



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



October 30, 2020

VIA ELECTRONIC MAIL

Michael D. Laycob
Compliance Officer
eClinicalWorks, LLC
2 Technology Drive
Westborough, MA 01581

RE: eClinicalWorks, LLC – Corporate Integrity Agreement

Dear Mr. Laycob:

As referenced during our call yesterday, the Office of Inspector General (OIG) is seeking the agreement of eClinicalWorks, LLC (eCW) to additional compliance obligations under the Corporate Integrity Agreement (CIA) between OIG and eCW. These additional compliance obligations are being requested by OIG as a result of its significant concerns regarding not only Patient Safety Issues that have been identified under the CIA, but also eCW's compliance with its obligations under that agreement.

Specifically, this letter outlines OIG's requirements for a Patient Safety Issue Advisory, enhanced Patient Safety Notifications, and targeted, monthly reporting by eCW to OIG, the Office of the National Coordinator for Health Information Technology (ONC), and the Software Quality Oversight Organization (SQOO) on several, critical issues relating to the safety of eCW's Electronic Health Record Software.

Patient Safety Issue Advisory

Within 30 days, OIG will require that eCW send a Patient Safety Issue Advisory to the designated Patient Safety Officer of each of its customers and to the primary contact(s) on file for its remaining customers that have not designated a Patient Safety Officer which will notify eCW's customers and users of the availability of information regarding Patient Safety Issues on eCW's Customer Portal. eCW must also provide a copy of the Patient Safety Issue Advisory to OIG, ONC and the SQOO within 30 days. In addition,

OIG will require eCW to provide the Patient Safety Issue Advisory to all new customers within 30 days of becoming a customer. This Patient Safety Issue Advisory will be signed by eCW's President, Girish Navani, and Compliance Officer, Michael Laycob. eCW will send the Patient Safety Issue Advisory by electronic mail and First-Class Mail, and it will read as follows:

The purpose of this letter is to notify the customers of eClinicalWorks, LLC (eClinicalWorks) that Patient Safety Issues have been identified in eClinicalWorks' Electronic Health Record Software.

Patient Safety Issues are defects, deficiencies, design flaws, usability problems, or other conditions with respect to eClinicalWorks' Electronic Health Record Software that reasonably present a material risk of harm to patients. Patient Safety Issues with eClinicalWorks' Electronic Health Record Software have resulted in clinical data loss, prescription errors, and clinical information from different patients appearing within one record.

eClinicalWorks entered into a Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services (OIG) on May 30, 2017. The Corporate Integrity Agreement is available at: https://oig.hhs.gov/fraud/cia/agreements/eclinicalworks_05302017.pdf.

The Corporate Integrity Agreement requires that eClinicalWorks promptly notify its customers and users of Patient Safety Issues, including whether appropriate urgency is being given to Patient Safety Issues. The Corporate Integrity Agreement also requires that eClinicalWorks maintain on its Customer Portal, in a clear and conspicuous manner, a current and comprehensive list of all Patient Safety Issues that specify, in addition to any other pertinent information: (1) the nature of the issue; (2) the date the issue was classified as a Patient Safety Issue by eClinicalWorks; (3) the actions eClinicalWorks is taking to address the issue, and (4) where applicable, the actions that customers and users should take to mitigate risks to patient safety until the issue is fully remedied.

Notifications of all specific Patient Safety Issues identified to date have been posted on the company's Customer Portal which is accessible at: <https://my.eclinicalworks.com/eCRM/jsp/index.jsp>.

OIG has requested that eClinicalWorks send this letter to customers and users of eClinicalWorks' software, and to request that they review the Patient Safety

Issues as posted on the Customer Portal and follow instructions contained in the notifications in order to mitigate and/or correct the Patient Safety Issues.

Please call eClinicalWorks at (508) 475-0450 (Ext.) or submit an inquiry in the eClinicalWorks' Customer Portal if you have questions about this letter or eClinicalWorks' Corporate Integrity Agreement, or to report any instances in which you believe a Patient Safety Issue exists within the software.

eClinicalWorks' customers may also directly report any Patient Safety Issues or other concerns to:

- The Department of Health and Human Services, Office of the National Coordinator for Health Information Technology at (202) 690-7151 or <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2/create/53>; and
- OIG at (800) 447-8477 or <https://tips.oig.hhs.gov/>.

In addition to this Patient Safety Issue Advisory, OIG will require eCW's Compliance Officer (or a designee) to maintain a log of all calls and messages received by eCW in response to the Patient Safety Issue Advisory. The log should include a record and summary of each call and message received (whether anonymous or not) and any corrective action taken in response to the call or message. OIG will further require eCW to provide a monthly log to OIG and ONC of all calls and messages received in response to the Patient Safety Issue Advisory.

Enhanced Patient Safety Notifications

OIG will also require eCW to enhance its Patient Safety Notifications for the remainder of the CIA. In addition to the information required under Section III.A.2.b.vi of the CIA, OIG will require Patient Safety Notifications to include a description of the underlying deficiency, defect or usability problem in lay terms (*i.e.*, a plain language description of the problem that exists in the software and why it presents a Patient Safety Issue), and the specific steps that customers/users must take to mitigate or correct the issue (by way of upgrading the software, following eCW's "workaround" steps, etc.). Further, OIG will require eCW to explicitly indicate in the Patient Safety Notification that the software issue detailed in the Patient Safety Notification presents a "Patient Safety Issue." eCW

will submit all Patient Safety Notifications to the SQOO for review and approval prior to posting by eCW on the Customer Portal.

Monthly Progress Reporting

For the remainder of the CIA, OIG will require eCW to submit monthly progress reports on the status of its implementation and completion of remediation and corrective action on certain critical issues relating to the safety of eCW's Electronic Health Record Software. Monthly progress reports must include, among other information, specific and measurable items to determine progress toward full implementation and completion of remediation and corrective action. Monthly progress reports will be due to OIG, ONC and the SQOO on the first business day of each month. The specific issues that will be the subject of monthly progress reporting are:

1. Identification and repair of all special character, incorrect data type, and data truncation problems in all eCW products by January 31, 2021.
2. Identification and repair of instances in which two different patients' data appear on a screen at one time for all eCW products by January 31, 2021.
3. Reduction in "mean time to repair" (MTTR) and delays in release of "fixes" to underlying software bugs resulting in Patient Safety Reportable Events by January 31, 2021. Achievement of reduction in MTTR for Reportable Events as follows: for Reportable Events of "High" Clinical Risk, the MTTR must be less than 7 days; for Reportable Events of "Medium" Clinical Risk, the MTTR must be less than 45 days; and for Reportable Events of "Low" Clinical Risk, the MTTR must be less than 60 days.
4. Coding 85% of all entries of allergens such that they can be used for automated Drug-Allergy interaction checking by June 1, 2021.
5. Development of a comprehensive plan to achieve and maintain compliance with ISO 62304, ISO 25010, and DCB-0129 by July 31, 2021.

Please indicate eCW's agreement to these terms by signing below and returning this letter

with signatures by October 30, 2020. If you have any questions, please contact me.

Sincerely,

/Felicia E. Heimer/

Felicia E. Heimer
Senior Counsel

Agreed:

/Girish Navani/

10/30/2020

Girish Navani
Chief Executive Officer
eClinicalWorks, LLC

DATE

/Aaron Katz/

10/30/20

Aaron Katz, Esq.
Counsel for eClinicalWorks, LLC

DATE

/Lisa M. Re/

11/02/2020

Lisa M. Re
Assistant Inspector General for Legal Affairs
Office of Inspector General

DATE

cc: Aaron Katz, Esq., Ropes & Gray LLP
Andrew Gettinger, M.D., Office of the National Coordinator for Health IT
David Hunt, M.D., Office of the National Coordinator for Health IT
Brad Ulrich, Quandary Peak Research