UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. ENAAME FARRELL, M.D. Defendant.	)	Civil Action No.

COMPLAINT

Plaintiff, the United States of America ("United States" or the "government"), brings this action against Defendant Enaame Farrell, M.D. ("Defendant" or "Dr. Farrell") to recover damages Defendant caused to Federal health care programs, including Medicare. For its cause of action, the United States alleges as follows:

NATURE OF THE ACTION

1. The United States brings this action to recover statutory damages and civil penalties under the False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-3733.

2. The United States alleges that, from on or about May 1, 2020 through at least April 30, 2021 (the "relevant time period"), Dr. Farrell knowingly caused false or fraudulent claims for payment to be submitted to Medicare, for medications, diagnostic testing, and durable medical equipment ("DME"). Dr. Farrell caused these false and fraudulent claims by ordering medications, diagnostic tests, and DME that were not "reasonable or 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)(l)(A), not supported by the patients' medical records, not the result of a bona fide patient relationship or patient encounter with Dr. Farrell, and

tainted by kickbacks knowingly and willfully solicited and received by Dr. Farrell in exchange for his illegal ordering.

3. As a result of these false and fraudulent orders, Dr. Farrell knowingly caused the submission of false and fraudulent claims for prescription drugs, diagnostic tests, and DME for more than 2,000 Medicare beneficiaries, for which Medicare paid approximately $3,394,811.61.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, as a case arising under the laws of the United States, and § 1345, because the United States is a Plaintiff.

5. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant can be found in, transacts business in, and/or has committed the alleged acts in the Western District of New York.

6. Venue is proper in the Western District of New York pursuant to 27 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732(a) because Defendant can be found in and transacts business in this District, a substantial part of the events or omissions giving rise to the claims occurred in this District, and Defendant is subject to the Court's personal jurisdiction under the FCA.

PARTIES

7. Plaintiff is the United States of America, suing on behalf of the United States Department of Health and Human Services ("HHS"), which includes its operating division, the Centers for Medicare and Medicaid Services ("CMS").

8. Dr. Farrell, at all relevant times, was a licensed Family Medicine physician in New York State and practiced within the Western District of New York and elsewhere. During the relevant time period, Dr. Farrell ordered prescription drugs, diagnostic tests, and DME (collectively, "items and services") for Federal health care program beneficiaries for which Federal health care programs, including Medicare, paid reimbursements.

LEGAL AND REGULATORY BACKGROUND

I. THE FALSE CLAIMS ACT ("FCA")

9. The FCA, 31 U.S.C. § 3729, provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A) [or] (B) . . . .

is liable to the United States for three times the amount of damages which the Government sustains, plus a civil penalty per violation. For violations occurring on or after November 2, 2015, the civil penalty amounts range from a minimum of $14,308 to a maximum of $28,618. 28 C.F.R. § 85.5.

10. For purposes of the FCA:

> the terms "knowing" and "knowingly" (A) 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; and (B) require no proof of specific intent to defraud. . . .

31 U.S.C. § 3729(b)(1).

11. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

II. THE MEDICARE PROGRAM

12. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare program, to pay for the costs of certain healthcare services. 42 U.S.C. § 1395 *et seq.* Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1.

13. HHS is responsible for administering and supervising the Medicare program, which it does through CMS, an agency of HHS.

14. Medicare is a federally subsidized health insurance program. *See* 42 U.S.C. § 1395c.

15. Medicare Part B generally covers physician services, outpatient treatment and diagnosis, and ancillary services and DME.

16. Medicare Part D is a prescription drug benefit that helps Medicare beneficiaries pay for prescription drugs.

17. Medicare reimburses only those services furnished to beneficiaries that are "reasonable and 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)(l)(A).

18. The Secretary is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a).

19. The Secretary acts through formal regulations, and periodically CMS and HHS, Office of Inspector General ("OIG"), issue industry guidance.

20. At all times relevant to this Complaint, CMS contracted with private contractors, known as Medicare Administrative Contractors ("MACs"), to perform various administrative functions on its behalf, including reviewing and paying claims submitted by healthcare providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104.

21. Because it is not feasible for the Medicare program or its contractors to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

22. Providers have a duty to be familiar with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

23. Providers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. *See e.g.*, 42 U.S.C. §§ 1320a-7a(a)(1) (civil monetary penalties), 1320a-7(b)(7) (permitting exclusion of providers for fraud, kickbacks, and other prohibited activities).

24. Providers must assure that their services are rendered "economically and only when, and to the extent, medically necessary," and that their services are "of a quality which meets professionally recognized standards of health care." 42 U.S.C. §§ 1320c-5(a)(l) and 5(a)(2).

25. To that end, to participate or "enroll" in the Medicare program, a healthcare provider must file a provider agreement with the Secretary of HHS ("Secretary"). 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the Medicare program and to receive reimbursement from Medicare.

26. To participate in the Medicare program as a new enrollee, providers, including physicians, must submit a Medicare Enrollment Application, known as a Form CMS-855I. Providers also must complete Form CMS-855I to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

27. Under 42 C.F.R. § 424.516(a)(1), Medicare providers must certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations.

28. Form CMS-855I requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 4A of this application. The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) . . . .
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf.

29. The provider must sign the "Certification Section" in Section 15 of Form CMS-855I, and in doing so "attest" to meeting and maintaining the Medicare requirements" excerpted above, among others. *Id.*

30. At all times relevant to this Complaint, Dr. Farrell was a Medicare provider.

31. Dr. Farrell enrolled with Medicare via a Form CMS-855I he submitted on or about August 2, 2017.

32. His enrollment with Medicare was effective as of July 15, 2017.

33. Dr. Farrell certified in the Form CMS-855I that he would, among other things, "agree to abide by the Medicare laws, regulations and program instructions"; "that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and Stark law)"; and "not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

34. On or about July 19, 2019, Dr. Farrell submitted another Form CMS-855I to Medicare, and he made the same certifications as in his earlier Form CMS-855I.

THE FRAUDULENT CONDUCT

35. Dr. Farrell engaged in a scheme to defraud Medicare by ordering unnecessary and unwanted items and services for Medicare beneficiaries, for which pharmacies and other entities (the "Billing Entities") who received the orders signed by Dr. Farrell submitted claims to Medicare.

36. Medicare paid approximately $3.4 million to the Billing Entities for items and services ordered by Dr. Farrell.

37. Dr. Farrell solicited and received between approximately $13 and approximately $19 per record or order to review records and sign orders for items and services for patients he never examined or met.

38. In total, Dr. Farrell received payment of approximately $88,000 for the orders he signed for items and services.

39. The resulting items and services were not reasonable and necessary, and the claims submitted to Medicare for the items and services were based on false and fraudulent statements, representations, and certifications made by Dr. Farrell.

40. As detailed below, Dr. Farrell acted with actual knowledge, deliberate ignorance, and/or reckless disregard of the laws, regulations and guidance applicable to the Medicare program when ordering items and services for Medicare beneficiaries during the relevant time period.

41. Dr. Farrell knowingly participated in this scheme to order items and services that were paid for by Medicare despite knowing that the items and services were not medically necessary or needed for patient care, that the claims submitted to Medicare by the Billing Entities were the result of false and fraudulent records or statements, and that the claims were the result of illegal kickbacks.

I. Defendant Caused the Submission of False and Fraudulent Claims to Medicare and Caused False Statements Material to False Claims

42. In or about March 2018, Dr. Farrell contracted with Barton & Associates ("Barton"), a locum tenens staffing company.

43. Under the agreement, Barton assigned Dr. Farrell to Barton's clients to perform duties as temporary medical practitioner.

44. Among other assignments, Barton assigned Dr. Farrell to perform "chart reviews" on behalf of various marketing companies, including PAS 24/7, Nationwide Health Advocates, and Realtime Physicians (collectively, the "Companies").

45. The Companies sent Dr. Farrell pre-populated patient files, which include pre-populated orders for items and services (the "patient files"), through email or an online portal.

46. After accessing the patient files electronically, Dr. Farrell was supposed to review the patient files to determine whether the patients were eligible to receive the pre-selected items and services.

47. Among other things, Dr. Farrell was to determine whether the items and services were reasonable and necessary.

48. If Dr. Farrell determined that they were reasonable and necessary and the patient was eligible to receive them, he was to electronically sign a pre-populated order.

49. Dr. Farrell would then return the signed orders to the Companies either by email or through an online portal provided by the Companies.

50. The Companies would then provide the signed orders to Billing Entities, who relied on the orders to provide the items and services to Medicare beneficiaries, and to submit claims for the items and services to Medicare.

51. The Companies, in some cases through Barton and in other cases directly, would pay Dr. Farrell between approximately $13 and approximately $19 for each patient file that he assessed and orders he signed.

A. Defendant signed orders that were not medically necessary and/or based on incorrect, false, and fraudulent information.

52. The orders that Dr. Farrell signed required that he certify that the items and services he was ordering were reasonable and necessary.

53. The orders for DME that Dr. Farrell signed included the following certification: "I, ENAAME FARRELL, verify and confirm this order for the above-named patient, and certify that I have personally performed the assessment of the patient for the prescribed treatment and device and verify that it is reasonably and medically necessary, according to accepted standards of medical practice within the community, for this patient's medical condition."

54. Similarly, the orders for medications that Dr. Farrell signed included a certification that Dr. Farrell "established a valid prescriber-patient relationship with the Patient identified above, which continued through the consult date and/or date of this prescription . . . . [and he] deemed the following medication medically necessary for" the patient.

55. Dr. Farrell also signed orders for diagnostic tests in which he "confirm[ed] that this is medically necessary for the diagnosis or detection of a disease, illness, impairment, syndrome or disorder, and that these results will be used in the medical management and treatment decisions for this patient." He also confirmed that he "(a) ha[d] an on-going relationship with the patient, (b) will use the results in the management of the patient's medical condition, (c) will follow up with the patient once the test results are received to render additional treatment decisions based on the test results, (d) will maintain a detailed chart with SOAP notes specifying how the test results impacted the medical care and treatment of the patient in follow-up visits, (e) that you understand that if the patient is a Medicare beneficiary that Medicare does not cover routine screening tests, and (f) the test ordered is not a screening test, and that all local and national CMS coverage guidelines to determine medical necessity of the ordered test have been met."

56. Dr. Farrell's certifications were false and fraudulent because he did not and could not have certified that the items and services he ordered were reasonable and necessary because, among other reasons, he did not personally assess or examine the patients or even review the patient files.

i. Defendant did not assess the patients for whom he ordered prescription drugs, diagnostic tests, and DME

57. Contrary to the certifications he made, Dr. Farrell did not personally assess or examine the patients for whom he ordered items and services because he did not personally interact with the patients—he did not meet with the patients in person or speak with the patients on the phone or videoconference.

58. At most, Dr. Farrell briefly accessed the patient files that the Companies sent him.

59. Because Dr. Farrell did not personally interact with the patients, he could not have "personally performed the assessment of the patient," as he certified for the DME orders, or "establish[] a valid prescriber-patient relationship," as he certified in orders for medications, or "have an on-going relationship with the patient," as he certified on test orders.

60. He was, therefore, unable to certify that the items and services he ordered were medically necessary.

a. Representative DME patients

61. Medicare will not pay for certain DME, such as knee braces billed to Medicare under Healthcare Common Procedures Coding System ("HCPCS") Codes L1833 and L1851, without documentation that a joint laxity test was performed on the patient.

62. Dr. Farrell did not perform joint laxity tests for more than 900 patients for whom he ordered knee braces that were billed to HCPCS Codes L1833 and L1851.

63. Nor did Dr. Farrell confirm that any such joint laxity tests occurred, despite his false representations that such tests were performed.

64. Dr. Farrell understood that, if patients spoke with anyone at all, the conversation occurred remotely and the person with whom they spoke had no medical training.

65. A joint laxity test, like those required to order knee braces, cannot be performed over the phone or remotely, let alone by a person with no medical training.

66. Patients who were ordered knee braces by Dr. Farrell confirmed that they were not examined by Dr. Farrell, or any other provider in relation to the braces ordered on their behalf, and that no joint laxity test was performed on them.

67. Dr. Farrell signed orders for two knee braces for Medicare Beneficiary D.R. on or about December 24, 2020.

68. Dr. Farrell certified that the knee braces were reasonable and necessary for D.R. and that a joint laxity test was performed on D.R.

69. Although Dr. Farrell ordered knee braces, as well as a back and shoulder brace, to D.R., he never examined D.R. and D.R. had never met or spoken with Dr. Farrell.

70. Medicare was billed approximately $1,600 for these braces and it paid approximately $1,214.94.

71. D.R. received knee braces, but she did not want or need them because, among other reasons, both of her legs had been amputated at the time Dr. Farrell ordered her knee braces.

72. Dr. Farrell ordered two knee braces for Medicare beneficiary G.D. on or about December 23, 2020, and, in doing so, certified that the braces were reasonable and necessary, and a joint laxity test was performed.

73. Medicare paid approximately $1,391.86 for the braces ordered by Dr. Farrell.

74. G.D. recalled getting calls from telemarketers purporting to be from Medicare and telling her that she could receive free braces.

75. She did not, however, know Dr. Farrell, except that his name was on a box of braces that she received, nor was she examined by him.

76. The braces that G.D. received based on Dr. Farrell's signed order did not fit.

77. Dr. Farrell ordered other types of DME for Medicare beneficiaries without examining them.

78. Dr. Farrell ordered a back brace for Medicare Beneficiary A.T. on or about December 8, 2020 and certified that the brace was reasonable and necessary.

79. Medicare paid approximately $803.03 for the back brace, which A.T. subsequently received in the mail, despite not knowing Dr. Farrell and never being evaluated by him.

80. Although she did recall getting calls, including from people representing themselves as doctors, she never requested a back brace or reported needing one.

81. Dr. Farrell ordered a back brace on or about December 8, 2020 to Medicare Beneficiary M.R., and certified it was reasonable and necessary, at a cost to Medicare of approximately $803.03.

82. M.M. also did not know Dr. Farrell and was never evaluated by him in connection with the shoulder and wrist brace orders, or otherwise.

83. Dr. Farrell ordered DME for over 1,600 Medicare beneficiaries, and Medicare paid for DME for over 1,250 of those beneficiaries at a cost of over approximately $1.8 million.

b. Representative medication patients

84. Dr. Farrell did not examine or speak with patients for whom he ordered medications.

85. Because Dr. Farrell had no interactions with patients, he falsely represented in medical records and on orders that he had established a "valid prescriber-patient relationship" and that the medications were reasonable and necessary.

86. On or about January 21, 2021, Dr. Farrell signed orders for medications, and certified that the medications were reasonable and necessary, for Medicare Beneficiary D.P. at 9:24 pm, which was less than three minutes after the previous order he signed.

87. In that time, Dr. Farrell purported to have reviewed D.P.'s patient file and ordered fifteen different medications and other items:

88. Not only did Dr. Farrell order these medications after, at most, a brief, cursory review of D.P.'s patient file, he could not, and did not, establish that the medications were reasonable and necessary.

89. For instance, Dr. Farrell ordered diflorasone, which is a highly potent topical corticosteroid used to treat skin conditions, such as psoriasis and eczema. However, nothing in the patient file indicated that D.P. suffered from psoriasis or eczema.

90. Dr. Farrell also ordered D.P. 360 grams of calcipotriene cream and clobetasol ointment, both of which are used to treat plaque psoriasis on specific, localized areas of the body. However, the patient file did not indicate that D.P. suffered from plaque psoriasis.

91. Furthermore, the amount of diflorasone (120 grams), calcipotriene (360 grams), and clobetasol (360 grams) that Dr. Farrell ordered exceeds the reasonable or recommended daily quantity of these medication that D.P. could or should use.

92. The over-use of high potency corticosteroids, such as diflorasone, calcipotriene, and clobetasol, can have significant side-effects, including adrenal suppression and hyperglycemia.

93. Nothing in D.P.'s patient file indicated the need for these medications, let alone the need to depart in such a significant way from standard practices.

94. Medicare Beneficiary D.E. did speak to Farrell, but only after receiving medications ordered by Dr. Farrell that he did not need or request, but for which Dr. Farrell certified that the medications were reasonable and necessary.

95. Prior to receiving the medications, D.E. had never heard of or spoken to Dr. Farrell.

96. After receiving the medications, D.E. called Dr. Farrell to inform him he did not need the medication.

97. Dr. Farrell told D.E. that it was okay to use the medications, give them to a friend, or throw them away.

98. Medicare paid approximately $7,398.94 for the medications that Dr. Farrell ordered for D.E.

99. Medicare Beneficiary B.H. also did not know Dr. Farrell or recall ever speaking with him, yet she received adapalene, lidocaine-prilocaine, and desonide because of an order signed by Dr. Farrell, in which Dr. Farrell certified that the medications were reasonable and necessary.

100. Medicare paid approximately $1,385.63 for these orders.

101. Dr. Farrell ordered medications for over 600 Medicare beneficiaries for which Medicare paid approximately $1.45 million.

c. Representative diagnostic testing patients

102. Dr. Farrell's failure to interact with patients for whom he ordered diagnostic tests rendered his signed orders for diagnostic tests not reasonable and necessary, and caused the resulting claims to Medicare to be false. *See* 42 C.F.R. § 410.32 (requiring that diagnostic laboratory tests "must be ordered by the physician who is treating the beneficiary . . . and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary").

103. Dr. Farrell certified that the diagnostic tests he ordered were reasonable and necessary and would be "used in the medical management and treatment decisions for this patient," among other things.

104. But because Dr. Farrell did not interact with the patient, or even know if the patient was under the care of another provider, he had no way of knowing if the tests he ordered would be used in the management of treatment decisions for the patient.

105. Dr. Farrell ordered a "cardiovascular health NGS test for Medicare Beneficiary M.G. on or about February 11, 2021.

106. Dr. Farrell was not M.G.'s treating physician, nor did he use the result of the test in the management of M.G.'s specific medical problem.

107. As a result of Dr. Farrell's order, Medicare paid a Supplier, Boca Toxicology LLC, approximately $5,104.32.

108. Dr. Farrell ordered tests for approximately thirty-four Medicare beneficiaries for which Medicare paid over approximately $230,000.

ii. Defendant did not review patient files before signing orders

109. For the reasons set forth above, Dr. Farrell could not have assessed whether his orders were reasonable and necessary solely by reference to the patient files.

110. Even assuming he could have done so, Dr. Farrell did not review the patient files for many, if not all, of the orders he signed.

111. Dr. Farrell electronically signed orders often within seconds of accessing the patient file, even though some patient files were many pages long and contained multiple orders—each requiring a separate assessment of medical necessity.

112. As noted above, Dr. Farrell signed orders for fifteen different medications for D.P. within fewer than three minutes after signing orders for another patient.

113. Medicare Beneficiaries D.P.'s patient file, including the order forms that Dr. Farrell signed, was over 30 pages.

114. In many cases, Dr. Farrell electronically signed orders through an online platform maintained by Zoho Corporation ("Zoho").

115. Zoho maintained data related Dr. Farrell's online signatures, including the internet protocol ("IP") address from which the signature was applied, the date and time the files were accessed or opened, and the date and time that electronic signatures were applied to the files, among other information.

116. On February 11, 2021, Dr. Farrell signed an order for cardiovascular health test for M.G. just 13 seconds after accessing the patient file.

117. The Billing Entity billed Medicare approximately $9,314 for this test, and Medicare paid the Billing Entity approximately $5,014.

118. On November 14, 2020, Dr. Farrell signed orders for fourteen DME items for five Medicare beneficiaries within three and a half minutes—approximately 15 seconds per order.

119. As a result, Billing Entities billed Medicare approximately $13,806 and Medicaid paid approximately $5,251.

120. Specifically, Dr. Farrell ordered:

i. Two knee braces and a back brace for Medicare Beneficiary M.F. Dr. Farrell accessed M.F.'s patient file at 5:54:49 PM EST and electronically signed the orders at 5:55:37 PM EST—or 48 seconds after accessing the patient file. Medicare was billed approximately $3,000 for the braces and it paid approximately $2,018.

ii. Two knee braces and a back brace for Medicare Beneficiary V.V. Dr. Farrell accessed V.V.'s patient file at 5:56:17 PM EST and electronically signed the orders at 5:56:42 PM EST—or 25 seconds after accessing the patient file. Medicare was billed approximately $3,000 for the braces.

iii. Two knee braces for Medicare Beneficiary S.M. Dr. Farrell accessed S.M.'s patient file at 5:56:52 PM EST and electronically signed the order at 5:57:09 PM EST—or 17 seconds after accessing the patient file. Medicare was billed approximately $1,806 for the braces and it paid approximately $1,215.

iv. Two knee braces and a back brace for Medicare Beneficiary G.A. Dr. Farrell accessed G.A.'s patient file at 5:57:21 PM EST and electronically signed the

orders at 5:57:43 PM EST—or 22 seconds after accessing the patient file. Medicare was billed approximately $3,000 for the braces and it paid approximately $2,018.

v. Two knee braces and a back brace for Medicare Beneficiary F.S. Dr. Farrell accessed F.S.'s patient file at 5:57:52 PM EST and electronically signed the orders at 5:58:17 PM EST—or 25 seconds after accessing the patient file. Medicare was billed approximately $3,000 for the braces.

121. Despite accessing the patient files for the above patients for less than a minute in each case, Dr. Farrell certified for each that "the prescribed treatment and device is reasonably and medically necessary, according to the accepted standards of medical practice within the community, for this patient's medical condition."

122. In ordering knee braces for each of the above-listed patients, Dr. Farrell purported to have verified that joint laxity tests were performed on the patients, and that he confirmed that the results of those tests justified ordering knee braces.

123. He also purported to verify that the patient met with their primary care provider in the last six months, consented to the use of video technology for the encounter, and that the patient's eligibility for a brace was verified during the encounter.

124. Without interacting with the patients and without taking time to review the patient files, Dr. Farrell could not, and did not, verify that these patients underwent joint laxity tests, had an encounter with the primary care provider within the last six months, consented to the use of video technology for their encounter—or even had a video encounter with anyone—, and that the patient qualified for the braces Dr. Farrell ordered.

125. By not reviewing the patients' files, let alone interacting with the patients in anyway, Dr. Farrell not only failed to assess whether his orders were reasonable and necessary, he made numerous false and misleading representations—including representations about the performance and outcome of certain tests, the nature of his interactions with the patients, the information provided to the patients, consents obtained from the patients, and the purpose of the ordered items and services, among other false and misleading representations.

126. These false and fraudulent representations were material to claims submitted to Medicare for orders and, consequently, caused the submission of false and fraudulent claims to be made to and paid by Medicare.

B. Defendant caused submission of claims to Medicare tainted by kickbacks

127. To submit a claim to Medicare, the Billing Entities required a signed order from a provider enrolled with Medicare.

128. As described above, Dr. Farrell was enrolled in Medicare during the relevant time period.

129. In his enrollment application, the CMS-855I, he certified that, among other things, he would "abide by Medicare laws, regulations and program instructions" and that he "underst[oo]d that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) . . .)."

130. The Federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), makes it unlawful for anyone to "knowingly and willfully solicit[] or receive[] 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 whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for the 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." 42 U.S.C. § 1320a-7b(b)(1)(A)-(B).

131. Under 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from [an AKS violation] constitutes a false or fraudulent claim for purposes of [the FCA]." *See also Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016) ("An AKS violation that results in a federal health care payment is a per se false claim under the FCA.").

132. Dr. Farrell thus certified that he understood and would comply with Medicare laws, including the AKS and that a claim submitted in violation of the AKS is a false and fraudulent claim for purposes of the FCA.

133. Dr. Farrell also certified in the CMS-855I that he signed that he would "not knowingly . . . cause to be presented a false or fraudulent claim for payment by Medicare."

134. He thus agreed that he would not cause claims to be submitted to Medicare that violated that AKS—that is, Medicare claims submitted for items and services he ordered in exchange for a kickback.

135. The claims submitted to Medicare resulting from Dr. Farrell's orders violated the AKS because they were procured through the payment of kickbacks meant to induce orders for items and services.

136. The Billing Entities submitted claims to Medicare based on orders that they purchased from the Companies.

137. The Companies, in turn, paid providers, including Dr. Farrell, for signed orders.

138. Specifically, Barton and/or its clients, the Companies, paid Dr. Farrell between approximately $13 to approximately $19 for each patient file he reviewed, on a per-patient basis, which took into account the volume of Dr. Farrell's orders for items and services.

139. Because Dr. Farrell only spent seconds reviewing the medical records of beneficiaries, the kickback scheme resulted in Dr. Farrell receiving lucrative payments for the actual amount of work performed.

140. The Medicare claims submitted as a result of Dr. Farrell's signed orders would not have been submitted without kickbacks received by Dr. Farrell because, as discussed above, there was no independent basis for the orders.

141. Not only did Dr. Farrell cause false claims to be submitted because they resulted from a kickback, but he caused the actual claims submitted by the Billing Entities to falsely certified that they were in compliance with Medicare statutes, rules, and regulations, including compliance with the AKS.

142. As part of this scheme, Dr. Farrell ordered items and services for more than 2,000 Medicare beneficiaries.

143. As a result of Dr. Farrell being paid to sign orders, the Billing Entities submitted over 9,000 claims to Medicare for items and services that were tainted by kickbacks.

144. Medicare paid approximately $3.4 million for these items and services.

145. In return for signing false, fraudulent, unnecessary, and unwanted orders, Dr. Farrell knowingly and willfully solicited and received kickbacks of approximately $88,000 from Barton and/or the Companies.

II. Defendant Knowingly Violated the False Claims Act

a. Dr. Farrell knowingly caused the submission of false claims to Medicare

146. As explained above, Dr. Farrell was enrolled as a Medicare provider during the relevant time period.

147. Dr. Farrell certified "that payment of a claim by Medicare . . . is condition on the claim and the underlying transaction complying with such laws, regulations and program instructions . . . and on a provider/supplier being in compliance with any application conditioned of participation in any federal health care program."

148. Dr. Farrell also stated that he would "abide by the Medicare or other federal health care program laws, regulations, and program instructions that apply . . . ."

149. He thus agreed to comply with 42 U.S.C. § 1395y(a)(1)(A), which provides that "no payment may be made under part A or part B for any expenses incurred for items of services—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."

150. Dr. Farrell knew, was deliberately ignorant, or recklessly disregarded that he was signing orders that were to be reimbursed by Medicare because, among other reasons, the patient files contained the patients' Medicare information.

151. Dr. Farrell also knew, was deliberately ignorant, or recklessly disregarded that he falsely certified that the orders were reasonable and necessary because he did not personally

interact with the patients in any way and he was aware that, at most, the patients had spoken to a person with no medical training during an intake call.

152. Dr. Farrell knew, was deliberately ignorant, or recklessly disregarded that the representations in the patient files were false and fraudulent, including false representations that certain tests and examinations had been performed; that he personally examined patients; and/or that he had a valid physician-patient relationship.

153. Additionally, Dr. Farrell signed orders in which he certified that the items and services were reasonable and necessary despite failing to even review the information in the patient files.

154. As discussed above, in many instances Dr. Farrell signed orders mere seconds after accessing the patient files, even when those patient files were many pages and included numerous individual orders.

155. Moreover, in agreeing to "abide by the Medicare or other federal health care program laws, regulations, and program instructions that apply . . . ," Dr. Farrell further agreed to obey 42 C.F.R. § 410.32, which provides that a diagnostic laboratory test "must be ordered by the physician who is treating the beneficiary . . . and who uses the results in the management of the beneficiary's specific medical problem. Test not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

156. Dr. Farrell knew, was deliberately ignorant, or recklessly disregarded that his orders for diagnostic tests were not reasonable and necessary because he was not the patient's treating physician and he did not use results of the test in the management of the patient's medical problem, nor did he have any intention of doing so.

157. Despite having no relationship with the patients, Dr. Farrell falsely certified, among other things, that he had an "ongoing relationship" with the patient.

158. Medicare would not have paid the claims for the items and services if it had known that Dr. Farrell's orders were not reasonable and necessary.

159. Medicare regularly denies claims for medications, diagnostic tests, and DME where the provider falsely certified medical need.

160. Despite knowing that it is unlawful to cause the submission of claims that are not reasonable and necessary, Dr. Farrell ordered items and services for Medicare beneficiaries, during the relevant time period, which he knew were not reasonable and necessary.

161. In agreeing to "abide by the Medicare or other federal health care program laws, regulations, and program instructions that apply . . . ," Dr. Farrell further agreed to comply with the Anti-Kickback Statute, which, as discussed above, prohibits providers from receiving payments in return for referrals.

162. Despite knowing, being deliberately ignorant, or recklessly disregarding that it is unlawful to cause the submission of claims that are the result of kickbacks, Dr. Farrell ordered items and services for Medicare beneficiaries, during the relevant time period, which were the result of kickbacks paid to him.

163. As a direct result of his actions, Medicare paid the Billing Entities approximately $3.4 million.

b. Dr. Farrell knowingly caused to be made or used false records or statements material to false or fraudulent claims to Medicare.

164. Dr. Farrell also knew, was deliberately ignorant, or recklessly disregarded that the orders he signed would be used to submit claims to Medicare for items and services.

165. Dr. Farrell knew that the patients for whom he was signing orders were Medicare beneficiaries and that the orders would be reimbursed by Medicare.

166. Dr. Farrell also knew, was deliberately ignorant, or recklessly disregarded that the orders he signed contained numerous false and misleading statements and representations, including statements and representations material to the submission of a claim to Medicare, including that the items and services that he ordered were reasonable and necessary.

167. The Billing Entities relied on Dr. Farrell's false statements, representations, and certifications, including certifications of medical necessity, when submitting claims to Medicare.

168. Certifications of medical necessity, in particular, caused the Billing Entities to make false certifications to Medicare on the Form CMS 1500, which required the entity submitting a claim to Medicare to certify that the services rendered were "medically necessary."

169. The CMS 1500 also required the Billing Entity to certify that the claim "complies with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute . . . ."

170. These certifications are material to Medicare's decision to pay, as it has "a natural tendency to influence the government's payment decision." *See U.S. ex rel. Groat v. Boston Health Diagnostics Corp.*, 255 F. Supp. 3d 13, 31 (D.D.C. 2017).

171. For the reasons described above, Dr. Farrell's knowing false and fraudulent statements and representations, including those attesting to the reasonableness and necessity of the items and services, on orders he signed, caused the Billing Entities to make false and fraudulent statement on the CMS 1500.

172. Had Medicare known that the CMS 1500 certifications of medical necessity related to Dr. Farrell's referral were false, Medicare would not have paid the claim.

173. The United States regularly pursues false claims related to orders for medications, diagnostic testing, and DME that are not reasonable and necessary, not supported by the patients' medical records, not the result of a bona fide patient relationship or patient encounter, and/or are tainted by kickbacks.[1]

FIRST CAUSE OF ACTION

Causing False Claims to be Presented for Payment (31 U.S.C. § 3729(a)(1)(A))

174. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

175. Dr. Farrell knowingly caused to be presented false or fraudulent claims to Medicare for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A).

176. During the relevant time period, Dr. Farrell, with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false, caused to be presented false or fraudulent claims that were not reasonable and necessary.

177. During the relevant time period, Dr. Farrell, with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false,

[1] *See* https://www.justice.gov/usao-edwa/pr/doctor-agrees-pay-95000-settle-allegations-health-care-fraud; https://www.justice.gov/usao-de/pr/united-states-settles-claims-durable-medical-equipment-fraud-against-wilmington; https://www.justice.gov/usao-de/pr/united-states-settles-claims-genetics-testing-fraud; https://www.justice.gov/usao-me/pr/provider-agrees-pay-over-629000-settle-allegations-false-claims-act-violations; https://www.justice.gov/usao-wdky/pr/paducah-doctor-admits-violating-false-claims-act-and-being-liable-millions-his-role; https://www.justice.gov/usao-ndia/pr/iowa-nurse-practitioner-agrees-pay-over-50000-resolve-suit-alleging-fraudulent-durable.

caused to be presented false or fraudulent claims that were tainted by kickbacks, in violation of 42 U.S.C. § 1320a-7b(g).

178. Because of the above-described conduct, the United States sustained damages in the amount of approximately $3,394,811.61 and is entitled to treble damages plus a civil penalty for each violation.

SECOND CAUSE OF ACTION

Causing False Statements Material to False Claims (31 U.S.C. § 3729(a)(1)(B))

179. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

180. Dr. Farrell knowingly caused to be made or used false or fraudulent records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

181. During the relevant time period, Dr. Farrell, with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false, caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of Dr. Farrell's statements and actions.

182. These false records and statements included false and misleading representation on claim forms that claims for medications, diagnostic tests, and DME submitted to Medicare were reasonable and necessary when, in fact, they were not medically necessary.

183. These false records and statements included false and misleading representation on claim forms that claims for medications, diagnostic tests, and DME

submitted to Medicare complied with the Anti-Kickback Statute when, in fact, those claims violated the Anti-Kickback Statute.

184. Because of the above-described conduct, the United States sustained damages in the amount of approximately $3,394,811.61 and is entitled to treble damages plus a civil penalty for each violation.

PRAYER FOR RELIEF

185. WHEREFORE, the United States demands and prays that judgment be entitled in its favor against Defendant as follows:

i. On Counts I and II, under the FCA, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law;

ii. For a jury trial; and

iii. For all such further relief as may be just and proper.

Respectfully submitted,

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