

Exhibit D

Compliance Addendum

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

UNITED STATES OF AMERICA)	
)	
v.)	Docket No. <u>2:20-CR-11</u>
)	
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 16th day of January, 2020.


UNITED STATES OF AMERICA

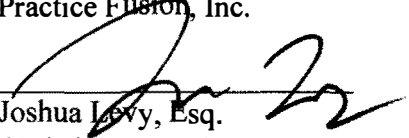
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