UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA, *ex rel.* BRENDAN DELANEY, **Plaintiffs,** **vs.** **ECLINICALWORKS, LLC** **Defendant.**	**FILED UNDER SEAL** **Case No. 2:15-CV-00095-WKS** **UNITED STATES' COMPLAINT IN INTERVENTION** **JURY TRIAL DEMANDED**

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1. The United States of America (United States) files this complaint in intervention for the limited purpose of settlement to recover damages arising from false statements made and caused by Defendant eClinicalWorks, LLC (ECW) and false claims that ECW caused to be submitted to the Department of Health and Human Services (HHS) for federal incentive payments through the Electronic Health Record (EHR) Incentive Programs.

2. Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), HHS established the Medicare and Medicaid EHR Incentive Programs (also known as the "Meaningful Use program"), which provided incentive payments to healthcare providers who demonstrated "meaningful use" of certified EHR technology.

3. ECW developed and sold EHR software to healthcare providers throughout the United States. ECW falsely represented to its certifying bodies and the United States that its software complied with the requirements for certification and for the payment of incentives under the Meaningful Use program.

4. ECW's software was unable to satisfy certain certification criteria. To ensure that its product was certified and that its customers received incentive payments, ECW: (a) falsely

attested to its certifying body that it met the certification criteria; (b) prepared its software in order to pass certification testing without meeting the certification criteria; (c) caused its users to falsely attest to using a certified EHR technology, when ECW's software could not support the applicable certification criteria in the field; and (d) caused its users to report inaccurate information regarding Meaningful Use objectives and measures in attestations to the Centers for Medicare & Medicaid Services (CMS). In addition, ECW provided remuneration to certain customers to recommend its products to prospective customers in violation of the Anti-Kickback Statute.

5. Since 2011, healthcare providers who used ECW's software and attested to satisfying the Meaningful Use objectives and measures received incentive payments through the Meaningful Use program.

6. Had ECW disclosed that its software did not meet the certification criteria, it would not have been certified and its customers would not have been eligible for incentive payments. In addition, requests for incentive payments that resulted from unlawful kickbacks constituted false claims.

7. ECW's false and fraudulent statements and conduct violate the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, and the United States is entitled to treble damages and penalties.

I. PARTIES

8. The United States, acting through HHS, administers the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395kkk-1 (Medicare), and administers grants to states for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, *et seq.* (Medicaid). The United States, acting through HHS, also

administers the Meaningful Use program and a certification program for EHR technology.

9. Relator Brendan Delaney is a resident of New York. On May 1, 2015, Mr. Delaney commenced this action against ECW alleging violations of the FCA on behalf of himself and the United States pursuant to the *qui tam* provision of the FCA, 31 U.S.C. § 3730(b)(1). Mr. Delaney alleged in his *qui tam* complaint that bugs and problems with ECW's software rendered it ineligible for incentive payments.

10. ECW is a privately held software company founded in 1999, incorporated in Delaware and headquartered in Massachusetts. ECW was founded by a small group of individuals, including Chief Executive Officer Girish Navani, Chief Medical Officer Rajesh Dharampuriya, and Chief Operating Officer Mahesh Navani. According to its website, ECW's software is used by more than 850,000 users across the United States.

II. JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court has supplemental jurisdiction over the common law cause of action under 28 U.S.C. § 1367(a).

12. The Court has personal jurisdiction over ECW and venue is appropriate in this Court under 31 U.S.C. § 3732(a) because ECW transacts business and caused the submission of false claims from this District.

III. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

13. The FCA imposes civil liability to the United States on any person who, *inter alia*: (1) knowingly presents, or causes to be presented, to an officer or employee of the United

States Government a false or fraudulent claim for payment or approval; and (2) knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government, 31 U.S.C. §§ 3729(a)(1)(A) and (B); as well as (3) conspires to violate the FCA. *Id.* at § 3729(a)(1)(C).

14. The FCA defines a "claim" to include "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 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 . . . . " *Id.* at § 3729(b)(2).

15. The FCA defines the terms "knowing" and "knowingly" 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. *Id.* at § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. *Id.* at § 3729(b)(1)(B).

16. The FCA provides that the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4).

17. Any person who violates the FCA is liable for a mandatory civil penalty for each such claim, plus three times the damages sustained by the Government. *Id.* at § 3729(a)(1).

B. The Anti-Kickback Statute

18. The federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), provides, in pertinent part:

> (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 $25,000 or imprisoned for not more than five years, or both.

19. Accordingly, manufacturers of products paid for in whole or in part by federal healthcare programs may not offer or pay any remuneration, in cash or in kind, directly or indirectly, to induce physicians or hospitals or others to order or recommend products paid for in whole or in part by Federal healthcare programs such as Medicare and Medicaid.

20. The Patient Protection and Affordable Care Act (PPACA), Publ. L No. 111-148, 124 Stat. 119 (2010), provides that violations of the AKS are *per se* violations of the FCA: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]."

21. The PPACA also clarified the intent requirement for the Anti-Kickback Statute, and provides that "a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation."

C. Certified EHR Technology and the Meaningful Use Program

22. On February 17, 2009, the HITECH Act was enacted to promote the adoption and meaningful use of certified EHR technology. Under the HITECH Act, the HHS Office of the National Coordinator for Health Information Technology (ONC) established a certification program for EHR technology. As part of the certification program, EHR vendors attest to ONC-authorized certification bodies (ACB) and accredited testing laboratories that their software meets the certification requirements established by ONC. The certification bodies and testing laboratories test and certify that vendors' EHRs are compliant with the certification requirements.

23. Through the Meaningful Use program CMS makes incentive payments to healthcare providers for demonstrating meaningful use of certified EHR technology. Individual practitioners (Eligible Professionals) could qualify for up to $43,720 over five years from Medicare (ending after 2016) and up to $63,750 over six years from Medicaid (ending after 2021).

24. In order to qualify for incentive payments under the Meaningful Use program, Eligible Professionals were required, among other things, to: (1) use an EHR system that qualified as certified EHR technology; and (2) satisfy certain objectives and measures relating to their meaningful use of the certified EHR technology.

25. HHS implemented the certification criteria and incentive payment requirements in multiple stages. On January 13, 2010, HHS published in the Federal Register interim final rules setting forth the "2011 Edition" certification criteria and a proposed rule setting forth the "Stage 1" requirements for incentive payments. HHS finalized these rulemakings by publication in the Federal Register on July 28, 2010. In Stage 1, an Eligible Professional's use of certified EHR

technology generally needed to satisfy fifteen "core objectives" and five out of ten "menu set objectives."

26. On September 4, 2012, HHS published in the Federal Register the final rules setting forth the "2014 Edition" certification criteria and "Stage 2" requirements for incentive payments. In Stage 2, an Eligible Professional's use of certified EHR technology generally needed to satisfy seventeen "core objectives" and three out of six "menu set objectives."

27. On October 16, 2015, CMS published in the Federal Register a final rule with comment period setting forth the "Modified Stage 2" requirements for incentive payments. For years 2015 through 2017, Modified Stage 2 eliminated the concept of "menu set objectives" and required all Eligible Professionals to attest to a single set of objectives and measures.

28. To qualify for incentive payments in each Stage of the Meaningful Use program, healthcare providers were required to attest each year that they used certified EHR technology and satisfied the applicable Meaningful Use objectives and measures. Use of certified EHR technology and satisfaction of applicable Meaningful Use objectives and measures are material to payment under the Meaningful Use program.

29. To obtain certification, EHR vendors must attest to an ACB that their EHR product satisfies the applicable certification criteria, submit to certification testing by an accredited testing laboratory, and pass such testing.

30. Certification testing is based on the certification criteria the vendor represents its software satisfies and on which it requests to be tested and certified. The certification body uses standardized testing protocols ("test scripts"), which identify each step the vendor will be required to take during testing. The test scripts are available to vendors in advance of their testing date.

31. After obtaining certification, an EHR vendor must maintain that certification by complying with all applicable conditions and requirements of the certification program. Among other things, the EHR product must be able to accurately, reliably, and safely perform its certified capabilities while in use in doctors' offices. EHR vendors must cooperate with the processes established by ONC for testing, certifying, and conducting ongoing surveillance and review of certified EHR technology.

32. The CMS rules governing the Meaningful Use program recognize that healthcare providers rely on certification for assurance that an EHR product meets the applicable certification criteria, including that it possesses the certified capabilities that healthcare providers will need to use to achieve relevant objectives and measures, and that the software will perform in accordance with applicable certified capabilities.

IV. ECW FAILED TO SATISFY THE CERTIFICATION CRITERIA AND MADE FALSE STATEMENTS IN OBTAINING CERTIFICATION AND MARKETING ITS SOFTWARE

33. ECW submitted an attestation form dated April 17, 2013 to its ACB representing that its software satisfied the certification criteria applicable to Complete EHRs and was capable of performing those criteria and standards in the field.

34. ECW's attestation to its certification body was false. ECW's software did not satisfy the certification criteria for a Complete EHR and could not operate in the field in compliance with the requisite certification criteria. Because its EHR technology did not meet ONC's certification criteria, its technology also failed to satisfy the requirements for Meaningful Use incentive payments, for which the use of certified EHR technology is a prerequisite.

35. Certification testing does not confirm that each criteria and standard is satisfied in full and under every conceivable scenario. Rather, testing takes a snapshot of a product's capabilities by ensuring it can pass certain pre-disclosed test cases.

36. ECW could -- and did -- pass certification testing without fully implementing all the technological changes required for its 2014 Edition certification. ECW did not seek to ensure that the standards, implementation specifications, and criteria were truly met.

37. ECW similarly failed to adequately review its bugs or service tickets to analyze whether or not software issues impacted the software's ability to meet the standards, implementation specifications, and certification criteria and perform in a reliable manner consistent with its certification.

A. ECW Falsely Attested to Compliance With Certification Requirements And Hardcoded its Software to Pass Certification Testing

38. Since the start of the Meaningful Use program, eligibility for incentive payments required Eligible Professionals to use certified EHR technology. An EHR product cannot be certified unless all applicable certification criteria and standards have been met. Certification is material to payment under the Meaningful Use program.

39. Eligibility for Meaningful Use Stage 2 incentive payments required healthcare providers to use certified EHR technology to, among other things, generate and transmit prescriptions electronically (commonly referred to as ePrescriptions) using the capabilities and standards specified at 45 CFR 170.314(b)(3), which requires the use of RxNorm.

40. RxNorm is a standardized drug vocabulary that specifies each unique drug, formulation, and dosage. RxNorm codes provide a mechanism for ensuring the accuracy of ePrescriptions and for allowing EHR systems to communicate and interact accurately and efficiently with other EHR systems, with pharmacies, and with health information networks.

41. Developer Jagan Vaithilingam was in charge of developing the software functionality necessary to satisfy the RxNorm requirement. Bryan Sequeira submitted ECW's final certification application for ECW.

42. On its application for certification to the 2014 Edition of the certification criteria, ECW attested that it satisfied the requirement to implement the RxNorm vocabulary. However, at that time and for years afterwards, ECW had not implemented the RxNorm vocabulary into its electronic prescription functions. The attestations related to RxNorm in ECW's application for certification were false.

43. In advance of its certification testing, ECW reviewed the publicly available test scripts for ePrescribing and identified the sixteen drugs for which ECW would need to generate a prescription during testing.

44. ECW then "hardcoded" into its testing software only the sixteen RxNorm codes it knew in advance that its certification body would test. In other words, rather than programming the capability to retrieve any code from the entire database of RxNorm codes, ECW simply typed the sixteen RxNorm codes necessary for testing directly into its software. ECW hardcoded the requisite RxNorm codes for the purpose of making its certification body believe it had implemented the RxNorm drug vocabulary and to pass certification testing.

45. During certification testing, the certifying body followed the test scripts that included only the sixteen RxNorm codes that ECW knew in advance and had hardcoded into its system. Based on the test results, the certification body certified ECW's software on July 24, 2013 as meeting the ONC 2014 Edition requirements for a Complete EHR.

46. In internal communications following certification, ECW employees acknowledged that ECW's software did not transmit RxNorm codes for ePrescriptions.

47. In May 2015, ECW was re-tested by its certification body on its ability to transmit RxNorm codes as required for ePrescribing. ECW knew in advance that its certification body would simply re-test it using the same testing protocol, including the same sixteen RxNorm

codes that ECW had hardcoded to pass its original testing in 2013. As a result, despite still failing to transmit RxNorm codes, ECW passed this surveillance testing.

48. Instead of adopting RxNorm codes, ECW relied on either proprietary drug identifiers developed by private business partners or on National Drug Codes (NDCs) for purposes of transmitting prescriptions.

49. As with other vendors, in some cases ECW's software did not send accurate NDC codes when transmitting medication orders. ECW was aware of this issue and was advised by a third party business partner in 2014 and 2015 that prescriptions were being sent with drug descriptions that did not match the transmitted NDC code.

50. In January 2016, ECW conducted a series of meetings relating to RxNorm codes and its issuance of inaccurate NDC codes.

51. On December 23, 2016, after learning of the Government's investigation, ECW informed HHS that before August 2016, it had not included RxNorm codes when transmitting ePrescriptions. ECW stated that for most customers, it had implemented the RxNorm vocabulary for ePrescriptions by August 2016.

52. In addition to RxNorm codes, ECW also failed to transmit patient education materials through the required database and universal standard for identifying medical laboratory tests, measurements, and observations: the Logical Observation Identifiers Names and Codes (LOINC). On August 23, 2013, in an internal email with the subject line "Patient Education MU Certification," ECW employees confirmed that ECW did not transmit LOINC codes.

53. In February 2014, an ECW employee inquired whether he should contact ECW's certification body and ask if ECW would "be able to meet the certification criteria" if a patient

education vendor did not use LOINC codes. In response, another ECW employee confirmed that ECW did not transmit LOINC codes.

54. On November 9, 2016, ECW disclosed to HHS for the first time that, with respect to a patient education vendor, ECW "retrieved patient education materials for labs using lab names rather than LOINC codes."

55. Likewise, ECW was required to use the Systematized Nomenclature of Medicine – Clinical Terminology (SNOMED-CT) to specify the medical conditions on a patient's problem list when transmitting a patient's chart. SNOMED-CT is recognized internationally and is available at no cost through the National Library of Medicine. Using SNOMED-CT enables providers and electronic medical records to communicate in a common language, thus increasing the quality of patient care across many different provider specialties. On January 4, 2017, ECW informed HHS that in "certain, specific scenarios," its product did not transmit SNOMED codes.

B. ECW Failed To Satisfy The Required Certification Criteria

56. During the time period relevant to this complaint, ECW released software without adequate testing and overly relied on customers to identify bugs and other problems. Some bugs and problems -- even some identified as "critical" or "urgent" -- persisted on ECW's bug list for months and even years. ECW lacked reliable version control, so problems addressed in one version of the software or for one particular user could reappear in later versions or remain unaddressed for other customers.

57. In 2016, ECW began addressing the above issues by implementing new policies and procedures, improving its documentation, and enhancing its training. ECW also engaged a third party consultant to assist it in assessing its processes and to evaluate ways in which it could enhance its product.

58. Also in 2016, ECW issued a series of notices advising its customers of potential problems that arose during particular uses of its software and when certain workflows were utilized by practitioners, including:

- In certain scenarios, displaying incorrect information relating to labs and diagnostic imaging orders. eClinicalWorks Advisory on Patient Safety, November 4, 2016;
- In certain scenarios, issuing incorrect NDC codes for prescriptions. eClinicalWorks Advisory on Patient Safety, March 11, 2016, p. 6 ("Incorrect mapping may lead to the incorrect drug, drug strength, or drug form being dispensed at the pharmacy.");
- In certain scenarios, overwriting and/or improperly replicating medication dose, route, frequency, and formulation information. eClinicalWorks Patient Safety Alert – Overwriting medication Information, November 11, 2016; revised November 11/17/16;
- Periodically displaying incorrect medical information in the right chart panel of the patient screen. eClinicalWorks Patient Safety – Progress Note Chart Panel Failure to Refresh, July 2016, p. 1 ("Refresh failure . . . may cause one or more of the three panels to display the incorrect patient information.");
- Periodically displaying "[m]ultiple patients' information . . . concurrently." eClinicalWorks Advisory on Patient Safety, March 11, 2016, p. 21; Resolved Patient Safety Items, August 2016;
- In specific workflows, failing to accurately display medical history on progress note. eClinicalWorks Patient Safety Notice, November 2016, p.1; and
- Orders placed through order sets that are not associated with a diagnosis code failing to display in progress notes. eClinicalWorks Advisory on Patient Safety, November 4, 2016.

59. As discussed further below, as a result of these and other issues with its software, ECW failed to satisfy the certification requirements for both the 2011 and 2014 Editions.

1. ECW Failed to Satisfy Data Portability Requirements

60. To satisfy the 2014 Edition certification criteria, an EHR system must "[e]nable a user to electronically create a set of export summaries for all patients in EHR technology

formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient . . . ." 45 C.F.R. § 170.314(b)(7).

61. In addition to generating a set of export summaries, a certified EHR technology must permit batch export of these summaries in a single export action. On December 14, 2012, ONC published its "2014 Edition Test Procedure for §170.314(b)(7) Data Portability, Approved Test Procedure Version 1.2." That guidance provided: "This test evaluates the ability for EHR technology to create a set of export summaries (according to Consolidated CDA format) for all patients (for example, a batch export) contained within the EHR technology . . . ."

62. ECW did not comply with these batch export requirements. In response to user concerns that ECW did not permit batch export, an ECW employee internally confirmed that he did not believe ECW "does a 'batch' process," and that he did not think ECW wanted "to make it easy to extract tons of patient data."

63. In December 2014, an ECW user reminded ECW of prior conversations addressing batch export as part of certification requirements and that he expected ECW to have "figured out a workable solution to this in the past 6 months given the advance warning."

64. In spring 2015, ECW's certification body concluded that ECW was noncompliant with the data portability requirements.

2. ECW's Software Failed to Satisfy Audit Log Requirements

65. In order to be certified to the 2011 and 2014 Edition certification criteria, EHR software must reliably and accurately record user actions in an audit log. Audit logs track user activity in an EHR and provide a chronology of a patient's care.

66. ECW represented to its certification body that it satisfied this audit log requirement and also represented that "audit logs are also generated for all system adds/deletes/changes to patient records." However, ECW's audit logs did not accurately record

user actions, and in certain cases, the audit logs misled users as to events that were conducted in the course of a patient's treatment.

67. For example, in 2009, ECW acknowledged that its audit logs incorrectly reflected that diagnostic imaging orders were *created*, when they were only *modified*. ECW's audit logs also failed to consistently and reliably track deletions of certain medical orders. In July 2012, ECW acknowledged that its audit logs did not accurately record diagnostic imaging orders. Again, in June 2013, ECW knew that its access logs were not showing the names of diagnostic imaging orders or the details of what was ordered.

3. ECW's Software Failed To Reliably Record Diagnostic Imaging Orders

68. To be certified as a Complete EHR under the 2011 and 2014 Edition certification criteria, a vendor's software must provide computerized provider order entry, which requires users to be able to electronically order and record laboratory and radiology/imaging orders. This functionality must perform accurately, reliably, and safely to meet the certification requirement.

69. In ECW's EHR system, diagnostic imaging orders that were not "linked" to an assessment could fail to display in certain sections of the EHR that providers may rely on to place or follow up on such orders. Diagnostic imaging orders that were not linked to an assessment may continue to be displayed in the progress note, yet not appear in these other screens.

70. In particular scenarios, ECW's software would represent deleted diagnostic imaging orders as current by displaying the order in the progress note even after it had been deleted.

71. On November 4, 2016, ECW notified its users in a Patient Safety Advisory as to additional issues with its laboratory and radiology/imaging functionalities.

4. ECW's Software Did Not Reliably Perform Drug-Drug and Drug-Allergy Checks

72. To be certified as a Complete EHR under the 2011 and 2014 Edition certification criteria, an EHR must reliably perform drug-drug and drug-allergy checks in an accurate and safe manner.

73. In particular scenarios, ECW's software did not reliably perform drug interaction checks. Prescriptions that are modified by a doctor to suit a particular patient's needs are referred to as custom drugs. ECW noted that "any change to a custom strength, custom formulation, etc. will strip the NDC code from the medication and cause interaction checking not to fire." ECW warned customers of this issue in March 2016.

V. ECW CAUSED ITS CUSTOMERS TO SUBMIT FALSE INFORMATION IN ATTESTATIONS TO CMS

74. In order to qualify for Meaningful Use incentive payments, healthcare providers must not only use certified EHR technology, but must also attest to satisfying certain objectives and measures that correspond and relate to the certification criteria and standards.

75. However, in light of the misrepresentations to the ACB and the failings described above, ECW's EHR did not qualify as certified EHR technology.

76. Relying on ECW's representations that its product was certified, ECW's users unknowingly submitted tens of thousands of claims falsely attesting that they had satisfied the requirements of Meaningful Use by using certified EHR technology and thereby were eligible to receive Meaningful Use incentive payments.

77. Additionally, in certain cases, ECW knowingly utilized an incorrect calculation methodology for purposes of attesting to Meaningful Use measures. For example, in July 2012, an ECW customer's attestations were audited. The auditor noted, "It looks like the clinical visit summaries report is only reporting on one encounter per patient within a reporting period, but it

should be reporting on every office visit." The client notified ECW of this issue. In an internal e-mail, an ECW employee noted that "We've known for a long time Visit Summaries is supposed to count all encounters on the denominator but the MAQ Dashboard only counts unique patient visits. I'm not sure how to justify our numbers on this one."

78. Consequently, ECW caused its users to submit inaccurate attestation information in connection with their requests for Meaningful Use incentive payments.

VI. ECW'S PAYMENTS VIOLATING THE ANTI-KICKBACK STATUTE

79. ECW paid unlawful remuneration to influential customers to recommend its product to prospective customers. Among other things, ECW employed a "referral program," a "site visit program," and a "reference program."

80. Through its "referral program," ECW paid current users as much as $500 for each provider they referred who executed a contract with ECW. According to ECW's own estimates, it paid no less than $143,441.92 in referral payments between 2011 and into 2015. According to ECW, its referral program resulted in between 2.2 and 4.6 percent of new customers between 2011 and into 2015. ECW tracked its referral program payments.

81. Through its "site visit program," ECW paid current users to host prospective customers at their facility. The financial payouts for these site visits were based on the number of users at the prospective customer's practice. The current user could receive an additional payment if the visiting practice purchased ECW's software. According to ECW's own estimates, it paid no less than $248,715.70 in site visit payments between 2011 and into 2015.

82. Through its "reference program," ECW paid current users as much as $250 to serve as references for prospective customers who wanted to speak with current users about the

product. As with the site visit program, the current user could receive an additional payment if the prospective customer purchased ECW's software.

83. ECW provided "consulting" and "speaker" fees to influential users who promoted its software, and also provided users American Express gift cards, iPads, meals, travel, and entertainment.

84. One prominent physician was paid tens of thousands of dollars in "consulting" fees while sourcing many new customers for ECW. The physician never executed any written agreement with ECW or tracked the hours he worked as a consultant.

85. ECW tracked how recipients of its funds performed in obtaining sales. Providers that would not provide favorable statements about ECW's product were identified on customer lists as "not referenceable."

VII. CLAIMS FOR RELIEF

86. ECW obtained its EHR certifications through a series of false statements. ECW's EHR system did not -- and could not -- meet both the certification criteria and the incentive payment requirements in its operation in the field, and ECW concealed the failure from its certification bodies and the Government. ECW caused Eligible Professionals falsely to attest to using certified EHR technology and to satisfying Meaningful Use objectives and measures and to submit false information on their attestations requesting incentive payments.

87. ECW knowingly caused the submission of false claims and false statements material to false claims to be submitted to the Government. Through the conduct discussed above, ECW caused its customers to submit false claims to CMS for federal incentive payments. As of November 17, 2016, a total of 39,480 healthcare providers using ECW's software had submitted attestations of Meaningful Use to CMS.

COUNT I
False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

88. Through the conduct alleged above, ECW knowingly caused healthcare providers who used its software to present false or fraudulent claims for federal incentive payments that were paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(1)(A).

89. The United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT II
False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

90. Through the conduct alleged above, ECW knowingly made or used false records or statements material to false or fraudulent claims paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(1)(B).

91. As a result of the false records or statements made by ECW, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT III
Unjust Enrichment

92. The United States claims the recovery of all monies by which ECW has been unjustly enriched, including profits earned by ECW because of the unlawful conduct alleged above.

93. ECW was unjustly enriched, and is liable to account and pay such amounts, which are to be determined at trial, to the United States.

94. By this claim, the United States requests a full accounting of all revenues and costs incurred by ECW, and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

PRAYER

WHEREFORE, Plaintiff the United States of America prays for judgment against the Defendant as follows:

95. On Counts I and II under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with such further relief as may be just and proper.

96. On Count III for unjust enrichment, for the damages sustained and/or amounts by which ECW retained illegally obtained monies, plus interest, costs, and expenses, and such further relief as may be just and proper.

Dated: May 12, 2017

Respectfully submitted,

UNITED STATES OF AMERICA

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