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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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA, ex rel. BRENDAN DELANEY, **Plaintiff,** **vs.** **ECLINICALWORKS,** **Defendant.**	**Case No.** ***EX PARTE* MOTION TO FILE COMPLAINT UNDER SEAL** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)**

PLAINTIFF-RELATOR'S *EX PARTE* MOTION TO FILE COMPLAINT UNDER SEAL

Pursuant to Local Rule 5.2 and the mandatory requirements of the False Claims Act, 31 U.S.C. § 3730(b)(2), Plaintiff-Relator Brendan Delaney, through his attorneys, Phillips & Cohen LLP and Downs Rachlin Martin PLLC, files this *Ex Parte* Motion to file the Complaint (and Civil Cover Sheet) in this action under seal.

The Complaint in this *qui tam* action asserts violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq. The FCA mandates that the Complaint be filed under seal. 31 U.S.C. § 3730(b)(2). That section of the statute provides: "The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders." 31 U.S.C. § 3730(b)(2).

For the foregoing reasons, Relator requests that the Court grant this Motion and issue an Order requiring that the Complaint be filed under seal. A Proposed Order is attached.

Respectfully submitted,

Dated: May 1, 2015

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA, ex rel. BRENDAN DELANEY, **Plaintiff,** **vs.** **ECLINICALWORKS,** **Defendant.**	**Case No.** **ORDER** **(Filed In Camera and Under Seal)**

ORDER

UPON CONSIDERATION of Plaintiff-Relator Brendan Delaney's *Ex Parte* Motion To File Complaint Under Seal, and for good cause shown, it is hereby

ORDERED, that the Motion is Granted, and it is further

ORDERED, that the Complaint in this action shall be filed under seal pursuant to 31 U.S.C. § 3730 and remain under seal until further order of the Court.

DATED this _____ day of _____, 2015. BY THE COURT:

_____

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

[UNDER SEAL], **Plaintiff,** **v.** **[UNDER SEAL],** **Defendant.**	**Case No.** *EX PARTE* MOTION TO FILE COMPLAINT UNDER SEAL **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)**

DOCUMENT TO BE KEPT UNDER SEAL
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

[UNDER SEAL], **Plaintiff,** **v.** **[UNDER SEAL],** **Defendant.**	**Case No.** **COMPLAINT** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)**

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Attorney for Plaintiff-Relator [Under Seal]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA, ex rel. BRENDAN DELANEY, **Plaintiff,** **vs.** **ECLINICALWORKS,** **Defendant.**	**Case No.** **COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED**

Plaintiff-Relator Brendan Delaney, through his attorneys, on behalf of the United States of America (the "Government" or the "Federal Government"), for his Complaint against defendant eClinicalWorks ("eCW or "Defendant") alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made and caused to be made by Defendant and/or its agents and employees, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq. ("the FCA").

2. This action seeks to recover millions of federal dollars spent to purchase and subsidize the purchase and implementation of defective Electronic Health Record ("EHR") systems sold by eCW to healthcare providers in Vermont and across the United States. An EHR system -- sometimes also referred to as an Electronic Medical Record ("EMR") system -- allows healthcare providers to record patient information electronically instead of using paper records. It is intended to provide a complete replacement for the patient's paper medical chart.

3. Since 2009, the Federal Government has spent billions of dollars in "stimulus"

funding under the American Recovery and Reinvestment Act ("ARRA"), as well as other federal funding, to advance the adoption and meaningful use of electronic health records systems throughout the United States.

4. Under the ARRA, the Federal Government provides EHR Incentive Payments to eligible healthcare professionals and institutions that purchase an electronic health record system that complies with "Meaningful Use" ("MU") requirements established by the United States Department of Health and Human Services ("HHS").

5. eCW is one of the largest suppliers of EHR systems in the United States. Many healthcare professionals and institutions in Vermont and throughout the United States have purchased and implemented eCW's EHR system.

6. This action alleges that eCW has falsely represented to customers that its EHR system complies with federal Meaningful Use requirements, while concealing fundamental defects with the system. These hidden defects not only violate material conditions of the EHR Incentive Payment program but also create a significant risk to patient health and safety.

7. Among its most significant flaws, eCW's EHR system fails reliably (1) to document and display the medications administered to patients, and (2) to report the results of laboratory tests -- features that are fundamental to a reliable medical record system. As a result of these failings, the eCW system fails to comply with the core requirements for Meaningful Use to qualify for federal incentive payments.

8. Corporate managers at eCW have been aware of the significant flaws in the EHR system since at least 2010, and likely earlier. Despite this knowledge, eCW has misrepresented to purchasers who are recipients of federal funding that its EHR system complies with MU requirements and concealed from purchasers the significant defects in the system. Moreover,

despite numerous "upgrades" to its EHR system, Relator is informed and believes that eCW has consistently failed to fix the system's flaws.

9. eCW has a financial disincentive to fix its EHR system. A fix would require not just addressing the problems in the core of the software but in virtually all of eCW's modules sold nationwide. Admitting that the eCW software is defective would put eCW at a severe competitive disadvantage in the competitive EHR marketplace.

10. The FCA was enacted during the Civil War, and was substantially amended in 1986, and again in 2009 and 2010. Congress amended the FCA in 1986 to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the FCA, which Congress characterized as a primary tool for combating government fraud, was in need of modernization. The amendments create incentives for individuals to come forward with information about fraud against the Government without fear of reprisals or Government inaction, and enable the use of private legal resources to prosecute fraud claims on the Government's behalf.

11. The FCA prohibits, inter alia: (1) knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval; and (2) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim. 31 U.S.C. §§3729(a)(1)(A), (B). Any person who violates the FCA is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. §3729(a)(1)(A) (as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 [28 U.S.C. §2461 note; Public Law 104-410]).

12. In 2009, Congress amended the FCA to clarify that a "claim" includes "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 . . . . " 31 U.S.C. §3729(b)(2).

13. The FCA allows any person having information about an FCA violation to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

14. Based on the foregoing laws, *qui tam* plaintiff Brendan Delaney seeks through this action to recover all available damages, civil penalties, and other relief for the violations alleged herein in every jurisdiction to which Defendant's misconduct has extended.

II. PARTIES

15. Plaintiff/Relator Brendan Delaney ("Relator") is a resident of Rock Tavern, New York. He is an experienced project manager with expertise in the field of electronic health records systems. Between 2010 and 2014, he worked as a project manager or consultant for several institutions that implemented eCW's electronic health records system. These work assignments included:

a. From April 2010 through August 2011, Relator was as an Implementation Specialist with the New York City Division of Health Care Access and Improvement, and in that position worked on the implementation of eCW's EHR system at the Rikers Island jail complex in New York City.

b. From September 2011 to October 2012, Relator worked as a senior consultant

for Arcadia Solutions and in that position consulted with the following healthcare providers among others concerning their implementation of eCW's EHR system: Beth Israel - Phillips Ambulatory Care Facility and Beth Israel Medical Group in New York City; Mount Sinai - University Medical Practice Associates in New York City; St. Luke's-Roosevelt Hospital Center and St. Luke's Division of Nephrology & Critical Care in New York City; and several ambulatory clinics in New York City's high schools. In addition during this same time period, Relator worked at the Arcadia Solutions Service Desk troubleshooting problems with eCW's EHR system encountered by dozens of medical facilities serviced by the Arcadia Solutions Service Desk in Chelmsford, Massachusetts.

c. From September 2013 through March 2014, Relator worked as a consultant for HSM Consulting in Quincy, Massachusetts, and in that position consulted with the following healthcare providers among others concerning their implementation of eCW's EHR system: Anna Jaques Hospital in Newburyport, MA; Atlantic Surgical Associates in Newburyport, MA; North Shore Internal Medicine Clinic, in Newburyport, MA; Northeast Endocrinology & Diabetes Center in Newburyport, MA; and Southcoast Hospital in Fairhaven, Massachusetts.

Relator is currently a project manager for UnitedHealth Group, a diversified healthcare company. He brings this action on behalf of the United States of America, the real party in interest.

16. Defendant eClinicalWorks is a privately held electronic health records company headquartered at 2 Technology Drive, Westborough, Massachusetts. eCW states on its website that its EHR products are used by "more than 100,000+ physicians and 600,000+ users across all 50 states with revenues for 2013 exceeding $290 million." Several Vermont healthcare

providers have purchased eCW's EHR products, including but not limited to: White River Family Practice in White River Junction, Vermont; Little Rivers Health Care in Wells River, East Corinth, and Bradford, Vermont; and Community Health Services of the Lamoille Valley (which includes several healthcare centers in Vermont).

III. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Although the issue is no longer jurisdictional after the 2009 amendments to the FCA, to Relator's knowledge there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e), as amended by Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02.

18. Moreover, whether or not such a disclosure has occurred, Relator would qualify as an "original source" of the information on which the allegations or transactions in this Complaint are based. Before filing this action, Relator voluntarily disclosed to the Government the information on which the allegations or transactions in this Complaint are based. Additionally, Relator has direct and independent knowledge about the misconduct alleged herein and that knowledge is independent of and materially adds to any publicly disclosed allegations or transactions relevant to his claims.

19. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendant has minimum contacts with the United States. Moreover, the Defendant can be found in and/or transacts or has transacted business in the District of Vermont.

20. Venue is proper in the District of Vermont pursuant to 28 U.S.C. §§ 1391(b)-(c) and 31 U.S.C. § 3732(a) because the Defendant can be found in and/or transacts or has transacted business in this district, and because violations of 31 U.S.C. §§ 3729 *et seq.* alleged herein occurred within this district. At all times relevant to this Complaint, Defendant regularly conducted substantial business within this district and/or made significant sales within this district.

IV. THE FEDERAL EHR INCENTIVE PROGRAM

A. The "Meaningful Use" Requirement

21. The Health Information Technology for Economic and Clinical Health ("HITECH") Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act ("PHSA") and established "Title XXX – Health Information Technology and Quality" to improve health care quality, safety and efficiency through the promotion of health information technology ("HIT") and the electronic exchange of health information.

22. On December 30, 2009, the Secretary of HHS published an interim final rule setting forth an initial set of standards, implementation specifications, and certification criteria that EHR technology must meet in order for users to be entitled to receive Government financial incentive payments.

23. Congress tied the HHS standards, implementation specifications, and certification criteria to the incentives available under the Medicare and Medicaid EHR Incentive Programs by requiring the "Meaningful Use" of EHR Technology.

24. Through HITECH, the Federal Government has committed unprecedented

resources, up to $27 billion over 10 years, to supporting the adoption and use of EHRs. HITECH's goal is not adoption alone, however, but meaningful use of EHRs. Thus, the statute specifically ties payments to providers to the achievement of advances in health care processes and outcomes. Eligible professionals who demonstrate meaningful use of certified EHR technology can receive up to $43,720 over five continuous years from the Medicare EHR Incentive Program and up to $63,750 over six years from the Medicaid EHR Incentive Program. Through the EHR Incentive Programs, eligible hospitals, including critical access hospitals (CAHs), can qualify for EHR incentive payments beginning with a $2 million base payment.

25. The objective of the HITECH Act is to provide reimbursement support for eligible medical providers, including institutional providers that are able to demonstrate meaningful use of EHR technology. As such, Congress intended to ensure that EHR programs supported by federal funding provide certain capabilities and that those capabilities are implemented in accordance with adopted standards and implementation specifications. In other words, to qualify for federal funding, EHR programs must meet certain defined standards.

26. The ARRA identified three objectives for EHR meaningful use: (1) use of EHR in a meaningful manner; (2) use of certified EHR technologies for electronic exchange of health information to improve quality of care; and (3) use of certified EHR technology to achieve clinical quality measures (CQM) and other measures selected by CMS.

27. On July 28, 2010, the federal Centers for Medicare and Medicaid Services ("CMS") finalized and published the Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology as well as Meaningful Use standards for the first "Stage" of EHR implementation for purposes of the federal incentive programs and stimulus grant monies.

28. Meaningful Use standards are to be implemented in stages. Stage 1 set forth the meaningful use objectives and measures for the first two reporting years, 2011 and 2012, and focused on objectives including electronically capturing health information in a coded format, facilitating disease and medication management, and reporting clinical quality measures.

29. On September 4, 2012, CMS published the Stage 2 final rule, which expanded on the Stage 1 criteria and focused on the next step after the foundation of data capture in Stage 1, namely, the exchange of essential health data among health care providers and patients to improve care coordination. On March 30, 2015, CMS published proposed rules for Stage 3. Once finalized the Stage 3 rules will focus on using EHR systems to improve quality, safety and efficacy of health care, including promoting patient access to self management tools and improving population health.

30. Regardless of the year the medical provider starts its EHR program, the first two years are governed by the Stage 1 Meaningful Use criteria and do not move onto the more rigorous Stage 2 criteria until the third year of participation.

31. To qualify for incentive payments and subsidies from the federal government, all users of ERH must satisfy the Stage 1 Meaningful Use criteria.

32. The Stage 1 Meaningful Use regulations, codified at 42 C.F.R. §§ 495.6(d) & (e), set the basic requirements that eligible professionals and eligible hospitals must meet in order to receive Medicare and Medicaid Incentive payments for the purchase and implementation of EHR technology. The Meaningful Use Stage 1 objectives are split into two groups:

- **Core Objectives** – The EHR system must satisfy all of these 15 objectives in order to fulfill the Meaningful Use requirements.

- **Menu Set Objectives** - The EHR system must satisfy 5 out of these 10 objectives in order to fulfill the Meaningful Use requirements

33. Of particular relevance to this Complaint are the following Core and Menu Objectives that an EHR system must satisfy in order to fulfill the Meaningful Use requirements:

- maintenance of an active medication list that allows a user to electronically record, modify and retrieve a patient's active medication list as well as medication history (42 C.F.R. §§ 495.6(d)(5)(i), a Core Objective);
- ability to perform drug-drug and drug-allergy interaction checks, and notification of the user at the point of care (42 C.F.R. §§ 495.6(d)(2)(i), a Core Objective);
- ability to computerize provider order entry, which allows a user to electronically record, store, retrieve and modify orders for medication, laboratory testing, and radiology/imaging (42 C.F.R. §§ 495.6(d)(1)(i), a Core Objective);
- ability to complete medication reconciliation of two or more medication lists by comparing and merging into a single medication list (42 C.F.R. §§ 495.6(e)(7)(i), a Menu Objective); and
- ability to electronically receive clinical laboratory test results in a structured format and display such results in human readable format (42 C.F.R. §§ 495.6(e)(2)(i), a Menu Objective).

34. To qualify to receive an EHR incentive payment from the Government, providers must attest to demonstrating meaningful use each year that the provider applies for the payment. As part of the attestation process, CMS requires each eligible professional and eligible hospital to confirm that it is using an EHR that is certified specifically for the EHR Incentive Program.

35. The Office of the National Coordinator for Health Information Technology

(ONC) Certification Program provides a defined process for certifying EHR technologies.

36. In collaboration with ONC, the National Institute of Standards and Technology (NIST) has developed the functional and conformance testing requirements, test cases, and test tools to support the health IT certification programs. The purpose of the conformance test methods is to ensure that the EHR system offers the necessary technological capability to meet the Meaningful Use criteria.

37. Even if the EHR system receives certifications under the ONC Certification Program, the EHR system must meet Meaningful Use standards *in its operation* in each place of business to qualify providers for EHR incentive payments.

38. During the time period covered by this Complaint, eCW's EHR system was certified as a qualifying EHR technology for purposes of the EHR Incentive Program under the American Recovery and Reinvestment Act.

39. This Complaint alleges that notwithstanding the certification it received, eCW knew that its EHR system in operation did not meet Meaningful Use requirements of federal law, that eCW concealed the failure to meet Meaningful Use requirements from purchasers, and that eCW knowingly caused providers falsely to attest to compliance with Meaningful Use standards in support of claims for federal EHR incentive payments.

40. Under the FCA, these claims constitute false and fraudulent claims, and the providers' attestations of compliance with Meaningful Use standards in support of these claims constitute false and fraudulent statements material to the false claims, all in violation of the FCA.

B. eCW Represents That Its EHR Technology Complies with Federal Meaningful Use Requirements

41. eCW represents to the provider community that its EHR technology satisfies each of the Meaningful Use Stage 1 requirements and, therefore, that users of its technology are

eligible to receive EHR incentive payments from the Federal Government.

42. For example, eCW's website states that its EHR software "provides all of the features needed for qualifying to receive Meaningful Use reimbursement for Stage 1, Stage 2 and beyond." [Available at http://www.eclinicalworks.com/resources/meaningful-use/; last accessed on 4/10/15].

43. eCW disseminates a "Meaningful Use Training Scenarios Guide" that provides, at p. 13, the following question and answer:

> **Does eCW guarantee meeting requirements of Meaningful Use?**
> eClinicalWorks guarantees that our software will meet the Meaningful Use criteria as defined through ARRA, thereby reducing the risk that practices face in investing in new technology.

This eCW manual, published in 2011, is available at various locations on the internet, *e.g.*, http://www.nycreach.org/reach_wiki/images/5/56/Meaningful_Use_Training_Scenarios_Guide_February_2011.pdf

44. On its website, eCW explains how its EHR system fulfills each of the Stage 1 Meaningful Use Core Objectives. eCW lists each Core Objective and then, for each objective, purports to answer the question, "How does eClinicalWorks fulfill this requirement?" For example:

a. With regard to the Meaningful Use requirement that an EHR system "Maintain the patient's active medication list," eCW's website states that "eClinicalWorks fulfill[s] this requirement" in the following manner: "eClinicalWorks maintains an active patient medication list and allows a provider to manage all patient medications for optimum continuity of care. The Right Panel [of the computer screen] provides a functional display of the patient's current medication list for every encounter." [Available at: http://www3.eclinicalworks.com/knowledge-center-meaningful-use-stage-

one-criteria-core-objectives-active-medication-list.htm; last accessed on 4/10/15.] Essentially the Right Panel should replicate the list of medication in the patient's progress note, but, as explained below, in many instances it does not.

b. With regard to the Meaningful Use requirement that the EHR system allow "Computerized physician order entry (CPOE) of medications," eCW's website states that its EHR product "fulfill[s] this requirement" in the following way: "eClinicalWorks provides the ability to order medications through our Treatment window in the Progress Note, Order Sets, eCliniSense, and Templates. These medications can then be e-prescribed, faxed, or printed through eClinicalWorks." [Available at: http://www3.eclinicalworks.com/knowledge-center-meaningful-use-stage-one-criteria-core-objectives-cpoe.htm; last accessed on 4/10/15].

c. With regard to the Meaningful Use requirement that the EHR system provide "Drug-drug and drug-allergy interaction checks," eCW's website states that "eClinicalWorks fulfill[s] this requirement" in the following manner: "Drug-to-Drug and Drug-to-Allergy checks are performed real time at the time of prescribing based upon the patient's current medications and medication allergy list. In addition, the system also checks for any drug-disease contraindications." [Available at: http://www3.eclinicalworks.com/knowledge-center-meaningful-use-stage-one-criteria-core-objectives-allergy-interaction-checks.htm; last accessed on 4/10/15 .]

d. With regard to the Meaningful Use requirement that the EHR system "Document Lab Test Results," eCW's website states that its EHR system fulfills this requirement in the following manner: "Through the Lab Results window, all lab results can be captured in a structured manner. . . . Increased efficiencies can be experienced in

capturing the results of labs through our uni-directional and bi-directional lab interfaces with national and local lab partners." [Available at: http://www3.eclinicalworks.com/knowledge-center-meaningful-use-stage-one-criteria-menu-set-objectives-document-test-results.htm; last accessed on 4/10/15.]

45. eCW also offers an online Webinar training session called "Becoming a Meaningful User" conducted by eCW staff. According to eCW's website, during this training, eCW's Webinar team explains to the user "[h]ow eCW meets the objectives of Meaningful Use." [http://support.eclinicalworks.com/training/docs/mu.pdf; last accessed on 4/20/15.]

46. The above are just a small sample of the many representations that eCW has made to the provider community that its EHR products meet federal Meaningful Use requirements.

V. ALLEGATIONS

A. Relator's Background

47. Relator is a project management professional who specializes in the field of electronic health records systems. Relator has worked as a project manager or consultant with several healthcare providers – individual practices, small clinics, as well as large institutions -- that implemented eCW's electronic health records system. These providers, and the time frame that Relator worked with them in regard to their use of eCW's EHR system, are listed in the chart below:

Medical Facility	Type of Facility	Medical Specialty	Location	Dates Worked on eCW issues
Rikers Island Clinics				
Robert N. Davoren Center (RNDC)	Ambulatory Clinic	General Medicine	Queens, NY	Apr 2010 - Aug 2011
George Motchan Detention Center (GMDC)	Ambulatory Clinic	General Medicine	Queens, NY	Apr 2010 - Aug 2011
Eric M. Taylor Center (EMTC)	Ambulatory Clinic	General Medicine	Queens, NY	Apr 2010 - Aug 2011
Anna M. Kross Center (AMKC)	Ambulatory Clinic	General Medicine	Queens, NY	Apr 2010 - Aug 2011
Rose M. Singer Center (RMSC)	Ambulatory Clinic/	General Medicine	Queens, NY	Apr 2010 - Aug 2011

Otis Bantum Correctional Center (OBCC)	Ambulatory Clinic	General Medicine	Queens, NY	Apr 2010 - Aug 2011
George R. Vierno Center (GRVC)	Ambulatory Clinic	General Medicine	Queens, NY	Apr 2010 - Aug 2011
West Facility - Contagious Disease Unit (WF)	Ambulatory Clinic/ Inpatient	Multi-Specialty	Queens, NY	Apr 2010 - Aug 2011
Manhattan Detention Complex (MDC)	Ambulatory Clinic	General Medicine	Manhattan	Apr 2010 - Aug 2011
Vernon C. Bain Center (VCBC)	Ambulatory Clinic	General Medicine	Bronx, NY	Apr 2010 - Aug 2011
James A. Thomas Center (JATC)	Ambulatory Clinic	General Medicine	Queens, NY	Apr 2010 - Aug 2011
North Infirmary Command (NIC)	Inpatient	General Medicine	Queens, NY	Apr 2010 - Aug 2011
Continuum Health Partners				
Beth Israel - Phillips Ambulatory Care Facility	Ambulatory Clinic	Oncology Pediatric Surgery Breast Surgery	Union Square, NYC	Sep 2011 - Oct 2012
Beth Israel Medical Group	Ambulatory Clinic	Cardiology	34th Street, NYC	Sep 2011 - Oct 2012
Beth Israel Medical Group	Ambulatory Clinic	Gastrointestinal	35th Street, NYC	Sep 2011 - Oct 2012
Beth Israel Medical Group	Ambulatory Clinic	Ophthalmology	36th Street, NYC	Sep 2011 - Oct 2012
Beth Israel Medical Group	Ambulatory Clinic	Orthopedic	37th Street, NYC	Sep 2011 - Oct 2012
Mount Sinai - University Medical Practice	Ambulatory Clinic	Cardiology	West 59th St., NYC	Sep 2011 - Oct 2012
St. Luke's-Roosevelt Hospital Center -	Ambulatory Clinic	Breast Surgery	West 59th St., NYC	Sep 2011 - Oct 2012
Beth Israel - Phillips Ambulatory Care	Ambulatory Clinic	Gastrointestinal	Union Square, NYC	Sep 2011 - Oct 2012
Beth Israel - Phillips Ambulatory Care	Ambulatory Clinic	Orthopedics	Union Square, NYC	Sep 2011 - Oct 2012
Beth Israel - General Medical Associates	Ambulatory Clinic	General Medicine	West 57th St., NYC	Sep 2011 - Oct 2012
Beth Israel - Hand Surgery Center	Ambulatory Clinic	Hand Surgery	East 34th St., NYC	Sep 2011 - Oct 2012
St. Luke's Division of Nephrology & Critical Care	Ambulatory Clinic	Vascular Transplant Renal (Nephrology)	Amsterdam Ave, NYC	Sep 2011 - Oct 2012
NYC Based Clinics				
A. Philip Randolph High School	Ambulatory Clinic	General Medicine	West 135th St., NYC	Sep 2011 - Oct 2012
Louis D. Brandeis High School	Ambulatory Clinic	General Medicine	West 84th St., NYC	Sep 2011 - Oct 2012
Martin Luther King High School	Ambulatory Clinic	General Medicine	Amsterdam Ave,	Sep 2011 - Oct 2012
Arcadia Solutions Service Desk				
Serving Boston Area Hospitals	Ambulatory Clinic	General Medicine	New England Area	Sep 2011 - Oct 2012
HSM Consulting – Quincy MA				
Anna Jaques Hospital	Ambulatory Clinic	General Medicine	Newburyport, MA	Sep 2013 - Nov 2013
Atlantic Surgical Associates	Ambulatory Clinic	General Medicine	Newburyport, MA	Sep 2013 - Nov 2013
North Shore Internal Medicine	Ambulatory Clinic	General Medicine	Newburyport, MA	Sep 2013 - Nov 2013
Northeast Endocrinology & Diabetes Center	Ambulatory Clinic	General Medicine	Newburyport, MA	Sep 2013 - Nov 2013
Women's Health Care	Ambulatory Clinic	General Medicine Endocrinology	Newburyport, MA	Sep 2013 - Nov 2013
Southcoast Hospital	Ambulatory Clinic	General & Specialty Medicine	Fairhaven, MA	Nov 2013 - Mar 2014

48. In each setting, Relator witnessed significant flaws in eCW's EHR system that rendered the system fundamentally unreliable and unable to meet Meaningful Use standards. These defects also posed a risk to patient health and safety,

49. Because Relator observed the same flaws repeatedly throughout the facilities that used eCW's EHR system, Relator is informed and believes, and therefore alleges, that the defects are embedded in the software and render eCW's EHR technology noncompliant with

Meaningful Use requirements in all of the facilities that use eCW's technology.

50. These defects, and how Relator discovered them, are explained more fully below.

B. How Relator First Learned of The Defects in ECW's EHR System

51. Relator first learned of the defects in eCW's electronic health records system in 2010 while working as an Implementation Specialist with the New York City Division of Health Care Access and Improvement, Correctional Health Services, in New York City.

52. New York City received over $20 million in federal "stimulus" funds in 2010 under ARRA to purchase and implement an EHR system for its correctional facility at Rikers Island, a complex with an annual inmate population of over 100,000 (hereafter "Rikers Island"). Prior to the receipt of the stimulus funds, Rikers Island had a small pilot project using eCW's EHR system; however, the stimulus funds allowed Rikers Island to extend the EHR system to the entire jail complex.

53. New York City entered into a contract with eClinicalWorks for the implementation of its EHR system throughout the Rikers Island complex, initially in the female jail in the complex (the Rose M. Singer Center), and later the remaining jails. The eCW contract was for $27,713,333 through December 31, 2010 with an anticipated extension through December 31, 2014 at a cost of $14,308,390.

54. As an Implementation Specialist for New York City, Relator was tasked with the implementation of the rollout of eCW's EHR system at Rikers Island. After the initial implementation of eCW's EHR system in the female jail in November 2008, it became apparent to Relator as well as to officials at Rikers Island by 2010, that eCW's EHR software was significantly flawed, since physicians and others operating the software were unable to generate any type of accurate Current Medication Report.

55. The purpose of an EHR system is to function as the complete patient medical record, replacing the paper chart. Maintaining a current list of the patient's medications is an essential component of a medical record. Through an EHR system, a provider must have the ability to order medication, print the medication order, and display the patients' current medication as well as the patients' medication history.

56. eCW knew that the EHR system at Rikers Island was intended to replace the paper chart system entirely and that there would be no backup system to accurately track the patients' medication.

57. As early as April 2010, key implementation specialists and others charged with working with the EHR system in the jails, including the Rikers pharmacist Thomas Hayden and Development Specialist Erika Sheridan, raised their concerns about the systemic failures of the EHR system to record medications given to inmates.

58. New York City's Department of Health and Mental Hygiene ("NYC DOHMH") notified eCW of the problems and tried to persuade eCW to correct the flaws in the EHR system that prohibited the Current Medication section of the patient's record from displaying the correct medication.

59. eCW refused to make any corrections to the software and proceeded with the implementation of the software in the male jails before the second cycle of corrections and modifications were complete, thereby putting inmates at risk.

60. This was Relator's initial, but by no means last, exposure to defects in eCW's EHR technology.

61. As Relator continued to work on the rollout of the EHR system at Rikers Island, and as he subsequently worked with eCW's EHR system at several other healthcare facilities,

Relator discovered that the problems were not limited to the failure to generate accurate Current Medication Reports and that the same fundamental problems were present in every provider setting that used eCW's EHR system. These systemic problems are described in greater detail below.

62. Although eCW has released several versions of its EHR software, Relator is informed and believes that the fundamental flaws described herein exist in each version of the software and render the technology unreliable, dangerous, and non-compliant with Meaningful Use requirements.

C. eCW's EHR System Fails to Document and Display Several Pieces of Critical Medical Information

1. eCW's EHR System Fails Reliably To Document and Track Medications Administered to Patients

a. Failure to Keep Accurate Record of Current Medications

63. One of the most significant defects that Relator discovered in eCW's electronic health records system, in virtually every setting in which Relator witnessed the system in operation, is its inability to reliably document and track medications administered to patients. Relator witnessed many examples of this defect.

64. For example, Helpdesk tickets at Rikers Island revealed many instances in which eCW's EHR system did not accurately record current medications, such as:

a. A doctor at Rikers Island concluded that patient E.B. should not be taking Advair, discontinued his use of the drug, and ordered a Q-Var prescription instead, all within the eCW system. However, when the patient's record was pulled up later, the right panel of the screen showed the Advair prescription as current and made no indication that the patient was on Q-Var. [Rikers Helpdesk

Ticket No. 1150991, June 10, 2010].

b. The medical record for another Riker's inmate did not display his current HIV medications. [Rikers Helpdesk Ticket No. 735589, January 19, 2009].

c. The medical record for another Riker's inmate did not display his Methadone taper. [Rikers Helpdesk Ticket No. 894664, August 7, 2009.]

65. The flaw in eCWs software that caused an inaccurate record of a patient's medication to display in the patient's electronic chart persisted well into 2011 and 2012 at Rikers Island, after eCW claimed that the issue was "resolved." *See, e.g.*, Rikers Helpdesk Ticket no. 1022589 (1/15/10), no. 1241833 (10/14/10), no.1288146 (11/3/10); and no. 1392406 (2/6/11).

66. The inability of eCW's EHR system to display accurately and reliably the patient's Current Medication List was observed by Relator at the other institutions where he consulted on eCW EHR issues, including Beth Israel - Phillips Ambulatory Care Facility and Beth Israel Medical Group in New York City; Mount Sinai - University Medical Practice Associates in New York City; St. Luke's-Roosevelt Hospital Center and St. Luke's Division of Nephrology & Critical Care in New York City; several ambulatory clinics in New York City's high schools; Boston Children's Hospital and several other medical facilities serviced by the Arcadia Solutions Service Desk in Chelmsford, Massachusetts; Anna Jaques Hospital in Newburyport, MA; Atlantic Surgical Associates in Newburyport, MA; North Shore Internal Medicine Clinic, in Newburyport, MA; Northeast Endocrinology & Diabetes Center in Newburyport, MA; and Southcoast Hospital in Fairhaven, Massachusetts.

67. For example, on July 19, 2012, Relator received an email from Dr. Steven Smith, a nephrologist practicing at St. Luke's-Roosevelt Hospital in New York City, which uses eCW's EHR system. Dr. Smith reported that medications that were ordered for a

patient, and modifications to prescription orders, did not show up in the patient's electronic record. Notably, Dr. Smith observed that the eCW medication module presents "a serious patient safety issue. eCW does not change and properly document/track medication changes."

68. Similarly, while Relator was working at the Arcadia Solutions Service Desk in Chelmsford, Massachusetts – a Helpdesk for addressing EHR problems – between September 2011 and October 2012, he learned of many examples of eCW's EHR system not properly documenting and tracking medications. For example, on December 21, 2011, a physician at the Pediatric Medical Clinic in Chelsea, Massachusetts reported that eCW's EHR system displayed two patients' medications in the same chart. Relator encountered many similar examples while working at the Service Desk.

b. Incorrect Patient Record Displayed

69. eCW's EHR technology also regularly causes one patient's record to be pulled up and visible in the overview pane, while the accompanying progress note displays the information for an entirely different patient.

70. Dr. Brenda Harris, the physician at Rikers Island who initially identified this error, reported in May 2011 that the software defect nearly caused her to forward a diagnosis intended for the patient described in the right panel to the patient described in the left panel. A less cautious and observant provider could easily make that mistake, risking serious patient harm.

71. Likewise, Relator found that at Boston Children's Hospital, eCW's software regularly displayed the incorrect patient's information, and even caused prescriptions to be ordered for the wrong patient. For example, Dr. Sonya Stevens, a physician at Boston Children's

Hospital reported to Relator that, on an almost daily basis, she pulled up a patient record and the eCW software caused the system to display two different patients' information in the different sections of the same screen. On at least one occasion, November 18, 2011, this resulted in the system sending a prescription to the pharmacy for the wrong patient. Fortunately, Dr. Stevens caught the software's error and was able to contact the pharmacy with the correction, but were it not for her cautious observation, a prescription would have been given to the wrong child.

72. Relator experienced this problem at virtually all of the facilities where he worked, listed in ¶ 47 above.

c. Failure to Log Start and Stop Dates of Medication

73. The eCW EHR system also fails to log, or incorrectly logs, the start and stop dates of medication, causing various medication errors. Both start and stop dates should be logged automatically. A medication that is recorded without a stop date will remain listed under a patient's "Current Medication" indefinitely, even where the ordering physician or other provider has specified a "Duration" (e.g., "10 days") for the order.

74. To document his concerns regarding blank or inaccurate start and stop dates in the electronic medical records at Rikers Island, Relator created two Excel report files downloaded from the eCW system at Rikers Island.

75. The first file showed Medication Orders With Invalid Start Dates from 01-01-2011 through 04-23-2011. There were literally thousands of files from eCW's system with invalid start dates, each one of which could lead to an overdose or a failure to prescribe a needed medication. Relator also created a separate spreadsheet for the year 2010 documenting 30,000 records with invalid start dates for medication orders.

76. The second file showed Medication Orders With Blank Start or Stop Dates from

01-01-2011 through 04-23-2011. It documented thousands of Rikers Island files in eCW's EHR system with blank start and stop dates, the ramifications of which included potential overdosing or neglecting to prescribe a needed medication.

77. The eCW "Informed Prescribing Users Guide" specifically states that "[t]he stop date is automatically calculated by the difference between the start date and the duration of the prescription, and is populated by default." (See Exhibit 19). However, in practice, even when physicians follow eCW's instructions, the system often leaves the Stop Date field for a prescription empty.

78. Relator experienced the unreliability of eCW's EHR system in recording stop and start dates for medication at virtually all of the facilities where he worked, listed in ¶ 47 above.

d. Failure to Document Previous Medications

79. The eCW system is further flawed in that the medications a patient may have taken in the past are not consistently loaded into the "Current Medication" section of the record, only the "Complaint" section, which may not be checked by providers or the system itself when medication is being prescribed.

80. Relator experienced this problem at virtually all of the facilities where he worked, listed in ¶ 47 above.

81. This failure to appropriately record medications can lead to serious patient harm, because the system will not identify potential hazards associated with the past medication, such as risk factors for a diagnosis or contraindications for other prescriptions.

e. Inability to Accommodate More than One Dosage

82. eCW's EHR system does not reliably accommodate orders where prescribed dosages vary over time; therefore, the data is not accurate with respect to those medications.

This happens when, for example, a medication is to be administered twice a day at two different dosages or when a medication, such as methadone or steroids, is to decrease in dosage over several days. This is particularly a serious problem in prison settings given that prison clinics typically administer many doses of methadone each day to inmates.

83. Additionally, on at least one occasion at Rikers Island, on October 10, 2009, the eCW system doubled the dosage of a medication ordered by the attending physician. The physician directed the patient to take the medication twice a day, yet the system recorded that the medication should be taken four times a day.

84. Other physicians have experienced the eCW system replacing a physician's order for a branded medication with the generic. Although the active ingredients are the same in a branded drug and its generic, there can still be risks associated with substituting a generic medication without physician approval. For example, patients with hypothyroidism, a population that is often sensitive to very small changes in a medication's dosage, have been warned against making changes to their brand of medication without first discussing the benefits, risk and outcomes with their doctors.

f. Telephone Encounter Flaws

85. The Telephone Encounter system, which was used extensively across all Rikers facilities, contained serious defects when ordering, re-ordering, or discontinuing medications. Any time a medication was stopped or re-ordered over eCW's Telephone Encounter system, the directive did not show in the right pane of the computer screen.

g. Multiple Appointments Override

86. When patients have multiple appointments in one day, but are seen out of order, eCW's EHR system does not reliably record medications in the correct sequence in which they

are prescribed. For example, if an appointment is scheduled as last in a day, but occurs first, that visit's medication record is stored in the system until the end of the day, even if a follow-up appointment later in the day resulted in a change to the medication order. Thus, the system treats the appointment time as more important than the actual time of the encounter. As such, encounters may be documented out of sequence and orders made during the encounters may be read in the wrong sequence, resulting in incorrect prescription information. The only way to correct the problem when an appointment occurs out of order, is to manually shift the appointment times to reflect the order in which the appointments actually occurred, which is contrary to the fundamental reason for having an automated EHR system.

87. The multiple appointments defect becomes particularly problematic through the incorporation of the Telephone Encounter system, as it is not uncommon for a physician to submit a telephone encounter on the same day as an appointment. System generated telephone encounters are identified by the time the Telephone Encounter was created; thus, an order placed via a Telephone Encounter created after an appointment occurs, but before the appointment was scheduled to occur, will be overridden by any conflicting orders entered with the appointment. This failure to process a correction to a medication order can result in a patient receiving the wrong medication, and/or not receiving the medication he or she needs.

2. eCW's EHR System Fails Reliably to Record and Track Laboratory Results

88. eCW represents that its EHR technology allows providers to order medical laboratory tests electronically and that the laboratory results will be included in the patient's electronic chart. However, in Relator's experience, eCW's EHR system in operation does *not* reliably record and track laboratory results.

89. The procedure for ordering laboratory tests using eCW's EHR system is, first, to

place the Lab Order electronically in the patient chart. The order specifies the patient's name and date of birth, the type of test, and the order date, among other information. The order generates a unique numeric number that identifies that exact order against the patient's demographic data. The Lab results return electronically via the eCW Lab Interface and should automatically populate the patient chart; however, a number of flaws in the EHR system result in the Lab results not populating the patient chart.

90. For example, at the Rikers Island jail complex, eCW set up within the EHR system a Lab Interface with BioReference, through which providers could order medical laboratory tests for inmates. However, the interface was completely ineffective. As of July 2011, approximately 1,884 labs had been sent to BioReference through the eCW system for which the results had never been received. This number underrepresented the extent of the problem as many of the labs that were received would not have been received if providers had not gone outside the eCW system to obtain the results.

91. Relator encountered many similar examples of the failure of eCW's EHR system to record and track lab results at the other facilities where Relator worked on EHR issues, listed in ¶ 47 above.

92. For example, when Relator worked as an EHR consultant at Southcoast Hospital in Fairhaven Massachusetts, from November 2013 through March 2014, he was tasked with analyzing and reconciling a massive backlog of Lab Tests ordered by attending physicians for their patients.

93. During the course of analyzing the backlog of test results at Southcoast Hospital, Relator encountered tens of thousands of Lab results left pending in the system, unassigned to any patient record, that were processed by the Meditech system via the eCW Lab Interface.

These Lab test results never made it into the correct individual patient charts. This caused serious concern for the medical providers treating patients because they were unaware that the Lab results were pending in the system unless they spent hours looking for them. Treatment of chronically ill patients was compromised by this flaw in eCW's EHR, which prevented a physician from taking timely and corrective action in developing a treatment plan for a patient based on Lab results.

94. At Southcoast Hospital Relator found the following five categories of Lab-related errors in the EHR system, all of which are indicative of fundamental flaws in eCW's Lab interface:

a. Unique Specimen Number Not Found. In this category of error, the Lab results were returned without the unique numeric patient identifier and therefore failed to populate the Patient Chart; hence they remained pending in the Lab Interface Queue until they were manually reconciled much later.

b. Exception Occurred During Processing. In this category, the Lab results were returned with the name of the Lab Order transposed, e.g. from "T4 Free" to "Free T4"; consequently the Lab result did not match the Lab Test ordered and did not make it into the Patient Chart.

c. Patient Match Not Found. In this category, the Lab results were returned with the Patient's Name missing from the Lab Order and remained mismatched and not placed in the correct patient's record.

d. Latest Copy of Laboratory Result Not Found on the System. In this category, the Lab results were returned with all the parameters in place, yet inexplicably failed to attach to the Patient Chart.

e. Test Not Found In Dictionary. In this category of error, the Lab results were returned with all the parameters in place, yet failed to attach to the Patient Chart as a result of an outdated compendium of Lab Orders in the eCW database that did not recognize the type of Lab test performed.

95. As a consequence of all of these flaws in eCW's Lab Interface, Lab results do not reliably make it into the patient's electronic chart, which seriously compromises patient treatment and safety.

D. eCW's EHR System Does Not Contain Adequate Protections Against Abuse

1. Inadequate Protections to Retain a Record of Prescriptions.

96. eCW's EHR system does not contain sufficient security protections to ensure that a record of prescriptions is maintained within the system. Prescriptions can be printed without being logged, and can be deleted permanently after being logged.

97. The eCW technology produces a "Prescription Print" pdf document of the prescription when it is sent to the printer. However, the image merely captures a copy of the prescription. Accordingly, a provider can have a prescription filled with the pharmacy and then delete *all* records including the progress note while it is still unlocked.

98. This flaw leaves the system wide open for abuse, as users can easily create a prescription order in the system, print it, and then delete it without leaving evidence of the prescription order in the electronic system. This can be done with prescriptions for all types of medication, including narcotic drugs.

99. In addition, the EHR system does not display individual medication orders when multiple medications orders are placed together.

100. Because the software program cannot register multiple simultaneous entries by

different providers, and because providers can permanently delete prescription orders even after printing them, over-prescription and under-prescription can occur both purposefully and by accident.

101. Relator observed that certain providers have abused the system's flaws by giving out more drugs than lawful, and then deleting orders. For example one New York City Department of Health and Mental Hygiene employee, Ariel Ludwig, reported to Relator on or about April 17, 2010 that she was aware of a sick call patient at Rikers Island that had overdosed on psychiatric medications. The patient appeared to have been given a "stat order" which, in addition to the medications he had already taken, became a dangerous combination. Ms. Ludwig checked the medication log and discovered that the "stat order" had been deleted in the system.

2. Inadequate Protections Against Overmedication

102. eCW's system is further flawed in that it does not contain adequate protections against overmedicating and other risks to patients' health. Although the software prevents a second order of the same brand medication to be filled, it permits a physician to order one prescription for a brand medication, and a second medication for its generic equivalent. Relator witnessed this happen in October 2011 at Beth Israel Medical Center in New York City. This flaw creates a significant risk that a physician who is not familiar with a branded drug's generic equivalent could order a second, unnecessary prescription.

103. At the Rikers Island jail complex, Dr. Arthur Pellowe (Supervising Psychiatrist), Thomas Hayden (Chief Pharmacist), and Dr. Emmanual Cruz (Resident) all expressed concern to Relator over this inadequate protection.

104. Additionally, on at least one occasion the eCW system documented a text message sent by a patient through the system's "patient portal," as though it was created by a

physician. This happened to a patient of Dr. Heena Banker of Waltham, Massachusetts in December 2011. This vulnerability in the system essentially permits a patient to create an entry in his or her medical record.

3. The eCW Software Does Not Automatically Lock Notes.

105. When notes by physicians in a patient's medical record are not locked, another person can later enter the system and edit the notes. The failure to lock notes is primarily an issue of human error, but the dangers can easily be eliminated by the software if it were programmed to automatically lock notes as soon as a physician closes the current note or opens another note. Under the current eCW software, however, any note left unlocked stays unlocked.

106. Relator ran a report at the Rikers jail complex and discovered that from 01-01-2010 through 07-17-2011 one jail had over 63,000 unlocked notes and another jail had in excess of 100,000.

107. Another related problem is that the eCW software allows anyone to create, modify, and delete the patient's "Problem List," which houses the Patient's Diagnosis on the Right Pane of the screen. Providers depend on the Problem List to guide them in determining what medication to order, and the course of treatment they plan. Thus, changes to the list can result in patients receiving medications that are incompatible with their medical histories and potentially dangerous. In addition, the inability of eCW's software to ensure the integrity of the patient's "Problem List" renders it non-compliant with the Meaningful Use Stage 1 Core Objective that requires the EHR system to "Maintain an up-to-date problem list of current active diagnoses." 42 C.F.R. § 495.6(d)(3)(i).

E. The Flaws in eCW's EHR System Have Been Brought to eCW's Attention Numerous Times, but the Company Continues to Sell the System Without Fixing the Flaws

108. At every location where Relator worked or consulted on the implementation of eCW's EHR system, complaints were made to eCW regarding flaws of the type described in this Complaint.

109. For example, several officials within DOHMH expressed significant concern to eCW concerning flaws in the EHR system implemented at the Rikers Island jail complex. The complaining officials included Dr. Homer Venters, Assistant Commissioner for Correctional Health Services; Danielle Petrocelli, DOHMH Director of Pharmacy; Jeffrey Herrera, Director of Application Integration and Infrastructure; Thomas Langer, Clinical Specialist; and Dr. Kalimulina, Corizon employee. Dr. Venters and Tom Hayden both proposed using the MYSIS (PHS System) for processing medication orders.

110. Erika Sheridan, the NYC DOHMH Development Specialist, also confirmed critical software flaws with the system implemented at Rikers, including the following: (i) the failure to maintain an accurate history of prescribed medications, resulting in over-medication and under-medication of patients; (ii) the failure to record critical information from medication orders resulting in inaccurate data in certain patients' charts; (iii) the failure to build in safeguards to ensure that prescribed medication was processed through the appropriate pharmacy, resulting in inmates being released without critical medication and ensuing injury; and (iv) the failure to prevent prescriptions that were processed and given to patients from being removed from the system, leaving no record of the medication order, and resulting in inaccurate records and an inability to track accountability.

111. Ms. Sheridan brought these problems to the attention of eCW officials and eCW personnel responded that users had to be trained "not" to take certain actions in order for the system to function properly.

112. The problems with eCW's EHR system led to actual patient harm because of medication mismanagement at Rikers Island. In August 2010, the head pharmacist, Mr. Thomas Hayden, reported that he found eCW printed medication orders that were filled by the pharmacy and subsequently given to the inmates that were not recorded in the eCW patient chart.

113. Dr. Hayden, Director of Pharmacy, informed Relator as well as eCW that there was no way to determine in the eCW system whether a prescription was legitimately ordered or not because the system did not lock progress notes, even where prescription orders had been made.

114. In the numerous other facilities where Relator worked with eCW's EHR system – listed in ¶ 47 above – many Helpdesk Tickets and complaints were submitted to eCW concerning the flaws described in this Complaint. Given the consistency and similarities of the problems reported to eCW, it was apparent to Relator, and would have been apparent to any reasonable person, that the flaws were inherent in the software and not due to user error.

115. Despite knowing of these serious flaws in its EHR system, eCW continued to conceal from purchasers its failure to comply with Meaningful Use requirements and has continued to sell its flawed EHR system to hundreds of other customers, many of whom have sought federal subsidies.

F. eCW Has Knowingly Caused The Submission Of False Or Fraudulent Claims For EHR Incentive Payments To The Government

116. eCW knowingly misrepresented to customers in Vermont and throughout the nation that its EHR products satisfied federal Meaningful Use requirements. These misrepresentations foreseeably caused customers to purchase eCW's EHR products. These misrepresentations also foreseeably caused the purchasers to attest to compliance with Meaningful Use requirements when they were not in compliance with those requirements, and

foreseeably caused the purchasers to submit claims to the Federal Government for EHR incentive payments to which they were not entitled. In this manner, eCW knowingly caused false claims, and false statements material to false claims, to be submitted to the Government.

117. Despite knowing about the flaws in its EHR system, and without correcting them, eCW has continued to promote its EHR system while concealing these flaws from potential customers. These promotional efforts have caused the purchase of eCW's EHR system by providers in Vermont and throughout the country, and caused providers to submit claims for federal incentive payments to which they are not entitled.

118. eCW's sales of its EHR products with the flaws described in this Complaint system have caused federal monies to be paid for eCW's EHR products that are defective and do not meet fundamental requirements for performance as defined by the Meaningful Use criteria. These standards for performance are core requirements for any EHR system.

119. Every claim for payment submitted to the Government for an EHR product that is defective and/or does not meet Meaningful Use requirements is a false or fraudulent claim in violation of the FCA.

G. eCW Has Also Knowingly Caused The Submission Of False Or Fraudulent Claims For Payments To The Government Under The Medicare Electronic Prescribing Incentive Program

120. Under the Medicare Electronic Prescribing Incentive program, which began in January 2009, CMS began offering eligible providers incentive payments for their use of an electronic prescribing (ePrescribing) system to prescribe medications for Medicare patients. Under the law, for 2009 and 2010, ePrescribing incentive amounts were 2 percent of a provider's total estimated allowed charges for covered professional services during the reporting period (one calendar year). The incentive amount was reduced to 1 percent in 2011 and 2012, and 0.5

percent in 2013 (the last year of the program).

121. As defined by CMS, a qualified electronic prescribing system utilized with intent to participate in the ePrescribing Incentive Program must "Generate a complete active medication list incorporating electronic data received from applicable pharmacies and pharmacy benefit managers (PBMs), if available," and be able to "select medications, print prescriptions, electronically transmit prescriptions, and conduct all alerts." 76 Fed. Reg. 54953, 54954 (September 6, 2011). CMS defines "alerts" as, "Written or acoustic signals to warn prescriber of possible undesirable or unsafe situations, including potentially inappropriate dose or route of administration of a drug, drug-drug interactions, allergy concerns, or warnings and cautions." *Id.*

122. eCW falsely represents that its EHR software meets the requirements for the Medicare Electronic Prescribing Incentive program. *See, e.g,* "Medicare E-Prescribing Incentive Guide October 2011 Update" (eClinicalWorks, 2011), at p. 6 (stating that subscribing to eCW's EHR system "should permit providers to meet the Medicare definition of a Qualified Electronic Prescribing System" for purposes of receiving Medicare electronic prescribing incentive payments).

123. With its ongoing systemic flaws and inadequate protections, eCW's system falls far short of the ePrescribing standards. Every claim presented to the Government for payment of an ePrescribing Incentive payment as a result of false or fraudulent representations by eCW constitutes a false or fraudulent claim under the FCA.

False Claims Act

31 U.S.C. §§ 3729(a)(1)(A)-(B)

124. Relator realleges and incorporates by reference the allegations contained in

paragraphs 1 through 123 above as though fully set forth herein.

125. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

126. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

127. By virtue of the acts described above, Defendant knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the Government.

128. Relator cannot at this time identify all of the false claims for payment that were caused by Defendant's conduct. The false claims were presented by several separate entities. Relator does not have access to the records of all such false or fraudulent statements, records or claims.

129. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

130. By reason of Defendant's acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

131. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation arising from Defendant's unlawful conduct alleged herein.

PRAYER

WHEREFORE, *qui tam* Plaintiff-Relator Brendan Delaney prays for judgment against the Defendant as follows:

1. That Defendant cease and desist from violating 31 U.S.C. § 3729 *et seq.*

2. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act.

4. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: May 1, 2015

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SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the "United States"), eClinicalWorks, LLC (ECW), and Brendan Delaney ("Relator"), through their authorized representatives.

RECITALS

A. ECW is a privately held electronic health record (EHR) software limited liability company headquartered in Westborough, Massachusetts. Girish Navani, Rajesh Dharampuriya, M.D., and Mahesh Navani are founders of ECW and serve as executives at the company.

B. On May 1, 2015, Relator filed a *qui tam* action against ECW in the United States District Court for the District of Vermont captioned *United States ex rel. Delaney v. eClinicalWorks, LLC*, Case No. 15-CV-00095 (D. Vt.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) ("the Civil Action"). The United States intervened in the Civil Action on January 13, 2017, and filed the United States' Complaint in Intervention against ECW on May 12, 2017.

C. The United States contends that it has certain civil claims against ECW as set forth in the United States' Complaint in Intervention for claims submitted to Medicare and Medicaid for federal incentives during the period August 2008 through February 1, 2017 (the "Covered Conduct").

D. This Agreement is neither an admission of liability by ECW, nor a concession by the United States that its claims are not well founded. ECW denies the allegations in the Civil Action and the United States' allegations in Paragraph C of this Agreement and the Complaint in Intervention.

E. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. ECW, Girish Navani, Rajesh Dharampuriya, M.D., and Mahesh Navani (collectively, the "ECW Parties") shall pay to the United States a total of $154,920,000.00, plus interest accruing at an annual rate of 2 percent from February 1, 2017 and continuing until and including the date of payment (collectively, the "Settlement Amount"), no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the Settlement Amount, and as soon as feasible after receipt, the United States shall pay $30,000,000.00, plus interest accrued on that amount, to Relator by electronic funds transfer. No other payments shall be made by the United States with respect to matters covered by this Agreement.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon the ECW Parties' full payment of the Settlement Amount, the United States releases the ECW Parties together with ECW's current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current and former owners; and the corporate successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program

Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 6 below (concerning excluded claims) and in Paragraph 16 below (concerning reasonable fees, expenses, and costs) and conditioned upon the full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases ECW, and its current and former owners, officers, agents, and employees, from any civil monetary claim that Relator has on behalf of the United States for the Covered Conduct and the allegations in the Civil Action under the False Claims Act, 31 U.S.C. §§ 3729-3733.

5. In consideration of the obligations of ECW in the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and ECW and this Agreement, and conditioned upon full payment of the Settlement Amount by ECW, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against ECW under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 6 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude ECW from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding the releases given in Paragraphs 3, 4, and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals other than the liability of Girish Navani, Rajesh Dharampuriya, M.D., Mahesh Navani, and ECW's owners for civil or administrative monetary claims released in Paragraph 3 of this Agreement;

g. Any liability for failure to deliver goods or services due; and

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. The ECW Parties waive and shall not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. The ECW Parties fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that the ECW Parties have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution of the ECW Parties.

10. The ECW Parties fully and finally release Relator and his heirs, successors, attorneys, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that the ECW Parties have asserted, could have asserted, or may assert in the future against Relator or his heirs, successors, attorneys, and agents, related to the Civil Action, the Covered Conduct, or the United States' investigation and prosecution of the ECW Parties.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare contractor or any state payer any

previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

12. The ECW Parties agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the ECW Parties or ECW's present or former officers, directors, employees, shareholders, and agents, or incurred, in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audits and civil and criminal investigations of the matters covered by this Agreement;

(3) the ECW Parties' investigations, defenses, and corrective actions undertaken in response to the United States' audits and civil and criminal investigations in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payments the ECW Parties make to the United States pursuant to this Agreement and any payment that ECW may make to Relator, including costs and attorneys fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain a Software Quality Oversight Organization and an independent review organization to perform reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in Paragraph 12(a)(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to the ECW Parties.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the ECW Parties, and the ECW Parties shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by the ECW Parties or any of ECW's subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: The ECW Parties further agree that within 90 days of the Effective Date of this Agreement, they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by the ECW Parties, or any subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. The ECW Parties agree that the United States, at a minimum, shall be entitled to recoup from the ECW Parties any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by the ECW Parties, or any subsidiaries or affiliates, on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on the ECW Parties, or any subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine the ECW Parties' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. The ECW Parties agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, ECW shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall make requested documents and evidence available and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. The ECW Parties further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that the ECW Parties have undertaken, or that has been performed by another on their behalf.

14. This Agreement is intended to be for the benefit of the United States, the ECW Parties, and Relator only. The United States, the ECW Parties, and Relator do not release any claims against any other person or entity, except to the extent provided for in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. The ECW Parties agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

16. Upon receipt of the payment described in Paragraph 1, above, the Relator and United States shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1) and subject to the terms of this Agreement (the "Stipulation"). The Stipulation shall state that the allegations described in the United States' Complaint in Intervention shall be dismissed with prejudice as to the United States. Any remaining claims in the action shall be dismissed without prejudice as to the United States. All claims shall be dismissed with prejudice as to Relator, provided that Relator's claims for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d)(1) shall not be dismissed until they are settled, adjudicated, or otherwise resulted, and the Court is so informed.

17. Each Party, other than as described in Paragraph E and Paragraph 16, shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Vermont. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the United States, the ECW Parties and Relator and shall not, therefore, be construed against any of them for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the United States, the ECW Parties, and Relator. This Agreement may not be amended except by written consent of the United States, the ECW Parties, and Relator.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on the ECW Parties' successors, transferees, heirs, and assigns.

24. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

25. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 5-30-17 BY: _____

OWEN FOSTER
Assistant United States Attorney
United States Attorney's Office
District of Vermont

DATED: 5/30/17 BY: _____

NIKOLAS KEREST
Assistant United States Attorney
United States Attorney's Office
District of Vermont

DATED: _____ BY: _____

KELLEY HAUSER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

EDWARD CROOKE
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____
OWEN FOSTER
Assistant United States Attorney
United States Attorney's Office
District of Vermont

DATED: _____ BY: _____
NIKOLAS KEREST
Assistant United States Attorney
United States Attorney's Office
District of Vermont

DATED: 5/31/17 BY: _____
KELLEY HAUSER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 5-30-17 BY: _____
EDWARD CROOKE
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____
OWEN FOSTER
Assistant United States Attorney
United States Attorney's Office
District of Vermont

DATED: _____ BY: _____
NIKOLAS KEREST
Assistant United States Attorney
United States Attorney's Office
District of Vermont

DATED: _____ BY: _____
KELLEY HAUSER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____
EDWARD CROOKE
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 5/30/17 BY: Lisa M. Re
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE ECW PARTIES

DATED: 5/26/2017 BY: _____
ECLINCIALWORKS, LLC
Girish Navani, CEO

DATED: 5/26/2017 BY: _____
GIRISH NAVANI

DATED: 5/26/2017 BY: _____
RAJESH DHARAMPURIYA, M.D.

DATED: 5/26/2017 BY: _____
MAHESH NAVANI

DATED: 5/26/17 BY: _____
R. JOSEPH BURBY
Attorney for the ECW Parties

RELATOR BRENDAN DELANEY

DATED: 5-26-17 BY: Brendan Delaney
BRENDAN DELANEY

DATED: 5/26/17 BY: Colette G. Matzzie
COLETTE G. MATZZIE
Attorney for Relator