB on file in violation of the False Claims Act.

148. By virtue of the internal audits of Arriva failure to obtain of its beneficiary's AoBs, Arriva and Alere had knowledge that Arriva was overpaid by Medicare as these claims would have been denied had Medicare known that Arriva lacked the necessary assignments.

149. Pursuant to 42 U.S.C. 1320a-7k(d), Arriva and Alere were required to notify Medicare of these overpayments and return the overpayment.

150. Arriva's and Alere's managers had knowledge of this requirement and discussed the requirement to repay Medicare for such overpayments, in particular, discussed hospitals that settled with the Government to resolve claims that the hospital failed to repay overpayments it received from Medicare in October 2016.

151. Arriva's and Alere's did not alert Medicare of these overpayments or refund all overpayments in violation of 42 U.S.C. 3729(b)(3).

C. Medically Unnecessary Medical Devices

152. As of April 2013, when Mr. Olhausen became an employee of Arriva, Mr. Olhausen became aware of Arriva's practice of shipping items to its beneficiaries automatically and without ensuring medical necessity or that a beneficiary's device was no longer working. This improper practice continued through Mr. Olhausen's departure from Alere.

153. Pursuant to 42 U.S.C. § 1395y(a)(1)(A), no payment will be made from Medicare for any expenses incurred for items which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

154. Under 42 C.F.R. § 424.5(a), as a basis for Medicare payment, the following conditions must be met:

(1) Types of services. The services must be—

(i) Covered services, as specified in part 409 or part 410 of this chapter; or

(ii) Services excluded from coverage as custodial care or services not reasonable and necessary, but reimbursable in accordance with §§ 405.332 through 405.334 of this chapter, pertaining to limitation of liability.

(2) Sources of services. The services must have been furnished by a provider, nonparticipating hospital, or supplier that was, at the time it furnished the services, qualified to have payment made for them.

. . .

(4) Certification of need for services. When required, the provider must obtain certification and recertification of the need for the services in accordance with subpart B of this part.

. . .

(6) Sufficient information. The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

155. CMS LCD L33822 requires a DMEPOS supplier to assess whether durable items remain functional and whether a beneficiary is beginning to run out of useable supplies. If a supplier does not comply with these requirements, it is likely the supplies shipped cannot be confirmed as medically necessary.

156. Arriva repeatedly ignored these statutes, along with CMS regulations and shipped several items—batteries, lancing devices, and control solution—automatically and without ensuring medical necessity or that a beneficiary's device was no longer working.

157. Arriva would prepackage boxes of test strips, lancets, and control solution based on the amounts of test strips provided by the manufacturer and the number of times a beneficiary would test each day.

158. For example, Arriva would prepackage boxes with two packages of test strips, one box of lancets, and one bottle of control solution, or, for instance, would prepackage boxes with four packages of test strips, two boxes of lancets, and one bottle of control solution.

159. Arriva would ship the entire box of supplies to its beneficiaries if they ordered additional test strips, regardless of whether the beneficiary's physician ordered the additional supplies or not.

160. Arriva continued to ship and bill for these unnecessary supplies until switching to a new billing system in 2015.

161. In a February 11, 2015, email to Arriva's management, it is noted:

> PLEASE SHARE the following ORDERS UPDATE with your teams!
> All meter boxes include the battery/batteries appropriate for the meter. With this being the case, DO NOT include batteries on an order that includes a meter. As per policy, replacement batteries (in orders without meters) may be shipped every 6-Months.
> Let me know if you have questions.

162. Arriva also shipped durable medical equipment and orthotic devices every five years, regardless of whether the beneficiary indicated their current device needed replacing, in violation of CMS regulations and 42 C.F.R. § 414.210(f).

163. Arriva's employees did not check to see if the beneficiary needed replacement durable medical equipment or an orthotic brace or to see if their current monitor was worn down. Instead, Arriva's employees merely indicated it had been five years since the beneficiary received their glucose monitor and asked that a new one be sent.

164. Pursuant to 42 C.F.R. § 414.210(f), if durable medical equipment or an orthotic device has been in continuous use by the beneficiary for the equipment's reasonable useful lifetime (or if the carrier determines the item is lost, stolen, or irreparably damaged), the beneficiary may elect to obtain a new piece of equipment.

165. That statute, however, does not obviate the need to check whether the equipment is medically necessary.

166. Arriva's call scripts instructed its employees to send DMEPOS without checking with the beneficiary or the beneficiary's doctor as to whether the DMEPOS was medically necessary.

167. A June 4, 2014, Reorder Call Script circulated to Arriva's upper management states the following:

> **If patient has private primary insurance, refer to the <u>Arriva Medical Contracted in-Network Payers Upsells Coverage to determine if upsells are covered.</u>**
>
> **<u>Back Brace:</u>**
> "Medicare/insurance covers a back brace for lower back pain once every 5 years. Our back brace is comfortable and easy to put on. It is designed for treating chronic and acute back pain. We have a 30-day money back guarantee, so it is at no risk to you. Would you like to receive a back brace through your Medicare?"
>
> **<u>Heating Pad:</u>**
> "Because of your back pain, or other conditions you have, you may be eligible to receive a heating pad. Medicare/insurance covers a heating pad once every 5 years. Would you like me to see if you are eligible?"
>
> **<u>E-Pump – OFFERED ONLY TO MALE PATIENTS, SPOUSE CAREGIVER, OR NURSE CAREGIVER (DO NOT DISCUSS WITH OTHER FAMILY MEMBERS):</u>**
> "Medicare/insurance also covers a product for Erectile Dysfunction once every 5 years. Our vacuum therapy pump is the safest treatment

> for ED and it is 95% successful. We also provide a 30-day money back guarantee if you are not completely satisfied. I can place an order for this today along with your supplies."

168. The June 4, 2014, Reorder Call Script included the following instructions to its employees if the beneficiary indicated they agreed to the delivery of the extra product:

> **IF PATIENT RESPONDS YES TO UPSELL:**
> **Confirm the Dr. that treats the patient for their condition.** "Is Dr. ____ (patient diabetes treating physician) also your physician for (Bbrace/HPad /EPump)? We will be faxing a prescription request for the (BBrace/HPad/ EPump) to Dr. _____ today."

169. While Arriva's June 4, 2014, call script instructs its employees to check if the beneficiary's doctor was also their doctor for the device Arriva was upselling, Arriva did not instruct its employees to check with the beneficiary as to whether he/she needed the device or check with the beneficiary's physician as to whether the device was necessary before requesting a prescription.

170. Arriva's instructions even provide guidance for when a beneficiary already has an item:

> **HEATING PAD FEATURES/REBUTTALS:**
> **"I already have a heating pad."** "Our heating pad features Ultra Heat technology that maintains consistent heat for great comfort and allows for either moist or dry heat."

171. Through use of instructions such as those in the June 4, 2014, Reorder Call Script, Arriva shipped thousands of medically unnecessary devices to its beneficiaries and submitted claims for those items to CMS.

172. Arriva knew its shipment of medically unnecessary devices was improper and received complaints from its beneficiaries' physicians, of which Arriva management was aware, regarding Arriva's practice of sending medically unnecessary items.

173. In a January 28, 2014, email from Elizabeth Wallace to Claudio Araujo, Tricia Romero, Mr. Olhausen, and other members of Arriva's management, Ms. Wallace noted the complaints Arriva received about its claims for its beneficiaries:

> The following is part of an email exchange between me, Jessica, and Lance in which I propose adding just one sentence to our existing script for upsales. I would like to discuss this at Claudio's 2pm meeting today, please:
>
> - Our script for selling ancillary products- is making doctors extremely angry. Doctors, in general, don't appreciate receiving DOF [("Doctor Order Form")] requests for ancillary products. Traditionally, as a result of office visits and blood tests, etc., a doctor will identify medications and products that they deem appropriate for their patients. I have had to spend many hours explaining to doctors that we believe that commercials on TV, posters in pharmacies, and phone calls

from Arriva are all legitimate ways for patients to find out about products that may help them to live healthier lives.

But lately what is really making them angry is that they are receiving and increasing number of DOF requests for products that they know their patients don't need. The point they are trying to make is that, although they don't appreciate these requests, at least they shouldn't be surprised by them. At the very least they should receive a request and think, "Yes, this pt does have an issue with (impotence, back pain). I'm not surprised that the pt ordered this product."

I would suggest that part of the script for offering ancillary products is to ask for the dr's information who is currently treating them for that malady. Agents are already required to ask if pt sees a different dr, other than the one we have on file for diabetic supplies, but there is no standard script for asking that question at this time. I would suggest that agents ask, ***"Is Dr. ____ treating you for (back pain/erectile dysfunction) or is there a different doctor to whom we should send a prescription request for the (epump/ hpad/bbrace)?***

We would achieve two things if we made this the standard script: 1. We would call/fax the correct physician. 2. We would indirectly

> communicate to the patient, "This is not just some freebie you can have because you want free stuff. It is a product that will only be prescribed by your dr if it is medically necessary and we want to know who is already treating you for this problem."

174. Despite Ms. Wallace's suggestion in January 2014, Arriva did not confirm its beneficiaries were being treated for their particular issues before asking the beneficiary if they should ship particular products as illustrated in the June 2014 call script quoted above.

175. Arriva's claims for several devices were denied as Medicare contractors would conduct random audits to determine whether Arriva's claims provided sufficient information to warrant payment by Medicare.

176. In an audit by CMS contractor SafeGuard Services LLC ("SafeGuard") evaluating claims from May 15, 2015, to June 30, 2015, SafeGuard concluded that twenty of twenty-one reviewed claims for back braces, heating pads, and knee braces were denied.

177. Primarily, the claims were denied for lack of documentation showing medical necessity and for lack of a physician order within the office notes supporting that the physician initiated the dispensing of the item.

178. For example, one claim for $1,018.78 was denied "as not reasonable and necessary due to lack of MD notes showing the necessity for the Knee Brace . . . Documentation does not include sufficient data to support knee instability or a recent injury or surgery.

Also the CPT code ordered by MD does not match that dispensed."[6]

179. Another claim for $28.40 was denied because the electric heating pad was not medically necessary as "a heating pad is not reasonable and necessary to treat pain due to peripheral neuropathy including but not limited to diabetic neuropathy."

180. A claim for $301.08 was denied due to "lack of MD notes showing the medical necessity for the Spinal orthosis . . . No Documentation from MD submitted to support medical necessity."

181. In the letter transmitting the audit, SafeGuard warned Arriva that it "estimated that you have been overpaid $11,120.38 by Medicare" and informed Arriva:

> This letter is educational in regards to the appropriate submission of Medicare claims. You will be contacted in writing by the MAC regarding any overpayment assessed as a result of this review and your appeal rights. Any concerns related to an overpayment assessed by the MAC must be address to them.
>
> In addition, we remind you that our regulation at 42 CFR § 424.535 authorizes us to revoke Medicare billing privileges under certain conditions. In particular, we note that per 42 CFR § 424.535(a)(8)(ii), CMS has the authority to revoke a currently enrolled provider's or

[6] Relator has omitted Medicare patient numbers for this order and orders identified below to avoid public disclosure of protected health information.

> supplier's Medicare billing privileges if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.

182. Despite SafeGuard's warning, Arriva continued to submit claims it knew were deficient.

183. A January 28, 2016, audit by NHIC Corp., a Durable Medical Equipment Medicare Administrative Contractor, concluded that 1474 claims Arriva submitted to Medicare between September 14, 2015, and December 10, 2015, were denied based on medical necessity issues (99% of total claims reviewed).

184. In a November 24, 2014, audit by AdvanceMed, a Zone Program Integrity Contractor for CMS, thirty claims were audited, and it was determined that each should be denied and that several lacked documentation indicating the medical necessity of the items shipped to Arriva's beneficiaries.

185. For example, AdvanceMed determined that one claim (paid on September 9, 2012) should have been denied as "[t]he detailed written order did not specify what type or level of brace the MD is ordering for the beneficiary nor give a HCPCS number. The order only states lumbar orthosis which is not sufficient information. Therefore the claim is denied payment for invalid order based on Medicare guidelines." The claim should also have been denied because "[t]here was no clinical documentation submitted for review as required by Medicare guidelines to aid in determination of need for the billed item. Therefore the

claim is denied payment based on Medicare guidelines."

186. AdvanceMed determined another claim (paid by Medicare on October 4, 2012) should have been denied as "[t]he detailed written order did not specify what type or level of brace the MD is ordering for the beneficiary nor give a HCPCS number. The order only states lumbar orthosis which is not sufficient information. Therefore the claim is denied payment for invalid order based on Medicare guidelines." The claim should also have been denied as

> [t]he documentation indicates that the only pain that the beneficiary suffers from is lower extremity pain with no mention of back pain. The supplier sent paperwork to MD stating his pt had requested a back brace. They sent an MD order for signature to the MD, and MD signed. The need for the brace was not based on an current or recent evaluation of back pain by the MD of the beneficiary or a complete exam of the back to make the medical decision that this beneficiary needs a specific back brace that stabilizes a specific portion of the spine, in order to treat a current complaint or an issue for which the MD is currently treating as an acute problem. There is nothing in the documentation to show what level of the spine is affected and why an L0627 will be affective for this beneficiary. Therefore the claim is denied payment for insufficient clinical documentation based on Medicare guidelines.

187. In the letter enclosing the audit, AdvanceMed cautioned Arriva that "[b]ased on the findings in this

review, AdvanceMed has determined just cause in requesting an overpayment. As a result of our findings we have determined that you have been overpaid by Medicare in the amount of $9,157.68."

188. Despite this warning, Arriva continued to ship items to its beneficiaries and bill Medicare without regard to the medical necessity (or documentation proving medical necessity) of the items.

189. These audits and denials represent just a small portion of the total claims Arriva submitted.

190. Had further audits or statistical samplings of Arriva's claims been conducted, thousands of Arriva's claims would have been denied, Arriva would have been assessed thousands in overpayment fees, and its billing privileges may have been revoked.

191. Despite the audits and results listed in the above paragraphs, Arriva did not change its practices and billed Medicare (and was subsequently paid by Medicare) for thousands of items that were not medically necessary or lacked sufficient documentation to illustrate medical necessity.

192. Mr. Olhausen recommended that Arriva fax its beneficiaries' doctors upon receipt of a prescription for orthotics, vacuum erection devices, heating pads, and high frequency testers to obtain medical records that document the medical necessity.

193. Despite this knowledge, Arriva maintained its practice of not collecting medical records and continued to ship items which were not medically necessary,

including orthotic braces, vacuum therapy devices for erectile dysfunction, and heating pads.

194. Arriva additionally failed to collect medical records or verify that its high frequency testers visited a doctor in the six months prior to obtaining a prescription and every six months for refills in violation of Medicare regulations and guidance.

195. In an August 14, 2014, email to Arriva managers, it is explained that the call scripts were revised to no longer collect beneficiaries' glucose logs. Instead of obtaining proof the beneficiaries were testing a particular number of times a day, the call center would tell them to see their doctor every six months and assume they are testing a particular number of times each day:

> If High Frequency: "In order for your insurance to pay for your supplies, your physician must receive a Glucose Log from you every 6 months showing that you are testing _____x/day for 15 consecutive days. A glucose log will be included with your order and it's important to see your Dr. every 6 months."

196. Arriva deliberately ignored its duty to meet the documentation requirements to show medical necessity and recklessly disregarded its presentation of claims when it knew the claims presented were not medically necessary.

197. Arriva continued its practice of sending medically unnecessary items when it shipped its beneficiaries more testing strips than the number of

times those beneficiaries were testing their glucose levels.

198. Per CMS LCD33822, suppliers must only send their beneficiaries a number of glucose testing strips sufficient to meet the amount of testing those beneficiaries complete each day, regardless of their doctors' orders.

199. In its call logs, Arriva instructed its employees to ask how often the beneficiary tested each day and compared this to the doctors' orders and instead of sending the number of testing strips to correspond with the beneficiary's actual testing amount, Arriva would send the amount listed on the doctor's order, even if that amount included more testing strips than necessary.

200. Relatedly, Arriva would mail high frequency testing beneficiaries a glucose monitoring test log. If the beneficiary returned the log, Arriva would submit the logs to the beneficiary's doctor for the doctor to sign in violation of the Blood Glucose LCD.

201. Arriva knew it was supposed to corroborate the medical necessity of the testing strips it sent its beneficiaries through the medical record, but instead simply sent the testing logs directly to its beneficiary's physicians in violation of the CMS Program Integrity Manual.

202. In a January 6, 2014, email to Arriva upper management, Arriva confirmed the glucose log letters would be forwarded to the beneficiaries' physicians instead of Arriva corroborating the medical necessity of the testing strip:

> In process – scripting updates to minimize transfers
>
> - Glucose logs are being processed the same way as before the LCD changes. John will setup process to send logs to physicians automatically, by 10/11.

203. Arriva did not change this practice until 2016.

204. Arriva consistently contacted its beneficiaries earlier than necessary and/or permitted in order to ask whether the beneficiary needed more glucose testing supplies. Arriva knowingly and impermissibly instructed its employees to contact its beneficiaries regarding new supplies 28 days prior to their expected depletion date, four days earlier than permitted.

205. Arriva did not change this tactic until October 2016.

206. Arriva took these deliberate, calculated actions knowing it had not obtained a determination of medical necessity.

207. The supplier must provide "sufficient information to determine whether payment is due" under 42 C.F.R. § 424.5(a)(6). Pursuant to 42 U.S.C. § 1395y(a) and 42 C.F.R. § 424.5(a)(1), this means sufficient information to determine the item shipped is medically necessary.

208. Arriva knew it was required to submit documentation illustrating medical necessity pursuant to 42 C.F.R. § 424.5(a)(6), however, continued to submit claims lacking the necessary documentation while

knowing such claims should be denied as they were not entitled to payment.

209. Because Arriva knew Medicare regularly denied claims for the failure to submit documentation illustrating medical necessity and knew that the claims it submitted regularly lacked the necessary documentation to illustrate medical necessity, Arriva submitted false claims to Medicare for payment.

210. By virtue of sharing officers and directors with Arriva and communications with Arriva, Alere knew of the audit results.

211. By virtue of its shared directors and officers, along with its control of its subsidiary Arriva Philippines which processed and submitted the majority of claims under Arriva's DMEPOS Competitive Bidding Contracts, Alere had knowledge of the facts alleged in paragraphs 152 through 210.

212. By virtue of its control of its subsidiary, Arriva Philippines, Alere caused false claims to be submitted to Medicare for medically unnecessary items and claims for items Alere knew it did not possess documentation sufficient to evidence medical necessity.

213. Despite this knowledge, Alere continued to direct Arriva to submit these claims to Medicare.

214. By virtue of the internal audits of Arriva failure to obtain necessary documentation to illustrate medical necessity, Arriva and Alere had knowledge that Arriva was overpaid by Medicare as these claims would have been denied had Medicare known that Arriva lacked the necessary assignments.

215. Pursuant to 42 U.S.C. 1320a-7k(d), Arriva and Alere were required to notify Medicare of these overpayments and return the overpayment.

216. Arriva's and Alere's managers had knowledge of this requirement and discussed the requirement to repay Medicare for such overpayments, in particular, discussed hospitals that settled with the Government to resolve claims that the hospital failed to repay overpayments it received from Medicare in October, 2016.

217. Arriva's and Alere's did not alert Medicare of these overpayments or refund all the overpayments in violation of 42 U.S.C. 3729(b)(3).

218. By virtue of Mr. Olhausen's warning to Abbott that many of Arriva's claims were for medically unnecessary items and Abbott's direction to Arriva to submit claims in December 2017 through January 2018 for dates of service from November, 2016 through December, 2017, Abbott directed the submission of false claims in violation of 42 U.S.C. 3729.

D. Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts

219. Arriva fraudulently certified its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS because it knew compliance with the anti-switching rule was a requirement of the contract, but nonetheless entered the contract with CMS indicating it would abide by CMS's rules and the DMEPOS Competitive Bidding Contracts' provisions.

220. Specifically, Arriva's call logs expressly required its employees to note when a beneficiary did not own an Arriva-carried glucose monitor and offer the option to switch in violation of CMS's anti-switching rule.

221. In various call scripts circulated and revised from time to time by Arriva's upper management, Arriva instructed its employees to bring up that Arriva did not have the glucose meter the beneficiary used and ask the beneficiary if they wanted to discuss other meters Arriva did supply.

222. In a call script circulated to Arriva senior managers on November 27, 2013, Arriva instructed its employees to use the following language:

> **If Medicare Eligible and the existing meter is <u>not serviced by Arriva</u> <u>Medical</u>, state,** "We do not supply the meter you are using. We do have other glucose meters if you would like to discuss them."
>
> **<u>WAIT FOR RESPONSE</u>**
>
> **If Yes**, proceed to discuss the Solus V2 and/or Embrace meter features.

223. In an August 14, 2013, call script, Arriva instructed its employees to:

> **VERIFY METER (Medicare Eligible):**

"What meter are you currently using?"

If the patient is using a meter serviced by Arriva:

"We can get the supplies for ____ meter, unless you would like to hear about of easy to use glucose meters and free home delivery"

If patient is using a meter <u>NOT</u> serviced by Arriva Medical:

"We do not carry supplies for the meter you are using. We do have other glucose meters if you would like to discuss them?"

If Yes, discuss Prodigy or True Result

If No, state "I can refer you to the Medicare website <u>www.medicare.gov.</u>"

224. In an August 14, 2013, call script, Arriva instructed its employees to use the following language:

If Medicare Eligible and the existing meter is another <u>meter serviced by Arriva Medical</u>, state, "Our records show that you are currently using the ____ meter and we can get supplies for this meter unless you would like to hear about our other easy to use meters and free home delivery."

<u>WAIT FOR RESPONSE</u>

If Yes, proceed to discuss the Prodigy and/or TRUEresult meter features.

If No, proceed to # 7 to continue to fill the order with a new meter from the same manufacturer and interchangeable supplies.

If Medicare Eligible and the existing meter is <u>not serviced by Arriva Medical</u>, state, "We

do not supply the meter you are using. We do have other glucose meters if you would like to discuss them."

WAIT FOR RESPONSE

If Yes, proceed to discuss the Prodigy and/or TRUEresult meter features.

If No, state, "I can refer you to the Medicare website www.medicare.gov." **If the patient would like, you may also supply the telephone for Medicare of *1-800-633-4227* and/or recommend that the patient check with a local retail pharmacy.**

225. In another August 14, 2013, call script, Arriva instructed its employees to use the following language:

VERIFY METER:

If Prodigy, TRUEresult, Embrace or One-Touch Ultra2,

Proceed to # 7 to continue to fill the order.

If Medicare Eligible and the existing meter is not serviced by Arriva Medical, state, "We do not supply the meter you are using. We do have other glucose meters if you would like to discuss them."

WAIT FOR RESPONSE

If Yes, proceed to discuss the Prodigy and/or TRUEresult meter features.

> **If No, state,** "I can refer you to the Medicare website www.medicare.gov." **If the patient would like, you may also supply the telephone for Medicare of *1-800-633-4227* and/or recommend that the patient check with a local retail pharmacy.**

226. Arriva tracked its profits using these methods to sell medically unnecessary meters and carefully tailored its call scripts to maximize profits, noting when meter switching was offered.

227. In addition, Arriva was provided marketing funds by several manufacturers to mail letters to current and previous beneficiaries offering free meters if they switched their test strips to a different brand, or if the beneficiary hadn't ordered testing supplies after a particular time period, in violation of the anti-switching rule.

228. When Arriva stopped carrying a meter and test strips, they would mail letters to the beneficiaries advising them to switch to a new product.

229. Arriva also had knowledge of the anti-switching regulations and requirements by virtue of its possession of a document titled Arriva competitive Bidding/National Mail Order Program Module (the "Module").

230. The Module was shared amongst Arriva's management and illustrates its knowledge that its employees were required by law to wait until the beneficiary brought up another meter before Arriva's employees were permitted to suggest another meter.

231. Specifically, the Module provides:

> If the [beneficiary] expresses an interest in alternate brands, the agent may discuss the benefits of the other products such as, Prodigy and TrueResult. However, the patient must first ask about alternate brands before they can be discussed. If Arriva Medical carries the brand of testing supplies that the [beneficiary] uses and they have no desire to change, we must furnish those supplies.

232. By comparison, in the scripts Arriva circulated to its employees, the employees were instructed to first ask whether the beneficiary was using a particular meter; if the beneficiary responded they were not using an Arriva-preferred meter, the employee was instructed to introduce the preferred meter.

233. Using this tactic, Arriva fraudulently billed Medicare for thousands of glucose monitors it shipped to its beneficiaries after improperly convincing them to switch monitors.

234. Arriva further had notice of the anti-switching requirements by virtue of its possession of Discount Diabetic's DMEPOS Competitive Bidding Contract with CMS.

235. Mr. Olhausen provided Discount Diabetic's DMEPOS Competitive Bidding Contract with CMS to Arriva prior to Arriva's purchase of Discount Diabetic in April 2013.

236. Discount Diabetic's contract with CMS provides, in relevant part:

This Contract is entered into by and between the Centers for Medicare & Medicaid Services (CMS) and DISCOUNT DIABETIC LLC (hereinafter referred to as the "Contract Supplier") for the purpose of authorizing and requiring the Contract Supplier to furnish certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under the Medicare DMEPOS Competitive Bidding Program.

. . .

The Contract Supplier and its affiliated companies and subcontractors shall comply with all applicable Federal laws and regulations

. . .

The Contract Supplier shall submit Medicare claims for payment of items it has furnished under this Contract using the Health Insurance Portability and Accountability Act (HIPPA) compliant standard electronic format. No paper claims are accepted.

. . .

Pursuant to 42 C.F.R. § 414.422(e)(3), the Contract Supplier shall furnish the brand of diabetic testing supplies that works with the home blood glucose monitor selected by the beneficiary. The Contract Supplier is prohibited from influencing or incentivizing beneficiaries by persuading, pressuring, or advising them to switch from their current brand (or, for new

> beneficiaries, from their preferred brand) of glucose monitor and testing supplies. The contract supplier may not furnish information about alternative brands to the beneficiary unless the beneficiary requests such information.

237. The contract provides a certification statement that provides the following:

> By my signature as the authorized representative name below, I certify that the Contract Supplier identified in this Contract will adhere to the provisions of this Contract.
>
> I understand that any deliberate omission, misrepresentation, or falsification of any information contained in any communication supplying information to Medicare or its contractors, or any deliberate alteration of any text on this form, may render this Contract null and void and be punished by criminal, civil, or administrative penalties including, but not limited to, the revocation of Medicare billing number(s), and/or the imposition of fines, civil damages, and/or imprisonment.

238. Upon information or belief, Arriva executed the same or substantially similar contract when Arriva obtained its 2013 DMEPOS Competitive Bidding Contract with CMS.

239. As stated herein, Arriva had knowledge of the anti-switching regulations prior to and at the time it submitted its 2016 DMEPOS Competitive Bidding Contract application with CMS.

240. Arriva's 2016 DMEPOS contract provides, in relevant part:

> This Contract is entered into by and between the Centers for Medicare & Medicaid Services (CMS) and ARRIVA MEDICAL, LLC (hereinafter referred to as the "Contract Supplier") for the purpose of authorizing and requiring the Contract Supplier to furnish certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under the Medicare DMEPOS Competitive Bidding Program.
>
> . . .
>
> The Contract Supplier and its affiliated companies and subcontractors shall comply with all applicable federal laws and regulations
>
> . . .
>
> In accordance with 42 CFR §414.408, §414.422 and the DMEPOS Quality Standards, the Contract Supplier shall furnish all items and services in the product category, indicated in Attachment A, to any Medicare beneficiary throughout the CBA who maintains a permanent residence in or who visits a CBA that requests those items and services.
>
> . . .
>
> The Contract Supplier shall submit Medicare claims for payment of items it has furnished under this Contract using the Health Insurance

> Portability and Accountability Act (HIPPA) compliant standard electronic format. No paper claims are accepted.
>
> . . .
>
> Pursuant to 42 C.F.R. § 414.422(e)(3), the Contract Supplier shall furnish the brand of diabetic testing supplies that works with the home blood glucose monitor selected by the beneficiary. The Contract Supplier is prohibited from influencing or incentivizing beneficiaries by persuading, pressuring, or advising them to switch from their current brand (or, for new beneficiaries, from their preferred brand) of glucose monitor and testing supplies. The contract supplier may not furnish information about alternative brands to the beneficiary unless the beneficiary requests such information.

241. The letter accompanying Arriva's 2016 DMEPOS Competitive Bidding Contract included a description of steps necessary to complete the contract, which included "Step 5 – read and electronically sign the Contract certification statement (if accepting offer in Attachment A)."

242. Upon information and belief, Arriva's 2016 DMEPOS Competitive Bidding Contract contained the same or substantially similar Certification alleged in paragraph 237, which Arriva would have executed.

243. Pursuant to 42 C.F.R. § 414.402, a Contract Supplier "means an entity that is awarded a contract by CMS to furnish items under a competitive bidding

program," with items defined in 42 C.F.R. § 414.402, *see* paragraph 117.

244. Pursuant to 42 C.F.R. § 414.408(e)(1), "all items that are included in a competitive bidding program must be furnished by a contract supplier for that program."

245. Pursuant to 42 C.F.R. § 414.408(e)(3), unless certain exceptions apply (which neither Arriva nor Alere qualify for), "Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section."

246. Thus, in order to obtain payment for items included in the competitive bidding program, a supplier must have previously obtained a contract from CMS to furnish items under a competitive bidding program.

247. CMS has indicated that it would deny claims from non-contract suppliers for items covered by the DMEPOS competitive bid program and established particular denial codes for denying claims for items furnished by non-contract suppliers. CMS, Durable Medical Equipment (DME) National Competitive Bidding (NCB) Implementation – Phase 11E: Remittance Advice (RA) and Medicare Summary Notice (MSN) Messages for Round One (Sept. 24, 2010), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7066.pdf.

248. Arriva entered both its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS intending to violate the anti-switching regulation.

249. Arriva entered both its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS intending to ship items it knew it would not have sufficient documentation establishing medical necessity.

250. Arriva improperly incentivized and persuaded its beneficiaries to switch glucose meters before and after it obtained its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

251. Arriva billed Medicare for items it shipped knowing it did not have sufficient documentation to show medical necessity for the item before and after it obtained its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

252. Arriva knew if it disclosed to CMS that it intended to incentivize or persuade its beneficiaries to switch glucose monitors after it obtained a DMEPOS Competitive Bidding Contract with CMS, CMS would not have awarded Arriva the contracts.

253. Had Arriva failed to indicate it would not violate the anti-switching regulations when it signed its 2013 and 2016 DMEPOS Competitive Bidding Contracts, CMS would not have awarded Arriva the contracts.

254. Had CMS known Arriva intended to violate the anti-switching regulations, it would not have awarded Arriva the 2013 or 2016 DMEPOS Competitive Bidding Contracts.

255. In its 2013 and 2016 DMEPOS Competitive Bidding Contracts, Arriva falsely certified it would not

incentivize or persuade its beneficiaries to switch glucose monitors, violating the False Claims Act by virtue of this false statement and further violating the False Claims Act for each claim submitted wherein Arriva incentivized or persuaded its beneficiaries to switch glucose monitors.

256. By virtue of its shared directors and officers, along with its control of its subsidiary Arriva Philippines which submitted most claims under Arriva's DMEPOS Competitive Bidding Contracts, Alere had knowledge of the facts alleged in paragraphs 219 through 255.

257. By virtue of its control of its subsidiaries, Arriva Philippines and Arriva, Alere caused false claims to be submitted to Medicare for medically unnecessary glucose monitors as it unlawfully incentivized and persuaded Arriva's beneficiaries to switch glucose monitors and unlawfully induced Medicare to enter into Arriva's DMEPOS competitive bidding contracts.

E. Use of Undisclosed Locations

258. Per 42 U.S.C. § 1395w-3(b)(3)(C), suppliers are required to disclose to CMS information on each subcontracting relationship that the supplier has in furnishing items and services under the contract and whether each subcontractor meets the requirement of Section 1395m(a)(20)(F)(i).

259. Pursuant to 42 U.S.C. § 1395m(a)(20)(F)(i), DMEPOS suppliers must disclose to CMS whether the subcontractors the DMEPOS supplier uses are accredited and provide evidence of that accreditation.

260. Pursuant to 42 C.F.R. § 414.422(f), DMEPOS Competitive Bidding Contract holders must:

(1) Initial disclosure. Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) Subsequent disclosure. Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

261. Under 42 U.S.C. § 1395m(j), no payment should be made to a supplier unless that supplier obtains a supplier number.

262. Pursuant to 42 C.F.R. § 424.57, Medicare-enrolled supplier's subcontractors are limited to: (1) the purchase of inventory; (2) the delivery of that inventory and instruction to beneficiaries on the use of Medicare-covered items; and (3) the maintenance and repair of rented equipment. It is the Medicare-enrolled supplier who must complete intake and assessment, coordinate care with the physician, submit claims on behalf of the beneficiary, respond to the beneficiary, and ensure product safety.

263. Pursuant to 42 C.F.R. § 424.57(b), to be eligible to receive payment for a Medicare-covered item, a DMEPOS supplier must (*inter alia*) submit an application to CMS for accreditation and furnish to CMS all information or documentation required to process the claim for payment.

264. Under 42 C.F.R. § 424.57(c)(2), a DMEPOS supplier must certify it:

> Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.)

265. Under 42 C.F.R. § 424.57(c)(18), a DMEPOS supplier "must not convey or reassign a supplier number."

266. Under 42 C.F.R. § 424.57(c)(22) and (23), all DMEPOS suppliers must be accredited by a CMS approved accreditation organization to retain a supplier billing number and must notify their accreditation organization when a new DMEPOS location is opened.

267. Under 42 C.F.R. § 424.57(c)(24):

> All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

268. In April 2013, Arriva Philippines became operational with 250 full-time employees.

269. Over the course of 2013, Arriva Philippines grew from 250 full-time employees to over 600 and, at its peak, employed over 800 individuals.

270. Angelo "Gel" Guiao was the head of Arriva Philippines.

271. Mr. Guiao reported to Chip Stocksdale while Mr. Stocksdale was president of Arriva.

272. Once Mr. Stocksdale left Arriva, Mr. Guiao reported to Claudio Araujo, an Alere employee and Vice President of Alere Cardiometabolic.

273. With regard to Arriva Philippines, Mr. Araujo reported to Daniella Cramp, Global President of Alere Cardiometabolic.

274. Upon information and belief, Ms. Cramp was heavily invested in the management and performance of Arriva Philippines and directed much of Arriva's push to move Arriva's workforce to the Philippines.

275. Upon information and belief, through the directives of Mr. Araujo and Ms. Cramp, and as Arriva Philippines was a subsidiary of Alere, Alere directed and controlled Arriva Philippines.

276. Arriva Philippines was not an accredited organization through CMS and did not have its own DMEPOS supplier number.

277. Despite purposefully failing to notify CMS of its use of Arriva Philippines, Arriva and Alere employed over 800 employees in that location and routed the majority of Arriva's intake and orders through it.

278. Arriva Philippines submitted claims to CMS for supplies ordered by Arriva's beneficiaries.

279. Arriva Philippines processed these claims, however, when the claims were submitted it appeared as if they were processed in Arriva's Florida office using a billing software that indicated the claims were processed from Florida, when they were actually

processed in (and Arriva's services conducted in) the Philippines.

280. The billing software could be configured to identify where the claim was processed; however, Arriva directed Arriva Philippines not to use this option, instead making it appear as if Arriva Philippines' claims were processed through Arriva's Florida office.

281. The billing software was moved to a datacenter in Atlanta, Georgia, and all Arriva claims were first sent to the billing software company processor and then sent to Medicare from that location despite indicating to CMS that the claims were submitted from Florida.

282. Arriva Philippines employees used the same call scripts as Arriva's call center employees located in the United States.

283. Those call scripts instructed Arriva Philippines employees to perform duties the primary supplier must perform, including: intake and assessment, coordination of care with the physician, submitting claims on behalf of the beneficiary, and providing instructions regarding ownership and responsibility for equipment furnished to the beneficiary.

284. Arriva subcontracted nearly all its duties to Arriva Philippines even though it had only an informal business association agreement with Arriva Philippines that authorized Arriva Philippines to handle Protected Health Information ("PHI") from Arriva.

285. Alternatively, if Arriva Philippines was considered an additional location of Arriva, which was not disclosed to CMS, which was required to bill DMEPOS items to Medicare under the DMEPOS competitive billing contract.

286. Arriva Philippines did not have a national provider identification number or a DMEPOS supplier number, which was required to bill DMEPOS items to Medicare.

287. Arriva never disclosed its use of Arriva Philippines to CMS.

288. Arriva directed many of these same duties to its Arizona, Tennessee, and Kentucky locations.

289. The Arizona and Kentucky locations were not accredited through CMS and did not have their own DMEPOS supplier numbers.

290. Upon information and belief, the Tennessee location did have a national provider identification number but did not have a DMEPOS supplier number.

291. And although Arriva acquired its Tennessee location prior to submitting its application for its 2013 DMEPOS Competitive Bidding Contract with CMS, it shut down its Tennessee location prior to submitting its application for its 2016 DMEPOS Competitive Bidding Contract with CMS.

292. Arriva acquired its Arizona and Kentucky locations prior to submitting its application for its 2016 DMEPOS Competitive Bidding Contract with CMS but after it submitted its 2013 application.

293. Arriva's Arizona and Tennessee locations used the same call scripts as those used in the Philippines and other United States' locations.

294. Those call scripts improperly instructed Arriva's Arizona and Tennessee employees to perform duties the primary supplier must perform, including intake and assessment, coordination of care with the physician, submitting claims on behalf of the beneficiary, and providing instructions regarding ownership and responsibility for equipment furnished to the beneficiary.

295. Arriva did not notify CMS or its accreditation organization when it opened its Arizona, Tennessee, or Kentucky locations.

296. Neither Arriva nor Alere notified CMS or its accreditation organization when Arriva began using Arriva Philippines as an additional location or as a subcontractor.

297. Arriva's Arizona and Tennessee locations processed claims, however, when the claims were submitted it appeared as if they were processed in Arriva's Florida office using a billing software that indicated the claims were processed from Florida, when they were actually processed in (and Arriva's services conducted in) Arizona or Tennessee.

298. The billing software could be configured to identify where the claim was processed; however, Arriva directed Arriva's Arizona and Tennessee locations not to use this option, instead making it appear as if Arriva's Arizona and Tennessee claims were processed through Arriva's Florida office.

299. The billing software was moved to a datacenter in Atlanta, Georgia, and all Arriva claims were first sent to the billing software company processor and then sent to Medicare from that location despite indicating to CMS that the claims were submitted from Florida.

300. Upon information and belief, evidence indicating Arriva Philippines and Arriva's Arizona and Tennessee locations processed claims and billed Medicare from their respective locations using software to indicate the claim was being processed in Florida is in the sole possession of Defendants.

301. Mr. Olhausen discussed obtaining supplier numbers and accreditation for the Arizona, Tennessee, and Kentucky locations[7] with Arriva's management, but due to the time and cost associated with these applications, along with the added risk of Medicare compliance visits, Arriva decided against obtaining supplier numbers for these locations.

302. Pursuant to 42 C.F.R. § 414.402, a Contract Supplier "means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program," with items defined in 42 C.F.R. § 414.402, *see* paragraph 117.

303. Pursuant to 42 C.F.R. § 414.408(e)(1), "all items that are included in a competitive bidding

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[7] Mr. Olhausen did not suggest obtaining a supplier number for the Philippines location, because Mr. Olhausen did not believe Arriva could use this location in the first place.

program must be furnished by a contract supplier for that program."

304. Pursuant to 42 C.F.R. § 414.408(e)(3), unless certain exceptions apply (which neither Arriva nor Alere qualify for), "Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section."

305. Thus, in order to obtain payment for items included in the competitive bidding program, a supplier must have previously obtained a contract from CMS to furnish items under a competitive bidding program.

306. Pursuant to 42 U.S.C. § 1395m(a)(20):

> Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—
>
> (i) furnish any such item or service for which payment is made under this part; and
>
> (ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this subchapter.

307. CMS has indicated that it would deny claims from non-contract suppliers for items covered by the DMEPOS competitive bid program and established particular denial codes for denying claims for items furnished by non-contract suppliers. CMS, Durable Medical Equipment (DME) National Competitive Bidding (NCB) Implementation – Phase 11E: Remittance Advice (RA) and Medicare Summary Notice (MSN) Messages for Round One (Sept. 24, 2010), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7066.pdf.

308. CMS has additionally indicated it would deny any claims for payment from a supplier that does not have a supplier number and is not accredited. CMS, Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (Jul. 5, 2011), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-NetworkMLN/MLNMattersArticles/downloads/MM7333 .pdf.

309. CMS has revoked billing privileges of suppliers who have billed for services and supplies without accreditation or supplier number. *Biomed Texas Inc., d/b/a All. Pharmacy, (Ptan: 6494950001) v. Centers for Medicare & Medicaid Serv.*, DAB No. CR4791, 2017 WL 4882630 (H.H.S. Feb. 13, 2017).

310. Arriva had notice, through its possession of Discount Diabetic's DMEPOS Competitive Bidding Contract with CMS, of the requirement to disclose to CMS any and all subcontracting relationships it had pursuant to 42 C.F.R. § 414.422(f) and further disclose

whether each subcontractor was accredited under 42 U.S.C. §1395w-3(b)(3)(C).

311. Mr. Olhausen provided Discount Diabetic's DMEPOS Competitive Bidding Contract with CMS to Arriva prior to Arriva's purchase of Discount Diabetic in April 2013.

312. Discount Diabetic's contract with CMS states those provisions contained in paragraphs 236 and 237 and further provides:

> Article IX: Requirement to Maintain Medicare Billing Privileges and Accreditation. The Contract Supplier shall satisfy the enrollment standards specified in 42 CFR §424.57(c), meet applicable quality standards (both general quality standards and product specific quality standards) developed by CMS in accordance with section 1834(a)(20) of the Social Security Act, and be accredited by a CMS-approved accreditation organization for the duration of the Contract period.

313. Discount Diabetic's contract with CMS also specifically highlights the subcontracting requirement under 42 C.F.R. § 414.422(f), as well as the limitations on what services a subcontractor is permitted to complete for the DMEPOS competitive contract holder under 42 C.F.R. § 424.57(c).

314. In particular, Discount Diabetic's contract with CMS provides:

A. Subcontracting Arrangements

Consistent with Medicare DMEPOS Supplier Standards in 42 C.F.R. §424.57(c), a Contract Supplier may subcontract for the purchase of inventory, delivery, and instruction on use of a Medicare-covered item, or the maintenance and repair of rented equipment. Services such as intake and assessment, coordination of care with the physician, submitting claims on behalf of the beneficiary, ownership and responsibility for equipment furnished to the beneficiary, and ensuring product safety are all services for which the Contract Supplier is responsible. The Contract Supplier entering into a subcontracting relationship to furnish items and services under this Contract may be held liable for actions of its subcontractors, which may result in a breach of contract.

As described in 42 C.F.R. §414.422(f), the Contract Supplier shall disclose information about each subcontracting relationship the Contract Supplier has entered into to furnish items and services under this Contract. The Contract Supplier shall also disclose whether the subcontractor is accredited as required by section 1847(b)(3)(C) of the Social Security Act, if applicable. The required disclosure must occur no later than 10 business days after the date a supplier enters into this Contract with CMS (i.e. the date of final contract execution) or, for subcontracting arrangement executed after contract award, 10 business days after the date a Contract Supplier enters into a subcontracting arrangement.

B. Communication Regarding Disclosure of Subcontracting Arrangements

> Disclosure of subcontracting arrangements shall be submitted to CMS through the CBIC in the manner specified by CMS at the time that a contract award is made and in compliance with 42 C.F.R. §414.422(f).

315. Attached to the Competitive Bidding Contract between Discount Diabetic and CMS was an Attachment B which listed the Contractor Supplier locations to which the Competitive Bidding Contract applied.

316. With respect to the locations in Attachment B, the Competitive Bidding Contract provided that:

> Only a location (identified by Provider Transaction Access Number) that is shown on Attachment B as being included in a contract offer or added using the Contract Supplier Location Update Form on the CBIC website is eligible to receive Medicare payment for competitively bid items within the CBA/product category. As explained in Attachment B, the list of locations eligible for payment may be updated upon execution of this contract.

317. By virtue of its possession of Discount Diabetic's Competitive Bidding Contract with CMS, Arriva was put on notice of its requirement to identify all locations providing services and receiving payment under Arriva's Competitive Bidding Contract.

318. The contract also provides a certification statement, as stated in paragraph 237..

319. Upon information or belief, Arriva executed the same or substantially similar contract, including the same provisions identified in paragraphs 236, 237 312, 314 and 316 when Arriva obtained its 2013 DMEPOS Competitive Bidding Contract with CMS.

320. As Arriva falsely certified it was not using any additional locations or subcontractors, any claims submitted by any additional location or subcontractor using Arriva's 2013 DMEPOS Competitive Bidding Contract was a violation of the False Claims Act.

321. Upon information and belief, multiple individuals of Arriva's management, including but not limited to Chip Stocksdale (President), Ryan Wettergren, Associate Director Global Compliance and an Alere employee (later an Abbott employee), Jessica Crowell (Director of Patient Services), Claudio Ajauio (Vice President of Alere Cardiometabolic), and Brant Reamer (Vice President of Operations) were in possession of CMS contractor educational information emails that reiterated the requirements contained in 42 U.S.C. § 1395w-3(b)(3)(C), 42 U.S.C. § 1395m(a)(20)(F)(i), 42 C.F.R. § 414.422(f), 42 U.SC. § 1395m(j), and 42 C.F.R. § 424.57 and stated in paragraphs 302 through 313.

322. Arriva had additional notice of 42 C.F.R. §424.57(c) and 42 C.F.R. §414.422(f) by virtue of its possession of Discount Diabetic's DMEPOS Competitive Bidding Contract with CMS.

323. On March 26, 2012, Arriva filed its application for its 2013 DMEPOS Competitive Bidding Contract with CMS.

324. Upon information and belief, Arriva had notice and knowledge of the requirements of 42 U.S.C. § 1395w-3(b)(3)(C), 42 U.S.C. § 1395m(a)(20)(F)(i), 42 C.F.R. § 414.422(f), 42 U.SC. § 1395m(j), and 42 C.F.R. § 424.57 prior to filing its application for its 2013 DMEPOS Competitive Bidding Contract with CMS.

325. Arriva's application for its 2013 DMEPOS Competitive Bidding Contract with CMS states:

> Displayed below is a summary for the location(s) for which you are submitting a bid. Please carefully review the information you provided on Form A application information for accuracy. Only locations identified by the PTANs listed on this summary page will be eligible to be awarded a contract and to receive payment under the DMEPOS Competitive Bidding Program.

326. Arriva knew it was required to disclose its subcontracting relationships with which it intended to subcontract its DMEPOS services prior to filing its 2013 application for its DMEPOS Competitive Bidding Contract with CMS.

327. Arriva knew it was required to disclose each of its locations which it intended to use for DMEPOS services prior to filing its 2013 application for its DMEPOS Competitive Bidding Contract with CMS.

328. Despite Arriva's knowledge of the laws and regulations outlined in paragraphs 302 through 313,

322 and 324, Arriva filed its application for its 2013 DMEPOS Competitive Bidding Contract with CMS without disclosing any subcontracting relationships.

329. Specifically, Arriva affirmatively indicated it did not intend to use subcontractors in its application for its 2013 DMEPOS Competitive Bidding Contract with CMS.

330. Despite Arriva's knowledge of the laws and regulations outlined in paragraphs 302 through 313, 322 and 324, Arriva filed its application for its 2013 DMEPOS Competitive Bidding Contract with CMS without disclosing its Tennessee location.

331. Upon information and belief, CMS relied upon the information Arriva provided in its application for its 2013 DMEPOS Competitive Bidding Contract in deciding to award Arriva the contract.

332. Upon information and belief, had Arriva disclosed that it intended to use locations and/or unaccredited subcontractors without DMEPOS supplier numbers, CMS would not have awarded Arriva its 2013 DMEPOS Competitive Bidding Contract.

333. Upon information and belief, Arriva's 2013 DMEPOS Competitive Bidding Contract with CMS included the same certification described in paragraph 237, which Arriva fraudulently agreed to when it executed the contract as it did not, nor did it intend to, disclose its additional locations or subcontracting arrangements.

334. Arriva's submission of claims utilizing the Arizona, Tennessee, or Philippines locations were violations of the False Claims Act as Arriva falsely certified compliance with its 2013 DMEPOS Competitive Bidding Contract.

335. On April 9, 2013, Mr. Olhausen received a letter from Palmetto GBA, a CMS subcontractor that facilitated the application and accreditation process for CMS's DMEPOS Competitive Bidding Contracts.

336. The letter enclosed a copy of the fully executed contract for the DMEPOS competitive bidding program and stated:

> Only those locations identified on Attachment B of the contract are included in the national mail-order competition of the DMEPOS Competitive Bidding Program and considered contract supplier locations. These locations, as identified by the Provider Transaction Access Number (PTAN) on Attachment B, may submit claims to Medicare as a contract supplier compliant with all Medicare rules and guidelines. It is important to note that, in accordance with Medicare regulations, the location that furnishes the item to the beneficiary must be the location identified on the claim form.
>
> . . .
>
> In accordance with Article VI of the contract, contract suppliers must notify the Centers for Medicare & Medicaid Services (CMS) of each

> subcontracting relationship and whether a subcontractor is accredited, if applicable.

337. Mr. Olhausen provided this letter to Arriva upon his receipt and again when Arriva purchased Discount Diabetic.

338. Upon information and belief, Arriva received a similar, if not identical, letter with the same disclosures when it obtained its 2013 DMEPOS Competitive Bidding Contract with CMS.

339. On March 24, 2015, Arriva submitted its application for its 2016 DMEPOS Competitive Bidding Contract with CMS.

340. Arriva's application for its 2016 DMEPOS Competitive Bidding Contract with CMS states:

> Displayed below is a summary for the location(s) for which you are submitting a bid. Please carefully review the information you provided on Form A application information for accuracy. Only locations identified by the PTANs listed on this summary page will be eligible to be awarded a contract and to receive payment under the DMEPOS Competitive Bidding Program.

341. The application for Arriva's 2016 DMEPOS Competitive Bidding Contract with CMS additionally asked whether the applicant "plan[ned] to use a subcontractor" to which Arriva affirmatively responded "No."

342. Despite Arriva's knowledge of the requirement to disclose all locations and subcontractors it intended

to use to furnish DMEPOS related services as described in paragraphs 302 through 313, 322 and 324, Arriva failed to disclose its Arizona or Kentucky locations to CMS or disclose its subcontracting relationship with Arriva Philippines when its submitted its application for its 2016 DMEPOS Competitive Bidding Contract.

343. Upon information and belief, CMS relied upon the information Arriva provided in its application for its 2016 DMEPOS Competitive Bidding Contract in deciding to award Arriva the contract.

344. Upon information and belief, had Arriva disclosed that it intended to use unaccredited locations and/or subcontractors without DMEPOS supplier numbers, CMS would not have awarded Arriva with its 2016 DMEPOS Competitive Bidding Contract.

345. Arriva's 2016 DMEPOS contract provides for those provisions contained in paragraphs 236, 237, 240, 312, 314, and 316.

346. The letter accompanying Arriva's 2016 DMEPOS Competitive Bidding Contract included a description of steps necessary to complete the contract, which included "Step 5 – read and electronically sign the Contract certification statement (if accepting offer in Attachment A)."

347. Upon information and belief, Arriva's 2016 DMEPOS Competitive Bidding Contract contained the same or substantially similar certification statement as alleged in paragraph 237.

348. Upon information and belief, Arriva signed the same or substantially similar certification in its 2016 DMEPOS Competitive Bidding Contract as alleged in paragraph 237.

349. Upon information and belief, Arriva's 2016 DMEPOS Competitive Bidding Contract with CMS included the same certification described in paragraph 237 which Arriva fraudulently agreed to when it executed the contract as it did not, nor did it intend to, disclose its additional locations or subcontracting arrangements.

350. As Arriva falsely certified it was not using any additional locations or subcontractors, any claims submitted by an additional location or subcontractor using Arriva's 2016 DMEPOS Competitive Bidding Contract were violations of the False Claims Act.

351. As only Contract Suppliers may furnish and bill Medicare for DMEPOS competitive bidding items, Arriva would not have been able to obtain payment for any DMEPOS competitive bidding items it furnished to its beneficiaries if it did not have its DMEPOS Competitive Bidding Contract.

352. Arriva and Alere knew Arriva would not be able to obtain either the 2013 or 2016 DMEPOS Competitive Bidding Contracts if Arriva disclosed to CMS that it intended to utilize undisclosed and/or unaccredited locations and subcontractors that did not have supplier numbers.

353. As Arriva and Alere knew Arriva would not be able to obtain the 2013 or 2016 DMEPOS Competitive Bidding Contracts if Arriva disclosed to CMS that it

intended to utilize unaccredited subcontractors and/or locations, neither of which had supplier numbers, Arriva submitted applications to CMS to obtain a DMEPOS Competitive Bidding Contract that included false statements that Arriva would not use any other locations or subcontractors.

354. Upon information and belief, CMS relied upon Arriva's representations in paragraph 356 in awarding Arriva its 2013 and 2016 DMEPOS Competitive Bidding Contracts.

355. As Arriva and Alere fraudulently obtained Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts, each claim submitted under those contracts are violations of the False Claims Act.

F. Unsolicited Telephone Contacts

356. In approximately April 2013, Express Scripts began sending names of its Part D beneficiaries to Liberty Medical which would then send these same names to Arriva.

357. Liberty Medical would email the names it received from Express Scripts to Arriva.

358. Arriva called these beneficiaries to sell them diabetic supplies under Arriva's supplier number.

359. These beneficiaries had not previously contacted Arriva or Liberty Medical, and neither Arriva nor Liberty Medical previously furnished these beneficiaries any covered items.

360. Pursuant to 42 U.S.C. § 1395m(a)(17), suppliers may only contact an individual regarding the

furnishing of a covered item if that individual has given written permission to the supplier, the supplier has previously furnished a covered item to the individual before and is calling regarding that item, or if the supplier furnished at least one covered item to the individual during the 15 months preceding the date the supplier makes contact.

361. Arriva knew the solicitation rule was a special payment rule for DMEPOS suppliers as it was required to have the supplier requirements posted at each of its locations and send the supplier requirements to each of its beneficiaries.

362. Arriva knowingly violated the requirements of 42 U.S.C. § 1395m(a)(17) and knew it was not permitted to be paid for items furnished to such individuals.

363. By sharing common officers and directors and by virtue of its control of its subsidiaries, Arriva and Liberty Medical, Alere had the same knowledge as Arriva as alleged in paragraphs 356 through 362 and further caused the same false claims to be submitted to Medicare for the reasons stated in paragraphs 356 through 362.

FIRST CAUSE OF ACTION AGAINST ARRIVA AND ALERE FOR VIOLATION OF THE FALSE CLAIMS ACT DEFENDANTS' FALSE CLAIMS FOR INVALID PRESCRIPTIONS (31 U.S.C. §§ 3729(a)(1)(A) and (b))

364. Relator repeats and re-alleges each allegation contained in the paragraphs above as though fully set forth herein.

365. At all times relevant to this Complaint, Arriva and Alere knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States.

366. At the time Arriva and Alere presented the claims for payment, they knew the claims were supported by invalid prescriptions and knew of the laws and regulations in each of the paragraphs above, specifically those laws and regulations identified in paragraphs 89–110.

367. Defendants knew the prescriptions were invalid because:

a. the prescriptions expired after 12 or 18 months and state law mandated new prescriptions after that time period; and/or

b. the beneficiaries switched doctors without obtaining a new prescription.

368. By virtue of the above-described acts, Arriva and Alere knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States in violation of 31 U.S.C. § 3729(a)(1)(A), and Defendants knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved in violation of 31 U.S.C. § 3729(a)(1)(B).

369. The United States has incurred damages as a result of Arriva and Alere's unlawful scheme in an amount to be determined at trial.

370. Arriva and Alere are jointly and severally liable to the United States for treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each false claim presented or caused to be presented by Defendants.

SECOND CAUSE OF ACTION AGAINST ARRIVA AND ALERE FOR VIOLATION OF THE FALSE CLAIMS ACT DEFENDANTS' FALSE CLAIMS FOR THEIR FAILURE TO OBTAIN ASSIGNMENTS OF BENEFITS (31 U.S.C. §§ 3729(a)(1)(A) & (b))

371. Relator repeats and re-alleges each allegation contained in the paragraphs above as though fully set forth herein.

372. At all times relevant to this Complaint, Arriva and Alere knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States.

373. At the time Arriva and Alere presented these claims for payment, they knowingly and falsely represented that they had an Assignment of Benefits ("AoBs") from their beneficiaries when, in fact, they did not.

374. Specifically, Arriva and Alere intentionally instructed their employees not to discuss AoBs unless the beneficiary asked about them.

375. When Arriva and Alere submitted their claims to Medicare and Medigap crossover for heating pads, vacuum erection devices, back braces, knee braces,

ankle braces, and wrist braces shipped to their beneficiaries, Arriva and Alere knowingly and falsely indicated they had signatures on file for their beneficiaries, when in fact Defendants did not.

376. Pursuant to 42 C.F.R. § 424.32(a)(3), 42 C.F.R. § 424.36(a), 42 C.F.R. § 424.55(a), and the CMS Medicare Claims Processing Manual, all Medicare billing suppliers, including Arriva and Alere, were required to obtain AoBs from their beneficiaries before billing Medicare for supplies shipped to their beneficiaries, including heating pads, vacuum erection devices, back braces, knee braces, ankle braces, and wrist braces, and/or for services.

377. Arriva and Alere were aware of the requirement stated in paragraph 376 along with those laws and regulations identified in each of the paragraphs above, specifically paragraphs 111-151.

378. Arriva and Alere knew Medicare would deny claims for heating pads, vacuum erection devices, back braces, knee braces, ankle braces, and wrist braces without an AoB on file.

379. Arriva and Alere knew Arriva was overpaid by Medicare, however, failed to refund all overpayments as required by 42 U.S.C. 1320a-7k(d) and in violation of 31 U.S.C. § 3729(b)(3).

380. By virtue of the above-described acts, Arriva and Alere knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States in violation of 31 U.S.C. § 3729(a)(1)(A), and Defendants knowingly made, used, or caused to be made or used, false records or

statements to get false or fraudulent claims paid or approved in violation of 31 U.S.C. § 3729(a)(1)(B).

381. The United States has incurred damages as a result of Defendants' unlawful scheme in an amount to be determined at trial.

382. Defendants are jointly and severally liable to the United States for treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each false claim presented or caused to be presented by Defendants.

THIRD CAUSE OF ACTION AGAINST ALL DEFENDANTS FOR VIOLATION OF THE FALSE CLAIMS ACT DEFENDANTS' FALSE CLAIMS FOR SUBMITTING CLAIMS FOR MEDICALLY UNNECESSARY MEDICAL ITEMS (31 U.S.C. §§ 3729(a)(1)(A) AND (b))

383. Relator repeats and re-alleges each allegation contained in the paragraphs above as though fully set forth herein.

384. At all times relevant to this Complaint, Defendants knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States.

385. At the time Defendants presented these claims for payment, Defendants knew the claims were for medically unnecessary devices and/or knew they did not have sufficient documentation to illustrate medical necessity as required by 42 C.F.R. § 424.5(a).

386. Pursuant to 42 U.S.C. § 1395y(a)(1)(A), no payment will be made from Medicare for any expenses incurred for items which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

387. At the time Defendants presented these claims for payment, Defendants had failed to obtain medical records to support the necessity of the medical supplies it sent to its beneficiaries.

388. Defendants conducted internal reviews and received audits from CMS contractors indicating Defendants did not have proper documentation to support the medical necessity of the supplies Defendants sent their beneficiaries.

389. Despite these internal reviews and audits, Defendants continued their practice of submitting claims to Medicare, knowing the claims were not supported by medical records illustrating medical necessity.

390. Specifically, Defendants instructed their employees to automatically ship certain supplies after a given time had passed without ensuring the beneficiary needed the item, in violation of CMS LCD L33822, 42 C.F.R. § 414.210(f), and 42 U.S.C. § 1395y(a)(1)(A).

391. Defendants also instructed their employees to impermissibly switch their beneficiaries' glucose monitors to those supplied by Arriva in violation of 42 C.F.R. § 414.210(f), 42 C.F.R. § 414.422(e)(3), and the CMS Medicare Program Integrity Manual.

392. Defendants further shipped more testing strips to its beneficiaries than medically necessary in violation of CMS LCD33822.

393. Defendants knew these actions were in violation of the law and CMS's regulations provided in paragraphs 385 through 392, along with each of the paragraphs above, specifically paragraphs 152–257.

394. Arriva and Alere knew of the regulations and laws stated in paragraphs 385 through 392, , along with each of the paragraphs above, specifically paragraphs 152–257, before applying for Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

395. Arriva and Alere intended to influence their beneficiaries to switch glucose monitors prior to applying for Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

396. Arriva and Alere falsely certified to CMS that Arriva would not influence Arriva's beneficiaries to switch glucose monitors when Arriva entered its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

397. CMS relied upon Arriva's and Alere's misrepresentations when it awarded Arriva its 2013 and 2016 DMEPOS Competitive Bidding Contracts.

398. Arriva and Alere knew CMS would rely on these misrepresentations in awarding Arriva its 2013 and 2016 Competitive Bidding Contracts.

399. After Arriva entered into its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS, Arriva and Alere caused Arriva's employees to incentivize and persuade Arriva's beneficiaries to switch glucose monitors in violation of 42 C.F.R. § 414.210(f), 42 C.F.R. § 414.422(e)(3), and the CMS Medicare Program Integrity Manual despite certifying in these contracts that Defendants would not conduct such activity.

400. Defendants knew Arriva was overpaid by Medicare, however, failed to refund all overpayments as required by 42 U.S.C. 1320a-7k(d) and in violation of 31 U.S.C. § 3729(b)(3).

401. Abbott, having knowledge that Arriva submitted false claims to Medicare for medically unnecessary items, directed Arriva to submit claims in December 2017 through January 2018 for dates of service from November 2016 through December 2017.

402. By virtue of the above-described acts, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States in violation of 31 U.S.C. § 3729(a)(1)(A), and Defendants knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved in violation of 31 U.S.C. § 3729(a)(1)(B).

403. The United States has incurred damages as a result of Defendants' unlawful scheme in an amount to be determined at trial.

404. Defendants are jointly and severally liable to the United States for treble damages under the False

Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each false claim presented or caused to be presented by Defendants.[8]

FOURTH CAUSE OF ACTION AGAINST ALL DEFENDANTS FOR VIOLATION OF THE FALSE CLAIMS ACT DEFENDANTS' FALSE CLAIMS SUBMITTED BY UNDISCLOSED, UNACCREDITED LOCATIONS (31 U.S.C. §§ 3729(a)(1)(A) & (b))

405. Relator repeats and re-alleges each allegation contained in the paragraphs above as though fully set forth herein.

406. At all times relevant to this Complaint, Defendants knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States.

407. At the time Defendants presented these claims for payment, they knew the claims were impermissibly processed by Arriva Philippines, an undisclosed and unaccredited location.

408. Arriva Philippines was not an accredited organization through CMS and did not have its own DMEPOS supplier number.

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[8] Relator does not claim damages for the individual claims submitted to Medicare in violation of the anti-switching rule, but instead seeks damages for Arriva's and Alere's false certification in and inducement of Arriva's 2013 and 2016 DMEPOS competitive bidding contracts. The anti-switching rule information is provided as background.

409. In their call scripts, Arriva and Alere instructed Arriva Philippines' employees to perform duties the primary supplier must perform, including intake and assessment, coordination of care with the physician, submitting claims on behalf of the beneficiary, and providing instructions regarding ownership and responsibility for equipment furnished to the beneficiary in violation of 42 C.F.R. § 424.57.

410. Arriva's Arizona and Kentucky locations also were not accredited organizations through CMS and did not have their own DMEPOS supplier numbers.

411. Arriva's Tennessee location did not have its own DMEPOS supplier number.

412. In its call scripts, Arriva and Alere instructed Arriva Arizona and Tennessee location employees to perform duties the primary supplier must perform, including: intake and assessment, coordination of care with the physician, submitting claims on behalf of the beneficiary, and providing instructions regarding ownership and responsibility for equipment furnished to the beneficiary in violation of 42 C.F.R. § 424.57.

413. Pursuant to 42 C.F.R. § 424.57(c)(18), (22)–(24), DMEPOS suppliers must not convey their supplier number and DMEPOS suppliers must be separately accredited and notify CMS upon opening a new location (which must also be separately accredited).

414. Defendants did disclose to CMS Arriva's use of its Arizona, Tennessee, or Kentucky locations.

415. Defendants did not notify CMS of Arriva Philippines or identify it as a subcontractor in violation of 42 U.S.C. § 1395w-3(b)(3)(C).

416. Despite Defendants knowledge of the laws and regulations outlined in paragraphs 409, 412, 413 and 415, and each of the paragraphs above, specifically paragraphs 258–355, Defendants continued to submit claims to the United States using Arriva Philippines and the Arizona and Tennessee locations to process these claims and contact their beneficiaries.

417. Arriva and Alere knew of the regulations and laws stated in paragraphs 409, 412, 413, and 415, and each of the paragraphs above, specifically paragraphs 258–355, before submitting the bid for Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

418. Arriva and Alere intended to use Arriva Philippines and Arriva's Tennessee location before submitting the bid for Arriva's 2013 DMEPOS Competitive Bidding Contract with CMS.

419. Arriva and Alere intended to use Arriva Philippines and Arriva's Arizona and Kentucky locations before submitting the bid for Arriva's 2016 DMEPOS Competitive Bidding Contract with CMS.

420. Arriva and Alere represented to CMS that Arriva had no location besides the Florida location and that Arriva did not intend to use subcontractors when Arriva submitted the bid for Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

421. Arriva and Alere represented to CMS that Arriva had no location besides the Florida location and that Arriva did not intend to use subcontractors when Arriva entered its 2013 and 2016 DMEPOS Competitive Bidding Contracts with CMS.

422. CMS relied upon Arriva's and Alere's misrepresentations when it awarded Arriva its 2013 and 2016 DMEPOS Competitive Bidding Contracts.

423. Arriva and Alere knew CMS would rely on these misrepresentations in awarding Arriva its 2013 and 2016 Competitive Bidding Contracts.

424. Without the DMEPOS Competitive Bidding Contracts, Arriva and Alere knew Arriva would be unable to submit claims to or bill Medicare for items it furnished covered by the DMEPOS competitive bidding program.

425. As a result of Arriva's and Alere's misrepresentations, every claim submitted under Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts is a false claim.

426. As Arriva and Alere further falsely certified Arriva was not using any additional location or any subcontractors when Arriva submitted its bids for its 2013 and 2016 DMEPOS Competitive Bidding Contracts and again when Arriva entered those contracts, each claim submitted by Arriva and Alere in which the claim was submitted or billed to Medicare using Arriva's Arizona or Tennessee locations or Arriva Philippines was the submission of a false claim.

427. Additionally, Arriva's and Alere's false certifications in Arriva's bids for its 2013 and 2016 DMEPOS Competitive Bidding Contracts along with the false certifications in Arriva's 2013 and 2016 DMEPOS Competitive Bidding Contracts that Arriva was not using subcontractors or additional locations caused each claim submitted to Medicare (and the services conducted pursuant to such claims) by the Arizona or Tennessee locations or Arriva Philippines to be a false claim in violation of the False Claims Act.

428. Abbott, having knowledge that Arriva submitted false claims to Medicare for medically unnecessary items, directed Arriva to submit claims in December 2017 through January 2018 for dates of service from November 2016 through December 2017.

429. By virtue of the above-described acts, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States in violation of 31 U.S.C. § 3729(a)(1)(A), and Defendants knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved in violation of 31 U.S.C. § 3729(a)(1)(B).

430. The United States has incurred damages as a result of Defendants' unlawful scheme in an amount to be determined at trial.

431. Defendants are jointly and severally liable to the United States for treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each false

claim presented or caused to be presented by Defendants.

FIFTH CAUSE OF ACTION AGAINST ARRIVA AND ALERE FOR VIOLATION OF THE FALSE CLAIMS ACT DEFENDANTS' UNSOLICITED CONTACTS (31 U.S.C. §§ 3729(A)(1)(A) & (B))

432. Relator repeats and re-alleges each allegation contained in the paragraphs above as though fully set forth herein.

433. At all times relevant to this Complaint, Arriva and Alere knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States.

434. These claims included claims for covered items in situations where Arriva and Alere had contacted beneficiaries regarding the furnishing of that item.

435. Specifically, Arriva and Alere knowingly contacted individuals for the furnishing of a covered item when Arriva and Alere knew they did not meet any of the exceptions under 42 U.S.C. § 1395m(a)(17) that would permit them to contact the individuals and receive payment of the claims.

436. By virtue of the above-described acts, Arriva and Alere knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States in violation of 31 U.S.C. § 3729(a)(1)(A), and Defendants knowingly made, used, or caused to be made or used, false records or

statements to get false or fraudulent claims paid or approved in violation of 31 U.S.C. § 3729(a)(1)(B).

437. The United States has incurred damages as a result of Arriva's and Alere's unlawful scheme in an amount to be determined at trial.

438. Arriva and Alere are jointly and severally liable to the United States for treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each false claim presented or caused to be presented by Defendants.

SIXTH CAUSE OF ACTION AGAINST ALL DEFENDANTS FOR VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. §§ 3729(a)(I)(c)

439. Relator repeats and re-alleges each allegation contained in the paragraphs above as though fully set forth herein.

440. By virtue of the above-described acts, at all times relevant to this Complaint Defendants, and each of them, conspired with each other to commit violations of 31 U.SC. §§ 3729(a)(1)(A) and (B) and had actual knowledge, or acted in deliberate ignorance or reckless disregard, of the fact that their individual conduct as part of the conspiracy and the conduct of their co-conspirators would cause and did cause the submission of false claims for payment or approval for payment to the United States and that such claims were false.

441. Upon information and belief, the United States has incurred damages as a result of Defendants' unlawful scheme in an amount to be determined at trial.

442. Defendants are jointly and severally liable to the United States for treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each false claim presented or caused to be presented by Defendants.

WHEREFORE, Plaintiff prays that judgment be entered as followed:

A. In an amount equal to three times the amount of damages the United States has sustained because of Defendants' false or fraudulent claims and civil penalties up to $11,000 and no less than $5,500 for each false claim, for the maximum *qui tam* percentage share allowed pursuant to 31 U.S.C. § 3730(d) and for attorney's fees, costs and reasonable expenses; and

B. For any and all other relief to which Plaintiff may be entitled.

JURY DEMANDED

Plaintiff demands trial by jury on all issues triable as a right by jury.

RESPECTFULLY SUBMITTED this 6th day of April, 2020.

/s Lea P. Bucciero
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Lea P. Bucciero
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Kenneth N. Ralston (application for *Pro Hac Vice* to be submitted)
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Attorneys for Qui Tam Plaintiff Troy Olhausen

[*Certificate of Service and Service List Have Been Omitted for Printing Purposes*]

APPENDIX F

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

Case No. 21-10366

[Filed: May 13, 2022]

TROY OLHAUSEN, et al.,	)
	)
Appellant,	)
	)
v.	)
	)
ARRIVA MEDICAL, LLC, et al.,	)
	)
Appellees.	)
	)

PETITION FOR REHEARING

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA

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Counsel for Appellant

The Appellant submits this list, which includes all trial judges, attorneys, persons, associations of persons, firms, partnerships or corporations that have an interest in the outcome of this appeal:

1. Abbott Laboratories, Inc. (ABT)

2. Alere, Inc.

3. Arriva Medical, LLC

4. Bucciero, Lea V., Esq.

5. Gallagher & Kennedy, P.A.

6. Hess, Elizabeth S., Esq.

7. Homer, Peter W., Esq.

8. Homer Bonner Jacobs Ortiz

9. Kassof, Andrew A., Esq.

10. Kirkland & Ellis LLP

11. Lauck, Lisa, Esq.

12. Martinez, Christina, Esq.

13. Neal, Kevin D., Esq.

14. Olhausen, Troy

15. Podhurst Orseck, P.A.

16. Ralston, Kenneth N., Esq.

17. Rosenthal, Stephen F., Esq.

18. Scola, Jr., Hon. Robert N.

19. Sigfried, Daniel I., Esq.

20. Trask, Gregory J., Esq.

Corporate Disclosure Statement

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rules 26.1-1 through 26.1-3, Appellant states upon information and belief that Appellee Arriva Medical, LLC is not a publicly owned company, but a private subsidiary of Appellee, Alere, Inc., which is a private subsidiary of Appellee, Abbott Laboratories, Inc., a public company whose stock trades under the symbol ABT.

/s/ Stephen F. Rosenthal
Stephen F. Rosenthal

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PETITION FOR REHEARING

Appellant Troy Olhausen petitions this Court for rehearing of its decision because, most respectfully, it employed a legally erroneous approach which runs counter to binding precedent in this Circuit. In addition to this overarching error, the opinion overlooks several nuances specific to this case that require emendation.

The global flaw in the Court's approach to deciding this appeal on the scienter element of the False Claims Act claims is the Court's premise that Defendants-Appellees' *post hoc* identification of a reasonable interpretation of ambiguities in applicable Medicare regulations precludes scienter as a matter of law. Slip. Op. (attached) at 5-6. The Court's embrace of a purely objective standard for scienter under the False Claims Act *directly conflicts* with the precedential holding in *United States ex rel. Phalp v. Lincare Holdings, Inc.,* 857 F.3d 1148, 1155-56 (11th Cir. 2017). The *Phalp* court expressly rejected the approach this Court has taken, and for good reason: it allows a defendant alleged to have defrauded the federal government to escape through creative lawyering after the fact, even if the defendant subjectively knew at the time of its conduct that it violated the law.

While resolving this case using the scienter element sidestepped a more complex thicket of other issues, by doing so, the Court acted without the benefit of comprehensive briefing on the issue of scienter. The district court decided the claims on appeal (in Counts II and IV) on the different ground of failure to plead the submission of a claim with requisite particularity. The briefing on appeal therefore focused on that issue.

Scienter briefing was just the tail on the dog. As this petition reflects, that issue should not wag this appeal. Under this Circuit's governing law, scienter is *not* a basis to affirm the dismissal of Olhausen's claims, and a proper resolution of this appeal requires the Court to wrestle with the pleading-with-particularity issues squarely presented.

I. The Opinion Departs from Circuit Precedent by Allowing a Defendant to Dodge False Claims Act Liability Through a *Post Hoc* Proffer of a Reasonable Interpretation of an Ambiguous Regulation, Irrespective of Its Actual State of Mind

To understand why the Court's opinion clashes with binding precedent, it is best to begin with the law of this Circuit as set forth in *Phalp*:

> In the ... Summary Judgment Order ... , the district court concluded that Relators failed to produce sufficient evidence that Defendant submitted false claims with the requisite level of scienter because "a defendant's reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." ***The district court's conclusion that a finding of scienter can be precluded by a defendant's identification of a reasonable interpretation of an ambiguous regulation that would have permitted its conduct is erroneous.*** Although ambiguity may be relevant to the scienter analysis, it does not foreclose a

finding of scienter. Instead, a court must determine whether the defendant actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation. *See United States v. R&F Props. of Lake Cty., Inc.,* 433 F.3d 1349, 1358 (11th Cir. 2005) (finding a question of fact as to the defendants' understanding of a regulation precluded summary judgment despite ambiguity in the regulation).

Furthermore, under the district court's legal interpretation, a defendant could avoid liability by relying on a "reasonable" interpretation of an ambiguous regulation manufactured *post hoc,* despite having actual knowledge of a different authoritative interpretation. However, ***scienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable.*** *See United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.,* 276 F.3d 1032, 1053-54 (8th Cir. 2002) (holding that scienter is established if a defendant knowingly disregards the proper interpretation of an ambiguous regulation); *see also* S. REP. 99-345, at 6-7 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5271-72 (clarifying that instead of an actual knowledge standard, the Senate Judiciary Committee intended to adopt a standard which recognizes "that those doing business with the Government have an obligation to make a

> limited inquiry to ensure the claims they submit are accurate.").

Phalp, 857 F.3d at 1155-56 (emphasis added).

The earlier Eleventh Circuit precedent *Phalp* invoked, *R&F Properties,* similarly held in a False Claims Act case that it was error to end the inquiry when a defendant proffers a reasonable interpretation of an ambiguity in a regulation that would make its conduct legal. 433 F.3d at 1358. Although the defendant in that case pointed to an innocent alternative interpretation of a Medicare regulation, because the plaintiff offered evidence "relevant to the meaning of the Medicare regulation at issue and [defendant's] understanding of that meaning," the court concluded that the decision was one for the jury and inappropriate for a summary disposition. *Id.*

This governing approach—reversing *summary judgments* to defendants—is wholly at odds with the tack this Court took in reviewing the order granting a motion to dismiss in this case. Although the opinion cited *Phalp,* merely for its recitation of the statutory definition of "knowingly," Slip. Op. at 4, it failed to heed its holding on scienter, quoted in full above. Instead, and in direct contravention of that holding, this Court reasoned that a False Claims Act defendant's proffered reasonable interpretation of ambiguous law precludes a finding of scienter. The Court's reasoning cannot be squared with the holding in *Phalp*. The Court said, for instance, "Even if Arriva's interpretation is wrong (and it was required to obtain signatures), Olhausen cannot show that Arriva had the requisite scienter because it is an objectively

reasonable interpretation of the rules to conclude that signatures were not required." Slip Op. at 6. But *Phalp* held that "scienter is *not* determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable." *Phalp,* 857 F.3d at 1155 (emphasis added).

The Court's departure from precedent is even more striking considering this case's procedural posture—review of an order on a motion to dismiss. A plaintiff, even a False Claims Act relator, need only allege scienter *generally,* not with particularity. *Urquilla-Diaz v. Kaplan Univ.,* 780 F.3d 1039, 1055 n.13 (11th Cir. 2015); Initial Br. at 34. The complaint plausibly alleged that regulations and other authorities made Defendants' conduct unlawful and that they knew or should have known that. *See* Initial Br. at 34-37, 52-53. Defendants responded with *arguments* that the regulations are ambiguous and that their "conduct was *consistent with* a reasonable interpretation of th[e] requirement." Response Br. at 44 (emphasis added). The record at this stage contains nothing about Defendants' *actual* state of mind at the time of its conduct beyond the complaint's allegations, which the Court must "accept as true ... and draw all reasonable inferences in the plaintiff's favor." *Randall v. Scott,* 610 F.3d 701, 705 (11th Cir. 2010). Precedent requires consideration of what the defendant "actually knew or should have known ... at the time of the alleged violation." *Phalp,* 857 F.3d at 1155. It is impossible to assess that variable at the motion to dismiss stage when, as here, the complaint plausibly alleges an interpretation of the law under which the defendant's

conduct would be unlawful and no evidence has been obtained in discovery to show otherwise.

The Court's opinion also creates a new escape hatch from FCA liability: all a defendant needs do to win a dismissal on scienter at the threshold of the case is articulate, after the fact and through counsel, some reasonable interpretation of an ambiguity in the applicable authority. That eventuality is not just inconsistent with this Court's FCA precedent, it undercuts the FCA as a viable enforcement mechanism against those who in fact knowingly defrauded the government. Fraudsters will be incentivized to ignore red flags so they can muster plausible deniability later, trusting that what they actually knew will never be discovered. That runs counter to the purposes of the False Claims Act, which is designed to combat fraud upon the government.

The Court's decision offers no explanation for why it felt comfortable departing from the precedent of *Phalp*. Perhaps the Court felt that the Supreme Court's decision in *Safeco* charted the appropriate course. *See* Slip Op. at 5 (discussing the scienter rule from *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007)). But *Safeco* offers no shelter from following this Court's binding FCA precedent.

Safeco, decided ten years before *Phalp,* did not involve the False Claims Act, but the Fair Credit Reporting Act. In fact, the court in *Phalp* "received extensive briefing on the recklessness standard recognized in *Safeco* and declined to import it into the False Claims Act." *U.S. ex rel. Sheldon v. Allergan Sales, LLC,* 24 F.4th 340, 363-64 (4th Cir. 2022)

(Wynn, J., dissenting); *see* Brief for the United States of America as Amicus Curiae in Support of Neither Party in *Phalp* at 22-24, No. 16-10532 (11th Cir.), filed May 5, 2016 (explaining why the *Safeco* standard is a poor fit and urging the court not to adopt it); Appellees' Answer Brief in *Phalp,* 2016 WL 3098444, at *56 (responding that "the Government's reading of *Safeco* is too narrow. *Safeco* is instructive on the issue of FCA scienter in a case, like this, where Defendants adopted reasonable interpretations of the Medicare regulations at issue in the absence of contrary authorities."). The *Phalp* court plainly followed the Government's position and rejected the defendant-appellee's.

Not only did the court in *Phalp* refuse to import the *Safeco* standard, it also refused to follow two circuits that had embraced *Safeco* in False Claims Act cases and which had given rise to the *Phalp* district court's conclusion "that a finding of scienter can be precluded by a defendant's identification of a reasonable interpretation of an ambiguous regulation that would have permitted its conduct," 857 F.3d at 1155. This history is most apparent from the Government's amicus brief in *Phalp*. It noted that the district court in that case had relied for its scienter ruling upon the Eighth Circuit case this Court now cites: *U.S. ex rel. Hixson v. Health Mgt. Sys., Inc.,* 613 F.3d 1186 (8th Cir. 2010). *Compare* Slip. Op. at 6, *with* Gov't Amicus Br. in *Phalp* at 10-11, 19-21.[1] It also reasoned that the

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[1] *See U.S. ex rel. Phalp v. Lincare Holdings, Inc.,* 116 F. Supp. 3d 1326, 1359 (S.D. Fla. 2015) (citing *United States v. Space Coast Med. Assocs., L.L.P.,* 94 F. Supp. 3d 1250, 1262 (M.D. Fla. 2015) (in tum quoting *Hixson,* 613 F.3d at 1190)).

other out-of-circuit case this Court now cites, *U.S. ex rel. Purcell v. MWI Corp.,* 807 F.3d 281 (D.C. Cir. 2015), *see* Slip Op. at 5, "relied on an unwarranted extension of" *Safeco* into the False Claims Act context. Gov't Amicus Br. in *Phalp* at 22-23. Notably, the *Phalp* court steered clear of *Safeco, Hixson,* and *Purcell* in its decision. This Court's reliance on those authorities in this case simply cannot be reconciled with the *Phalp* court's deliberate decision to eschew them.

The governing scienter standard from *Phalp* which this Court should have applied does not allow resolution of plausible False Claims Act claims on scienter grounds at the motion to dismiss stage. That is because "a court *must* determine whether the defendant *actually* knew or should have known that its conduct violated a regulation in light of any ambiguity *at the time of the alleged violation*." *Phalp,* 857 F.3d at 1155 (emphasis added). That inquiry is necessarily evidence-based and must await discovery. It cannot be answered based on hypothetical positions proffered by a defendant in litigation, such as "the objectively reasonable conclusion by Arriva" on which the Court based its opinion. Slip Op. at 6. There is, of course, no basis to presume that this was actually Arriva's position back in 2012 to 2018. Moreover, if there was an authoritative interpretation of the ambiguous law that the defendant knew about, its reasonable *post hoc* explanation would not preclude scienter. *Phalp,* 857 F.3d at 1155.

Under the correct standard, it was improper to affirm the dismissal on the element of scienter, an issue the district court did not even reach. There are

additional reasons why the Court's conclusion was erroneous, particular to each count, addressed separately below.

II. As to Count II, the Court Also Failed to Account for an Authoritative Source That Undercuts the Scienter Defense

With respect to whether Defendants were required to obtain beneficiary signatures for every assignment of benefits, the Court affirmed the dismissal of Count II "because it is a reasonable interpretation of the rules to conclude that the signatures were not required." Slip Op. at 6. The Court also cited *Hixson,* which adds the caveat "'if there is no authoritative contrary interpretation of the [rule].'" *Id.* (quoting *Hixson,* 613 F.3d at 1190).

Even assuming it were proper to engage this inquiry on a motion to dismiss, the Court neglected to explore whether there was an authoritative source that contradicted Defendants' articulated rationale. Olhausen both plead and argued that there *was* an authoritative source, which Defendants were aware of, that interpreted the applicable regulations in a way that made their conduct unlawful. *See* Reply Br. at 16, 18 (discussing the Medicare Claims Processing Manual's explanation that a claimant must have signatures of beneficiaries for each claim).[2] Yet the opinion makes no reference to the Manual, let alone

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[2] Medicare Claims Processing Manual, Ch. 1, §§ 30.3.2 (Rev. 643, Aug. 12, 2005), 50.1.6 (Rev. 980, June 14, 2006), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf.

questions its authoritativeness. The existence of this official source underscores why it is improper to dismiss Count II on scienter grounds.

III. As to Count IV, the Court Overlooked Two Distinct Variables That Its Reasoning Does Not Affect

The Court decided that the allegations in Count IV fail on the "same" objective-reasonableness grounds. Slip Op. at 6. Setting aside the questionable propriety of that analytic framework, the Court's treatment of these claims overlooked two variants in the claims asserted in Count IV that are unaffected by the Court's scienter analysis: (1) the alternative allegation about Arriva Philippines' as an unaccredited subcontractor, and (2) the fraud-in-the-inducement claim.

A. The opinion overlooks the alternative pleading regarding Arriva Philippines' regulatory identity

By way of background, the complaint plead, alternatively, that Arriva Philippines was either an additional "physical location" of Arriva or an independent subcontractor. DE 58, ¶¶ 47, 284-85. On appeal, Olhausen separately discussed the two distinct theories. Initial Br. at 27-28. After Defendants responded with a scienter defense predicated *exclusively* upon their reading of the regulation that governs the enrollment requirement for "separate *physical locations* ... use[d] to furnish ... DMEPOS," 42 C.F.R. § 424.57(b)(l) (emphasis added), Answer Br. at 54-55, Olhausen pointed out their failure to address the alternative theory. Reply Br. at 26 ("Defendants

offer[ed] no scienter defense if Arriva Philippines was a subcontractor, effectively conceding that if it was, their failure to disclose it was willful.").[3]

The Court, like Defendants, nonetheless addressed only one of the two alternative analytic routes. Consistent with the Court's omission, its recitation of the facts makes no mention of the alternative subcontractor theory and only refers to the Philippines as one of several "call-center *locations."* Slip. Op. at 3 (emphasis added).[4] Likewise, the Court's statement that the "parties . . . fully briefed the scienter issue," *id.* at 4 n.1, ignores that the Defendants' briefing on scienter addressed just one of the two alternative theories in the operative complaint.

The ensuing analysis is therefore incomplete. The conclusion that "[i]t is an objectively reasonable interpretation of the rule that Arriva's call-center locations did not 'furnish' DMEPOS, so it was not required to enroll them," *id.* at 6, does not deal with the implications of Arriva Philippines having been a subcontractor.

The complaint alleges that Defendants unlawfully used Arriva Philippines to perform most of Arriva's

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[3] The reply brief also pointed out other places where the alternative allegation of Arriva Philippines having been a subcontractor impacts the legal analysis. *See* Reply Br. at 23 (discussing falsity element).

[4] The Background section of the opinion also contains what we presume to be a scrivener's error in that it refers to the "second amended complaint" instead of the operative pleading, the Third Amended Complaint. Slip. Op. at 3, 4.

material day-to-day operations and submit claims to Medicare. DE 58, ¶¶ 57, 278-79. Under Medicare regulations and contract terms unaffected by the ambiguity of the word "furnish," a supplier like Arriva could not subcontract out primary contract functions or the submission of claims. The initial brief explained:

> The outsourcing to Arriva Philippines of the performance of services that Arriva *itself* had to perform violated 42 C.F.R. § 424.57(c) and obligations under the 2013 and 2016 Contracts. TAC, ¶¶ 57-58, 262, 314. As a subcontractor, Arriva Philippines was only authorized to complete purchases of inventory, deliver and provide instructions on product use to the beneficiaries, and maintain and repair rented equipment. *Id.* ¶ 262; 42 C.F.R. § 424.57(c)(4), (12), (14). But Arriva secretly outsourced claims-processing and billing—services Arriva was legally required to handle itself—to personnel in the Philippines. *Id.* ¶¶ 57, 278-79. Arriva manipulated its billing software to mask the fact that the claims were processed in the Philippines and structured the electronic routing of claims to make them appear to have been submitted from Arriva's Florida location. *Id.* ¶¶ 58, 279-81. Even if Arriva had disclosed the involvement of Arriva Philippines, it would have been unlawful, since "Arriva Philippines was not an accredited organization through CMS and did not have its own DMEPOS supplier number" or "national provider identification number," "which was required to bill DMEPOS items to Medicare." *Id.* ¶¶ 263-267 (citing 42 C.F.R.

§§ 424.57(b), (c)(2), (c)(18), (c)(22)–(24)), ¶¶ 276, 286.

Initial Br. at 28. While the regulatory ambiguity the Court identified with respect to furnishing DMEPOS only bore on the obligation to *disclose* the use of additional supplier locations, the above-referenced regulations implicate the mere *use* of a subcontractor for certain tasks.

Arriva's contracts with CMS further reiterated the restriction on who can perform primary contract functions or bill Medicare. The contracts delineated certain functions that "a Contract Supplier may subcontract for," as opposed to "[s]ervices such as ... submitting claims on behalf of the beneficiary" which are ones "for which the Contract Supplier [itself] is responsible." DE 58, ¶¶ 314, 319. This contract-based restriction is unaffected by the definition of the term "furnish." These claims thus survive the Court's analysis.

B. The opinion also ignores the distinct nature of the fraud-in-the-inducement claim

The fraud-in-the-inducement claim in Count IV likewise stands unscathed by the "furnish" ambiguity the Court identified. In support of that theory, the complaint alleged that when Arriva submitted its applications for the 2013 and 2016 contracts Defendants "intended to utilize unaccredited subcontractors." DE 58, ¶ 352; *see id.* ¶¶ 353, 415-425. Yet Defendants affirmatively misrepresented to CMS "that Arriva did not intend to use subcontractors," and

"knew CMS would rely on these misrepresentations" in awarding Arriva its DMEPOS contracts. *Id.* ¶¶ 420-23; *see* Initial Br. at 13-14, 30, 36-37. The issue of scienter concerning this claim is entirely disconnected from any ambiguity concerning the meaning of "furnishing" of DMEPOS and therefore remains unresolved by the Court's opinion.

IV. The Conspiracy Claims Follow Accordingly

The conspiracy claims pled in Count VI flow from the substantive False Claims Act violations in Counts II and IV. Revisiting those counts requires reconsidering the conspiracy claims too.

CONCLUSION

The Court should grant rehearing because this appeal cannot, as the Court mistakenly believed, be resolved on the issue of scienter. The Court must address the main issues presented by the appeal concerning the adequacy of the pleading, focusing on "presentment" and "submission" issues.

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