

**FIRST AMENDMENT TO THE CORPORATE
INTEGRITY AGREEMENT BETWEEN THE OFFICE
OF INSPECTOR GENERAL OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES AND
ECLINICALWORKS LLC**

I. PREAMBLE

eClinicalWorks, LLC (eCW) and the Office of Inspector General of the United States Department of Health and Human Services (OIG) hereby enter into this First Amendment (Amendment) to the Corporate Integrity Agreement (CIA) that was executed by and between eCW and OIG and that became effective on May 30, 2017.

eCW and OIG hereby agree that the CIA between eCW and OIG shall be incorporated by reference and amended to include the terms, conditions, and requirements in this Amendment.

II. REQUIREMENTS

A. *Patient Safety Board.* eCW shall establish a Patient Safety Board and shall maintain the Patient Safety Board during the period of the CIA.

1. eCW will provide OIG with a draft charter for the Patient Safety Board by June 15, 2021.

2. The Patient Safety Board shall be comprised of at least five members, all of whom will have medical credentials (*i.e.*, physicians or nurses) and be independent, as defined in Appendix A, from eCW and the SQOO.

3. The Patient Safety Board shall be responsible for independently assessing the effectiveness of eCW's Patient Safety and Clinical Risk Management Department.

4. The Patient Safety Board shall meet at least quarterly.

5. The Patient Safety Board shall provide semi-annual written reports (Patient Safety Board Reports) to OIG and eCW's CEO, Chief Medical Officer, Chief Medical Information Officer, and Chief Compliance Officer.

a. The Patient Safety Board Reports shall assess the effectiveness of eCW's Patient Safety and Clinical Risk Management Department, identify any issues of concern, and make any recommendations for improvements.

- b. The Patient Safety Board shall have authority to provide the CEO with evaluations of the job performance (relative to patient safety issues) of the Chief Medical Officer, Chief Medical Information Officer, and Patient Safety Officer.

6. eCW's Compliance Department shall monitor and audit eCW's response to the Patient Safety Board's recommendations on a quarterly basis.

7. eCW's Chief Medical Officer, Chief Medical Information Officer, Chief Compliance Officer, and Patient Safety Officer shall meet with the Patient Safety Board on a quarterly basis.

8. eCW's Patient Safety Officer shall provide quarterly written reports to the Patient Safety Board including, without limitation, a description of the Patient Safety Reportable Events received during the preceding quarter, the steps that eCW took to remedy and resolve those Patient Safety Reportable Events, and any steps taken toward remediation or resolution of outstanding Patient Safety Reportable Events.

9. For the period June 1, 2022 – December 31, 2022, eCW shall provide OIG with a monthly report describing all Patient Safety Reportable Events.

B. *Personnel*

1. Quality Assurance and Standards Department. eCW shall budget at least an additional \$250,000 for calendar year 2022 for new hires in the Quality Assurance and Standards Department.

- a. The Company shall complete these hires by November 30, 2021, or sooner where possible.
- b. The principal goal of these hires will be to improve eCW's ability to quickly identify and remediate any patient safety issues in its EHR product (including improvements in the Company's RCA/CAPA processes).

2. Chief Medical Information Officer. eCW shall maintain a Chief Medical Information Officer (CMIO) during the term of the CIA.

- a. The CMIO shall have authority to interface directly with the SQOO.
- b. The CMIO shall be responsible for the Clinical Risk Management Team and Patient Safety Officer.

3. Patient Safety Officer. eCW shall maintain a Patient Safety Officer (PSO) during the term of the CIA.
 - a. The PSO shall be responsible for the Patient Safety Team and shall have authority to interface directly with the SQOO.
4. Director of EHR Certification Compliance. eCW shall maintain a Director of EHR Certification Compliance (DEHR) during the period of the CIA.
 - a. The DEHR shall be responsible for ensuring compliance with the EHR product certification requirements and shall be responsible for oversight of the EHR Certification Team.
5. Director of Quality Assurance. eCW shall maintain a Director of Quality Assurance (D-QA) during the period of the CIA.
 - a. The D-QA will have authority to interface directly with the SQOO.
 - b. The D-QA shall be responsible for oversight of the Quality Assurance Team.
6. Director of Project Management Office. eCW shall maintain a Director of Project Management Office (D-PMO) during the period of the CIA.
 - a. The D-PMO shall have authority to interface directly with the SQOO.
 - b. The D-PMO shall be responsible for oversight of the Project Management Office.

III. OTHER TERMS OF THIS AMENDMENT

1. eCW and OIG agree that a failure by eCW to comply with any of the terms, conditions, or requirements of this Amendment shall be a material breach of the CIA under Section X.D of the CIA.
2. All terms, conditions, and requirements of the CIA not modified in this Amendment shall remain in effect. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment.

3. The undersigned eCW signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that she is signing this Amendment in her official capacity and that she is authorized to execute this Amendment.

4. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.

ON BEHALF OF ECLINICALWORKS, LLC

/Girish Navani/

Girish Navani
Chief Executive Officer
eClinicalWorks, LLC

05/06/2021
DATE

/Aaron Katz/

AARON M. KATZ
Ropes & Gray LLP
Counsel for eClinicalWorks, LLC

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Lisa M. Re/

LISA M. RE

Assistant Inspector General for Legal Affairs

Office of Inspector General

U.S. Department of Health and Human Services

5/07/2021
DATE