

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA <i>ex rel.</i>)	Civil Action No.
GREGORY M. GOODMAN,)	
)	RELATORS' COMPLAINT PURSUANT TO
Plaintiff,)	THE FEDERAL FALSE CLAIMS ACT, 31
)	U.S.C. §3729 <i>ET SEQ.</i>
vs.)	
)	FILED UNDER SEAL
ARRIVA MEDICAL, LLC and ALERE, INC.,)	DO NOT PLACE ON PACER
)	
Defendants.)	
_____)	<u>DEMAND FOR JURY TRIAL</u>

**RELATOR’S COMPLAINT PURSUANT TO
THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 ET SEQ.**

Relator Gregory M. Goodman (referred to herein as “Relator”), on behalf of the United States of America, brings this action against Arriva Medical, LLC and Alere, Inc. (collectively, “defendants”) for violations of the federal False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, to recover all damages, civil penalties and other recoveries provided for under the FCA.

I. PARTIES

1. Defendant Arriva Medical, LLC (“Arriva”) is a Florida limited liability company with its headquarters in Coral Springs, Florida. Arriva was founded in 2009 and is a fast-growing mail order supplier of diabetic testing supplies, including glucose meters, test strips, lancets, lancet devices and control solution. As part of its mail order business, Arriva operates a call center in Antioch, Tennessee.

2. Defendant Alere, Inc. (“Alere”) is a publicly traded Delaware corporation headquartered at 51 Sawyer Road, Suite 200, Waltham, Massachusetts. Alere purchased Arriva in November 2012 for approximately \$65 million.

3. The United States of America (hereafter, “United States”) is a plaintiff to this action. The United States brings this action on behalf of the U.S. Department of Health & Human Services (“HHS”), the Centers for Medicare & Medicaid Services (“CMS”), and other federally funded health care programs, including Medicare.

4. Relator is a current employee of defendant Arriva and has standing to bring this action pursuant to 31 U.S.C. § 3730(b)(1). Relator’s Complaint is not based on any other prior disclosures of the allegations or transactions discussed herein in a criminal, civil, or administrative hearing, lawsuit or investigation, or in a Government Accounting Office or Auditor General’s report, hearing, audit or investigation, or from the news media.

II. SUMMARY OF THE ACTION

5. Relator, on behalf of the United States, brings this case to challenge defendants' various, interrelated schemes to defraud the Medicare system.

6. Specifically, defendants have defrauded and continue to defraud Medicare in defendants' role as a mail order supplier of diabetic testing supplies to Medicare beneficiaries.

7. Under Medicare Part B, the payments defendants receive for providing diabetic supplies are divided into three elements: (1) the allowable cost that is paid by federally funded health care programs (including Medicare Part B); (2) a deductible that is paid by the beneficiary; and (3) a copayment that is paid by the beneficiary. Under Medicare Part B, the deductible is approximately \$147 per year, and the copayment cost division is 80-20—*i.e.*, Medicare Part B pays 80% and the beneficiary (or the beneficiary's supplemental insurer) pays the remaining 20%. This copayment division applies to all diabetes supplies, including glucose meters and test strips.

8. As of July 1, 2013, Medicare Part B significantly altered its policies for compensating diabetic testing suppliers. Specifically, pursuant to the Medicare Modernization Act of 2003 ("MMA"), Medicare Part B implemented a competitive bidding system for mail order suppliers of diabetic testing equipment. Under this system, Medicare will only compensate those suppliers who have been awarded contracts pursuant to the competitive bidding program.

9. In the months leading up to this change, the business landscape for mail order diabetic testing supplies was in upheaval, with successful bidders rushing to acquire the assets and customer lists of unsuccessful bidders who would not be able to bill Medicare for diabetic testing supplies after July 1, 2013.

10. Arriva was one such successful bidder, and it spent much of 2012 acquiring other diabetic testing suppliers that were preparing to exit the market. Specifically, Arriva purchased Direct Diabetic Source, Inc., AmMed Direct LLC, and the diabetes home supply businesses of

NationsHealth, Inc. and Liberty Medical Supply, Inc. (“Liberty Medical”). During the same period, Arriva was itself acquired by defendant Alere.

11. Both during and after this period of transition, defendants have engaged in six distinct but related schemes to defraud the federal government.

12. First, defendants have fraudulently billed Medicare for thousands of glucose meters that were not medically necessary, and that defendants knew were not medically necessary.

13. Second, defendants have offered kickbacks to their customers—in the form of free, “upgraded” meters and forgiving copayments—to induce beneficiaries to obtain their diabetes testing supplies from defendants and to further induce beneficiaries to order unnecessary products and services covered and partially paid for by Medicare.

14. Third, defendants have offered kickbacks, in the form of forgiving copayments, to secondary insurance providers Express Scripts, Inc. (“ESI”) and United Healthcare (“United”) to induce those insurers to refer their Medicare-covered, diabetic patients to defendants to obtain diabetic testing supplies.

15. Fourth, defendants have illegally marketed heating pads, back braces, and impotence therapy devices to new patients during calls to place orders for diabetic testing supplies, and have billed Medicare for these illegally marketed items.

16. Fifth, defendants have illegally billed Medicare for diabetic supplies without having the necessary prescriptions on file from beneficiaries’ physicians.

17. Sixth, following the change in the law on July 1, 2013, defendants illegally induced Medicare beneficiaries to switch from one brand of diabetic testing supplies to another.

18. Underlying these fraudulent schemes was defendants’ general desire to convert as many of its customers as possible to two specific brands of diabetic testing supplies—Prodigy AutoCode and TRUEresult. Defendants had and have contracts in place with the makers of these

two brands that make them more lucrative for defendants to supply than other brands of testing supplies.

19. Accordingly, in order to increase their own profits, defendants have submitted false claims for payment to the United States, offered unlawful kickbacks to secondary insurers and to Medicare beneficiaries, and have illegally reduced the choices available to beneficiaries and their physicians for diabetic testing supplies.

III. JURISDICTION AND VENUE

20. Jurisdiction is founded upon the FCA, 31 U.S.C. § 3729 *et seq.*, specifically 31 U.S.C. § 3732(a) and (b), and also 28 U.S.C. §§ 1331 and 1345.

21. Venue in the Middle District of Tennessee is appropriate under 31 U.S.C. § 3732(a) in that, at all times material to this civil action, one or more of the defendants transacted business in the Middle District of Tennessee, or submitted or caused the submission of false claims in the Middle District of Tennessee.

IV. THE MEDICARE PART B PROGRAM

22. Title XVIII of the Social Security Act prescribes coverage requirements under Part B of the Medicare program. Medicare Part B covers services and items including 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.

23. Medicare Part B covers blood sugar self-testing equipment, including blood sugar monitors,¹ blood sugar testing strips, lancet devices, lancets, and glucose control solutions, if the patient meets these requirements: (1) the patient is under a physician’s care for diabetes; (2) the

¹ The devices diabetic patients use to test their blood sugar are known as both “monitors” and “meters.” The two terms are used interchangeably.

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