

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

January 27, 2020

Date of report (date of earliest event reported)

ALLSCRIPTS HEALTHCARE SOLUTIONS, INC.

(Exact name of registrant as specified in its charter)

**Delaware
(State or other jurisdictions of
incorporation or organization)**

**001-35547
(Commission
File Number)**

**36-4392754
(I.R.S. Employer
Identification No.)**

**222 Merchandise Mart Plaza, Suite 2024, Chicago, Illinois 60654
(Address of principal executive offices) (Zip Code)**

**(312) 506-1200
(Registrant's telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrants under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	MDRX	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On January 27, 2020 Practice Fusion, Inc. (“Practice Fusion”), an indirect, wholly-owned subsidiary of Allscripts Healthcare Solutions, Inc. (the “Company”), entered into a series of agreements to resolve a previously disclosed investigation conducted by the Department of Justice (“DOJ”) and the U.S. Attorney for the District of Vermont. The investigation related to the certification Practice Fusion obtained in connection with the U.S. Department of Health and Human Services’ Electronic Health Record Incentive Program and Practice Fusion’s compliance with the Anti-Kickback Statute (the “AKS”) as it relates to certain business practices previously engaged in by Practice Fusion. Practice Fusion has entered a three-year deferred prosecution agreement with the U.S. Attorney for the District of Vermont (“Deferred Prosecution Agreement”) and a civil settlement agreement with the DOJ (“Civil Settlement Agreement”), and is entering into separate civil settlement agreements with the Medicaid programs for each U.S. state, the District of Columbia and Puerto Rico (“State Settlement Agreements” and, together with the Deferred Prosecution Agreement and the Civil Settlement Agreement, the “Agreements”). The financial terms of the Agreements are substantially similar to the preliminary agreements in principle that Practice Fusion disclosed in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019 filed with the SEC on November 5, 2019.

Deferred Prosecution Agreement

Under the Deferred Prosecution Agreement, Practice Fusion consented to the filing of a two count criminal information: one felony count of violating the AKS and one felony count of conspiracy to violate the AKS. The Deferred Prosecution Agreement requires Practice Fusion to pay a criminal fine of \$25.3 million and a forfeiture payment of \$959,700 within ten days of the court accepting the Deferred Prosecution Agreement. The Deferred Prosecution Agreement also requires that the Company and Practice Fusion regularly review and certify compliance with the Deferred Prosecution Agreement. In the event that Practice Fusion fails to satisfy its obligations under the Deferred Prosecution Agreement, Practice Fusion could be subject to additional criminal penalties or prosecution. Practice Fusion has also agreed to implement Additional Civil Compliance Terms, which include the appointment of an Oversight Organization, and the implementation of a Compliance Addendum. The Oversight Organization Mandate requires Practice Fusion to retain an oversight organization selected by the U.S. Attorney’s Office for the District of Vermont for three years. The Oversight Organization is required to take steps to provide reasonable assurance that Practice Fusion establishes and maintains compliance systems, controls and processes reasonably designed, implemented and operated to ensure Practice Fusion’s compliance with the terms of the Deferred Prosecution Agreement. The Compliance Addendum requires Practice Fusion to, within 90 days of the execution of the Deferred Prosecution Agreement, implement and maintain a Sponsored Clinical Decision Support (“CDS”) Compliance Program that sets procedures and systems to review all current or future Sponsored CDSs on the Practice Fusion electronic health records system. Practice Fusion is subject to the Compliance Addendum for a three-year period from the effective date. The foregoing summary of certain terms of the Deferred Prosecution Agreement is qualified in its entirety by the terms of the Deferred Prosecution Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K.

Civil Settlement Agreement and State Settlement Agreements

Practice Fusion also entered into the Civil Settlement Agreement to resolve allegations by the DOJ that false claims were submitted to governmental healthcare programs. The Civil Settlement Agreement requires Practice Fusion to pay a civil settlement of \$118.6 million, which includes \$5.2 million designated for the state Medicaid program expenditures. The payment term is over a period of nine months from the effective date of the Civil Settlement Agreement. The foregoing summary of certain terms of the Civil Settlement Agreement is qualified in its entirety by the terms of the Civil Settlement Agreement, which is filed as Exhibit 10.2 to this Current Report on Form 8-K.

Practice Fusion also agreed to enter into the State Settlement Agreements to resolve Medicaid claims under state law analogues to the federal False Claims Act. The financial terms of the State Settlement Agreements are substantially similar to those set forth in the Civil Settlement Agreement. As noted above, participating states, the District of Columbia and Puerto Rico will receive up to \$5.2 million in the aggregate from the \$118.6 million paid pursuant to the Civil Settlement Agreement. The Office of the Inspector General of the U.S. Department of Health and Human Services has advised the Company that no Corporate Integrity Agreement will be imposed on the companies as a part of this resolution.

Item 9.01 Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	Deferred Prosecution Agreement, dated January 27, 2020.
10.2	Civil Settlement Agreement, dated January 26, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALLSCRIPTS HEALTHCARE SOLUTIONS, INC.

By: /s/ Brian P. Farley

Name: Brian P. Farley

Title: Executive Vice President, General Counsel and Chief Administrative Officer

Date: January 28, 2020

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

UNITED STATES OF AMERICA))	
))	Docket No. <u>2:20-CR-11</u>
v.))	
PRACTICE FUSION, INC.,))	
Defendant.))	
<hr/>			

DEFERRED PROSECUTION AGREEMENT

Pursuant to the understandings specified below, the United States of America (the “Government”) through its attorney Christina E. Nolan, United States Attorney for the District of Vermont (the “USAO” or the “Office”), and the defendant Practice Fusion, Inc. (“Practice Fusion” or the “Company”), under authority granted by its Board of Directors in the form of a Board Resolution (a copy of which is attached as **Exhibit A**), hereby enter into this Deferred Prosecution Agreement (the “Agreement”).

The Criminal Information

1. Practice Fusion acknowledges and consents to the filing of a two count Information (the “Information”) in the United States District Court for the District of Vermont (the “Court”), charging Practice Fusion with conspiring with a leading extended release opioid (“ERO”) company (“Pharma Co. X”) to receive remuneration in return for arranging for or recommending purchasing or ordering of a good or item for which payment may be made in whole or in part under a Federal health care program in violation of 18 U.S.C. § 371; and knowingly and willfully soliciting and receiving remuneration from Pharma Co. X in return for arranging for or recommending purchasing or ordering of a good or item for which payment may

be made in whole or in part under a Federal health care program in violation of 42 U.S.C. § 1320a-7b(b)(1). A copy of the Information is attached as **Exhibit B**. This Agreement shall take effect upon filing of the Information (the "Effective Date").

Acceptance of Responsibility and Admissions of Fact

2. The Office enters into this Agreement based on the individual circumstances presented by this case and the Company, including:

a. Practice Fusion stipulates that the facts set forth in the Statement of Facts, attached hereto as **Exhibit C** and incorporated herein, are true and accurate, and admits, accepts and acknowledges that it is responsible under United States laws for the acts of its officers and employees as set forth in the Statement of Facts. Should the Office pursue the prosecution that is deferred by this Agreement, Practice Fusion stipulates to the admissibility of the Statement of Facts in any proceeding, including any trial and sentencing proceeding;

b. Practice Fusion did not receive voluntary disclosure credit because it did not voluntarily disclose to the Office, or any other Governmental agency, the conduct described in the Statement of Facts. Even after the Office had issued formal legal process and requested documents relating to Pharma Co. X, Practice Fusion did not identify and disclose to the Office the conduct described in the Statement of Facts;

c. Practice Fusion did not self-disclose any wrongdoing or identify any potential legal or regulatory areas of concern to the Government; identify individual wrongdoers; disclose facts relevant to the Government's investigation that the Government was not previously aware of; or acknowledge and accept responsibility for any wrongdoing by Practice Fusion or any of its employees. Practice Fusion informed the Government on multiple occasions that it had found nothing troubling at the Company from a legal or regulatory perspective. Practice

Fusion additionally sought on multiple occasions to limit the documents produced in response to Government subpoenas, which resulted in the parties conducting multiple meet and confer conferences. In November 2018, the Office provided written notice to Practice Fusion that it did not view Practice Fusion as cooperating with the Government's investigation and any professed cooperation was deficient. Shortly thereafter, and as a consequence of the Office's view of Practice Fusion's approach to the investigation, the Office pursued a portion of its investigation covertly and in Spring 2019 advised Practice Fusion that it was prepared to charge Practice Fusion.

d. Only after the Government advised Practice Fusion that it was prepared to bring charges did Practice Fusion's conduct change. The terms of this Agreement reflect and take into consideration Practice Fusion's belated cooperation. Upon learning of the government's intent to bring charges, Practice Fusion promptly completed an additional internal investigation. Practice Fusion and Allscripts communicated immediately with the Government regarding Practice Fusion's intention and desire to cooperate fully with the Government. Practice Fusion's cooperation at this stage included conducting additional investigation into the conduct described in the Statement of Facts, making regular presentations to the Office, producing additional documents as requested by the Government, agreeing to accept responsibility, and collecting, analyzing, and preparing additional evidence and information to be shared with the Office;

e. Practice Fusion also engaged in remedial measures, including the following: promptly removing from its electronic health record ("EHR") all clinical decision support ("CDS") alerts for which it had received remuneration from its pharmaceutical company clients; conducting an immediate review of the medical appropriateness of its existing

pharmaceutical-sponsored CDS alerts; engaging outside counsel to conduct a review of all sponsored CDS alerts; and pausing sale of all new sponsored CDS alerts pending completion of expert and legal review;

f. Practice Fusion has enhanced and has committed to continuing to enhance its compliance program and internal controls, including ensuring its compliance program satisfies the requirements set forth in **Exhibit D** to this Agreement (“Compliance Addendum”), developing and implementing additional role-based training on the Anti-Kickback Statute, restructuring certain aspects of Practice Fusion’s organization to provide for enhanced separation between clinical and commercial activities and to provide increased supervision by qualified individuals of the clinical initiatives undertaken by the business, and revising existing policies and procedures to enhance controls around CDS alerts;

g. Based on the above, Practice Fusion’s remediation, agreement to the appointment of an Oversight Organization, implementation of the Compliance Addendum, agreement to undertake the terms of the Additional Compliance Terms (which is hereby incorporated by reference), and agreement to report to the Office as set forth in Paragraphs 7 and 8, the Office determined that an independent compliance monitor was unnecessary.

Criminal Fine, Forfeiture, and Civil False Claims Act Payment

3. Practice Fusion agrees to pay a total of \$145,000,000.00 to the United States and participating States, which includes a criminal fine in the amount of \$25,398,300.00 (“Criminal Fine”) and forfeiture of \$959,700.00 (“Forfeiture”) (together with the Criminal Fine, the “Criminal Penalty”). The Criminal Penalty is based on the conduct described in the Information and the Statement of Facts and shall be paid to the United States pursuant to this Agreement. Practice Fusion additionally agrees to the payment of \$118,642,000 to resolve allegations of

violations of the False Claims Act, 31 U.S.C. § 3729, *et seq.* Practice Fusion's conduct giving rise to violations of the False Claims Act are described in the Covered Conduct section of a Civil Settlement Agreement entered between the United States and Practice Fusion.

4. Practice Fusion shall transfer the Criminal Penalty to the United States by no more than 10 days following the Effective Date of this Agreement. Such payment shall be made by wire instructions provided by the Office. If Practice Fusion fails to timely make the payment required under this paragraph, interest (at the rate specified in 28 U.S.C. § 1961) shall accrue on the unpaid balance through the date of payment, unless the Office, in its sole discretion, chooses to reinstate prosecution pursuant to Paragraphs 14, and 15 below. Practice Fusion certifies that the funds used to pay the Criminal Penalty are not the subject of any lien, security agreement, or other encumbrance. Transferring encumbered funds or failing to pass clean title to these funds in any way will be considered a breach of this Agreement and the United States shall be released from any of its obligations hereto.

5. Practice Fusion agrees that the Criminal Penalty shall be treated as a penalty paid to the Government for all purposes, including all tax purposes. Practice Fusion agrees that it will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state, local, or foreign tax for any portion of the Criminal Penalty that Practice Fusion has agreed to pay the United States pursuant to this Agreement.

Practice Fusion's Non-Monetary Obligations

6. Practice Fusion agrees to cooperate fully with the Office, and any other governmental agency designated by the Office regarding (1) any matter relating to the conduct described in the Information or Statement of Facts, (2) the Covered Conduct described in the Civil Settlement Agreement, (3) its privacy practices and use of personal health information, (4)

any investigation or prosecution of Practice Fusion's current or former officers, agents, affiliates, directors, and employees related to the issues described in (1) - (3); or (5) any matter relating to unlawful conduct by Practice Fusion's current or former customers and/or counterparty or client related to the issues described in (1) - (3). Practice Fusion's obligation to cooperate shall continue until the later of the date upon which all investigations and prosecutions arising out of:

- a. the conduct described in the Statement of Facts;
- b. the Covered Conduct described in the Civil Settlement Agreement; and

the end of the term specified in Paragraph 10. Practice Fusion's subsidiaries and majority-owned and controlled affiliates are required to cooperate fully to the same extent as Practice Fusion. As described further in Paragraph 28 below, should Practice Fusion cease to exist as a going concern, or should substantially all of its employees and/or its assets be transferred to another entity, such successor in interest shall be required to cooperate fully to the same extent as Practice Fusion.

7. It is understood that Practice Fusion shall:

- a. truthfully and completely disclose all information with respect to the activities of Practice Fusion and its officers, agents, directors, affiliates and employees concerning all matters about which the Office inquires of it, which information can be used for any purpose;
- b. cooperate fully with the Office, the Department of Justice Commercial Litigation Branch, Fraud Section ("Civil Frauds"), and any other law enforcement agency designated by the Office;
- c. attend all meetings at which the Office requests its presence and use its best efforts to secure the attendance and truthful statements or testimony of any past or current

officers, directors, agents, or employees of Practice Fusion at any meeting, interview, deposition, sworn civil investigative demand (“CID”) testimony, before the grand jury, or at trial or at any other court proceeding;

d. provide to the Office, upon request, any document, record, or other tangible evidence relating to matters about which the Office or any designated law enforcement agency inquires of it;

e. assemble, organize, and provide in a responsive and prompt fashion, and upon request, on an expedited schedule, all documents, records, information and other evidence in Practice Fusion’s possession, custody or control, as may be requested by the Office, or other designated law enforcement agency;

f. volunteer and provide to the Office any information and documents that come to Practice Fusion’s attention that may be relevant to the Office’s investigation of this matter, any issue related to the Statement of Facts, and any issue that would fall within the scope of the duties of the Oversight Organization referred to in Paragraph 24;

g. provide testimony or information necessary to identify or establish the original location, authenticity, or other basis for admission into evidence of documents or physical evidence in any criminal or other proceeding as requested by the Office, or designated governmental agency, including, but not limited to information and testimony concerning the conduct set forth in the Information and Statements of Facts, and the Covered Conduct as described in the Civil Settlement Agreement;

h. bring to the Office’s attention all criminal conduct by Practice Fusion or any of its agents or employees acting within the scope of their employment related to violations

of the Federal laws of the United States, as to which Practice Fusion's Board of Directors, senior management, or legal and compliance personnel are aware;

i. bring to the Office's attention any administrative, regulatory, civil or criminal proceeding or investigation by a federal or state government agency of Practice Fusion or any of its agents or employees acting within the scope of their employment;

j. not directly or indirectly, or through its counsel, enter into any Joint Defense Agreements, provide any advice, information, documents, or otherwise provide any assistance to any third parties (including current or former employees, directors, agents, officers, affiliates, counterparties, and/or clients) in connection with any investigation and/or enforcement action by the Office or Department of Justice involving any such party, related to the issues described in Paragraph 6 (1)-(3) above; except, Practice Fusion may provide information and documents as required by law or as directed by the Office; and

k. commit (i) no criminal offenses, or (ii) regulatory violations pertaining to the CDS issues involved in this Agreement under the federal laws of the United States subsequent to the execution of this Agreement.

Nothing in this paragraph shall require Practice Fusion to produce information in violation of law or protected by a valid claim of attorney-client privilege or the attorney-work-product doctrine.

8. In addition to the obligations set forth in Paragraph 7, during the term of this Agreement, should the Company, or any of its subsidiaries or affiliates, learn of any evidence of a kickback violation by any other EHR vendor, Practice Fusion shall promptly report such evidence or allegation to the Office and Civil Frauds. This provision shall not apply (1) to the extent Practice Fusion is legally prohibited from reporting any evidence or allegation of

misconduct by any other EHR vendor or (2) to information obtained by Practice Fusion in the course of due diligence or other information exchanged as part of a potential strategic transaction or other corporate transaction.

9. For the duration of this Deferred Prosecution Agreement, Practice Fusion shall publicly host, at its own expense, the documents underlying the conduct described in the Statement of Facts. Such documents shall include, but not be limited to, the communications, presentations, contracts, negotiations, analyses, and reports agreed to by the Office as reflecting the relevant communications. Such documents shall be hosted on a public internet site and Practice Fusion shall bear all costs and responsibility for redacting any personal information, personal health information, trade secrets, and information sufficient to identify Pharma Co. X and its employees and drug brands unless and until directed by the Office that such information relating to Pharma Co. X need no longer be redacted.

10. Practice Fusion agrees that its obligation to cooperate pursuant to this agreement and the Additional Compliance Terms, which shall commence on the Effective Date, will continue for three (3) years from the date on which the Information is filed, unless otherwise extended pursuant to Paragraph 15 below. Practice Fusion's obligation to cooperate is not intended to apply in the event that a prosecution against Practice Fusion by this Office is pursued and not deferred.

Deferral of Prosecution

11. In consideration of Practice Fusion's entry into this Agreement, the Additional Compliance Terms, and its commitment to: (a) accept and acknowledge responsibility for its conduct, as described in the Statement of Facts, acknowledge the filing of the Information, and admit the facts in the Statement of Facts; (b) cooperate with the Office and any other law

enforcement agency designated by this Office; (c) make the payments specified in this Agreement; (d) comply with Federal criminal laws (as provided herein in Paragraph 7); and (e) otherwise comply with all of the terms of this Agreement and the Additional Compliance Terms, the Office shall recommend to the Court that prosecution of Practice Fusion on the Information be deferred for three (3) years from the Effective Date of this Agreement, except that the term of this Agreement may be extended as described in Paragraph 15 below, in the sole discretion of the Office.

12. Practice Fusion shall expressly waive indictment and all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, 18 U.S.C. § 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the District of Vermont for the period during which this Agreement is in effect. Practice Fusion further agrees to consent to venue in the United States District Court for the District of Vermont, and waive any statute of limitations defense should the Office pursue the prosecution of the crimes charged in the Information.

13. The Office agrees that, if Practice Fusion is in compliance with all of its obligations under this Agreement, the Office will, within thirty (30) days after the expiration of the deferral-of-prosecution period (including any extensions thereof), seek dismissal, with prejudice of the Information filed against Practice Fusion pursuant to this Agreement, except in the event of a violation by Practice Fusion of any additional charges against Practice Fusion relating to its conduct as described in the admitted Statement of Facts. This Agreement does not provide any protection against prosecution for any crimes except as set forth above and does not apply to any individual or entity other than Practice Fusion. Practice Fusion and the Office understand that the Agreement to defer prosecution of Practice Fusion can only operate as

intended if the Court grants a waiver of the Speedy Trial Act pursuant to 18 U.S.C. § 3161(h)(2). Should the Court decline to do so—or should the Court decline to defer prosecution for any other reason—both the Office and Practice Fusion shall be released from any obligation imposed upon them by this Agreement, and this Agreement shall be null and void, except for the tolling provision set forth in Paragraph 12.

Breach of the Agreement

14. It is understood that should the Office, in its sole discretion, but subject to the notice and cure provisions set forth in Paragraph 17 below, determine that Practice Fusion has: (a) knowingly given false, incomplete or misleading information, either during the term of this Agreement or in connection with the Office’s investigation of the conduct described in the Information and Statement of Facts, or described in the Covered Conduct section of the Civil Settlement Agreement, (b) committed any crime under the Federal laws of the United States subsequent to the execution of this Agreement, or (c) otherwise violated any provision of this Agreement, including the terms of the Additional Compliance Terms, Practice Fusion shall, in the Office’s sole discretion, thereafter be subject to prosecution for any federal criminal violation or suit for any civil cause of action—not released by the Civil Settlement Agreement—of which the Office has knowledge, including, but not limited to, a prosecution or civil action based on the Information, the Statement of Facts, the conduct described therein, or perjury and obstruction of justice. Any such prosecution or civil action may be premised on any information provided by or on behalf of Practice Fusion to the Office or any government agency at any time. In any such prosecution or civil action, it is understood that: (a) no charge or claim would be time-barred provided that such prosecution or civil action is brought within the applicable statute of limitations period, excluding the period from the Effective Date of this Agreement until its

termination; (b) Practice Fusion agrees to toll, and exclude from any calculation of time, the running of the applicable statute of limitations for the length of this Agreement starting from the Effective Date of this Agreement and including any extension of the deferral-of-prosecution period pursuant to Paragraph 15 below; and (c) Practice Fusion waives any objection to venue with respect to any charges in the District of Vermont. By this Agreement, Practice Fusion expressly intends to and hereby does waive its rights in the foregoing respects, including any right to make a claim premised on the statute of limitations, as well as any constitutional, statutory, or other claim concerning pre-indictment delay. Such waivers are knowing and voluntary, and in express reliance on the advice of Practice Fusion's counsel.

15. It is further agreed that in the event that the Office, in its sole discretion, determines that Practice Fusion has violated any provision of this Agreement, including failure to meet its obligations under this Agreement: (a) all statements made or acknowledged by or on behalf of Practice Fusion to the Office or any government agency, including, but not limited to the Statement of Facts, or any testimony given by Practice Fusion or by any agent of Practice Fusion before a grand jury, or elsewhere, whether before or after the Effective Date of this Agreement, or any leads from such statements or testimony, shall be admissible in evidence in any and all criminal or civil proceedings hereinafter brought by the Office against Practice Fusion; and (b) Practice Fusion shall not assert any claim under the United States Constitution, Rule 11 (f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other Federal rule, that statements made or acknowledged by or on behalf of Practice Fusion before or after the Effective Date of this Agreement, or any leads derived therefrom, should be suppressed or otherwise excluded from evidence. It is the intent of this Agreement to waive any and all rights in the foregoing respects. In addition, if the Office

determines that Practice Fusion has violated this Agreement and has failed to cure any such violation Practice Fusion agrees to admit, in any criminal or civil proceeding initiated by the Office or Department of Justice against Practice Fusion for the conduct covered in the Statement of Facts the following assertions: “The Pain CDS described in the Statement of Facts successfully resulted in increased ERO sales by Pharma Co. X. Based on the higher rate of opioid prescriptions among providers who received the Pain CDS, the alerts caused tens of thousands of additional prescriptions for extended release opioids, a substantial portion of which were paid for by federal health care programs such as Medicare and Medicaid.” Provided that Practice Fusion is in compliance with the Agreement, the assertions in the preceding sentences are not part of the factual admissions made by Practice Fusion in this matter. Practice Fusion agrees that, in the event that the Office determines (subject to the notice and cure provisions set forth in Paragraph 17 below) during the deferral-of-prosecution period described above in Paragraph 11 (or any extensions thereof) that Practice Fusion has violated any provision of this Agreement, an extension of the deferral-of-prosecution period may be imposed, in the sole discretion of the Office, up to an additional two (2) years, but in no event shall the total term of the deferral-of-prosecution period of this Agreement exceed five (5) years. Any extension of the deferral-of-prosecution period extends all terms of this Agreement for an equivalent period.

16. Additionally, as a contractual remedy, Practice Fusion and the Office agree that in the event that the Government determines that Practice Fusion has breached this Agreement, the Office may require—at its sole discretion but subject to the notice and cure provisions set forth in Paragraph 17 below, and in lieu of prosecuting the crimes deferred by this Agreement—Practice Fusion to provide stipulated penalties of up to \$25,000.00 per day for each day that Practice Fusion is in breach of this Agreement.

17. Should the Office determine that Practice Fusion has violated this Agreement and prior to pursuing the remedies as described in Paragraphs 14 through 16 or extending the deferral-of-prosecution period pursuant to Paragraph 15, the Office shall provide written notice to Practice Fusion of that determination (the "Written Notice"). Such Written Notice shall set forth: (a) the provision(s) breached; (b) the approximate date of the breach; (c) a description of the breach sufficient to permit Practice Fusion to cure or respond (as described below); and (d) an indication of which remedy the Office intends to pursue (prosecution under Paragraph 14, extension of the deferral-of-prosecution period under Paragraph 15, or Stipulated Penalties under Paragraph 16). If the Office seeks Stipulated Penalties pursuant to Paragraph 16, the Written Notice must also include the amount of Stipulated Penalties claimed by the Office as of the date of the Written Notice. After receiving such Written Notice, Practice Fusion shall have an opportunity to make a presentation to the Office to demonstrate that no violation occurred, or, to the extent applicable, that the violation should not result in the exercise of those remedies or in an extension of the deferral-of-prosecution period, including because the violation has been cured by Practice Fusion.

18. If the Office demands Stipulated Penalties, Stipulated Penalties calculated from the date of breach to the date of payment shall be payable to the United States within fourteen (14) days, payable according to the same instructions as the Criminal Penalty, or as otherwise directed by the Office. Practice Fusion agrees that the United States District Court for the District of Vermont shall have jurisdiction over any action to collect such a penalty. If Practice Fusion fails to timely make a payment required in this Paragraph, interest (at the rate specified in 28 U.S.C. § 1961) shall accrue on the unpaid balance through the date of payment.

19. Practice Fusion agrees that it is within the Office's sole discretion to choose, in the event of a violation, the remedies contained in Paragraphs 14 and 16 above, or instead to choose to extend the deferral-of-prosecution period pursuant to Paragraph 15, provided, however, if Practice Fusion's violation of this Agreement is limited to an untimely payment of the Criminal Penalty, the Office may elect instead to choose the additional financial penalties set forth in Paragraph 4 above. Practice Fusion understands and agrees that the exercise of the Office's discretion under this Agreement is unreviewable by any court.

20. It is further agreed that in the event that the Office, in its sole discretion, determines that Practice Fusion has violated any provision of this Agreement, including failure to meet its obligations under this Agreement: (a) all statements made or acknowledged by or on behalf of Practice Fusion to the Office or any government agency, including, but not limited to the Statement of Facts, or any testimony given by Practice Fusion or by any agent of Practice Fusion before a grand jury, or elsewhere, whether before or after the Effective Date of this Agreement, or any leads from such statements or testimony, shall be admissible in evidence in any and all criminal or civil proceedings hereinafter brought by the Office against Practice Fusion; and (b) Practice Fusion shall not assert any claim under the United States Constitution, Rule 11 (f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other Federal rule, that statements made or acknowledged by or on behalf of Practice Fusion before or after the Effective Date of this Agreement, or any leads derived therefrom, should be suppressed or otherwise excluded from evidence.

Public Statements

21. Practice Fusion, having truthfully admitted to the facts in the Statement of Facts, agrees that it shall not, through its attorneys, agents, or employees, make any statement, in

litigation or otherwise, contradicting the Statement of Facts or its representations in this Agreement. Consistent with this provision, Practice Fusion may raise defenses and/or assert affirmative claims and defenses in any proceedings brought by private and/or public parties as long as doing so does not contradict the Statement of Facts or such representations. Nothing in this agreement shall restrict Practice Fusion's ability to defend itself in ancillary investigations or proceedings brought by parties other than the Office and/or the United States Department of Justice ("DOJ") provided that Practice Fusion may not contradict or deny the facts admitted to in the Statement of Facts. Any such contradictory statement by Practice Fusion, its present or future attorneys, agents, or employees, shall constitute a violation of this Agreement and Practice Fusion thereafter shall be subject to prosecution and/or penalties as specified in Paragraphs 14 and 16 above, or the deferral-of-prosecution period shall be extended pursuant to Paragraph 15 above. The decision as to whether any such contradictory statement will be imputed to Practice Fusion for the purpose of determining whether Practice Fusion has violated this Agreement shall be within sole discretion of the Office. Upon the Office's notifying Practice Fusion of any such contradictory statement, Practice Fusion may avoid a finding of violation of this Agreement by repudiating such statement both to the recipient of such statements and to the Office within four (4) business days after having been provided notice by the Office. Practice Fusion consents to the public release by the Office, in its sole discretion, of any such repudiation. Nothing in this Agreement is meant to affect the obligation of Practice Fusion or its officers, directors, agents or employees to testify truthfully to the best of their personal knowledge and belief in any proceeding. Nothing herein applies to statements made, in litigation or otherwise, by any present or former officers, directors, agents or employees of Practice Fusion that are made solely in an individual capacity, and not on behalf of Practice Fusion.

Compliance Program

22. Practice Fusion represents that it has implemented and will continue to implement and maintain an effective compliance program designed to prevent and detect violations of the Anti-Kickback Statute. In order to address deficiencies in its compliance controls, policies, and procedures, Practice Fusion shall maintain and implement a CDS compliance program that meets the requirements set forth in the compliance addendum (the "Compliance Addendum") (a copy of which is attached as **Exhibit D**).

23. It is understood that Practice Fusion shall promptly notify the Office of (a) any deficiencies, failings, or matters requiring attention with respect to Practice Fusion's adoption, implementation, or maintenance of the compliance programs described in the Compliance Addendum; and (b) any steps taken or planned to be taken by Practice Fusion to address the identified deficiency, failing, or matter requiring attention. Practice Fusion's failure to adopt, implement, or maintain a compliance program as described in the Compliance Addendum shall constitute a violation of this Agreement.

Oversight Organization

24. Practice Fusion will implement the provisions regarding the Oversight Organization, as required in the addendum attached as **Exhibit E**.

Additional Compliance Terms

25. Practice Fusion will implement the provisions and comply with the terms of the Additional Compliance Terms, as required in the addendum attached as **Exhibit G**.

Limits of this Agreement

26. It is understood that this Agreement is binding on the Office, but does not bind any other Federal agencies, any state or local law enforcement agencies, any licensing

authorities, or any regulatory authorities. However, if requested by Practice Fusion, or its attorneys, the Office will bring to the attention of any such agencies, including, but not limited to, any regulators, as applicable, this Agreement, the cooperation of Practice Fusion, and Practice Fusion's compliance with its obligations under this Agreement.

27. It is further understood that the Department of Justice has provided Practice Fusion with a nationwide release in connection with its conduct described in the Statement of Facts, as set forth in **Exhibit E**, and that DOJ shall not, except as otherwise contemplated by this Agreement or global resolution with the Office, institute additional or other criminal proceedings against Practice Fusion for the conduct described in the Statement of Facts.

Sale, Merger, or Insolvency of Practice Fusion

28. Except as may otherwise be agreed by the parties hereto in connection with a particular transaction, Practice Fusion agrees that in the event it sells, merges, or transfers all or substantially all of its business operations as they exist as of the Effective Date of this Agreement, whether such sale is structured as a sale, asset sale, merger, or transfer, it shall include in any contract for sale, merger or transfer, a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. However, the terms of this Agreement shall not be construed to apply to that portion of any purchaser's or successor in interest's assets or operations that are unrelated to Practice Fusion's assets or operations. The Government shall consider any request by Practice Fusion that the Government, in its sole discretion, waive the requirement that all provisions in this Paragraph bind Practice Fusion and/or any of its purchasers or any successors in interest.

29. Practice Fusion also represents and warrants that it has reviewed its financial situation, that it currently is not insolvent as such term is defined in 11 U.S.C. § 101(32), and that

it reasonably believes that it shall remain solvent following payment to the Government of the Criminal Penalty. Further, Practice Fusion and the Government warrant that, in evaluating whether to execute this Agreement, they (1) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Practice Fusion, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to, and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Practice Fusion was or became indebted to on or after the Effective Date, within the meaning of 11 U.S.C. §548(a)(1).

30. If within ninety-one (91) days of the Effective Date of this Agreement or any payment made by Practice Fusion under this Agreement, (i) Practice Fusion commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences any involuntary case, action, or other proceeding against Practice Fusion under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of Practice Fusion's debts, or seeking to adjudicate Practice Fusion as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Practice Fusion or for all or part of Practice Fusion's, assets, or (ii) a third party commences against Practice Fusion any case, proceeding or other action referred to in clauses (a) or (b) above, and the same is not rescinded or dismissed within 60 days of the date of commencement of such case, proceeding or action, Practice Fusion agrees as follows:

a. Practice Fusion's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Practice Fusion shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Practice Fusion's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Practice Fusion was insolvent at the time this Agreement was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Practice Fusion.

b. If any of Practice Fusion's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, in its sole discretion, may rescind the Agreement and bring any criminal, civil and/or administrative claim, action, or proceeding against Practice Fusion for the claims that would otherwise be covered by the release in Paragraph 13 above. Practice Fusion agrees that to the fullest extent of applicable law (i) any such criminal charge, civil claim, or other action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the charge, case, action, or proceeding described in the first sentence of this Paragraph, and Practice Fusion shall not argue or otherwise contend that the Government's criminal charge, claim, action, or proceeding is subject to an automatic stay; (ii) Practice Fusion shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any charge, claim, action, or proceeding that is brought by the Government within sixty (60) calendar days of written notification to Practice Fusion that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of this Agreement; and (iii) the Government has a valid claim against Practice Fusion in the amount of

the Criminal Penalty and the Government may pursue its charge, claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.

c. Practice Fusion acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

Notice

31. Any notice or report to be provided to the Office under this agreement shall be made by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

United States Attorney's Office for the District of Vermont
Attn: Civil and Criminal Chiefs
United States Courthouse and Federal Building
Post Office Box 570
11 Elmwood Avenue, 3d Floor
Burlington, VT 05402-0570

32. Any notice or report to be provided to Practice Fusion under this agreement shall be made by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, and email addressed to:

ATTN: General Counsel
Allscripts Healthcare Solutions, Inc.
222 Merchandise Mart Plaza, 20th Floor
Chicago, IL 60654
Legal.notices@allscripts.com

Joshua S. Levy
Aaron Katz
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600

Public Filing

33. Practice Fusion and the Office agree that, upon the submission of this Agreement (including the Statement of Facts and other attachments) to the Court, this Agreement and its attachments shall be filed publicly in the proceedings in the United States District Court for the District of Vermont.

34. The parties understand that this Agreement reflects the unique facts of this case and is not intended as precedent for other cases.

Execution in Counterparts

35. This Agreement may be executed in one or more counterparts, each of which shall be considered effective as an original signature. Further, all facsimile and digital images of signatures shall be treated as originals for all purposes.

Dated at Burlington, in the District of Vermont, this 27th day of January, 2020.

Respectfully submitted,

UNITED STATES OF AMERICA

CHRISTINA E. NOLAN
United States Attorney

By: /s/ Owen C.J.

OWEN C.J.FOSTER
MICHAEL P. DRESCHER
Assistant U.S. Attorneys
P.O. Box 570
Burlington, VT 05402-0570
(802) 951-6725
Owen.C.J.Foster@usdoj.gov
Michael.Drescher@usdoj.gov

Foster

Accepted and agreed to:

/s/ Eric L. Jacobson, Esq.
Eric L. Jacobson, Esq.
Secretary
Practice Fusion, Inc.

/s/ Joshua Levy, Esq.
Joshua Levy, Esq.
Aaron Katz, Esq.
Patrick Welsh, Esq.
Ropes & Gray, LLP
Counsel to Practice Fusion, Inc.

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

)
UNITED STATES OF AMERICA)
) Docket No. 2:20-CR-11
v.)
)
PRACTICE FUSION, INC.,)
)
Defendant.)
_____)

Resolution of Practice Fusion, Inc. Board of Directors

WHEREAS, Practice Fusion, Inc., a Delaware corporation (hereafter “Practice Fusion” or the “Company”), has been engaged in discussions with the United States’ Attorney’s Office for the District of Vermont (“the United States”) regarding potential violations of law arising out of the marketing of certain aspects of Practice Fusion’s electronic health records software (“EHR”);

WHEREAS, the Board of Directors of Practice Fusion (the “Director”) understands that Practice Fusion has been notified by the United States that in the absence of any plea or deferred prosecution agreement (“DPA”) the United States intends to file criminal charges against Practice Fusion;

WHEREAS, the United States has informed Practice Fusion of its willingness to resolve the potential criminal charges against Practice Fusion in the form of a DPA, Criminal Information, Compliance Addendum, Independent Review Organization, Statement of Facts, and other associated documents (collectively, the “DPA and Associated Agreements”), each of which has been provided

to, and reviewed by, the Director prior to this meeting, to resolve all criminal charges against Practice Fusion, on the terms contained within those documents;

WHEREAS, the Director has determined, after review and due consideration and consultation with legal counsel, that it is in the best interest of the Company to enter into a DPA, pay the criminal penalty required by the terms of the DPA, stipulate to the accuracy of the Statement of Facts, and agree to all other provisions, including corporate governance and compliance provisions, contained within the DPA and Associated Agreements;

WHEREAS the Director recognizes that the DPA and Associated Agreements require Practice Fusion to cooperate fully with the United States in any and all related investigations, pay certain Criminal Penalties as well as expend all necessary funds for the improvement and maintenance of compliance functions at Practice Fusion, and effectuate certain corporate governance changes necessary to comply with the terms of the DPA and Associated Agreements;

NOW THEREFORE, pursuant to the governing documents of the Company and the laws of the State of Delaware, IT IS RESOLVED, that:

1. Practice Fusion and its management are hereby authorized to take any and all action required on behalf of the Company to enter into the DPA and Associated Agreements with the United States to resolve potential criminal actions against the Company relating to charges that Practice Fusion: (a) conspired to violate the Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), in violation of 18 U.S.C. § 371; and (b) violated the Anti-Kickback Statute 42 U.S.C. § 1320a-7(b).

2. Practice Fusion and its management are authorized to take any and all further action necessary to effectuate the purpose and intent of the DPA and Associated Agreements, as well as any

action necessary to ensure Practice Fusion's ongoing compliance with all state and federal laws relating to the Anti-Kickback Statute.

3. Practice Fusion Corporate Secretary, Eric Jacobson, or any other corporate officer, is hereby authorized, empowered and directed, on behalf of Practice Fusion to execute the DPA and Associated Agreements substantially in such form as reviewed by the Director at this meeting with such changes as Corporate Secretary Eric Jacobson, or any other corporate officer, may approve;

4. Corporate Secretary Eric Jacobson, or any other corporate officer, is hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions, including but not limited to acknowledging the filing of the Information, to authorize a representative or agent of Practice Fusion to waive indictment on behalf of Practice Fusion, act as Practice Fusion's authorized agent in court proceedings related to the DPA, and to accept the monetary penalty set forth in the DPA and Associated Agreements; and

5. All of the actions of the Corporate Secretary, Eric Jacobson, or any other corporate officer, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of Practice Fusion.

Accepted and agreed to:

/s/ Dennis Olis

Dennis Olis

Member of the Practice Fusion, Inc. Board of Directors

Date: January 10, 2020

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA,

Docket No. 2:20-CR-11

v.

PRACTICE FUSION, INC.,
Defendant.

INFORMATION

The United States Attorney charges:

I. INTRODUCTION

1. Beginning in or around fall 2013 Defendant PRACTICE FUSION solicited remuneration from a pharmaceutical company (“Pharma Co. X”) in exchange for creating and embedding an alert, known as a clinical decision support (“CDS”) alert, in PRACTICE FUSION’S electronic health record (“EHR”) to prompt doctors to take certain clinical actions in order to increase prescriptions of Pharma Co. X’s extended release opioids (“EROs”). Once implemented, this CDS alert (“the Pain CDS”) caused doctors to focus on assessing and treating a patient’s pain symptoms, and supplied healthcare providers a list of potential care plan treatment options. The Pain CDS suggested treatments, including opioids, without regard to the medical appropriateness of each option.

2. The remuneration offered and paid by Pharma Co. X and solicited and received by PRACTICE FUSION in return for PRACTICE FUSION designing the Pain CDS with a purpose of increasing Pharma Co. X’s ERO sales, portions of which were paid for by federal health care programs, was a kickback in violation of 42 U.S.C. § 1320a-7b(b)(1) & (b)(2).

3. PRACTICE FUSION and Pharma Co. X's agreement and acts in furtherance of their unlawful kickback scheme was a conspiracy to violate the Anti-Kickback Statute, in violation of 18 U.S.C. § 371.

II. BACKGROUND

At times relevant to this Information:

4. "Pharma Co. X" (a pseudonym) was a United States-based pharmaceutical company whose products included branded extended release opioids.

5. Defendant PRACTICE FUSION was a Delaware corporation with headquarters in San Francisco, California. PRACTICE FUSION was a cloud-based EHR company that generally provided its cloud-based EHR product to healthcare providers without charge.

6. Employee #1 was a PRACTICE FUSION Life Sciences Sales Representative initially in charge of the Pharma Co. X account.

7. Employee #2 was PRACTICE FUSION'S Senior Vice President for Life Sciences Practice and Strategic Partnerships.

8. Employee #3 was PRACTICE FUSION'S Chief Commercial Officer ("CCO"), and later Chief Executive Officer ("CEO").

9. Employee #4 was PRACTICE FUSION's Chief Medical Officer.

10. Employee #5 was PRACTICE FUSION'S Director of National Accounts and was ultimately responsible for the Pharma Co. X account at the time the Pain CDS deal closed. Employee #5 was the Practice Fusion employee credited with closing the Pain CDS deal and the only employee who received a commission in connection with the deal.

11. Employee #6 was PRACTICE FUSION'S Director of Strategic Development, Life Science Partnerships.

12. Pharma Co. X Employee #1 was Pharma Co. X's Director of eMarketing.
13. Pharma Co. X Employee #2 was a Pharma Co. X Brand Manager in charge of one of Pharma Co. X's ERO brands.
14. Pharma Co. X Employee #3 was a Pharma Co. X physician.
15. PRACTICE FUSION provided EHR services to tens of thousands of active healthcare provider users in the United States, including in Vermont, and its software was used during millions of patient encounters each month.

16. Though PRACTICE FUSION offered its EHR to healthcare providers free of charge, PRACTICE FUSION had various sources of revenue. Federal regulations provided for the implementation of CDS alerts in EHR software. Practice Fusion derived revenue from this clinical functionality in the form of payments from pharmaceutical companies in exchange for creating and implementing CDS alerts in its EHR.

17. PRACTICE FUSION'S CDS alerts typically worked as follows for a healthcare provider using the PRACTICE FUSION EHR: a message would appear on the PRACTICE FUSION EHR alerting the healthcare provider that, given the particular personal health information and circumstances of the patient before the provider at that moment, the provider should consider certain clinical information, perform certain tests or assessments, and complete certain documentation.

18. PRACTICE FUSION understood that pharmaceutical companies would pay for the CDS because the CDS could boost sales of the pharmaceutical companies' products.

19. PRACTICE FUSION understood that Pharma Co. X provided remuneration in exchange for the Pain CDS because the CDS could boost sales of Pharma Co. X's ERO products.

20. PRACTICE FUSION understood that it was unlawful to sell CDS programs based on anticipated returns on investment that a pharmaceutical company client could achieve through the CDS, and that any CDS program must be consistent with any applicable evidence-based medical guidelines and

21. Extended release opioids are highly addictive narcotics that are properly prescribed only in limited circumstances.

According to labeling for Pharma Co. X’s leading ERO, that product was indicated “for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” The ERO’s labeling moreover directed: “Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release formulations, reserve [Pharma Co. X’s ERO product] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.”

22. The FDA-approved labeling states that Pharma Co. X’s primary ERO was “[t]o be prescribed only by healthcare providers knowledgeable in use of potent opioids for management of chronic pain.”

23. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) prohibited PRACTICE FUSION from knowingly and willfully soliciting or receiving remuneration in return for “arranging for or recommending” ordering any good or item for which payment may be made in whole or in part under a Federal health care program. PRACTICE FUSION knowingly and willfully violated the Anti-Kickback Statute through its solicitation and receipt of remuneration from Pharma Co. X in connection with the Pain CDS.

24. 18 U.S.C. § 371 prohibits conspiracies and provides that “[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.” PRACTICE FUSION conspired with Pharma Co. X to violate the Anti-Kickback Statute through its solicitation and receipt

of remuneration from Pharma Co. X in connection with the Pain CDS.

III. PRACTICE FUSION SOLICITED REMUNERATION FROM PHARMA CO. X IN RETURN FOR A CDS THAT WOULD ARRANGE FOR AND RECOMMEND THE ORDERING OF EXTENDED RELEASE OPIOIDS

25. PRACTICE FUSION began discussing the prospect of using its EHR in furtherance of Pharma Co. X's marketing goals with Pharma Co. X personnel as early as fall 2013. These discussions included the possibility of using the PRACTICE FUSION EHR to screen potential patients for whether they were suitable for long-term opioid therapy, including assessing whether the patient had a history of substance abuse.

26. PRACTICE FUSION and Pharma Co. X did not pursue a CDS alert to assist doctors in screening patients for risk of opioid abuse; instead, they developed a CDS to increase sales of Pharma Co. X's ERO products.

27. As discussions between the parties increasingly focused on Pharma Co. X's commercial objectives, Employee #1 was counseled in an internal PRACTICE FUSION email in April 2014 that "[i]ndicating that [Pharma Co. X] influenced clinical decisions through sponsored money has legal implications versus a marketing program where a banner can be displayed and influence a prescribing behavior."

28. In or around May 2014, PRACTICE FUSION continued its solicitation of Pharma Co. X by forwarding to Pharma Co. X news stories concerning PRACTICE FUSION'S implementation of a CDS program paid for by a vaccine manufacturer. The article was forwarded within Pharma Co. X to its Chief Executive Officer with the message: "I know you know of Practice Fusion, we too are working to get our pain management tools into their platform." Pharma Co. X's CEO responded, "Thanks. The key is understanding how it grows or protects scripts."

29. Between May 2014 and March 2015, representatives from PRACTICE FUSION and Pharma Co. X continued to communicate regularly regarding potential transactions between the two companies.

30. In a March 23, 2015 internal PRACTICE FUSION email—written in preparation for a scheduled March 31, 2015 meeting at Pharma Co. X—Employee #1 described the opportunity to sell a CDS program to Pharma Co. X by explaining to PRACTICE FUSION colleagues that Pharma Co. X “has communicated that the average dosage of [Pharma Co. X’s leading ERO] is declining” and that “[providers are hesitant about using high dosages to combat pain for a variety of reasons, mostly, political pressure.” The email further stated that “[a]s a result, [Pharma Co. X] is toying with the idea of using Pain Assessment tools with the provider at every visit and before every RX.” RX is an abbreviation for prescription.

31. PRACTICE FUSION understood Pharma Co. X was concerned that as a result of heightened public awareness of the dangers of opioid use, healthcare providers were prescribing lower dosages of opioids. PRACTICE FUSION thus marketed its medical software as having the potential to influence provider behavior and counteract Pharma Co. X’s economic concerns regarding providers prescribing fewer and lower dosages of opioids.

A. PRACTICE FUSION’S MARCH 31,2015 SOLICITATION TO PHARMA CO. X AND ENSUING FOLLOW-UP SOLICITATIONS

32. On or about March 31, 2015, PRACTICE FUSION representatives travelled to Pharma Co. X’s headquarters to continue soliciting payment from Pharma Co. X in exchange for a CDS. PRACTICE FUSION’S solicitation materials included a PowerPoint presentation, commonly referred to as a “pitch deck.” PRACTICE FUSION’S pitch deck indicated that a pain CDS would be “based on” the “brand objectives” of Pharma Co. X’s three extended release opioid products. These objectives included targeting “opioid naive patients”—i.e., patients who were not previously prescribed opioids—and targeting patients who were using immediate release opioids (“IROs”). A slide from the pitch deck depicting Practice Fusion’s understanding of Pharma Co. X’s brand objectives is excerpted below:



Target: Opioid Naive Patients

Patients that cannot be controlled

Patients that cannot tolerate certain Opioids

Individually Titrate

How-to Use 2 patches of similar strengths, for example, two 7.5 mcg/hour patches

Patient Savings Card program

Target: Oxycodone IR patients

Individualize doses per patient

Pain Assessment at every visit

Titration Therapy

Abuse Deterrent Formulation

Patient Savings Card program

Target: Hydrocodone IR patients

FDA Approved Tier 1 and Tier 3 Abuse Deterrent labeling

Once/Day dosing

Titrate to individual patient needs

Perform Pain Assessment at every visit

Patient Savings Card Program

Brand Objectives

33. Pharma Co. X advised PRACTICE FUSION that it wished to utilize a CDS to “target” the opioid naive and IRO users. Those patients represented potential additional users of Pharma Co. X’s EROs. Further, Pharma Co. X would make more money selling its drugs if PRACTICE FUSION’S CDS helped “keep[] an appropriate patient on a consistent dose . . . ” PRACTICE FUSION thus recommended creating a CDS alert to address Pharma Co. X’s concerns.

34. While PRACTICE FUSION and Pharma Co. X employees used euphemisms like “appropriate patients,” “identify care gaps,” and “better manage patients,” both parties understood a goal of the program was to increase ERO use. As described *infra*, the parties did not ensure “appropriate” patients received EROs.

35. Following the March 31, 2015 presentation, Employee #2 emailed Employee #3 stating that “next steps” with respect to the Pharma Co. X solicitation included “build[ing] [a] model to show potential commercial impact of increased patients being screened for pain and risk of opioid abuse.”

36. According to this March 31, 2015 email, the PRACTICE FUSION personnel who were to “model” the “commercial impact” to Pharma Co. X’s drug sales from the CDS included: Employee #1, Employee #4, Employee #5, and Employee #6.

37. Employee #5 modelled the “commercial impact” that would accrue to Pharma Co. X as a result of the Pain CDS causing an increase in ERO prescriptions. PRACTICE FUSION calculated that Pharma Co. X would obtain a return on investment (“ROI”) of between 5.8 and 7.8 times its cost if it implemented the PRACTICE FUSION Pain CDS.

38. A version of the model estimated that Pharma Co. X would achieve a “patient gain”

of two thousand seven hundred seventy-seven (2,777) and between \$8,458,232 and

\$11,277,643 in additional opioid revenue by implementing the CDS.

39. PRACTICE FUSION developed a model to show the “commercial impact” to Pharma Co. X of a pain CDS, and Pharma Co. X eventually entered into a contract with PRACTICE FUSION for the Pain CDS based on the parties’ mutual expectation of increased ERO sales.

40. An April 1, 2015 internal PRACTICE FUSION email, containing an early version of the “commercial impact” model is excerpted below, showing that PRACTICE FUSION sought to align its EHR with the commercial objectives of Pharma Co. X:

We could use these values to present an economic benefit of the proposed program in three ways or any additional suggestions.

1. **Value of keeping an appropriate patient on a consistent dose of one of the products throughout the 2 year term of the program**
2. **Value of conversion from IR to ER and consistent dosing over the term of the program**
3. **Value of a % market share in the branded ERO space; [] mentioned they enjoy an 83% share in the branded ERO space. We can track and measure two things during the program. Share of the current branded EROs on our platform and potential new market entrants to ERO therapy as a result of the clinical intervention**

During our planning call, we can work with [] to help develop outcomes measures that can map back to these metrics.

41. PRACTICE FUSION solicited remuneration from Pharma Co. X to design the Pain CDS to cause healthcare providers to extend the duration of ERO prescriptions, convert patients receiving IROs to EROs, to increase the overall market of ERO-using patients, and to measure its ability to deliver such results.

42. In an April 22, 2015 internal PRACTICE FUSION email discussing follow up communications to Pharma Co. X, Employee #5 advised: “Since this is being sent to a marketing audience the idea of ROI has to be part of the plan to justify the costs of the program.”

Employee #5 further inquired “[d]o you think we can develop some sort of ROI model that can make assumptions of increased patient volumes or increased persistency on these products to calculate an estimated ROI?”

43. It is common in the healthcare industry for pitch decks to be scrutinized for purposes of ensuring legal and regulatory compliance. PRACTICE FUSION did not include its calculations of increased opioid patient volume, increased opioid sales, or increased persistency to opioid products in the pitch materials provided to Pharma Co. X. Rather, on or about April 23, 2015, Employee #5 directed in an internal PRACTICE FUSION email pertaining to the Pharma Co. X CDS written proposal: “Don’t include the ROI in the proposal. We’ll walk the client through the ROI.”

44. On April 28, 2015, Employee #2 described the final Pharma Co. X pitch deck as “concise and will allow us to voice over what we need to regarding how the program works and its commercial impact.” Practice Fusion “voiced over” the “commercial impact” of the program, rather than describe it in the pitch deck, because it knew and understood that CDSs should not be sold to pharmaceutical clients on the basis that the CDS could influence doctors’ prescribing in ways commercially beneficial to the sponsoring pharmaceutical client.

45. On April 29, 2015, Employee #2 stated in an internal email referring to the Pharma Co. X CDS proposal that “[t]he goal here is to sell it as a study-but get commercial \$ moved over or added to the funding to make the deal work.” This same email observed that there was “urgency” for PRACTICE FUSION to generate revenue.

46. On May 11, 2015, Employee #6 asked Employee #5 if he had “the final pricing model you used for [Pharma Co. X]?” Employee #6 then wrote: “Actually...without saying

ROI... I mean the ROI spreadsheet ;-).” Employee #5 then provided the Pharma Co. X ROI analysis.

B. PRACTICE FUSION’S SEPTEMBER 1,2015 PRESENTATION AT

PHARMA CO. X HEADQUARTERS AND SUBSEQUENT FOLLOW-UP

47. Employee #5 emailed personnel in Pharma Co. X’s marketing department on July 16, 2015, “to re-engage around the Practice Fusion Clinical Decision Support Real World Evidence Pain Management program.” He stated “[w]e feel that the proposed program can help meet the strategic commercial needs of the pain franchise at [Pharma Co. X.]”

48. Prompted by the July 16, 2015 email described in the preceding paragraph, PRACTICE FUSION and Pharma Co. X’s marketing personnel scheduled an additional presentation at Pharma Co. X’s headquarters for PRACTICE FUSION to propose the Pain CDS program in greater detail. This meeting was scheduled for September 1, 2015, at Pharma Co.

X’s headquarters.

49. On or about July 30, 2015, Pharma Co. X’s Executive Director for Marketing sent an email to Pharma Co. X Employee #1 (Pharma Co. X’s Director of eMarketing) advising that the Brand Managers in charge of two of Pharma Co. X’s three ERO brands “can benefit” by attending the upcoming meeting with PRACTICE FUSION at which the Pain CDS proposal would be presented.

50. On or about August 17, 2015, Employee #5 discussed PRACTICE FUSION’S

proposal with two Pharma Co. X employees, Pharma Co. X Employee #1 and Pharma Co. X Employee #2. In an email describing that discussion, Employee #5 stated that PRACTICE FUSION'S "proposed solution" would include, among other features, "appropriate pain assessment tools/screeners that will help providers in the decision to initiate ERO products," and "[u]nbranded clinical messaging to reinforce appropriate use of EROs in patient populations -

ERO users, chronic NSAID users, tramadol, etc." This email further explained that Pharma Co. X Employee #1 desired to see a "draft strategy by weeks end to discuss and refine for presentation to the broader commercial team during [the] meeting in Sept."

51. On or about August 21, 2015, Employee #5 forwarded a preliminary version of the September 1, 2015 presentation to Pharma Co. X Employee #1.

52. On or about September 1, 2015, two PRACTICE FUSION employees, including Employee #5, travelled to Pharma Co. X's headquarters to propose that Pharma Co. X pay PRACTICE FUSION approximately \$1,000,000 to develop and implement the Pain CDS to influence health care providers to prescribe more EROs.

53. Pharma Co. X marketing personnel representing each of its three ERO brands attended the September 1, 2015 presentation. The presentation included a pitch deck in which PRACTICE FUSION proposed the CDS program focus on the treatment of pain by: "Leverag[ing] Practice Fusion Platform to deliver Clinical Decision Support and measure the impact and real world outcomes on patient care"; delivering "clinical patient-centric provider messages" targeted at healthcare providers with "opioid naive patients with chronic pain," and with patients currently

receiving immediate release oxycodone and hydrocodone; and “Leveraging] the Practice Fusion EMR platform to help providers assess, diagnose, and treat Chronic Pain.”

54. The proposal also included PRACTICE FUSION providing “educational messages” targeted to healthcare providers with patients with diagnoses of “chronic pain and with history of non-Opioids in their chart.”

55. The proposed Pain CDS would prompt the provider to assess the patient’s pain, and to “evaluate conversion rates from IR opioid or chronic pain non opioid treatment to ERO.”

56. Employee #5 led discussion of the Pain CDS at the September 1, 2015 in-person proposal.

57. Pharma Co. X employees understood based on the presentation that the Pain CDS would keep pain top of mind and influence physicians to switch more patients from non-opioids and IROs to Pharma Co. X’s EROs. Marketing personnel within Pharma Co. X also liked that the proposed Pain CDS allowed Pharma Co. X to, in essence, be present in the exam room while they interacted with patients.

58. After the September 1, 2015 meeting, a PRACTICE FUSION employee provided the pitch materials by email on September 2, 2015 to the PRACTICE FUSION employee who advised Employee #1 regarding the legal implications of using a CDS as a marketing tool, as described in paragraph 27 above. That employee in turn forwarded those materials to another PRACTICE FUSION employee by email with a message that included: “I understand that the [Pharma Co. X] proposal has shifted to a commercial focus and that marketing folks were in the room instead of outcomes[.]” The message also included “[t]here are several things incorrect with this presentation/proposal from pricing to products. Please do not share. Just be aware....”

59. The September 1, 2015 pitch materials were forwarded within PRACTICE FUSION because of concerns about how Employee #5 had sold the CDS alert to Pharma Co. X, including discussions surrounding how the CDS would grow Pharma Co. X's opiate sales.

60. PRACTICE FUSION included a "study" as part of the September 1 proposal. A September 2 internal PRACTICE FUSION email observed, however, that Pharma Co. X was not interested in a study: "we were talking to product managers, and they could care less about RWE [real world evidence]. For them, this was all about marketing." The email further stated that during the September 1 meeting with Pharma Co. X "I made it clear that we would measure success (metrics, switches from IR to ER, etc.)[" The study was included in the proposal, in part, to make the deal appear as a legitimate medical project, and not a commercial endeavor.

61. A September 1, 2015 internal PRACTICE FUSION email from Employee #5 confirmed that Pharma Co. X's "brands" would contribute equally to the cost of the program "since this is a non branded effort."

62. On September 4, 2015, Employee #5 emailed Pharma Co. X Employee #1 a "revised deck" that was "based on our meeting this week." This "revised deck" included a new slide devoted to "Project Goals" (excerpted below). Those goals included (among others): "Educate providers around appropriate patients for ERO therapy"; "Identify care gaps through clinical decision support alert tools at the point of care"; "Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy"; and to provide Pharma Co. X a "[d]etailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics)."

- + Educate providers around appropriate patients for ERO therapy + Identify care gaps through clinical decision support alert tools at the point of care
- + Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy
- + Create or enhance pain score capture and functional assessment data + Provide to [] detailed data and analytics
 - Detailed process metrics (quarterly metrics)
 - Detailed analysis of current market landscape and treatment patterns (one time deliverable)
 - Detailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics)
- + Produce a published peer reviewed manuscript

IV. PRACTICE FUSION RECEIVED REMUNERATION FROM PHARMA CO. X IN RETURN FOR A PAIN CDS THAT WOULD ARRANGE FOR AND RECOMMEND THE ORDERING OF EXTENDED RELEASE OPIOIDS

63. Shortly after the September 1, 2015 meeting, Pharma Co. X and PRACTICE FUSION moved forward with designing the Pain CDS as pitched by PRACTICE FUSION.

64. In September and October 2015 Pharma Co. X marketing personnel integrated the PRACTICE FUSION Pain CDS proposal into their internal 2016 Marketing Tactic presentations. According to internal Pharma Co. X documents, the objective of the program was to “Grow ERO prescriptions within the Practice Fusion ehr [electronic health record],” by using the PRACTICE FUSION platform to cause providers to “reassess chronic pain patients for the need for Extended Release Opioids.” Pharma Co. X identified the “strategic pillar” of the Pain CDS as “Portfolio Tactic - Grow the ERO market” and described the program as “[a]lerts for patients with chronic pain will occur at the point of prescription.”

65. In a document titled Marketing Portfolio Budget Review, Pharma Co. X noted that “[promotion within an EMR may help to grow ERO market and [Pharma Co. X] products” and that Pharma Co. X would “achieve” an “[i]ncrease[d] awareness and usage of ER Opioids by educating providers around appropriate patients for ERO therapy” (emphasis in original).

66. Moreover, the document stated that the partnership with PRACTICE FUSION would “drive ERO demand thru EMR Patient Messages” (emphasis in original). A portion of that slide is depicted on the following page:

Promotion within an EMR may help to grow ERO market and [] products

What is it?

- *Develop a partnership with Practice Fusion eHR to help manage chronic pain patients by targeting Pain Specialists and PCPs and drive ERO Demand thru EMR Patient messages*

What We Will Do?

- *Leverage existing Chronic Pain Quality Measures to reassess chronic pain patients for the need for Extended Release Opioids*

67. In an internal September 10, 2015 Pharma Co. X email sent to marketing personnel working on each of Pharma Co. X’s ERO brands, Pharma Co. X Employee #1 noted “Practice Fusion estimates a high ROI of 5 to 1 but I think we should be more conservative going into this program for the first time in order to under promise and over deliver.”

68. Attached to that email was a Pharma Co. X summary of the PRACTICE FUSION proposal that listed the “KPI” [key performance indicator] of the Pain CDS as: “Increase in ERO prescribing.” The summary also estimated that the Pain CDS would cause 22,500 patients to switch to EROs. Based on Pharma Co. X’s share of the branded ERO market, Pharma Co. X estimated that it would obtain a favorable 2 to 1 return on its approximately one million dollar investment in the Pain CDS. A later, more conservative calculation estimated the program would return 1.31 to 1.

69. The PRACTICE FUSION CDS project received internal Pharma Co. X approval in or around late 2015. Each of Pharma Co. X’s three ERO brands contributed equal amounts from their marketing budgets to fund the marketing project. Pharma Co. X brand representatives agreed to provide PRACTICE FUSION the remuneration because they understood that the Pain CDS would increase sales of its EROs.

70. Shortly after authorizing the Pain CDS arrangement, beginning in late 2015 and

continuing in early 2016, Pharma Co. X Employee #1 and PRACTICE FUSION personnel began designing a CDS alert to proliferate ERO prescriptions.

71. Pharma Co. X Employee #1 and PRACTICE FUSION personnel—including Employee #4 and Employee #5—worked together to design the Pain CDS alert. Employee #5 and Pharma Co. X Employee #1 reviewed the draft Pain CDS from PRACTICE FUSION’S clinical personnel and proposed edits that would enhance the likelihood that the Pain CDS would increase prescriptions.

72. For example, a January 29, 2016 email from Pharma Co. X Employee #1 to Employee #5 included a proposed edit to the Pain CDS workflow that allowed healthcare providers to “check off ‘Extended Release Opioid initiated’ - by adding this we think this will trigger the prescriber to assess again if a change in therapy is needed as a follow up.” Pharma Co. X Employee #1 was a marketing employee and had no expertise in treating a patient’s pain or prescribing opioid medications and was not a physician.

73. Before signing off on the project, Pharma Co. X’s head of marketing required a mockup of the CDS alert. Pharma Co. X Employee #1 wrote to Employee #5: “see the request below from my boss. I think if we show him the workflow documents with ERO message added that should do it for him.” Employee #5 revised the proposed workflow “to reflect extended release opioid as a treatment option for a finding of pain during the initial assessment.”

74. As implemented, “long acting/extended release” opioids were referenced parenthetically in the care plan portion of the Pain CDS as one of the treatment options for providers to select.

A. THE PAIN CDS CONTRACT

75. PRACTICE FUSION and Pharma Co. X entered into a written statement of work

(“SOW”) contracting for the Pain CDS effective March 1, 2016, in which they agreed to, among other things: provide health care providers “who utilize the Practice Fusion Solution” with a CDS Program “directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs” that would “support the identification of and/or treatment of patients who are recommended to be screened for or receive the treatments specified in” what the contract described as “gold standard evidence-based clinical guidelines” that were attached to the contract. The SOW attached Clinical Quality Measure #131, which called for healthcare providers to prepare “documentation of a follow-up plan when pain is present” for patients over 18 years old “with documentation of a pain assessment using a standardized tool(s).”

76. The contract specified that Pharma Co. X “shall be the funding source for the CDS Program.”

77. In the contract, Pharma Co. X and PRACTICE FUSION agreed that Pharma Co.

X would pay PRACTICE FUSION \$144,600 for a “Retrospective Analysis” and \$815,100 for CDS-related work.

78. Despite the parties’ mutual understanding that the purpose of the Pain CDS program was to increase ERO prescriptions, the contract stated that the “Parties agree and acknowledge that the collaboration project will follow national evidenced-based guidelines, and will not encourage the prescribing or utilization of a [Pharma Co. X]-specific product or services.”

79. The contract also called for PRACTICE FUSION to target “awareness messages”

about the Pain CDS at healthcare providers who prescribed NSAIDs and IROs.

80. Pursuant to the parties' SOW, PRACTICE FUSION and Pharma Co. X were to "participate in an initial RWE Study kick-off meeting" and "[d]uring the course of the RWE Study, regular meetings will be held between [Pharma Co. X] and Practice Fusion teams to review progress on the RWE Study and the Project work plan. These meetings, which will be scheduled at RWE Study kick-off will enable continued attention to RWE Study tasks and deliverables." After the contract was agreed to, Employee #5 described the program as an "exciting use of EMR technology!"

V. PHARMA CO. X AND PRACTICE FUSION DESIGN THE PAIN CDS

81. Notwithstanding the SOW provision that the Pain CDS "will not encourage the prescribing or utilization of a [Pharma Co. X]-specific product or services," a written internal PRACTICE FUSION recap of the initial conference call between PRACTICE FUSION and Pharma Co. X to design the project confirmed that the "success" of the Pain CDS program would be "increased prescriptions for [Pharma Co. X's] meds APPROPRIATELY (EROs in general and specifically [Pharma Co. X's])." Another summary, circulated within both companies stated "Primary goal of the project is to increase Rx for [Pharma Co. X.'s] medications," and also noted that while there would be no specific pharmacotherapy intervention as part of the CDS program, the prescribing of EROs "will likely be one of the follow-up plans when pain scale is high." ‘

82. Contemporaneous to the development of the commercially-focused Pain CDS, on or about March 15, 2016, the United States Centers for Disease Control and Prevention ("CDC") published the "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016" ("CDC Guidelines"). Shortly after the CDC Guidelines were released, they were circulated within

both Pharma Co. X and PRACTICE FUSION, including among those involved in developing the Pain CDS.

83. Both PRACTICE FUSION and Pharma Co. X employees involved in creating the Pain CDS—including physicians Employee #4 and Pharma Co. X Employee #3—possessed and reviewed the CDC Guidelines during development of the Pain CDS. However, the parties did not incorporate the recommendations contained in those guidelines into the CDS.

84. The CDC Guidelines stated, among other things:

- a. extended release opioids “should be reserved for severe, continuous pain and should be considered only for patients who have received immediate- release opioids daily for at least 1 week”;
- b. “When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids”;
- c. “When opioids are started, clinicians should prescribe the lowest effective dosage”;
- d. “Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient”;
- e. “The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be

dose-dependent”; and

- f. Providers should “[b]e explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely.”

85. In or about April 2016, Pharma Co. X personnel requested that the Pain CDS include opioids as a treatment option in addition to treatments identified within a 2016 New England Journal of Medicine (“NEJM”) article entitled “Opioid Abuse in Chronic Pain - Misconceptions and Mitigation Strategies.” That article admonished, among other things, that it was not intended to provide clinical instruction in the treatment of chronic pain, and that the benefits of opioids for treatment of chronic pain were “much more questionable” than for treatment of acute pain.

86. Similar to the CDC Guidelines, the NEJM article identified concerns about overdosing and abuse by patients and “Factors associated with the risk of opioid overdose or addiction,” which included, among other things:

- a. Daily dosages greater than 100 MME [morphine milligram equivalents];
- b. Long-acting or extended-release formulation;
- c. Combination of opioids with benzodiazepines;
- d. Long-term opioid use (greater than 3 months);
- e. Depression;
- f. Substance-use disorder; and
- g. History of overdose.

87. The NEJM article further provided a table of “Mitigation Strategies against Opioid Diversion and Misuse.” These strategies included, among other things:

- a. Screening tools to identify patients with a substance-use disorder, such as the Opioid Risk Tool; the Screener and Opioid Assessment for Patients with Pain (SOAPP); the Brief Risk Interview;
- b. Use of data from the Prescription Drug Monitoring Program;
- c. Use of Urine Drug Screening; and
- d. Doctor-patient agreement on adherence.

88. Despite reviewing and purportedly relying on the NEJM article in developing the Pain CDS, Pharma Co. X and PRACTICE FUSION did not design the Pain CDS to address any of the factors listed above as risks of opioid overdose and addiction; nor did the parties incorporate any of the “Mitigation Strategies against Opioid Diversion and Misuse.” Both Employee #4, and Pharma Co. X Employee #3 possessed and reviewed both the NEJM article and CDC Guidelines; nonetheless, both physicians signed off on the Pain CDS despite their knowledge that the program had been commercially conceived, funded by opiate brand managers, and did not incorporate the above-referenced guidelines designed to curb opioid abuse.

89. Pharma Co. X marketing personnel remained involved in designing the Pain CDS at the time the NEJM article was selected and incorporated into the Pain CDS.

90. Indeed, Pharma Co. X marketing personnel, who lacked expertise in administering or prescribing opioids, were involved in decisions relating to key functionalities of the Pain CDS, including use of the Pain Score, use of the BPI, the contents of the Care Plan options, the guidelines and CQM on which the Pain CDS was purportedly based, and the CDS logic. As evidenced below,

personnel from Pharma Co. X's marketing teams remained involved in numerous aspects of designing the CDS:

- a. An April 8, 2016 internal Pharma Co. X email confirming that the eMarketing Director—not a physician—had “decided with the marketing team to use the BPI [brief pain inventory].”
- b. An April 8, 2016 internal Pharma Co. X email noting that “There are no guidelines that support teasing out chronic vs acute pain.”
- c. An April 11, 2016 email confirming that the Director of eMarketing was involved in defining chronic pain for purposes of the Pain CDS.
- d. An April 14, 2016 email between two Pharma Co. X physicians and the Director of eMarketing suggesting the Pain CDS care plan include options supported by the NEJM article “plus opioids?” Less than an hour later Pharma Co. X wrote PRACTICE FUSION that it was “noodling on” the “care plan.” The email was sent by a Pharma Co. X doctor to PRACTICE FUSION and Pharma Co. X's Director of eMarketing.
- e. An April 26, 2016 internal Pharma Co. X email noting that the Director of eMarketing “needs to sign off’ on the CDS Clinical Logic.

91. In a document dated April 5, 2016 [excerpted on the following page], Pharma Co. X Employee #3 listed “Concerns” relating to the Pain CDS, which included, among other things: “BPI can increase ERO use”; “Can’t look as if we are directing information or therapy”; and “Program must be retrospective in nature - it can not [sic] look as if we are causing a change in Rx.”

Concerns:

- Is this a STUDY or is a MARKETING project? Different issues depending on the answer.
- No mention of consent
- No mention of IRB
- Data collected just to see if BPI influences actions around Rx or Tx
- BPI can increase ERO use
- If data collected, can it be used for promotional work by MSLs or Reps down the road?
- No discussion of long term outcomes, no discussion of patient follow up for additional study
- Can't look as if we are directing information or therapy
- Program must be retrospective in nature - it can not look as if we are causing a change in Rx.
- What is the sample size possible with this study? Can we do a pre-look for possible responders and users of PHR
- Will there be sufficient responders? What is the in-silico possible response rate?
- Ask EHR co about use rates of their Portal by Pts - and other programs with response rates
- If this is done by Marketing, it CAN'T look like a study - if it's a STUDY it MUST be run by Medical
- Need more thought about outcomes and what we'd want to see from this.

92. On May 11,2016, a PRACTICE FUSION employee reported on a call with Pharma Co. X personnel about the development of the CDS and observed that he kept “hearing the client [Pharma Co. X] revert back to ‘Rx lift’ as the primary objective of the program, this came up in the kickoff meeting and again during last week’s meeting when we were talking about the objectives of the prospective and retrospective analyses.” “Rx lift” refers to increased prescriptions. The email is depicted below:

Hi:

I wanted to make sure that the two of you are aligned with your respective stakeholders in terms of what the goals of the [] pain program are. I keep hearing the client revert back to “Rx lift” as the primary objective of the program, this came up in the kickoff meeting and again during last week’s meeting when we were talking about the objectives of the prospective and retrospective analyses. [] seems to be championing this vision as the new commercial + analytics stakeholder.

During the last meeting [] mentioned that the goals of the analytic project were to “meet all marketing science objectives, and whatever other HEOR objectives we can get to” which does not at all align with the analytic plan the client already “approved”. Please let me know if I should setup some time for us to strategize internally here.

93. Despite knowledge that the Pain CDS was conceived with the intent of increasing Pharma Co. X’s drug sales, that Pharma Co. X marketing personnel participated in the design of the Pain CDS, that marketing personnel had selected the BPI to be used, and that the BPI could increase ERO usage during a time of great national concern around opioid abuse, Practice Fusion and Pharma Co. X nonetheless proceeded with implementing the CDS to broaden use of EROs.

94. Moreover, the Pain CDS program was not “run by medical” as the document

referenced in paragraph 91 conceded it “MUST” be if the program were a study. As detailed, *infra*, Pharma Co. X’s marketers remained involved throughout the design and implementation even after the Pain CDS went live and continued to inquire and assess whether it achieved their stated goal of influencing ERO prescribing.

VI. THE PAIN CDS IN OPERATION IN DOCTORS’ OFFICES ACROSS THE COUNTRY

95. The CDS program went live on PRACTICE FUSION’s platform in early July 2016. As finalized, the Pain CDS contained three separate alerts. The first alert encouraged healthcare providers to record a pain score. The second alert suggested that doctors take a BPI of patients who had recorded two or more pain scores of four or more (on a zero to ten-point scale) within the previous three months, or who had a chronic pain diagnosis. The BPI further focused providers on the patient’s pain symptoms and included a list of questions on the severity and impact of the patient’s pain, and prompted the patient to describe the patient’s pain “now,” “on the average,” and at its “worst” and “least” during the previous 24 hours. The third alert indicated that a follow up plan should be created for treating the patient’s pain, appearing only if the patient reported pain on the pain scale of four or higher twice within four months, or if a patient with chronic pain has had a BPI completed.

96. Pharma Co. X anticipated that prompting doctors to assess and re-assess pain would increase ERO prescriptions.

97. The CDS utilized a drop-down menu of options for pain treatments to populate the treatment plan. This menu listed the following options, alphabetically, each on equal footing:

FOLLOW-UP PLAN

Adjuvant pharmacotherapy (e.g. topical agents, antispasmodics)

Biofeedback

Education (e.g. reassurance; exercise; appropriate activities) interventional or neural stimulation therapy Nonopioid analgesics (e.g. acetaminophen; NSAIDs; antidepressants)

Nonpharmacologic (e.g. physical therapy; cognitive-behavioral therapy)

Opioid Therapy (short-acting, long-acting/extended release)

Pain resolved

Referral to pain specialist

Surgical Procedure

98. As implemented, the Pain CDS alert deviated from medical guidelines in several respects, including:
- a. the Pain CDS’s list of treatment options was in part sourced from the NEJM medical journal article that was not intended to address how to treat patients with chronic pain;
 - b. in addition to the non-opioid analgesics and other alternative pain- treatment options identified by the NEJM article, PRACTICE FUSION and Pharma Co. X added “Opioid Therapy (short-acting, long-acting/extended release)” as a treatment option within the care plan

without regard for whether the patient’s condition was indicated for either immediate or extended release opioids in that:
 - i. EROs are listed as an option for patients with less than severe pain;
 - ii. EROs appeared as an option for patients with pain without regard to

whether “alternative treatment options were ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain”;

- iii. EROs were suggested as a treatment option for patients whose pain was not around-the-clock, but who presented with separate complaints of acute pain within three months.
- c. The Pain CDS instructed providers to record a treatment plan only when pain was classified as “chronic” or was above a certain threshold over a period of time. The CQM’s performance standards required providers to record a treatment plan any time the pain assessment was documented as positive.
- d. The Pain CDS did not incorporate recommendations from the CDC Guidelines and did not incorporate the substance of the NEJM article from which the CDS sourced a list of treatment options.
- e. The Pain CDS listed EROs as a treatment option on equal footing with IROs and non-opioid therapy—contrary to accepted medical practice.
- f. The Pain CDS listed EROs as an option for patients who had not previously received opioid therapy (i.e., the opioid naive).

99. The Pain CDS also listed EROs as a treatment option without regard to whether the provider had the adequate expertise to prescribe EROs.

100. In sum, the value to Pharma Co. X of increased referrals arranged by the Pain CDS was used to justify the remuneration provided; the CDS was not consistent with guidelines such as the CDC Guidelines and NEJM article; the CDS was inconsistent with the applicable CQM; the

CDS was funded by Pharma Co. X's marketing department; and Pharma Co. X's drug marketers were involved in its design.

A. AFTER IMPLEMENTATION PRACTICE FUSION AND PHARMA CO. X CONTINUED TO VIEW THE PAIN CDS AS A COMMERCIAL PROGRAM

101. After the Pain CDS went live in doctors' EHRs across the country, Pharma Co. X continued to view the program as a commercial venture. In or about October 2016, internal Pharma Co. X marketing emails inquired when Pharma Co. X would see an analysis of the commercial impact of the Pain CDS. The Director of eMarketing responded that he was not sure whether Pharma Co. X would be allowed to perform such an analysis "in this environment."

102. On October 7, 2016, Pharma Co. X's Director of Marketing sent an email to brand representatives, corporate executives, and the Director of eMarketing with the subject line: "immediate action tactics to appropriately grow NTRx [i.e., new prescriptions] during Q4." In this context, "Q4" refers to the fourth quarter of Pharma Co. X's fiscal year.

103. On October 12, 2016, a document titled "Urgent Tactics" with a list of "HIT Ideas" was sent in response to the request for "immediate action tactics to appropriately grow NTRx." It stated, "Have the Analytics Group look at the Practice Fusion Pain Guideline Pilot data available to date to get an early read on the effectiveness of the Clinical Decision Support alerts on improving the pain management of members of the test group of HCPs [health care providers] vs. the control group." In this context, "improving pain management" was thus equated with growing new total prescriptions.

104. PRACTICE FUSION and Pharma Co. X planned an in-person meeting at Pharma Co. X's headquarters to report on a retrospective study and the results of the Pain CDS. PRACTICE FUSION was instructed to answer whether "the CDS alerts change prescribing behavior" and "show

ERO prescribing as it tracks with CDS.” Pharma Co. X continued to have an interest in understanding whether, and by what measure, the Pain CDS was achieving its intended goal of influencing ERO prescribing in ways commercially favorable to Pharma Co. X’s drug sales.

105. On or about December 14, 2016, PRACTICE FUSION personnel conducted the presentation at Pharma Co. X’s headquarters. During this meeting, PRACTICE FUSION reported that through November 30, 2016, the Pain CDS had alerted during 21 million patient visits, involving 7.5 million patients, and 97,000 healthcare providers. During this presentation PRACTICE FUSION explained:

- a. that since Pain CDS alerts went into effect “there is a general shift toward EROs from IROs”; and
- b. the “biggest shift [was] within Emergency Medicine, Orthopedics, and Pain Medicine.”

106. PRACTICE FUSION’s presentation included charts and graphs that depicted the relative share of IROs vs. EROs as prescribed by doctors utilizing the PRACTICE FUSION EHR since the Pain CDS went into effect.

107.

PRACTICE FUSION also analyzed the effectiveness of various pain treatment options, including

adjuvants, COX-2s, EROs, IROs, and NSAIDs, finding that overall EROs were the least effective in lowering pain as only 39.17% of patients treated with EROs had lower pain, as shown in the chart below from the December 14, 2016 presentation (emphasis added):

Pain Score Summary

Adjuvant	Change(ft)	Change(%)	COX-2	Change(ft)	Change (%)	ERO	Change(ft)	Change(%)
Lower Pain	3,022	41.96%	Lower Pain	394	47.30%	Lower Pain	805	39.17%
No Change	1,707	23.70%	No Change	195	23.41%	No Change	611	29.73%
Higher Pain	2,473	34.34%	Higher Pain	244	29.29%	Higher Pain	639	31.09%

IRO	Change (ft)	Change(%)	NSAID	Change(ft)	Change(%)
Lower Pain	3,622	46.31%	Lower Pain	5,647	45.45%
No Change	1818	23.24%	No Change	2,724	21.93%
Higher Pain	2,382	30.45%	Higher Pain	4,053	32.62%

108.

EROs were the second least effective treatment option in lowering pain among patients with chronic pain (emphasis added)

Pain Score Summary (Chronic Pain)

Adjuvant	Change(ft)	Change(%)	COX-2	Change(ft)	Change(%)	ERO	Change(ft)	Change(%)
Lower Pain	547	40.22%	Lower Pain	53	47.75%	Lower Pain	259	40.41%
No Change	329	24.19%	No Change	30	27.03%	No Change	185	28.86%
Higher Pain	484	35.59%	Higher Pain	28	25.83%	Higher Pain	197	30.73%

IRO	Change (ft)	Change(%)	NSAID	Change(ft)	Change(%)
Lower Pain	626	42.33%	Lower Pain	576	40.88%
No Change	399	26.98%	No Change	375	26.61%
Higher Pain	454	30.70%	Higher Pain	458	32.51%

109.

PRACTICE FUSION additionally provided data and information to Pharma Co. X identifying the “Top Diagnosis Groups” that received EROs. Pharma Co. X did not take any steps in connection with the Pain CDS to ensure that EROs were being prescribed to “appropriate” patients, let alone consistent with the

110. A Pharma Co. X attorney was present at the December 14, 2016 meeting. The attorney expressed reservations about the Pain CDS, noting that it had not received appropriate legal review within Pharma Co. X, and considered “pausing” the program.

111. Rather than pausing the program, the Pain CDS program continued. In a series of emails from December 2016 and January 2017, Pharma Co. X requested PRACTICE FUSION supply materials related to the Pain CDS for the purposes of Pharma Co. X’s legal review.

112. Employee #5 gathered the materials to be provided to Pharma Co. X for this belated legal review. The materials provided for this purpose did not disclose the commercial objective of the program.

113. The Pain CDS was not “paused” or modified to be consistent with medical guidelines. Instead, the parties allowed the Pain CDS alerts to continue. As had been initially contemplated during the proposal process, PRACTICE FUSION and Pharma Co. X prepared a poster detailing the “results” of the Pain CDS that was presented at a public symposium. The parties’ presentation concluded, among other things, that a CDS can “help physicians follow chronic pain management clinical guidelines and improve documentation of care-related data and activity.” While the poster observed that “[d]ocumentation of opioid therapy in care plans shifted from 33.1% at start to 20.2% at conclusion,” the parties did not include an analysis of actual opioid prescribing trends—as opposed to care plan documentation—and did not assess ERO prescribing. The presentation demonstrated that it caused a large increase in the number of patients having care plans recorded; approximately 4,800 to 6,300 more care plans per month were completed in association with the Pain CDS than by providers who did not receive the alerts. Moreover, the parties did not reveal in this presentation that a goal of the Pain CDS was to increase ERO prescribing, that Pharma Co. X’s marketers were involved in designing the program, that the Pain CDS was financed by marketing budgets, or whether the Pain CDS influenced prescribing of EROs.

B. THE PAIN CDS INCREASED PRESCRIPTIONS OF EXTENDED RELEASE OPIOIDS, INCLUDING PHARMA CO. X'S EROs

114. The Pain CDS alert was live on the PRACTICE FUSION platform from early July 2016 to the spring of 2019. The Pain CDS alerted more than 230,000,000 times during this period. Physicians wrote hundreds of thousands of ERO prescriptions after one of the Pain CDS alerts had been triggered.

115. Healthcare providers who received the Pain CDS alerts prescribed EROs at a higher rate than those that did not.

116. Based on the higher rate of opioid prescriptions among providers who received the Pain CDS, the alerts resulted in tens of thousands of additional prescriptions for EROs, a substantial portion of which were paid for by federal healthcare programs such as Medicare and Medicaid.

COUNT ONE

117. Paragraphs 1 through 116, are realleged and incorporated herein.

118. Beginning not later than 2015 and continuing to an unknown time but not earlier than June 30, 2017, in the District of Vermont and elsewhere, PRACTICE FUSION knowingly and willfully conspired, in violation of 18 U.S.C. § 371, with Pharma Co. X, and others known and unknown to the United States Attorney, to solicit, and receive remuneration in return for recommending and arranging for the ordering of extended release opioids, including Pharma Co. X's products, with such orders being paid for in whole or in part under a Federal health care program, in violation of 42 U.S.C. § 1320a-7b(b)(1) & (b)(2).

Manner and Means of the Conspiracy

The manner and means by which PRACTICE FUSION and its co-conspirators sought to accomplish the objects and purpose of the conspiracy included, among others, the following:

119. In late 2015, PRACTICE FUSION asked for and Pharma Co. X agreed to pay PRACTICE FUSION almost \$1 million in exchange for PRACTICE FUSION altering its EHR in order to induce healthcare providers to prescribe ERO medications.

120. Employees of PRACTICE FUSION modeled the estimated return on investment that Pharma Co. X could realize if it paid PRACTICE FUSION for the proposed Pain CDS.

121. PRACTICE FUSION justified the price Pharma Co. X paid for the CDS based upon PRACTICE FUSION'S return on investment calculations that estimated the increase in Pharma Co. X ERO prescriptions that would result from the Pain CDS.

122. Pharma Co. X decided to pay PRACTICE FUSION'S price by reference to Pharma Co. X's anticipated increase in ERO prescriptions.

123. Following September 1, 2015, PRACTICE FUSION and Pharma Co. X personnel

regularly communicated in order to collaborate on the design, approval, and execution of the Pain CDS.

124. On or about March 1, 2016, PRACTICE FUSION and Pharma Co. X executed a written contract by which PRACTICE FUSION was to receive almost \$1 million from Pharma Co. X principally in exchange for implementing the Pain CDS.

125. PRACTICE FUSION and Pharma Co. X developed the Pain CDS without incorporating the most recent CDC-promulgated guidelines.

126. PRACTICE FUSION and Pharma Co. X developed the Pain CDS without incorporating the mitigating measures recommended by recent medical literature to reduce the risk of addiction and abuse.

127. PRACTICE FUSION and Pharma Co. X designed the Pain CDS to present EROs as a treatment option on equal footing with other treatments for pain without regard to whether EROs were medically appropriate for patients including whether the patient had around-the-clock pain.

128. PRACTICE FUSION and Pharma Co. X designed the Pain CDS to direct providers to prepare a pain treatment plan only for some patients, and not whenever pain is present, in contrast to the CQM upon which the Pain CDS was purported to be based.

129. From in or about July 2016 to in or about April 2019, PRACTICE FUSION maintained the Pain CDS on its EHR, resulting in the CDS alerting during more than 230,000,000 patient visits, prompting doctors to focus on the treatment of pain and suggesting opioids as a treatment option, when another option may have been medically appropriate.

Overt Acts

130. The following overt acts were committed in furtherance of the conspiracy:

- a. On or about March 31, 2015, Practice Fusion employees travelled to Pharma Co. X's headquarters in an effort to persuade Pharma Co. X to pay PRACTICE FUSION to implement a CDS alert on the PRACTICE FUSION platform;
-

- b. PRACTICE FUSION personnel developed a model to estimate the return on investment that Pharma Co. X's ERO brands could be expected to receive in exchange for Pharma Co. X's sponsorship of the proposed Pain CDS;
 - c. PRACTICE FUSION personnel communicated the result of their model to Pharma Co. X in an effort to persuade Pharma Co. X to agree to the Pain CDS program;
 - d. On or about September 1, 2015, Practice Fusion employees travelled to Pharma Co. X's headquarters in an effort to persuade Pharma Co. X to pay PRACTICE FUSION to implement the Pain CDS on the PRACTICE FUSION EHR platform;
 - e. In or around September 2015, Pharma Co. X estimated the return on investment Pharma Co. X could expect to receive based on Pharma Co. X's sponsorship of the Pain CDS as proposed by Practice Fusion;
 - f. In or around September and October 2015, Pharma Co. X marketing personnel integrated the Pain CDS into their list of 2016 marketing tactics for internal Pharma Co. X consideration;
 - g. In or around March 2016, agents from Pharma Co. X and PRACTICE FUSION executed a written contract pertaining to the Pain CDS project;
 - h. From in or about December 2015 through June 2016, PRACTICE FUSION and Pharma Co. X personnel designed the Pain CDS logic;
 - i. In or around March 2016, personnel from Pharma Co. X and PRACTICE FUSION had telephonic meetings to refine the CDS design, during which the financial objective of the Pain CDS was re-stated;
-

- j. In early July 2016, PRACTICE FUSION implemented the Pharma Co. X- sponsored Pain CDS on the Practice Fusion EHR platform;
- k. From in or about March 2016 through in or about March, 2017, Pharma Co. X paid PRACTICE FUSION approximately \$959,700 in exchange for PRACTICE FUSION'S development and implementation of the Pain CDS;
- l. On or about December 14,2016, employees from PRACTICE FUSION travelled to Pharma Co. X headquarters to present information about, among other things, the effect the Pain CDS was having on healthcare provider prescribing behavior;
- m. From in or about July 2016 until it was taken down in or about April 2019, PRACTICE FUSION maintained the Pain CDS alert on its EHR platform, resulting in the alert triggering during more than 230,000,000 patient visits.

(18U.S.C. § 371)

COUNT TWO

131. The United States Attorney realleges paragraphs 1 through 130, and incorporates them herein.

132. From in or about late 2013 through March 2016, PRACTICE FUSION solicited remuneration from Pharma Co. X in return for utilizing PRACTICE FUSION'S EHR to arrange for and recommend the ordering of EROs, including Pharma Co. X's ERO products, items for which payment may be made in whole or in part under a Federal health care program.

133. From in or about March 2016 through at least March 2017, PRACTICE FUSION received remuneration from Pharma Co. X in return for arranging for and recommending the ordering of EROs, including Pharma Co. X's ERO products, items for which payment may be made in whole or in part

under a Federal health care program.

134. From in or about early July 2016 through in or about April 2019 in the District of Vermont and elsewhere the Pain

CDS was live on PRACTICE FUSION'S EHR and arranged for and recommended the ordering of EROs, including Pharma Co. X's EROs.

(42 U.S.C. § 1320a-7b(b)(1) & (b)(2))

FORFEITURE ALLEGATION

135. The allegations contained in and relied on in Counts One and Two of this Information are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Section 982(a)(7).

136. Upon conviction of the offense[s] in violation of Title 42, United States Code, Section 1320a-7b(b)(1) & (b)(2) and Title 18, United States Code, Section 371, set forth in Counts One and Two of this Information, PRACTICE FUSION shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense(s). The property to be forfeited includes, but is not limited to, \$959,700 in U.S. currency.

- a. If any of the property described above, as a result of any act or omission of the defendants]:
- i. cannot be located upon the exercise of due diligence;
 - ii. has been transferred or sold to, or deposited with, a third party;
 - iii. has been placed beyond the jurisdiction of the court;
 - iv. has been substantially diminished in value; or
 - v. has been commingled with other property which cannot be divided without difficulty,
-

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

All pursuant to 18 U.S.C. § 982(a)(7) and 28 U.S.C. § 2461(c).

Christina E. Nolan (OCJF/MPD)
CHRISTINA R. NOLAN
United States Attorney
Burlington, VT
January 27, 2020

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA,

v.

PRACTICE FUSION, INC.,
Defendant.

Docket No. 2:20-CR-11

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the “Agreement”) between the United States Attorney’s Office for the District of Vermont (the “Government”) and PRACTICE FUSION, INC. (“PRACTICE FUSION”). PRACTICE FUSION hereby agrees and stipulates that the following information is true and accurate. PRACTICE FUSION admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Should the Government pursue prosecution that is deferred by the Agreement, PRACTICE FUSION agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts establish beyond a reasonable doubt the charges set forth in the Information deferred by the Agreement:

I. INTRODUCTION

1. Beginning in or around Fall 2013 Defendant PRACTICE FUSION solicited remuneration from a pharmaceutical company (“Pharma Co. X”) in exchange for creating and embedding an alert, known as a clinical decision support (“CDS”) alert, in PRACTICE FUSION’s electronic health record (“EHR”) to prompt doctors to take certain clinical actions for purposes of increasing Pharma Co. X’s extended release opioid (“ERO”) prescriptions. This

CDS alert (“the Pain CDS”) suggested doctors focus on assessing and treating a patient’s pain symptoms, and provided the healthcare provider a list of potential care plan treatment options. The Pain CDS suggested treatments, including the prescription of opioid medications, without discussing the medical appropriateness of each option.

2. The remuneration offered and paid by Pharma Co. X and solicited and received by PRACTICE FUSION in return for PRACTICE FUSION designing the Pain CDS with a purpose of increasing Pharma Co. X’s ERO sales, portions of which were paid for by federal health care programs, was a kickback in violation of 42 U.S.C. § 1320a-7b(b)(1)(B) & (2)(B).

3. PRACTICE FUSION and Pharma Co. X’s agreement and acts in furtherance of their unlawful kickback scheme was a conspiracy to violate the Anti-Kickback Statute, in violation of 18 U.S.C. § 371.

II. BACKGROUND

At times relevant to this Information:

4. “Pharma Co. X” (a pseudonym) was a United States-based pharmaceutical company whose products included branded extended release opioids.

5. Defendant PRACTICE FUSION was a Delaware corporation with headquarters in San Francisco, California. PRACTICE FUSION was a cloud-based EHR company that generally provided its cloud-based EHR product to healthcare providers without charge.

6. Employee # 1 was a PRACTICE FUSION Life Sciences Sales Representative initially in charge of the Pharma Co. X account.

7. Employee #2 was PRACTICE FUSION’s Senior Vice President for Life Sciences Practice and Strategic Partnerships.

8. Employee #3 was PRACTICE FUSION’s Chief Commercial Officer (“CCO”).

9. Employee #4 was PRACTICE FUSION’s Chief Medical Officer.

10. Employee #5 was PRACTICE FUSION's Director of National Accounts and was ultimately responsible for the Pharma Co. X account at the time the Pain CDS deal closed. Employee #5 was the Practice Fusion employee credited with closing the Pain CDS deal and the only employee provided a commission in connection with the deal.

11. Employee #6 was PRACTICE FUSION's Director of Strategic Development, Life Science Partnerships.

12. Pharma Co. X Employee #1 was Pharma Co. X's Director of eMarketing.

13. Pharma Co. X Employee #2 was a Pharma Co. X Brand Manager in charge of one of Pharma Co. X's ERO brands.

14. PRACTICE FUSION provided EHR services to tens of thousands of active healthcare provider users in the United States, including in Vermont, and its software was used during millions of patient encounters each month.

15. Though PRACTICE FUSION offered its EHR to healthcare providers free of charge, PRACTICE FUSION had various sources of revenue. Federal regulations provided for the implementation of CDS alerts in EHR software. Practice Fusion derived revenue from this clinical functionality in the form of payments from pharmaceutical companies in exchange for creating CDS alerts in its EHR, which was used in doctors' offices across the country.

16. PRACTICE FUSION's CDS alerts typically worked as follows for a healthcare provider using the PRACTICE FUSION EHR: a message would appear on the PRACTICE FUSION EHR alerting the healthcare provider that the provider should consider certain clinical information, perform certain tests or assessments, and complete certain documentation, given the particular personal health information and circumstances of the patient before the provider at that moment.

17. PRACTICE FUSION understood that Pharma Co. X provided remuneration in exchange for the Pain CDS because the CDS could boost sales of Pharma Co. X's ERO products.

18. PRACTICE FUSION understood that it was unlawful to sell CDS programs based on anticipated returns on investment that a pharmaceutical company client could achieve through the CDS, and that any CDS program must be consistent with any applicable evidence-based medical guidelines and Department of Health and Human Services ("HHS") Centers for Medicare and Medicaid Services ("CMS") Clinical Quality Measures ("CQM").

19. Extended release opioids are highly addictive narcotics that are properly prescribed only in limited circumstances. According to the United States Food and Drug Administration ("FDA") approved labeling for Pharma Co. X's leading ERO that product was, as of 2015, indicated "for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." The FDA-approved labeling for Pharma Co. X's leading ERO product directed: "Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release formulations, reserve [Pharma Co. X's ERO product] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain."

20. The FDA-approved labeling says Pharma Co. X's primary ERO is "[t]o be prescribed only by healthcare providers knowledgeable in use of potent opioids for management of chronic pain."

21. The Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b) prohibited PRACTICE FUSION from knowingly and willfully soliciting or receiving remuneration in return for

“arranging for or recommending” ordering any good or item for which payment may be made in whole or in part under a Federal health care program. PRACTICE FUSION knowingly and willfully violated the Anti-Kickback statute through its solicitation and receipt of remuneration from Pharma Co. X in connection with the Pain CDS.

22. 18 U.S.C. § 371 prohibits conspiracies and provides that “[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.” PRACTICE FUSION conspired with Pharma Co. X to violate the Anti-Kickback Statute through its solicitation and receipt of remuneration from Pharma Co. X in connection with the Pain CDS.

III. OVERVIEW OF PRACTICE FUSION’S SOLICITATION OF REMUNERATION FROM PHARMA CO. X

23. PRACTICE FUSION began discussing the prospect of using its EHR in furtherance of Pharma Co. X’s marketing goals with Pharma Co. X personnel as early as fall 2013. These discussions included the possibility of using the PRACTICE FUSION EHR to screen potential patients for whether they were suitable for long-term opioid therapy, including assessing whether the patient had a history of substance abuse.

24. PRACTICE FUSION and Pharma Co. X did not pursue a CDS alert to assist doctors in screening patients for risk of opioid abuse; instead, the parties developed a CDS to increase sales of Pharma Co. X’s ERO products.

25. As discussions between the parties increasingly focused on Pharma Co. X’s commercial objectives, Employee #1 was counseled in an internal PRACTICE FUSION email in April 2014 that “[i]ndicating that [Pharma Co. X] influenced clinical decisions through sponsored

money has legal implications versus a marketing program where a banner can be displayed and influence prescribing behavior.”

26. In or around May 2014, PRACTICE FUSION continued its solicitation of Pharma Co. X by forwarding to Pharma Co. X news stories concerning PRACTICE FUSION’s implementation of a CDS program paid for by a vaccine manufacturer.

27. Between May 2014 and March 2015, representatives from PRACTICE FUSION and Pharma Co. X continued to communicate regularly regarding potential transactions between the two companies.

28. In a March 23, 2015 internal PRACTICE FUSION email—written in preparation for a scheduled March 31, 2015 meeting at Pharma Co. X—Employee #1 described the opportunity to sell a CDS program to Pharma Co. X by explaining to PRACTICE FUSION colleagues that Pharma Co. X “has communicated that the average dosage of [Pharma Co. X’s leading ERO] is declining” and that “[p]roviders are hesitant about using high dosages to combat pain for a variety of reasons, mostly political pressure.” The email further stated that “[a]s a result, [Pharma Co. X] is toying with the idea of using Pain Assessment tools with the provider at every visit and before every RX.” RX is an abbreviation for prescription.

29. PRACTICE FUSION understood Pharma Co. X was concerned that as a result of heightened public awareness of the dangers of opioid use, healthcare providers were prescribing lower dosages of opioids. PRACTICE FUSION thus marketed its medical software as having the potential to “influence provider behavior” and counteract Pharma Co. X’s economic concerns regarding providers prescribing fewer and lower dosages of opioids.

A. PRACTICE FUSION’S MARCH 31, 2015 SOLICITATION TO PHARMA CO. X AND ENSUING FOLLOW-UP SOLICITATIONS

30. On or about March 31, 2015, PRACTICE FUSION representatives travelled to Pharma Co. X's headquarters to continue soliciting payment from Pharma Co. X in exchange for a CDS. PRACTICE FUSION solicitation materials included a PowerPoint presentation, commonly referred to as a "pitch deck." PRACTICE FUSION's pitch deck indicated that a pain CDS would be "based on" the "brand objectives" of Pharma Co. X's three extended release opioid products. These objectives included targeting "opioid naïve patients"—i.e., patients who were not previously prescribed opioids—and targeting patients who were using immediate release opioids ("IROs"), which were less dangerous than EROs, but also less profitable to Pharma Co. X.

31. Pharma Co. X advised PRACTICE FUSION that it wished to utilize a CDS to "target" the opioid naïve and IRO users. Those patients represented potential additional users of Pharma Co. X's EROs. Further, Pharma Co. X would make more money selling its drugs if PRACTICE FUSION's CDS helped "keep[] an appropriate patient on a consistent dose . . ." PRACTICE FUSION thus recommended creating tools within its EHR that would "identify care gaps for appropriate patients," "provide validated tools for providers to better manage patients," and to "plan for and measure" patient outcomes.

32. Following the March 31, 2015 presentation, Employee #2 emailed Employee #3 stating that "next steps" with respect to the Pharma Co. X solicitation included "build[ing] model to show potential commercial impact of increased patients being screened for pain and risk of opioid abuse."

33. According to this March 31, 2015 email, the PRACTICE FUSION personnel who were to "model" the "commercial impact" to Pharma Co. X's drug sales from the CDS included: Employee #1, Employee #4, Employee #5, and Employee #6.

34. Employee #5 modelled the “commercial impact” that would accrue to Pharma Co. X as a result of the Pain CDS causing an increase in ERO prescriptions. PRACTICE FUSION calculated that Pharma Co. X would obtain a return on investment (“ROI”) of between 5.8 and 7.8 times its cost if it implemented the PRACTICE FUSION Pain CDS.

35. The model, as revised in an internal April 24, 2015 PRACTICE FUSION email from Employee #5, estimated that Pharma Co. X would achieve a “patient gain” of two thousand seven hundred seventy-seven (2,777) and between \$8,458,232 and \$11,277,643 in additional opioid revenue by implementing the CDS.

36. PRACTICE FUSION developed a model to show the “commercial impact” to Pharma Co. X of a pain CDS, and Pharma Co. X eventually entered into a contract with PRACTICE FUSION for the Pain CDS based on the parties’ mutual expectation of increased ERO sales.

37. An April 1, 2015, email containing a prior version of the April 24 model stated that PRACTICE FUSION “could use” the following “values to present an economic benefit of the proposed program” to Pharma Co:

- a. “Value of **keeping an appropriate patient on a consistent dose** of one of the products throughout the 2 year term of the program”;
 - b. “Value of **conversion from IR to ER and consistent dosing** over the term of the program”; and
 - c. “Value of a % market share in the branded ERO space; [Pharma Co. X] mentioned they enjoy an 83% share in the branded ERO space. We can track and measure two things during the program. Share of the current branded EROs on
-

our platform and ***potential new market entrants to ERO therapy as a result of the clinical intervention.***” (emphasis added).

38. PRACTICE FUSION thus sought remuneration from Pharma Co. X to design the Pain CDS to cause healthcare providers to extend the duration of ERO prescriptions, convert patients receiving IROs to EROs, and to increase the overall market of ERO-using patients and to measure its ability to deliver such results.

39. In an April 22, 2015 internal PRACTICE FUSION email discussing follow up communications to Pharma Co. X, Employee # 5 advised: “Since this is being sent to a marketing audience the idea of ROI has to be part of the plan to justify the costs of the program.”

40. PRACTICE FUSION did not include its calculations of increased opioid patient volume, increased opioid sales, or increased persistency to opioid products in the pitch materials provided to Pharma Co. X. Rather, on or about April 23, 2015, Employee #5 directed in an internal PRACTICE FUSION email pertaining to the Pharma Co. X CDS written proposal: “Don’t include the ROI in the proposal. We’ll walk the client through the ROI.”

41. On April 28, 2015, Employee #2 described the final Pharma Co. X pitch deck as “concise and will allow us to voice over what we need to regarding how the program works and its commercial impact.”

42. On April 29, 2015, Employee # 2 stated in an internal email referring to the follow up with Pharma Co. X that “[t]he goal here is to sell it as a study-but get commercial \$ moved over or added to the funding to make the deal work.” This same email observed that there was “urgency” for PRACTICE FUSION to generate revenue.

43. On May 11, 2015, Employee #6 asked Employee #5 if he had “the final pricing model you used for [Pharma Co. X]?” Employee #6 then wrote: “Actually...without saying

ROI...I mean the ROI spreadsheet ;).” Employee #5 then provided the Pharma Co. X ROI analysis.

B. PRACTICE FUSION’S SEPTEMBER 1, 2015 PRESENTATION AT PHARMA CO. X HEADQUARTERS AND SUBSEQUENT FOLLOW-UP

44. Employee #5 emailed personnel in Pharma Co. X’s marketing department on July 16, 2015, “to re-engage around the Practice Fusion Clinical Decision Support Real World Evidence Pain Management program.” He stated “[w]e feel that the proposed program can help meet the strategic commercial needs of the pain franchise at [Pharma Co. X.]”

45. Prompted by the July 16, 2015 email described in the preceding paragraph, PRACTICE FUSION and Pharma Co. X’s marketing personnel scheduled an additional presentation at Pharma Co. X’s headquarters for PRACTICE FUSION to propose the Pain CDS program in greater detail. This meeting was scheduled for September 1, 2015, at Pharma Co. X’s headquarters.

46. On or about August 17, 2015, Employee #5 discussed PRACTICE FUSION’s proposal with two Pharma Co. X employees, Pharma Co. X Employee # 1 and Pharma Co. X Employee #2. In an email describing that discussion, Employee #5 stated that PRACTICE FUSION’s “proposed solution” would include, among other features, “appropriate pain assessment tools/screeners that will help providers in the decision to initiate ERO products,” and “[u]nbranded clinical messaging to reinforce appropriate use of EROs in patient populations – IRO users, chronic NSAID users, tramadol, etc.” This email further explained that Pharma Co. X Employee #1 desired to see a “draft strategy by weeks end to discuss and refine for presentation to the broader commercial team during [the] meeting in Sept.”

47. On or about August 21, 2015, Employee #5 forwarded a preliminary version of the September 1, 2015 presentation to Pharma Co. X Employee #1.

48. On or about September 1, 2015, two PRACTICE FUSION employees, including Employee #5, travelled to Pharma Co. X's headquarters to propose that Pharma Co. X pay PRACTICE FUSION approximately \$1,000,000 to develop and implement the Pain CDS to influence health care providers to prescribe more EROs.

49. Pharma Co. X marketing personnel representing each of its three ERO brands attended the September 1, 2015 presentation. The presentation included a pitch deck in which PRACTICE FUSION proposed the CDS program focus on the treatment of pain by:

a. "Leverag[ing] Practice Fusion Platform to deliver Clinical Decision Support and measure the impact and real world outcomes on patient care."

b. Delivering "clinical patient-centric provider messages" targeted at healthcare providers with "opioid naïve patients with chronic pain," and with patients currently receiving immediate release oxycodone and hydrocodone; and

c. "Leverag[ing] the Practice Fusion EHR platform to help providers assess, diagnose, and treat Chronic Pain."

50. The proposal also included PRACTICE FUSION providing "educational messages" targeted to healthcare providers with patients with diagnoses of "chronic pain and with history of non-Opioids in their chart."

51. Employee #5 led discussion of the Pain CDS.

52. After the September 1, 2015 meeting, a PRACTICE FUSION employee provided the pitch materials by email on September 2, 2015 to the PRACTICE FUSION employee who advised Employee #1 regarding the legal implications of using a CDS as a marketing tool, as described in paragraph 25, above. That employee in turn forwarded those materials to another PRACTICE FUSION employee by email with a message that included: "I understand that the

[Pharma Co. X] proposal has shifted to a commercial focus and that marketing folks were in the room instead of outcomes[.]” The message also included “[t]here are several things incorrect with this presentation /proposal from pricing to products. Please do not share. Just be aware....”

53. PRACTICE FUSION included a study as part of the September 1 proposal. A September 2 internal PRACTICE FUSION email observed, however, that Pharma Co. X was not interested in a study: “we were talking to product managers, and they could care less about RWE [real world evidence studies]. For them, this was all about marketing.” The email further stated that during the September 1 meeting with Pharma Co. X “I made it clear that we would measure success (metrics, switches from IR to ER, etc.)[.]” The study was included in the proposal, in part, to make the deal appear as a legitimate medical project, and not a commercial endeavor.

54. A September 1, 2015 internal PRACTICE FUSION email from Employee #5 confirmed that Pharma Co. X’s “brands” would contribute equally to the cost of the program “since this is a non branded effort.”

55. On September 4, 2015, Employee #5 emailed Pharma Co. X Employee # 1 with a “revised deck” that was “based on our meeting this week.” This “revised deck” included a new slide devoted to “Project Goals.” Those goals included (among others): “Educate providers around appropriate patients for [extended release opioid] therapy”; “Identify care gaps through clinical support alert tools at the point of care”; “Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy”; and to provide Pharma Co. X a “[d]etailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics).”

IV. PHARMA CO. X AGREED TO PROVIDE PRACTICE FUSION REMUNERATION IN EXCHANGE FOR THE CREATION OF A PAIN CDS

THAT WOULD INFLUENCE PHYSICIANS AND INDUCE PRESCRIBING OF EXTENDED RELEASE OPIOIDS

56. Shortly after the September 1, 2015 meeting, Pharma Co. X and PRACTICE FUSION moved forward with designing the Pain CDS as pitched by PRACTICE FUSION.

57. Pharma Co. X Employee #1 and PRACTICE FUSION personnel—including Employee #4 and other Practice Fusion clinical personnel—began designing the Pain CDS alert. Employee #5 and Pharma Co. X Employee #1 reviewed the draft Pain CDS from PRACTICE FUSION’S clinical personnel and proposed edits that would enhance the likelihood that the Pain CDS would increase prescriptions.

58. For example, a January 29, 2016 email from Pharma Co. X Employee #1 to Employee #5 included a proposed edit to the Pain CDS workflow that allowed healthcare providers to “check off ‘Extended Release Opioid initiated’ – by adding this we think this will trigger the prescriber to assess again if a change in therapy is needed as a follow up.”

59. Similarly, on February 3, 2016, Employee #5—who also was not a physician and similarly lacked familiarity with treating pain and prescribing schedule II narcotics—responded by email with a draft of the proposed CDS alert that contained “Extended Release Opioids” as a treatment option as had been requested by Pharma Co. X’s drug marketers. Employee #4 approved the change to the Pain CDS workflow. Employee #4 also lacked experience with treating pain and prescribing EROs. As implemented, “Extended Release Opioids” were referenced parenthetically in the care plan portion of the Pain CDS, as one of three types of opioid treatment.

A. THE PAIN CDS CONTRACT

60. PRACTICE FUSION and Pharma Co. X entered into a written statement of work (“SOW”) contracting for the Pain CDS effective March 1, 2016, in which they agreed to, among

other things: provide health care providers “who utilize the Practice Fusion Solution” with a CDS Program “directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs” that would “support the identification of and/or treatment of patients who are recommended to be screened for or receive the treatments specified in” what the contract described as “gold standard evidence-based clinical guidelines” that were attached to the contract. The SOW attached Clinical Quality Measure #131, which called for health care providers to prepare “documentation of a follow-up plan when pain is present” for patients over 18 years old “with documentation of a pain assessment using a standardized tool(s).”

61. The contract specified that Pharma Co. X “shall be the funding source for the CDS Program.”

62. In the contract, Pharma Co. X and PRACTICE FUSION agreed that Pharma Co. X would pay PRACTICE FUSION \$144,600 for a “Retrospective Analysis” and \$815,100 for CDS-related work.

63. Despite the parties’ mutual understanding that the purpose of the program was to increase ERO prescriptions, the contract stated that the “Parties agree and acknowledge that the collaboration project will follow national evidenced-based guidelines, and will not encourage the prescribing or utilization of a [Pharma Co. X]-specific product or services.”

64. The contract also called for PRACTICE FUSION to target “awareness messages” about the Pain CDS at healthcare providers who prescribed NSAIDS and IROs.

65. Pursuant to the parties’ SOW, PRACTICE FUSION and Pharma Co. X were to “participate in an initial RWE Study kick-off meeting” and “[d]uring the course of the RWE Study, regular meetings will be held between [Pharma Co. X] and Practice Fusion teams to review progress on the RWE Study and the Project work plan. These meetings, which will be

scheduled at RWE Study kick-off will enable continued attention to RWE Study tasks and deliverables.”

V. PHARMA CO. X AND PRACTICE FUSION DESIGN THE PAIN CDS

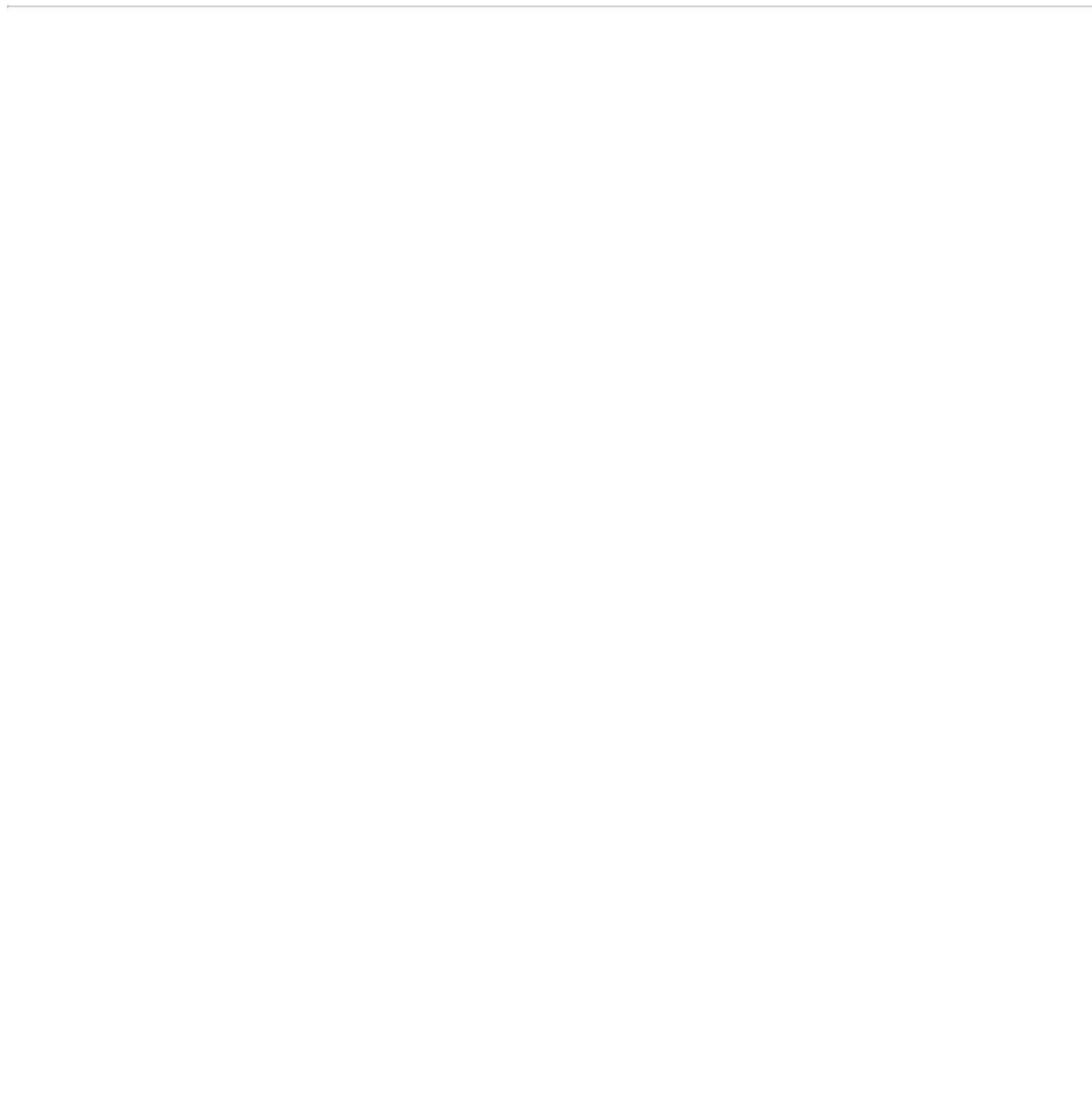
66. A recap of the initial conference call between PRACTICE FUSION and Pharma Co. X to design the project confirmed that the “success” of the Pain CDS program would be “increased prescriptions for [Pharma Co. X’s] meds APPROPRIATELY (EROs in general and specifically [Pharma Co. X’s]).” (emphasis in original). Other records noted that while there would be no specific pharmacotherapy intervention as part of the CDS program, the prescribing of extended release opioids “will likely be one of the follow-up plans when pain scale is high.”

67. Contemporaneous to the development of the commercially-focused Pain CDS the United States Center for Disease Control and Prevention (“CDC”) published the “CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016” (hereafter “CDC Guidelines”). The CDC Guidelines were published on or about March 15, 2016 and were circulated within both Pharma Co. X and PRACTICE FUSION shortly after their release, including among those involved in developing the Pain CDS.

68. Both PRACTICE FUSION and Pharma Co. X employees involved in creating the Pain CDS—including Employee #4—possessed and reviewed the CDC Guidelines during development of the Pain CDS; yet, the parties did not incorporate the recommendations contained in those guidelines.

69. The CDC Guidelines stated, among other things:

- a. extended release opioids “should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week”;



- b. “When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids”;
- c. “When opioids are started, clinicians should prescribe the lowest effective dosage”;
- d. “Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient”;
- e. “The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent”; and
- f. The Guidelines encouraged providers to “[b]e explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely.”

70. In or about April 2016, Pharma Co. X personnel requested the Pain CDS include a list of possible treatments for pain consisting of the treatments identified within a 2016 New England Journal of Medicine (“NEJM”) article entitled “Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies,” plus opioids. That article admonished, among other things, that it was not intended to provide clinical instruction in the treatment of chronic pain,

and that the benefits of opioids for treatment of chronic pain were “much more questionable” than for treatment of acute pain.

71. Similar to the CDC Guideline, the NEJM article identified “concerns about overdosing and abuse by patients” and “Factors associated with the risk of opioid overdose or addiction,” which included, amongst other things:

- a. Daily dosages greater than 100 MME [morphine milligram equivalents];
- b. Long-acting or extended-release formulation;
- c. Combination of opioids with benzodiazepines;
- d. Long-term opioid use (greater than 3 months);
- e. Depression;
- f. Substance-use disorder; and
- g. History of overdose.

72. The NEJM article further provided a table of “Mitigation Strategies against Opioid Diversion and Misuse.” These strategies included, among other things:

- a. Screening tools to identify patients with a substance-use disorder, such as the Opioid Risk Tool; the Screener and Opioid Assessment for Patients with Pain (SOAPP); the Brief Risk Interview;
- b. Use of data from the Prescription Drug Monitoring Program;
- c. Use of Urine Drug Screening; and
- d. Doctor-patient agreement on adherence.

73. Despite reviewing and purportedly relying on the NEJM article in developing the Pain CDS, Pharma Co. X and PRACTICE FUSION did not design the Pain CDS to address any

of the factors listed above as risks of opioid overdose and addiction; nor did the parties incorporate any of the “Mitigation Strategies against Opioid Diversion and Misuse.”

74. On May 11, 2016, a PRACTICE FUSION employee reported on a call with Pharma Co. X personnel about the development of the CDS and observed that he kept “hearing the client [Pharma Co. X] revert back to ‘Rx lift’ as the primary objective of the program, this came up in the kickoff meeting and again during last week’s meeting when we were talking about the objectives of the prospective and retrospective analyses.” “Rx lift” refers to increased prescriptions.

VI. THE PAIN CDS IN OPERATION IN DOCTORS’ OFFICES ACROSS THE COUNTRY

75. The CDS program went live on PRACTICE FUSION’s platform on or about July 6, 2016. As finalized, the Pain CDS contained three separate alerts. The first alert encouraged health care providers to record a pain score. The second alert suggested that doctors take a Brief Pain Inventory (“BPI”) of patients who had recorded two or more pain scores of four or more (on a zero to ten point scale) within the previous three months, or that had a chronic pain diagnosis. The BPI further focused providers on the patient’s pain symptoms and included a list of questions on the severity and impact of the patient’s pain, and prompted the patient to describe the patient’s pain “now,” “on the average,” and at its “worst” and “least” during the previous 24 hours. The third alert indicated that a follow up plan should be created for treating the patient’s pain, appearing only if the patient reported pain on the pain scale of four or higher twice within four months, or if a patient with chronic pain has had a BPI completed.

76. The CDS utilized a drop-down menu of options for pain treatments to populate the treatment plan. This menu listed the following options, on equal footing with each other:



77. As implemented, the Pain CDS alert deviated from the guidelines in several respects, including:
- a. the Pain CDS's list of treatment options was in part sourced from the NEJM medical journal article that was not intended to address how to treat patients with chronic pain;
 - b. in addition to the non-opioid analgesics and other alternative pain- treatment options identified by the NEJM article, PRACTICE FUSION and Pharma Co. X added "Opioid Therapy (short-acting, long-acting/extended release)" as a treatment option within the care plan without regard for whether the patient's condition was indicated for immediate or extended release opioids in that:
 - i. EROs are listed as an option for patients with less than severe pain;

- ii. EROs are listed as an option for patients with pain without regard to whether the pain could be adequately treated by non-ERO options;
- iii. EROs were suggested as a treatment option for patients whose pain was not chronic, but who presented with separate complaints of acute pain within three months.
- c. The Pain CDS instructed providers to record a treatment plan only when pain was classified as “chronic” or was above a certain threshold over a period of time. The CQM’s performance standards required providers to record a treatment plan any time the pain assessment was documented as positive.
- d. The Pain CDS did not incorporate recommendations from the CDC Guidelines and did not incorporate the substance of the NEJM article from which the CDS sourced a list of treatment options.
- e. The Pain CDS listed EROs as a treatment option on equal footing with IROs and non-opioid therapy—contrary to accepted medical practice.
- f. The Pain CDS listed EROs as an option for patients who had not previously received opioid therapy (i.e., the opioid naïve).

78. The Pain CDS also deviated from Pharma Co. X’s extended release opioids’ labelled indications in that it listed EROs as a treatment option without regard to whether the patient’s pain was severe or whether “alternative treatment options were ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain” or the provider had the adequate expertise to prescribe EROs.

79. In sum, the value to Pharma Co. X of increased referrals arranged by the Pain CDS was used to justify the remuneration provided; the CDS was not consistent with guidelines

such as the CDC Guideline; the CDS was inconsistent with the applicable CQM; and the CDS was funded by Pharma Co. X's marketing department and Pharma Co. X's drug marketers were involved in its design.

A. AFTER IMPLEMENTATION PRACTICE FUSION AND PHARMA CO. X CONTINUED TO VIEW OF THE PAIN CDS AS A COMMERCIAL PROGRAM

80. PRACTICE FUSION and Pharma Co. X planned an in-person meeting at Pharma Co. X's headquarters to report on a retrospective study and the results of the Pain CDS. PRACTICE FUSION was instructed to answer whether "the CDS alerts change prescribing behavior" and "show ERO prescribing as it tracks with CDS." Pharma Co. X continued to have an interest in understanding whether and by what measure the Pain CDS was achieving its intended goal of influencing ERO prescribing in ways commercially favorable to Pharma Co. X's drug sales.

81. On or about December 14, 2016, PRACTICE FUSION personnel conducted the presentation at Pharma Co. X's headquarters. During this meeting, PRACTICE FUSION reported that through November 30, 2016, the Pain CDS had alerted during 21 million patient visits, involving 7.5 million patients, and 97,000 healthcare providers. During this presentation PRACTICE FUSION explained:

- a. that since Pain CDS alerts went into effect "there is a general shift toward EROs from IROs";
 - b. the "biggest shift [was] within Emergency Medicine, Orthopedics, and Pain Medicine"; and
 - c. "[w]e also see a general shift from IROs to EROs-which is more pronounced in certain specialties and therapeutic areas."
-

82. PRACTICE FUSION’s presentation included charts and graphs that depicted the relative share of IROs vs. EROs as prescribed by doctors utilizing the PRACTICE FUSION EHR since the Pain CDS went into effect.

83. PRACTICE FUSION also analyzed the effectiveness of various pain treatment options, including adjuvants, COX-2s, EROs, IROs, and NSAIDs, finding that overall EROs were the least effective in lowering pain as only 39.17% of such patients had lower pain, as the below chart from the December 14, 2016 presentation shows.

Pain Score Summary

Adjuvant	Change (#)	Change (%)	COX-2	Change (#)	Change (%)	ERO	Change (#)	Change (%)
Lower Pain	3,022	41.96%	Lower Pain	394	47.30%	Lower Pain	805	39.17%
No Change	1,707	23.70%	No Change	195	23.41%	No Change	611	29.73%
Higher Pain	2,473	34.34%	Higher Pain	244	29.29%	Higher Pain	639	31.09%

IRO	Change (#)	Change (%)	NSAID	Change (#)	Change (%)
Lower Pain	3,622	46.31%	Lower Pain	5,647	45.45%
No Change	1,818	23.24%	No Change	2,724	21.93%
Higher Pain	2,382	30.45%	Higher Pain	4,053	32.62%

84. Similarly, PRACTICE FUSION’s data found that EROs were the second least effective treatment option in lowering pain among patients with chronic pain.

Pain Score Summary (Chronic Pain)

Adjuvant	Change (#)	Change (%)	COX-2	Change (#)	Change (%)	ERO	Change (#)	Change (%)
Lower Pain	547	40.22%	Lower Pain	53	47.75%	Lower Pain	259	40.41%
No Change	329	24.19%	No Change	30	27.03%	No Change	185	28.86%
Higher Pain	484	35.59%	Higher Pain	28	25.23%	Higher Pain	197	30.73%

IRO	Change (#)	Change (%)	NSAID	Change (#)	Change (%)
Lower Pain	626	42.33%	Lower Pain	576	40.88%
No Change	399	26.98%	No Change	375	26.61%
Higher Pain	454	30.70%	Higher Pain	458	32.51%

85. PRACTICE FUSION additionally provided data and information to Pharma Co. X identifying the “Top Diagnosis Groups” that received EROs.

86. A Pharma Co. X attorney was present at the December 14, 2016 meeting. She expressed reservations about the Pain CDS, noting that it had not received appropriate legal review within Pharma Co. X, and considered “pausing” the program.

87. Rather than pausing the program, the Pain CDS program continued. In a series of emails from December 2016 and January 2017, Pharma Co. X requested PRACTICE FUSION to supply materials related to the Pain CDS for the purposes of Pharma Co. X’s legal review.

88. Employee #5 gathered the materials to be provided to Pharma Co. X for this belated legal review. The materials provided for this purpose did not explain the commercial objective of the program.

B. THE PAIN CDS RESULTED IN ADDITIONAL PRESCRIPTIONS OF PHARMA CO. X’S EROs

89. The Pharma Co. X-developed CDS alert was live on the PRACTICE FUSION platform from on or about July 6, 2016 to the Spring of 2019. The Pain CDS alerted more than approximately 230,000,000 times during this period.

90. Health care providers who received the Pain CDS alerts prescribed EROs at a higher rate than those that did not.

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

)
UNITED STATES OF AMERICA)
) Docket No. 2:20-CR-11
v.)
)
PRACTICE FUSION, INC.,)
)
Defendant.)
_____)

Compliance Addendum

1. Practice Fusion, Inc. (“Practice Fusion”) shall maintain and implement a Sponsored Clinical Decision Support Compliance Program to apply to any Sponsored Clinical Decision Support (“Sponsored CDS”) to be designed or implemented (i) in the Practice Fusion electronic health record (“EHR”) or (ii) by former Practice Fusion employees currently employed by a Practice Fusion affiliate. The Sponsored CDS Compliance Program shall meet the requirements set forth in this Compliance Addendum.
 2. Effective Date and Term. The effective date of the Compliance Addendum shall be the date upon which the Deferred Prosecution Agreement (the “Agreement”) is executed by the United States Attorney’s Office for the District of Vermont (the “Office”) and Practice Fusion (the “Effective Date”). The obligations contained in this Compliance Addendum shall remain in full force and effect for a period of three (3) years from the Effective Date, unless otherwise specified herein.
 3. Scope. Practice Fusion acknowledges and agrees that the obligations undertaken in this Compliance Addendum do not fulfill the totality of Practice Fusion’s obligations to maintain
-

effective controls against potential violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the “AKS”), to ensure compliance with Clinical Quality Measures (“CQM”), and ensure regulatory standards regarding its product compliance with CDS requirements.

4. Definitions. The below terms shall be defined as follows for purposes of this Compliance Addendum. Capitalized terms not defined herein shall have the meaning set forth in the Agreement.

a. “Clinical Decision Support” or “CDS” means an EHR technology that provides clinicians, staff, patients or other individuals with information relating to treatment for purposes of enhancing health and health care and includes tools such as computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools.

b. “Clinical Quality Measure” means a mechanism for assessing and tracking the quality of health care provided, including observations, treatment, processes, experience, and/or outcomes of patient care. CQMs assess the degree to which a provider competently and safely delivers clinical services that are appropriate for the patient in an optimal timeframe and are required as part of meaningful use requirements for the Medicare and Medicaid Electronic Health Record Incentive Programs and reporting requirements under the Medicare Access and CHIP Reauthorization Act of 2015 Merit-Based Incentive Payment System program.

c. “Covered Activities” means promoting, marketing, selling, designing, implementing, maintaining, and/or reporting on Sponsored CDS programs. Such activities shall not be interpreted to include the activities of coders or other personnel who are responsible for general Practice Fusion EHR implementation, support, and software maintenance.

d. “Guideline” means any clinical practice guideline developed by third-party organizations to guide decisions regarding diagnosis, management, and treatment for specific clinical circumstances and include, but are not limited to, guidelines published in medical journals and articles addressing appropriate treatment and medical standards of care.

e. “Practice Fusion” means Practice Fusion, Inc., any subsidiary of Practice Fusion, and any successor in interest to Practice Fusion.

f. “Sponsor” means an organization that provides, or proposes to provide, funding to sponsor a CDS and may include, but is not limited to, a pharmaceutical company, trade association or foundation, or other agents or representatives of any pharmaceutical or life sciences company.

g. “Sponsored Clinical Decision Support” or “Sponsored CDS” means CDS functionality that is funded, or proposed to be funded, by a Sponsor.

5. Compliance Program Procedures. Within ninety (90) days of the Effective Date, Practice Fusion shall implement Sponsored CDS Compliance Program procedures and systems to review all current or future Sponsored CDSs (including any CDSs removed that are being re-introduced) on the Practice Fusion EHR for purposes of detecting and reporting any deviation from any CQM and/or Guideline on which the Sponsored CDS program relied.

6. Clinical Review. Practice Fusion shall review and enhance its methodology for reviewing and approving Sponsored CDS programs to ensure they are medically appropriate and not influenced or directed by its sponsors’ commercial interests (i.e. “commercially neutral”). Practice Fusion shall establish rigorous review protocols for any and all Sponsored CDSs to ensure the medical appropriateness of any Sponsored CDS. Such medical review of any Sponsored CDS

will include consultation with medical professionals with expertise in the area of medicine relating to the Sponsored CDS at issue.

7. Diligence Review. Practice Fusion shall not go-live with any Sponsored CDS without conducting a thorough and diligent review to determine whether the CDS is clinically appropriate, commercially neutral, and consistent with any applicable CQM and/or Guideline. All Sponsored CDS must receive written approval by the Practice Fusion Compliance Officer before launch. This review shall include, but not be limited to, confirming that Practice Fusion took reasonable steps to ensure that Sponsors' sales, marketing, or brand personnel were not involved, directly or indirectly, in designing, creating, or financing the CDS. Practice Fusion's compliance personnel trained in CDSs shall create documentation sufficiently specific to show the basis for their determination as to whether the Sponsored CDS is medically appropriate, commercially neutral, and consistent with any applicable CQM and/or Guideline, and shall maintain such documentation throughout the term of this Compliance Addendum (and for such longer period as may be required by other applicable law, regulation or guideline). Any proposed Sponsored CDS that does not satisfy the aforementioned criteria shall not be implemented and shall be reported by the Practice Fusion Compliance Officer to the Oversight Organization, with copy to the Office, together with an explanation of how the proposed Sponsored CDS is inconsistent with this Compliance Addendum, the AKS, a CQM, CDS requirements, and/or Guidelines, or if the proposed Sponsored CDS did not proceed for any other reason.

8. Oversight Organization Review. In addition, prior to implementing any proposed Sponsored CDS, Practice Fusion will notify the Oversight Organization retained in connection with the Agreement in writing and provide an appropriate period of time for the Oversight Organization to review the proposed Sponsored CDS, but no more than sixty (60) calendar days

for such review, unless there is adequate justification for any delay in review. Should a dispute arise as to whether delay beyond 60 days is justified arise the Office shall, in its sole discretion, make such determination. The Oversight Organization shall be promptly provided all documentation relating to the above reviews, ready access to any employees, a walk-through of the proposed Sponsored CDS workflow, and any other documentation or information necessary for it to perform its review. Upon completion of its review, the Oversight Organization shall provide its approval or disapproval of the proposed Sponsored CDS to Practice Fusion in writing. If the Oversight Organization disapproves of a proposed Sponsored CDS, it shall provide the basis for such disapproval, and Practice Fusion shall have an opportunity to cure any deficiencies noted. Any disputes between Practice Fusion and the Oversight Organization regarding the amount of time needed to allow the Oversight Organization to conduct its review, or the substance of the Oversight Organization's determinations, shall be adjudged by the Office.

9. Chief Clinical Officer Review. Practice Fusion's Chief Clinical Officer shall review and ensure that any portions of an applicable Guideline that are not incorporated into a Sponsored CDS will not adversely impact patient safety or health and shall document any decision, including the rationale for such decision, to omit any portion of an applicable Guideline and shall maintain such documentation for the term of this Compliance Addendum.

10. Chief Compliance Officer Review. Practice Fusion's Chief Compliance Officer shall review all Sponsored CDSs prior to launch and confirm in writing that any Sponsored CDS was subject to appropriate Oversight Organization review, Clinical Review as described above in Paragraph 6, and not in violation of any provision of this Compliance Addendum or the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b).

11. Sponsor Involvement. Practice Fusion shall prohibit any involvement, directly or indirectly, by a Sponsor in the design, workflow, alert language, alert triggers, Guideline, or CQM related to a Sponsored CDS. Practice Fusion shall permit the Sponsor to conduct its clinical, regulatory, and legal review to ensure compliance with applicable standards, including but not limited to ensuring consistency with the product's label or to promote patient safety based on consultation with the Sponsor's medical personnel.

12. CQM and Guideline Review. Practice Fusion shall review all CQMs and Guidelines relating to any Sponsored CDS annually to ensure that the CDS is consistent with current Guidelines and CQMs and not based on outdated medical standards.

13. No ROI. Practice Fusion shall prohibit any Sponsored CDS from being marketed or sold based on any anticipated return on investment or increase in sales of a Sponsor's drug or class of drugs, and shall prohibit Sponsors by contract from funding any Sponsored CDSs on this basis. Practice Fusion shall additionally not accept any success or contingent payments in connection with Sponsored CDSs.

14. Practice Fusion shall not knowingly, or with reckless disregard, accept remuneration, including but not limited to sponsorship money, in connection with any Sponsored CDS from any Sponsors' sales, marketing, or brand budget, and/or knowingly, or with reckless disregard, permit any Sponsors' sales, marketing or brand personnel to have any input or influence on the design or implementation of any Sponsored CDS.

15. Practice Fusion shall not knowingly, or with reckless disregard, accept, and take reasonable measures to prevent, any Sponsor from providing funding, directly or indirectly, from its sales, marketing, or brand budget. Practice Fusion shall also take reasonable measures to request that Sponsor identify the source of funds used to fund a Sponsored CDS.

16. Practice Fusion shall take reasonable measures to prevent personnel from a Sponsor's sales departments, marketing departments, or brands from attending or participating, directly or indirectly, in any meeting, teleconference, videoconference, etc., and shall take reasonable measures to notify any potential Sponsor in advance of this practice. Practice Fusion shall inquire in advance whether any representatives from such departments are attending and/or participating and shall not go forward with any such meeting, teleconference, videoconference, etc. if any such representative is attending and/or participating or if a potential Sponsor refuses to identify the attendees.

17. Sponsor Contractual Confirmations. Prior to implementing any Sponsored CDS, Practice Fusion shall ensure that the relevant contract with the Sponsor includes the following representations and warranties from the Sponsor:

- a. any remuneration provided to Practice Fusion was not sourced, directly or indirectly, from any sales, marketing or brand budgets;
- b. sales, marketing, or brand personnel were not directly or indirectly involved in any decision to implement or sponsor the Sponsored CDS;
- c. sales, marketing, or brand personnel were not directly or indirectly involved in any design decisions relating to the Sponsored CDS; and
- d. the Sponsor is without knowledge or reason to believe that the Sponsored CDS is in any way inconsistent in any respect with the AKS, any CQM, and/or Guideline.

18. Randomized Monitoring. Practice Fusion shall implement a randomized monitoring program to ensure its personnel are not in violation of this Compliance Addendum or the Anti-Kickback Statute, including but not limited to, review of written communications in which Practice Fusion employees are engaged in Covered Activities. Such monitoring shall be

conducted by a representative from Practice Fusion's Compliance department and shall include random surveillance of Covered Activities to ensure that Sponsored CDS programs are not being promoted or utilized in any manner inconsistent with this Compliance Addendum or otherwise potentially violate the Anti-Kickback Statute. Practice Fusion's Compliance department shall log all of its monitoring activities and provide such documentation to the Oversight Organization and the Office on request. The Compliance department shall additionally be notified of any potential violations of the Compliance Addendum or Anti-Kickback Statute, and the Compliance department shall disclose potential violations to the Oversight Organization, with copy to the Office.

19. Policies. Practice Fusion shall ensure that all policies and procedures relating to its Sponsored CDS Compliance Program are disseminated internally to all relevant employees.

20. Training. Practice Fusion shall conduct annual Anti-Kickback Statute training for all employees involved in Covered Activities and each employee shall certify in writing to completion of that training. Practice Fusion shall also conduct Anti-Kickback Statute training for all new employees that are to be involved in Covered Activities. Such trainings shall include a discussion of how the Anti-Kickback Statute specifically relates to the Covered Activities and examples of how Covered Activities could implicate and/or violate the Anti-Kickback Statute. In addition, the training shall include a discussion of the criminal, civil, and administrative sanctions that could be imposed on Practice Fusion and/or Practice Fusion employees for violating the Anti-Kickback Statute.

21. Initial Report. Practice Fusion shall submit periodic reports to the Office and the Oversight Organization. Practice Fusion shall submit its first report within 120 days of the Effective Date ("Initial Report"). The Initial Report shall include the following:

- a. The name and title of all Practice Fusion compliance personnel, as well as any third-party consultants used by Practice Fusion to implement the Sponsored CDS Compliance Program.
 - b. A description of the Sponsored CDS Compliance Program systems and procedures implemented by Practice Fusion pursuant to Paragraph 5 of this Compliance Addendum.
 - c. A description of Practice Fusion’s methodology for reviewing and approving Sponsored CDS programs to ensure they are medically appropriate and not influenced or directed by the commercial interests of the sponsor, as required by Paragraph 6 of this Compliance Addendum.
 - d. A description of the steps taken by Practice Fusion to determine whether a Sponsored CDS is medically appropriate, commercially neutral, and consistent with any applicable CQM and/or Guideline, and any reports of noncompliance made to the Practice Fusion Compliance Officer and the Oversight Organization, pursuant to Paragraph 7 of this Compliance Addendum.
 - e. A description of the systems, policies, and procedures used by Practice Fusion to implement the requirements of Paragraphs 8-16 of this Compliance Addendum.
22. Update Reports. After submitting the Initial Report, Practice Fusion shall thereafter provide an update report (“Update Report”) every year (a “Reporting Period”). The Update Reports shall be submitted on or before the last day of each Reporting Period. Each Update Report shall include the following:
- a. Any updates to the information provided in the Initial Report.
-

- b. Copies of any contractual confirmations from Sponsors obtained by Practice Fusion from the proposed Sponsor of any Sponsored CDS, pursuant to Paragraph 17 of this Compliance Addendum.
 - c. A summary of the results of the monitoring program described in Paragraph 18 of this Compliance Addendum. A copy of the Covered Activities log and the log of monitoring activities shall be provided upon request.
 - d. A description of any and all training provided pursuant to Paragraph 20 of this Compliance Addendum.
 - e. Notice if any Practice Fusion employee has prepared a report that reflects the impact of any Sponsored CDS alert on the sales of the Sponsor's products, including a projected difference in prescribing a Sponsor's product in a test group as compared to a control group.
 - f. A list of all proposed Sponsored CDSs, including identification of the potential Sponsors, that were rejected by the Practice Fusion Clinical Officer, Compliance department, and/or the Oversight Organization and the basis for such rejection.
-

Dated at Burlington, in the District of Vermont, this 26th day of January, 2020.

UNITED STATES OF AMERICA

CHRISTINA E. NOLAN
United States Attorney

Foster

By: /s/ Owen C.J.

OWEN C.J. FOSTER
MICHAEL P. DRESCHER
Assistant U.S. Attorneys
P.O. Box 570
Burlington, VT 05402-0570
(802) 951-6725
Owen.C.J.Foster@usdoj.gov
Michael.Drescher@usdoj.gov

Accepted and agreed to:

/s/ Eric L. Jacobson, Esq.
Eric L. Jacobson, Esq.
Practice Fusion, Inc.

/s/ Joshua Levy, Esq.
Joshua Levy, Esq.
Christine Moundas, Esq.
Aaron Katz, Esq.
Patrick Welsh, Esq.
Ropes & Gray, LLP
Counsel to Practice Fusion, Inc.

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

)
UNITED STATES OF AMERICA)
) Docket No. 2:20-CR-11
v.)
)
PRACTICE FUSION, INC.,)
)
Defendant.)
_____)

Oversight Organization Mandate Addendum

1. **Oversight Organization:** As a condition of its Deferred Prosecution Agreement Practice Fusion, Inc. (“Practice Fusion”) is required to retain an oversight organization (the “Oversight Organization”) for three (3) years from the date of appointment of the Oversight Organization.

2. **Selection of Oversight Organization Candidates, Timing.** Practice Fusion agrees to retain an Oversight Organization upon selection by the Office of the United States Attorney for the District of Vermont (the “Office”) whose powers, rights, and responsibilities are set forth herein. Within thirty (30) calendar days of the Effective Date of the Deferred Prosecution Agreement (“DPA”), PRACTICE FUSION shall provide to the Office a list of two (2) qualified candidates to serve as the Oversight Organization. PRACTICE FUSION shall identify which entity it would like to select as the Oversight Organization and provide a basis for such preference. Within thirty (30) calendar days of receiving the final list of qualified Oversight Organization candidates from PRACTICE FUSION, the Office shall either agree or disagree with PRACTICE FUSION’s selection, and notify PRACTICE FUSION in writing of whether it concurs with PRACTICE FUSION’s selection of the Oversight Organization or whether the alternate must be

used instead. Should the Office find none of the initial list of Oversight Organization candidates provided by PRACTICE FUSION acceptable it shall notify PRACTICE FUSION and PRACTICE FUSION shall consult with the Office and provide an additional list of candidates from which the Office may select an Oversight Organization. The Office shall consult with PRACTICE FUSION using its best efforts to select and appoint a mutually acceptable Oversight Organization (and any replacement Oversight Organization, if required) as promptly as possible. Within thirty (30) calendar days of receiving written notice of the selection of the Oversight Organization, PRACTICE FUSION shall retain the Oversight Organization and finalize all terms of engagement, supplying a copy of an engagement letter to the Office. In the event that the Office is unable to select an Oversight Organization acceptable to PRACTICE FUSION, the Office shall have the sole right to select an Oversight Organization (and any replacement Oversight Organizations), if required. To ensure the integrity of the Oversight Organization, the Oversight Organization must be independent and objective, and the following persons shall not be eligible as either an Oversight Organization or an agent, consultant or employee of the Oversight Organization: (a) any person currently or previously employed by PRACTICE FUSION (as used herein PRACTICE FUSION shall include any affiliates, subsidiaries, parent companies, employees, officers or directors, or otherwise related entities); any current or former PRACTICE FUSION board member; any person who holds an interest in PRACTICE FUSION, or has a relationship with PRACTICE FUSION, its affiliates, related entities, or its employees, officers or directors; or (b) any person who has been directly adverse to PRACTICE FUSION in any proceeding. In addition, PRACTICE FUSION must certify in writing that it will not employ or be affiliated with the Oversight Organization for a period of not less than two years from the date that the Oversight Organization is terminated. The parties shall endeavor to complete the Oversight Organization selection process within sixty

(60) calendar days of the execution of the PRACTICE FUSION Deferred Prosecution Agreement (the "Agreement").

3. **Mandate:** The Oversight Organization shall take steps, as described herein, to provide reasonable assurance that PRACTICE FUSION establishes and maintains compliance systems, controls and processes reasonably designed, implemented and operated to ensure PRACTICE FUSION's compliance with the terms of the Agreement, including the Compliance Addendum set forth under **Exhibit D** to the Deferred Prosecution Agreement, as well as reducing the risk of any recurrence of PRACTICE FUSION's misconduct as described in the Information and Statement of Facts (the "Mandate"). To fulfill the Mandate, the Oversight Organization shall: (i) evaluate the effectiveness of PRACTICE FUSION's processes, procedures and programs to ensure that all sponsored Clinical Decision Support ("Sponsored CDS") programs are operated in compliance with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b), any applicable Clinical Quality Measures ("CQM"), any applicable medical guideline or literature upon which any Sponsored CDS may be based, and any other regulations applicable to Sponsored CDSs; (ii) make recommendations regarding such processes, procedures and programs to reasonably ensure such compliance; (iii) assess whether PRACTICE FUSION, in connection with its Sponsored CDSs, complies with the requirements of the AKS, CQMs, medical literature and guidelines, and CDS rules and regulations; (iv) assess PRACTICE FUSION's policies and procedures relating to its Clinical Decision Support Compliance Program; (v) assess PRACTICE FUSION's Board of Directors' and senior management's commitment to, and effective implementation of, CDS compliance procedures; and (vi) make periodic reports concerning the foregoing. The Oversight Organization shall have the authority to take such reasonable steps as, in his or her view, may be necessary to fulfill the Mandate.

4. **Oversight Organization's Work Plan:** The Oversight Organization shall prepare a written work plan (the "Work Plan") within sixty (60) calendar days of being retained. In the Work Plan, the Oversight Organization shall include (i) a description of tasks, activities, and timeline for conducting its initial review of the items encompassed in the Mandate as set forth in Paragraph 3 and generating recommendations for Practice Fusion related to its Sponsored CDS controls, (ii) a timeline for and description of any additional tasks and efforts that it believes are necessary to fulfill the Oversight Organization's Mandate. In creating the Work Plan, the Oversight Organization may develop an understanding of the facts and circumstances surrounding any violations that may have occurred before the date of the Agreement, but shall rely on available information and documents provided by PRACTICE FUSION; and not conduct his or her own inquiry into such violations. The Work Plan also must account for and include the review of proposed Sponsored CDSs, as required in the Compliance Addendum set forth under **Exhibit D** to the Deferred Prosecution Agreement. The Oversight Organization shall submit the Work Plan to PRACTICE FUSION and the Office, which shall in turn provide comments, if any, within thirty (30) calendar days after receipt of the Work Plan. Any disputes between PRACTICE FUSION and the Oversight Organization with respect to the Work Plan shall be decided by the Office in its sole discretion.

5. **Initial Report and Progress Reports:** The Oversight Organization shall issue an initial report within one hundred and twenty (120) calendar days following the approval of the Work Plan (the "Initial Report"). The Initial Report shall include (i) a narrative summary of the scope of the Oversight Organization's review, and (ii) recommendations for Practice Fusion policy or process improvements consistent with the Mandate. Thereafter, the Oversight Organization shall issue reports twice annually ("Progress Reports") until issuance of the Final Report (see

Paragraph 7). Such Progress Reports shall include (i) a narrative summary of the Oversight Organization's progress to date in achieving the Mandate; (ii) a summary of the current Work Plan, including the current status, projected completion dates and other relevant information concerning the adoption of the Oversight Organization's preexisting recommendations, as well as of any new recommendations the Oversight Organization believes are required; and (iii) any issues, obstacles or difficulties that may prevent the Oversight Organization from achieving the Mandate. The Oversight Organization shall provide the finished report to the Board of Directors of PRACTICE FUSION and the General Counsel of Allscripts, and contemporaneously transmit copies to the Office.

6. **Recommendation Implementation:** Within ninety (90) calendar days after receiving the Initial Report or a Progress Report, PRACTICE FUSION shall adopt and implement the recommendations in the Initial Report or Progress Report unless, within fourteen (14) calendar days of receiving the Progress Report, PRACTICE FUSION notifies in writing the Oversight Organization and the Office of any recommendations that PRACTICE FUSION considers unduly burdensome, inconsistent with applicable law or regulation, impractical, or otherwise inadvisable. With respect to any such recommendation, PRACTICE FUSION need not adopt that recommendation within the ninety (90) calendar days of receiving the report but shall propose in writing to the Oversight Organization and the Office an alternative policy, procedure or system designed to achieve the same objective or purpose. In the event PRACTICE FUSION and the Oversight Organization are unable to agree on an acceptable alternative proposal, the Office shall in its sole discretion, determine what measures PRACTICE FUSION shall undertake, and may consider the Oversight Organization's recommendation and PRACTICE FUSION's reasons for not adopting the recommendation in determining whether PRACTICE FUSION has fully

complied with its obligations under the Agreement. Pending such determination, PRACTICE FUSION shall not be required to implement any contested recommendation(s). With respect to any recommendation that the Oversight Organization determines cannot reasonably be implemented within sixty calendar days after receiving the report, the Oversight Organization may extend the time period for implementation with prior written approval of the Office.

7. **Final Report:** Upon the termination of the Oversight Organization in accordance with Paragraph 1, the Oversight Organization shall issue a final report (the "Final Report") summarizing the tasks performed under the Work Plan and the results achieved. The Final Report shall also include a narrative summary of the Oversight Organization's overall efforts, discuss any outstanding tasks, and provide future recommendations designed to ensure that PRACTICE FUSION remains compliant with the Anti-Kickback Statute and that its CDS programs are medically appropriate, commercially neutral, and consistent with all applicable CQMs, medical literature and guidelines, and CDS rules and regulations after the expiration of the Oversight Organization. The Oversight Organization shall provide the Final Report to the Board of Directors of PRACTICE FUSION and contemporaneously transmit copies to the Office. Any objections to the Final Report, by the Office, Practice Fusion, or the Oversight Organization shall follow the dispute resolution procedures identified in Paragraph 8 herein.

8. **Dispute Resolution:** Within ninety (90) calendar days after receiving a Progress Report, PRACTICE FUSION shall adopt and implement the recommendations in the Progress Report unless, within fourteen (14) calendar days of receiving the Progress Report, PRACTICE FUSION notifies in writing the Oversight Organization and the Office of any recommendations that PRACTICE FUSION considers unduly burdensome, inconsistent with applicable law or regulation, impractical, or otherwise inadvisable. With respect to any such recommendation,

PRACTICE FUSION need not adopt that recommendation within the ninety (90) calendar days of receiving the report but shall propose in writing to the Oversight Organization and the Office an alternative policy, procedure or system designed to achieve the same objective or purpose. In the event PRACTICE FUSION and the Oversight Organization are unable to agree on an acceptable alternative proposal the Office shall in its sole discretion, determine what measures PRACTICE FUSION shall undertake, and may consider the Oversight Organization's recommendation and PRACTICE FUSION's reasons for not adopting the recommendation in determining whether PRACTICE FUSION has fully complied with its obligations under the Agreement. Pending such determination, PRACTICE FUSION shall not be required to implement any contested recommendation(s). With respect to any recommendation that the Oversight Organization determines cannot reasonably be implemented within sixty calendar days after receiving the report, the Oversight Organization may extend the time period for implementation with prior written approval of the Office.

9. **PRACTICE FUSION's Obligations:** PRACTICE FUSION shall cooperate fully with all reasonable requests from the Oversight Organization consistent with the Mandate. To that end, PRACTICE FUSION shall facilitate the Oversight Organization's access to PRACTICE FUSION's documents, resources, and employees as reasonably necessary for the Oversight Organization to fulfill the Mandate, and not limit such access, except as provided in Paragraph 10. PRACTICE FUSION shall provide the Oversight Organization with access to all information, documents, records, facilities, and employees, as reasonably requested by the Oversight Organization and is reasonably necessary for the Oversight Organization to fulfill the Mandate, and shall use its best efforts to provide the Oversight Organization with access to PRACTICE FUSION's former employees and its third-party vendors, agents, customers, and consultants. Any

disputes as to what qualifies as a “reasonable request,” what constitutes “reasonably necessary,” and/or what is “consistent” with the mandate or fulfilling the mandate shall be determined by the Office in its sole discretion.

10. **Withholding Access:** The parties agree that no attorney-client relationship shall be formed between PRACTICE FUSION and the Oversight Organization. In the event that PRACTICE FUSION seeks to withhold from the Oversight Organization access to information, documents, records, facilities, or current or former employees of PRACTICE FUSION that may be subject to a claim of attorney-client privilege or to the attorney work-product doctrine, or other recognized privileges and protections, or where PRACTICE FUSION reasonably believes production would otherwise be inconsistent with applicable law, PRACTICE FUSION shall work cooperatively with the Oversight Organization to resolve the matter to the satisfaction of the Oversight Organization. If the matter cannot be resolved, at the request of the Oversight Organization, PRACTICE FUSION shall promptly provide written notice to the Oversight Organization and the Office. Such notice shall include a general description of the nature of the information, documents, records, facilities or current or former employees that are being withheld, as well as the legal basis for withholding access. The Office may then consider whether to make a further request for access to such information, documents, records, facilities, or employees.

11. **Reporting Obligations:** Any disclosure by PRACTICE FUSION to the Oversight Organization relating to the Anti-Kickback Statute, its implementation regulations, or the Agreement shall not relieve PRACTICE FUSION of any otherwise applicable obligation to truthfully disclose such matters to the Office, the Department of Health and Human Services (including the Centers for Medicare and Medicaid Services, the Office of Inspector General, and/or

the Office of the National Coordinator for Health Information Technology) pursuant to the Agreement and its addendums.

12. **Oversight Organization's Discovery of Misconduct:** Should the Oversight Organization discover during the course of its engagement that PRACTICE FUSION, or any of its officers, employees, directors, consultants, vendors, or customers may have committed a violation of the Anti-Kickback Statute, or of any federal or state law the Oversight Organization shall immediately report such potential misconduct to the Office.

13. **Confidentiality:** The Oversight Organization and its staff shall maintain the confidentiality of any non-public information entrusted or made available to the Oversight Organization. The Oversight Organization shall share such information only with the Office, the Department of Justice, the Department of Health and Human Services, and/or any other governmental agency or body identified by the Office.

14. **Information Designation:** PRACTICE FUSION shall clearly identify any portions of any submissions it makes to the Office pursuant to the Compliance Addendum and the Oversight Organization Mandate (including the Oversight Organization's Work Plan, Progress Reports, and Final Report) that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, or otherwise potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. PRACTICE FUSION shall also be afforded the opportunity to identify any portions of submissions made by the Oversight Organization to the Office that PRACTICE FUSION believes are trade secrets, or information that is commercial or financial and privileged or confidential, or otherwise exempt from disclosure under FOIA. All such information may be exempt from disclosure under FOIA and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt

of a request to release any information identified as confidential by PRACTICE FUSION, the Office agrees to provide PRACTICE FUSION reasonable opportunity to respond to any such requests.

15. **Non-Disclosure:** The Oversight Organization shall sign a non-disclosure agreement with PRACTICE FUSION prohibiting disclosure of information received from PRACTICE FUSION to anyone other than to the Office, any governmental agency or body identified by the Office, or anyone hired by the Oversight Organization. Any breach by the Oversight Organization of such non-disclosure agreement shall result in sanctions imposed by the Office in its sole discretion. Within thirty (30) calendar days after the end of the Oversight Organization's term, the Oversight Organization shall either return anything obtained from PRACTICE FUSION, or certify that such information has been destroyed. Anyone hired by the Oversight Organization shall also sign a nondisclosure agreement with similar return or destruction requirements as set forth in this Paragraph 15.

16. **Hiring Authority:** The Oversight Organization shall have the authority to employ legal counsel, consultants, investigators, medical experts, and any other personnel reasonably necessary to assist in the proper discharge of the Oversight Organization's duties. It is explicitly understood and agreed that the Oversight Organization shall be required to retain medical experts in the fields relating to the Sponsored CDSs to ensure the medical appropriateness of the Sponsored CDSs and to ensure that they are commercially neutral and not designed to improperly influence the medical judgment or decision making of any physician and/or health care provider. Any such medical experts retained by the Oversight Organization shall have no conflicts or financial connection to the sponsor of any CDS and/or commercial interest relating to the CDS. Oversight Organization shall be mindful of costs when engaging and retaining outside personnel, and shall

ensure that experts are only engaged as needed in relation to the Sponsored CDSs. Any disputes as to whether a retention of personnel is “reasonably necessary” or whether experts are “only engaged as needed in relation to the Sponsored CDSs” shall be determined by the Office in its sole discretion.

17. **Compensation and Expenses:** Although the Oversight Organization shall operate under the supervision of the Office, the compensation and reasonable expenses of the Oversight Organization, and of the persons hired under his or her authority, shall be paid by PRACTICE FUSION. The Oversight Organization, and any person hired by the Oversight Organization, shall be compensated in accordance with their respective typical hourly rates. The Oversight Organization shall charge a reasonable amount for fees and expenses, and shall submit monthly invoices to PRACTICE FUSION with a reasonable level of detail reflecting all key categories of costs and fees billed. PRACTICE FUSION shall pay bills for compensation and all reasonable expenses promptly, and in any event within thirty (30) calendar days. In addition, within one week after the selection of the Oversight Organization, PRACTICE FUSION shall make available office space, telephone and internet service, and clerical assistance sufficient for the Oversight Organization to carry out his or her duties. PRACTICE FUSION may bring any disputed costs or bills to the Office’s attention for purposes of facilitating the resolution of any fee-related dispute. The Office will work in good faith with PRACTICE FUSION, as the Office determines is necessary in its sole discretion, to assess whether the costs and fees associated with the Oversight Organization are reasonable in light of the benefits provided, and shall determine in its sole discretion whether any disputed costs and/or fees are reasonable.

18. **Indemnification:** PRACTICE FUSION shall provide an appropriate indemnification agreement to the Oversight Organization with respect to any claims arising out of the performance of the Oversight Organization's duties.

Dated at Burlington, in the District of Vermont, this 26th day of January, 2020.

UNITED STATES OF AMERICA

CHRISTINA E. NOLAN
United States Attorney

By: /s/ Michael P.

Drescher

MICHAEL P. DRESCHER
OWEN C.J. FOSTER
Assistant U.S. Attorneys
P.O. Box 570
Burlington, VT 05402-0570
(802) 951-6725
Owen.C.J.Foster@usdoj.gov
Michael.Drescher@usdoj.gov

Accepted and agreed to:

/s/ Eric L. Jacobson, Esq.
Eric L. Jacobson, Esq.
Practice Fusion, Inc.

/s/ Joshua Levy, Esq.
Joshua Levy, Esq.
Christine Moundas, Esq.
Aaron Katz, Esq.
Patrick Welsh, Esq.
Ropes & Gray, LLP
Counsel to Practice Fusion, Inc.



U.S. Department of Justice
Criminal Division

Office of Enforcement Operations

Washington D.C. 20530

The Honorable Christina E. Nolan
United States Attorney
District of Vermont
Office of the United States Attorney
United States Courthouse and Federal Building
Post Office Box 570
11 Elmwood Avenue, 3rd Floor
Burlington, Vermont 05402-0570

Attention: Owen C. J. Foster
Assistant United States Attorney

Re: Global Deferred Prosecution Agreement for Practice Fusion, Inc.

Dear Ms. Nolan:

This is in response to your request for authorization to enter into a global agreement with Practice Fusion, Inc. (Practice Fusion).

I hereby approve the terms of the Deferred Prosecution Agreement with Practice Fusion, including the provisions on pp. 26-27, through which the United States agrees not to initiate further criminal proceedings against Practice Fusion for the conduct at issue, with the exceptions and conditions noted within those paragraphs and elsewhere within the Deferred Prosecution Agreement.

You are authorized to make these approvals a matter of record in this proceeding.

Sincerely,

/s/ Jennifer A. H. Hodge
Jennifer A. H. Hodge
Deputy Assistant Attorney General



U.S. Department of Justice
United States Attorney
District of Vermont

United States Courthouse and Federal Building
Post Office Box 570 (802) 951-6725
Burlington, Vermont, 05401-0570 Fax: (802) 951-6540

January 26, 2020

Mr. Joshua S. Levy
Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199

Re: *United States v. Practice Fusion, Inc.*
Additional Compliance Terms, Exhibit G To Practice Fusion, Inc. DPA

Dear Mr. Levy:

This letter (“Letter Agreement”) sets forth the Additional Compliance Terms contemplated by Paragraph 25 of the Deferred Prosecution Agreement (the “DPA”) between Practice Fusion, Inc. and the United States Attorney for the District of Vermont (the “Office”). In exchange for Practice Fusion’s full performance of the terms contained within this Letter Agreement and the DPA entered into by Practice Fusion, Inc., the United States and Practice Fusion hereby agree as follows:

I. Civil Settlement Agreement with Practice Fusion

Pursuant to the Civil Settlement Agreement entered into between Practice Fusion and the United States, Practice Fusion will pay to the United States and individual states a monetary

settlement. In exchange, as set forth in the Civil Settlement Agreement, the United States is releasing certain claims it has against Practice Fusion (the “Civil Release”).

II. Deferred Prosecution Agreement

Separately, Practice Fusion and the Office have entered into the DPA pursuant to which the Office will file a criminal information charging Practice Fusion with two criminal offenses relating to its interactions with an extended release opioid (“ERO”) company (the “Information”). Upon successful completion of the term of the DPA, the United States agrees to seek dismissal, with prejudice, of the Information filed against Practice Fusion.

III. Who Is Bound by Agreement

This Letter Agreement is binding upon the Office and Practice Fusion.

IV. Term of Agreement

This Letter Agreement is effective for a period beginning on the date on which the final signatory of the DPA executes the DPA (“Effective Date”), and shall be binding for a period of three years from the Effective Date.

V. Compliance Measures

Practice Fusion hereby agrees to the following Compliance Measures.

A. Clinical Decision Support Compliance Program Addendum

Practice Fusion shall comply with the terms of the Clinical Decision Support Compliance Program Addendum to this side letter set forth under **Addendum 1**. The Clinical Decision Support Compliance Program Addendum is also **Exhibit D** to the DPA.

B. Oversight Organization Mandate Addendum

Practice Fusion shall comply with the terms of the Oversight Organization Mandate Addendum to this side letter set forth under **Addendum 2**. The Oversight Organization Mandate Addendum is also **Exhibit E** to the DPA.

C. HIPAA And The Federal Trade Commission Act Cooperation

Practice Fusion shall cooperate fully with the Federal Trade Commission (FTC) and the Department of Health and Human Services Office for Civil Rights (OCR) with respect to any inquiries or review undertaken by those offices with respect to the conduct alleged in this global settlement. Such cooperation shall include, but not be limited to, providing necessary documents, information, and witnesses as may be required by either the FTC and/or OCR to conduct such review, including, but not limited to, with respect to issues relating to Practice Fusion's compliance with HIPAA and the Federal Trade Commission Act. Practice Fusion shall provide fully truthful, accurate, and candid information in interacting with either the FTC and/or OCR.

D. Health IT Functionality And Compliance Terms

1. *Data Export Functionality.* Practice Fusion shall, within 60 days of this Letter Agreement, engage, at its own expense, its ONC-ACB and ONC-ATL to review and re-test its current compliance with the data export functionality required for certification under the 2015 Edition electronic health record certification criteria set forth in 45 C.F.R. § 170.315(b)(6). In connection with such testing Practice Fusion shall disclose to its ONC-ACB and ONC-ATL all technical and/or structural issues impacting the ability of users to utilize data export functionality.

2. *Bug List.* Practice Fusion shall maintain on its customer portal a current and comprehensive version of its bug list, which includes, but is not limited to, bugs relating to any certification capabilities, patient safety, interoperability, and data portability. The bug list shall

specify the nature of the bug and the date the bug was first reported to, or identified by, Practice Fusion. In addition to its routine processes for detecting and addressing bugs, Practice Fusion shall also conduct bi-annual reviews of bug lists, service tickets and customer notifications relating to the performance of Practice Fusion's software to ensure that in all functionalities, capacities, and workflows Practice Fusion's software is performing in-the-field in full compliance with its intended scope and with certification criteria (if applicable).

3. *Patient Safety.* Practice Fusion shall review its policies and procedures, and where necessary implement enhanced policies and procedures, training, and processes, to ensure patient safety risks are identified and users appropriately and timely notified of patient safety issues, including by posting such issues and resolution specifics on Practice Fusion's customer portal. Practice Fusion shall ensure adequate systems to detect, identify, and record potential issues impacting patient safety. Such issues, for example, could include (a) transmission, retention, or display of inaccurate prescriptions, incorrect drug, diagnoses, or lab codes in connection with medication lists, problem lists, labs or imaging, drug-drug or drug-allergy checks, ePrescriptions, or CCDAs, (b) incorrect patient information appearing within the records displayed to providers, or in visit summaries provided to patients, (c) failure to transmit or receive imaging or laboratory orders or results, (d) inaccurate imaging or laboratory orders or results, (e) drug database or medical vocabularies not being updated, (f) patient records and/or medical information appearing under the name of another patient.

4. *Code Retention.* Practice Fusion shall retain all versions of its code that are utilized and/or relied upon in connection with any testing, certification, or surveillance relating to any Governmental program, including any program or regulation providing or applying incentives or penalties or any certification program.

VI. Remedies for Breach

A. Practice Fusion and the United States agree that the failure to adhere to the terms of the Additional Compliance Terms set forth in this Letter Agreement may result in the imposition of Stipulated Penalties in accordance with this section entitled Remedies for Breach, and/or grounds for termination of the DPA.

B. Stipulated Penalties shall be calculated as follows: \$15,000 per day for each day Practice Fusion fails to adhere to the Additional Compliance Terms set forth in Section V.

C. If the Office determines that Practice Fusion is in violation of the HIPAA Cooperation requirement (Section V.C) or the Health IT Functionality and Compliance Terms (Section V.D), the Office may, in lieu of demanding Stipulated Penalties for such violation(s) under this Agreement, pursue all remedies available to it under the breach provisions of DPA.

D. If the Office determines that Practice Fusion is in violation of the Clinical Decision Support Compliance Program (Section V.A; Addendum 1) or the Oversight Organization Mandate related to clinical decision support programs (Section V.B; Addendum 2), the Office may, in lieu of demanding Stipulated Penalties for such violation(s) under this Agreement, pursue all remedies available to it under the breach provisions of DPA.

E. Should the United States determine that Practice Fusion has breached this Letter Agreement, and prior to pursuing the remedies described in Sections VI.A through VI.D, the Office shall provide written notice to Practice Fusion of that determination (the "Written Notice"). Such Written Notice shall set forth in reasonable detail: (a) the provision(s) breached; (b) the approximate date of the breach; (c) a description of the breach sufficient to permit Practice Fusion to cure or respond (as described below); and (d) an indication of which remedy the Office intends to pursue (Stipulated Penalties or termination of the DPA). If the Office seeks Stipulated Penalties,

the Written Notice must also include (e) the amount of Stipulated Penalties claimed by the Office as of the date of the Written Notice, and (f) an explanation of how the Office calculated the Stipulated Penalties amount. After receiving such Written Notice, Practice Fusion shall have an opportunity to make a presentation to the Office to demonstrate that no breach occurred, or to the extent applicable, that the breach should not result in the exercise of the remedies available to the Office under this Agreement because Practice Fusion cured the breach.

F. If the Office demands Stipulated Penalties, Stipulated Penalties (calculated from the date of breach to the date of payment, or, where applicable, from the date of breach to the date that Practice Fusion cured the violation) shall be payable to the United States within fourteen (14) days, payable as directed by the Office. Practice Fusion agrees that the United States District Court for the District of Vermont shall have jurisdiction over any action to collect such a penalty. If Practice Fusion fails to timely make a payment required in this paragraph, interest (at the rate specified in 28 U.S.C. § 1961) shall accrue on the unpaid balance through the date of payment.

VII. Complete Agreement

In addition to the other documents being executed as part of this global resolution, this Letter Agreement, inclusive of its Addenda and Exhibits, sets forth all the terms of this agreement between Practice Fusion and the Office. No amendments, modifications, or additions to this Letter Agreement shall be valid unless they are in writing and signed by the Office, the attorneys for Practice Fusion, and a representative of Practice Fusion duly authorized by Practice Fusion's Board of Directors.

If the foregoing accurately reflects the agreement entered into between the Office and Practice Fusion, and Practice Fusion's Board of Directors has authorized you to enter into this

agreement, please sign below and return the original to AUSA Owen C.J Foster or Michael P. Drescher.

Dated at Burlington, in the District of Vermont, this 26th day of January, 2020.

CHRISTINA E. NOLAN
United States Attorney
District of Vermont

By: /s/ Owen C.J.

OWEN C.J. FOSTER
MICHAEL P. DRESCHER
Assistant U.S. Attorneys
P.O. Box 570
Burlington, VT 05402-0570
(802) 951-6725
Michael.Drescher@usdoj.gov
Owen.C.J.Foster@usdoj.gov

Foster

Accepted and agreed to:

/s/ Eric L. Jacobson, Esq.
Eric L. Jacobson, Esq.
Practice Fusion, Inc.

/s/ Joshua Levy
Joshua S. Levy
Aaron Katz
Christine Moundas
Patrick Welsh
Counsel to Practice Fusion

Addendum 1
Compliance Addendum

See attached.



Addendum 2
Oversight Organization Mandate Addendum

See attached.

SETTLEMENT AGREEMENT**I. PARTIES**

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”) and the Defense Health Agency (“DHA”), acting on behalf of the TRICARE program (collectively, the “United States”) and Practice Fusion, Inc. (“Practice Fusion”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

II. RECITALS

A. Practice Fusion is a vendor of health information technology incorporated in Delaware and headquartered in San Francisco, California. Allscripts Healthcare, LLC, an indirect subsidiary of Allscripts Healthcare Solutions, Inc. (“Allscripts”), acquired Practice Fusion on or around February 13, 2018.

B. The United States contends that it has certain civil claims against Practice Fusion for causing healthcare providers to submit (a) false claims for incentive payments to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”), and the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”) based on the use of Practice Fusion’s electronic health record (“EHR”) software; and (b) false claims to Medicare, Medicaid, and the TRICARE program, 10 U.S.C. §§ 1071-1110b (“TRICARE”) when such claims were tainted by unlawful remuneration.

C. Practice Fusion knew that in order to receive incentive payments under the Centers for Medicare & Medicaid Services (“CMS”) EHR Incentive Payment Programs, eligible healthcare providers were required to use certified EHR software. The United States contends that Practice Fusion knew that several versions of its EHR software as used by healthcare

providers would not satisfy applicable 2014 Edition criteria for certification under the Office of National Coordinator's ("ONC's") Health IT Certification Program. Specifically, the United States alleges that those versions of Practice Fusion's EHR software did not:

- (a) allow users to electronically create a set of standardized export summaries for all patients within the EHR technology in accordance with 45 CFR § 170.314(b)(7). Additionally, the United States contends that Practice Fusion disabled the self-service data export feature in its EHR software altogether, and instead required users to contact Practice Fusion to request export of patient data;
- (b) enable a user to electronically record a patient's active problem list using the standard vocabulary known as Systematized Nomenclature of Medicine - Clinical Terms ("SNOMED CT") as required for its certification in accordance with 45 CFR § 170.314(a)(5); and
- (c) always incorporate clinical laboratory tests and values/results using the standard vocabulary known as Logical Observation Identifiers Names and Codes ("LOINC"), or create clinical summaries using LOINC codes as required for its certification in accordance with 45 CFR § 170.314(b)(2), (b)(5), and (b)(7).

Nevertheless, to ensure that its EHR software was certified, the United States contends that Practice Fusion falsely represented to its ONC Authorized Certification Body ("ONC- ACB") that its EHR software complied with all applicable requirements for certification to the 2014 Edition criteria under ONC's Health IT Certification Program. Consequently, the United States alleges that Practice Fusion knowingly caused eligible healthcare providers who used certain versions of its EHR software to falsely attest to compliance with CMS requirements necessary to receive Medicare incentive payments during the reporting periods for 2014 through

2016 and Medicaid incentive payments during the reporting periods for 2014 through 2017.

D. Clinical decision support (“CDS”) is a key functionality of EHR software that enables evidence-based clinical decision support interventions when a user is interacting with the EHR technology. The United States contends that, between November 2013 and August 2017, Practice Fusion solicited and received improper remuneration from certain pharmaceutical manufacturers based on the anticipated financial benefit to the pharmaceutical manufacturers from increased sales of pharmaceutical products that would result from CDS alerts Practice Fusion would deploy within its EHR software. Practice Fusion permitted pharmaceutical manufacturers that paid Practice Fusion to participate in designing the CDS alert, including selecting the guidelines used to develop the alert, setting the criteria that would determine when a healthcare provider received an alert, and in some cases, even drafting the language used in the alert itself. The United States alleges that the CDS alerts that Practice Fusion agreed to implement did not always reflect accepted medical standards. Indeed, in at least one case, Practice Fusion’s own legal department noted that the guidance was “not the gold standard.” Although the CDS alerts appeared to healthcare providers as unbiased medical information, the United States contends that the CDS alerts were, in some instances, designed to encourage users to prescribe a specific product or class of products. Therefore, the United States alleges that Practice Fusion knowingly and willfully solicited and received remuneration from pharmaceutical manufacturers in return for arranging for or recommending purchasing or ordering of a good or item for which payment may be made in whole or in part under a Federal health care program in violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b, and that the claims for payment that providers submitted, between April 2014 and April 2019 to Medicare, Medicaid, and TRICARE for prescriptions which were tainted by these kickbacks are false claims. The agreements covered

by this subparagraph are those entered into between Practice Fusion and various pharmaceutical manufacturers for fourteen separate CDS arrangements that were first entered into on the following dates: November 11, 2013; June 26, 2014; September 10, 2014; October 16, 2014; April 7, 2015; May 26, 2015; December 4, 2015 (two arrangements in a single contract); March 1, 2016; April 1, 2016; May 17, 2016; November 23, 2016; February 27, 2017; and, August 17, 2017. The conduct described in Paragraphs C and D is the “Covered Conduct.”

E. Practice Fusion will enter into a separate deferred prosecution agreement (“DPA”) with the United States Attorney’s Office for the District of Vermont pertaining to a specific CDS arrangement.

F. Practice Fusion has entered or will enter into separate settlement agreements, described in Paragraph 1 .b below (the “Medicaid State Settlement Agreements”) with certain states and the District of Columbia in settlement of the conduct described in Paragraph D. States with which Practice Fusion executes a Medicaid State Settlement Agreement in the form to which Practice Fusion and the National Association of Medicaid Fraud Control Units (“NAMFCU”) have agreed, or otherwise in a form to which Practice Fusion and an individual State agree, shall be defined as “Medicaid Participating States.”

G. Except to the extent admitted in Practice Fusion’s deferred prosecution agreement, this Settlement Agreement is not an admission of liability by Practice Fusion. This Settlement Agreement is also not a concession by the United States that its claims are not well founded.

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 Settlement Agreement, the Parties agree and covenant as follows:

III.

TERMS AND CONDITIONS

1. Practice Fusion shall pay to the United States and the Medicaid Participating States, collectively, the sum of \$118,642,000 plus interest at the rate of 2.125 percent per annum from August 6, 2019, and continuing until and including the day of full and final satisfaction of the Settlement Amount (the “Settlement Amount”). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement, as defined below. This debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

a. Practice Fusion shall pay to the United States a total of \$113,374,952 (the “Federal Settlement Amount”) plus interest as set forth above, of which \$56,687,476 is restitution. Practice Fusion will pay the Federal Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice in accordance with the payment schedule attached hereto as Exhibit A (“Payment Schedule”).

b. Practice Fusion shall deposit \$5,267,048 (the “Medicaid State Settlement Amount”) plus interest as set forth above, into one or more interest-bearing money market or bank accounts that are held in the name of Practice Fusion or a subsidiary of Practice Fusion, but segregated from other Practice Fusion accounts (the “State Settlement Accounts”) pursuant to the Payment Schedule, and make payment from the State Settlement Accounts to the Medicaid Participating States, including interest accrued pursuant to the terms of the State Settlement Agreements, pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that Practice Fusion will enter into with the Medicaid Participating States.

c. The entire balance of the Settlement Amount, or any portion thereof, plus any

interest on the principal as of the date of any prepayment, may be prepaid without penalty.

d. Allscripts has executed a guaranty agreement with the United States covering the Settlement Amount (“Guaranty Agreement”) attached hereto as Exhibit B.

e. In the event of the sale or other disposition of Practice Fusion, the outstanding balance of the Settlement Amount (including interest then accrued) will be accelerated and immediately due.

f. In the event that Practice Fusion fails to pay the designated portion of the Federal Settlement Amount or deposit the designated portion of the Medicaid State Settlement Amount as provided in Paragraph 1 and Exhibit A by the date when each such payment is due, Practice Fusion shall be in Default of its payment obligations (“Default”). If Practice Fusion fails to cure such Default by making the full payment within ten (10) calendar days, then the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the unpaid balance of the Settlement Amount shall thereafter accrue at the rate of 12 percent per annum, compounded daily from the eleventh calendar day after Default, on the remaining unpaid total (principal and interest balance). In the event of Default that is not cured within ten (10) calendar days, the United States, at its sole discretion, may, after notice to Practice Fusion of Default, (a) offset the remaining unpaid balance from any amounts due and owing to Practice Fusion by any department, agency, or agent of the United States at the time of the Default; or (b) exercise any other rights granted by law or in equity, including the option of referring such matters for private collection. Practice Fusion agrees not to contest any offset imposed and not to contest any collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States. At its sole option, in the event of a Default by Practice Fusion and

Guarantor's failure to make payment within the time set forth in paragraph 3 of the Guaranty attached hereto as Exhibit B, the United States alternatively may, with notice to Practice Fusion and Allscripts, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Practice Fusion for the claims that would otherwise be covered by the release provided in Paragraph 2, below. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph or Paragraph 8 or Paragraph 10, Practice Fusion agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are: (a) filed by the United States against Practice Fusion within 90 days of written notification that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on or before the Effective Date of this Agreement. For purposes of this Paragraph, notice to Practice Fusion will be effected by email to Practice Fusion's undersigned counsel, and notice to Allscripts will be effected in accordance with the terms of the Guaranty Agreement.

g. Further, in the event of a Default as defined in Paragraph 1 .f., above, and in the event that Practice Fusion fails to cure such Default within the ten (10) calendar day timeframe and under the conditions set out in that Paragraph, OIG-HHS may exclude Practice Fusion from participating in all Federal health care programs until Practice Fusion pays the Settlement Amount and all reasonable costs as set forth above. OIG-HHS will provide written notice of any such exclusion to Practice Fusion. Practice Fusion waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion Practice Fusion wishes to apply for reinstatement, Practice Fusion

must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Practice Fusion will not be reinstated unless and until OIG- HHS approves such request for reinstatement.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and subject to Paragraph 8 below (concerning disclosure of assets) and Paragraph 1.f above (concerning default), and upon Practice Fusion's full payment of the Federal Settlement Amount and full deposit of the Medicaid State Settlement Amount pursuant to Paragraph 1 .b, the United States' releases Practice Fusion, together with its predecessors, and its current and former divisions, parents, subsidiaries, successors, and assigns, from any civil or administrative monetary claim the United States has against Practice Fusion 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.

3. Notwithstanding the release given in Paragraph 2 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 (except as separately released by the DP A);
- 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;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Practice Fusion waives and shall not assert any defenses Practice Fusion 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.

5. Practice Fusion fully and finally releases 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 Practice Fusion has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. 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), TRICARE, or any state payer, related to the Covered Conduct; and Practice Fusion agrees not to resubmit to any Medicare contractor, TRICARE, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

7. Practice Fusion agrees 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-l and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Practice Fusion, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related plea agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Practice Fusion's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement and any Plea Agreement; and
- (5) the payment Practice Fusion makes to the United States pursuant to this Agreement

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).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Practice Fusion, and Practice Fusion 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 Practice Fusion or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Practice Fusion further agrees that within 90 days of the Effective Date of this Agreement it 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 Practice Fusion or any of its 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. Practice Fusion agrees that the United States, at a minimum, shall be entitled to recoup from Practice Fusion 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 Practice Fusion or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Practice Fusion or any of its 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 Practice Fusion's books and records to determine that no

Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Practice Fusion has provided sworn financial disclosure statements (Financial Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. Practice Fusion warrants that the Financial Statements are complete, accurate, and current. If the United States learns of asset(s) in which Practice Fusion had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by Practice Fusion on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by \$8 million or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of Practice Fusion previously undisclosed. Practice Fusion agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

9. Practice Fusion warrants that it has reviewed its financial situation and that, subject to the Guaranty Agreement, it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Practice Fusion, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant

that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Practice Fusion was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

10. Practice Fusion agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Practice Fusion shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, 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. Practice Fusion further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

11. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 12 (waiver for beneficiaries paragraph), below.

12. Practice Fusion agrees that it waives 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.

13. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

15. 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 all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

16. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

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

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

19. This Agreement is binding on Practice Fusion's successors, transferees, heirs, and assigns.

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

21. 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

CHRISTINA E. NOLAN
United States Attorney District of Vermont

DATED: 1/26/2020 BY: /s/ Owen Foster
OWEN FOSTER
Assistant United States Attorney

DAVID L. ANDERSON
United States Attorney
Northern District of California

DATED: 1/21/2020 BY: /s/ Sara Winslow
SARA WINSLOW
Assistant United States Attorney

DATED: 1/24/2020 BY: /s/ Christelle Klovers
CHRISTELLE KLOVERS
KELLEY HAUSER
EDWARD CROOKE
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 12/17/2019 BY: /s/ Lisa M. Re
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
United States Department of Health and Human Services

PRACTICE FUSION – DEFENDANT

**DATED: 1/17/2020 BY: /s/ Eric L. Jacobson
ERIC L. JACOBSON,
ESQ. Secretary
Practice Fusion, Inc.**

**DATED: 1/22/2020 BY: /s/ Joshua Levy
JOSHUA LEVY
AARON KATZ
PATRICK WELSH
Counsel for Practice Fusion, Inc.**

EXHIBIT A
Federal Settlement Amount Payment Schedule

Due Date	Payment
Within 10 calendar days of the Effective Date of this Agreement	\$28,343,738 plus accrued interest
No later than three months after the Effective Date of this Agreement	\$28,343,738 plus accrued interest
No later than six months after the Effective Date of this Agreement	\$28,343,738 plus accrued interest
No later than nine months after the Effective Date of this Agreement	\$28,343,738 plus accrued interest

Medicaid State Settlement Amount Payment Schedule

Due Date	Payment
Within 10 calendar days of the Effective Date of this Agreement	\$1,316,762 plus accrued interest
No later than three months after the Effective Date of this Agreement	\$1,316,762 plus accrued interest
No later than six months after the Effective Date of this Agreement	\$1,316,762 plus accrued interest
No later than nine months after the Effective Date of this Agreement	\$1,316,762 plus accrued interest

EXHIBIT B**GUARANTY AGREEMENT**

This Guaranty Agreement is entered into by and among Allscripts Healthcare Solutions, Inc., (“Guarantor”) and the United States of America (“United States”) (collectively the “Parties”).

WHEREAS, the United States contends that it has certain civil claims 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, and the common law theories of payment by mistake, unjust enrichment, and fraud against Guarantor’s subsidiary, Practice Fusion, Inc. (Practice Fusion), for causing healthcare providers to submit (a) false claims for incentive payments to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”), and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”) based on the use of Practice Fusion’s electronic health record (“EHR”) software; and (b) false claims to Medicare, Medicaid, and the TRICARE program, 10 U.S.C. §§ 1071- 1110b (“TRICARE”) when such claims were tainted by unlawful remuneration.

WHEREAS, the United States and Practice Fusion wish to settle the allegations through the execution of a Settlement Agreement (attached as Exhibit 1);

WHEREAS, as of February 13, 2018, Guarantor became the ultimate parent of Practice Fusion and is released by the Settlement Agreement;

WHEREAS, at the time of execution of this Guaranty Agreement, Guarantor is the ultimate parent and majority owner of Practice Fusion;

IT IS HEREBY AGREED that, in exchange for adequate consideration, the Parties shall undertake the following obligations:

TERMS AND CONDITIONS

1. Statement of Guaranty. The Guarantor unconditionally guarantees the prompt payment of all financial obligations of Practice Fusion to the United States and the Medicaid Participating States as set forth in the Settlement Agreement. Hereinafter, these financial obligations will be referred to as the “Guaranteed Obligations”.

2. Nature of Guaranty. The Guaranty set forth in Paragraph 1 of this Guaranty Agreement constitutes a guaranty of payment of the Guaranteed Obligations and shall not be affected by any event, occurrence or circumstance which might otherwise constitute a legal or equitable discharge or defense of a guarantor or surety (other than full and complete payment of the Guaranteed Obligations). In the event that any payment by Practice Fusion of the Guaranteed Obligations is rescinded or must otherwise be returned by virtue of any action by any bankruptcy court, the Guarantor shall remain liable hereunder with respect to such Guaranteed Obligations as if payment had not been made. The Guarantor agrees that the United States may resort to Guarantor for payment of the Guaranteed Obligations if Practice Fusion fails to pay the full amount of any of the Guaranteed Obligations in accordance with the terms of the Settlement Agreement, without regard to whether the United States should have proceeded against any other person or entity primarily or secondarily obligated with respect to any of the financial obligations, which are set forth in the Settlement Agreements.

3. Acceleration. Guarantor agrees that, within 20 calendar days of receipt of written notice from the United States that Practice Fusion has failed to pay the full amount of any of the Guaranteed Obligations in accordance with the terms of the Settlement Agreement, Guarantor will pay in full the amount then due under the Settlement Agreement. Guarantor understands that the failure to adhere fully to the terms of this paragraph would be a material breach of this Guaranty Agreement.

4. No Waiver; Cumulative Rights. No failure on the part of the United States to exercise, and no delay in exercising, any right, remedy or power hereunder shall operate as a waiver thereof, nor shall any single or partial exercise by the United States of any right, remedy or power hereunder preclude any other or future exercise of any right, remedy or power. Each and every right, remedy and power hereby granted to the United States or allowed by law or other agreement shall be cumulative and not exclusive of any other, and may be exercised by the United States from time to time.

5. Effective Date. This Guaranty Agreement shall become effective on the date the Settlement Agreement is executed.

6. Subrogation. Guarantor shall not exercise any subrogation rights it may acquire against Practice Fusion as a result of this Guaranty Agreement until all of the financial obligations to the United States have been paid in full.

7. Notice. Any notices that must be sent to the Guarantor as required by this Guaranty Agreement shall be sent by express mail and email addressed to the following:

Allscripts Healthcare Solutions, Inc.
ATTN: General Counsel
222 Merchandise Mart Plaza, 20th Floor
Chicago, IL 60654
legal.notices@allscripts.com

8. Duration. This Guaranty shall continue in full force and effect until payment in full of the Guaranteed Obligations or until all the Parties mutually agree in writing that this Guaranty Agreement shall be revoked.

9. Entire Agreement. Each Party hereto represents and warrants that the Guaranty Agreement, including the Settlement Agreement which is incorporated by reference into the Guaranty Agreement, constitute a valid and binding agreement enforceable against each Party in

accordance with its terms. The Guaranty Agreement and all Exhibits thereto, including the Settlement Agreement, embody the entire agreement among the Parties. There are no promises, terms, conditions, or obligations other than those contained in this Guaranty Agreement and the Exhibits thereto. The Guaranty Agreement and the Exhibits thereto supersede all previous communications, representations or agreements, either verbal or written, between Guarantor and the United States.

10. Severability. Should any one or more provisions of this Guaranty Agreement be determined to be illegal, unenforceable, void or voidable, all other provisions shall remain in effect.

11. Assignment. No Party hereto may assign its rights, interest or obligations hereunder to any other person or entity without prior written consent of the other Party. The provisions of this Guaranty Agreement shall be binding on the Parties hereto and their successors and assigns.

12. Miscellaneous. This Guaranty Agreement shall not be amended except in a writing signed by all Parties. Each signatory hereto represents and warrants that he or she is authorized to execute and deliver this Agreement on behalf of the Party for whom he or she is purporting to act. This Guaranty Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same agreement.

13. Governing Law: Consent to Jurisdiction. This Guaranty Agreement shall be governed by and construed in accordance with federal common law. The Parties consent to the jurisdiction of the United States District Court for the District of Vermont in any action to enforce any term of this Guaranty Agreement.

THE UNITED STATES OF AMERICA

CHRISTINA E. NOLAN
United States Attorney District of Vermont

DATED: 1/26/2020 BY: /s/ Owen Foster
OWEN FOSTER
Assistant United States Attorney

DAVID L. ANDERSON
United States Attorney
Northern District of California

DATED: 1/21/2020 BY: /s/ Sara Winslow
SARA WINSLOW
Assistant United States Attorney

DATED: 1/24/2020 BY: /s/ Christelle Klovers
CHRISTELLE KLOVERS
KELLEY HAUSER
EDWARD CROOKE
Commercial Litigation Branch
Civil Division
United States Department of Justice

GUARANTOR

DATED: 1/17/2020 BY: /s/ Brian P. Farley
BRIAN P. FARLEY, ESQ.
General Counsel
Allscripts Healthcare Solutions, Inc.